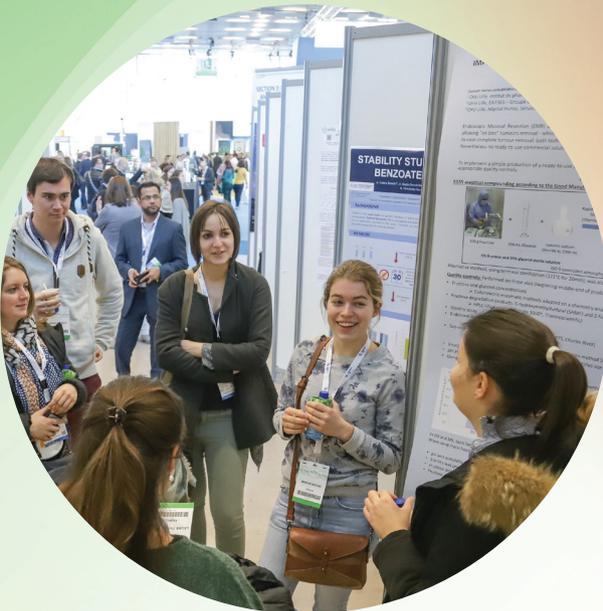


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26th EAHP Congress
Hospital pharmacists –
changing roles in
a changing world

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Abstracts from the 2022 EAHP Congress

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Section 1: Introductory statements and governance

1ISG-001 WHAT DO EMERGENCY DOCTORS THINK ABOUT USING THE ELECTRONIC PRESCRIBING SYSTEM FOR STANDARD TREATMENTS?

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Background and importance Success in the implementation of electronic prescription for standard treatments (RELE) at the level of specialised care depends largely on the acceptance by professionals to use the tool and its ease of use.

Aim and objectives The study aimed to find out the opinion of emergency physicians on the use of RELE after 1 year of implementation, to analyse the degree of acceptance and interest in its use, to know the advantages and to identify the weaknesses and barriers to its use.

Material and methods Qualitative, descriptive and cross-sectional research study, carried out by an opinion survey among the 52 attending physicians of the emergency department in January 2021. A structured questionnaire was developed with closed questions about the interest aroused, satisfaction, advantages, weaknesses and barriers found in the use of RELE and an open question about difficulties in handling the tool. Satisfaction was measured on a scale of 1–10 and advantages, weaknesses and barriers were assessed using a five-item Likert-type scale. A descriptive statistical analysis of the data obtained was carried out. The invitation to participate in the study and access to the questionnaire, available on Google Drive, was sent by WhatsApp mail group.

Results A response rate of 71.1% (37/52) was obtained. The mean interest in using RELE was 8.6/10 (95% CI 8.13 to 9.07) and overall satisfaction was 8.24 (95% CI 7.7 to 8.78). The most valued advantages were the possibility of consulting the patient's therapeutic adherence (99%) and accessing full outpatient treatment, facilitating review of all the patient's medication (99%). As regards barriers and weaknesses, 54% (20/37) of the physicians considered that RELE increases the bureaucratic burden and two physicians indicated that it generates greater attendance at the emergency room. However, only nine physicians (24%) considered that including a patient in RELE required too much time. The main difficulties in handling the application were access to the platform, the assignment of the diagnosis to the prescription, and the delay in attendance due to the inherent bureaucratic burden.

Conclusion and relevance Clinicians showed remarkable interest in using RELE and high satisfaction with how the tool works.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

1ISG-003 IMPACT OF TELEPHARMACY AND COMMUNITY PHARMACY REMOTE-DISPENSING ON PATIENTS ON ORAL ANTINEOPLASTIC AGENTS

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Background and importance Oral antineoplastic agents (OAA) are dispensed through the hospital pharmacy service. COVID-19 restrictions have accelerated implementation of alternative ways of remote dispensation and pharmaceutical care to minimise patients' virus exposure.

Aim and objectives To describe the results from the implementation of an OAA remote-dispensing programme and telepharmacy to cancer patients.

Material and methods Observational prospective study from October 2020 to April 2021 in a 400-bed university hospital. Patients received virtual pharmaceutical care and agreed to collect medication at their nearest community pharmacy within our pharmacy network.

A follow-up visit was made by telephone scoring level of satisfaction (1 to 10). Treatment Satisfaction Questionnaire for Medication II (TSQM v.II) was also employed to evaluate effectivity, tolerance, convenience and global satisfaction.

Adherence was graded from 1 to 3 depending on the number of missed doses, where 1 meant none and 3 indicated more than four missed administrations. Demographic and treatment data were also collected. Quantitative variables were expressed as median (range) and bivariate correlations by Spearman test.

Results A total of 83 patients were enrolled; 44 (53%) patients also benefitted from telepharmacy. Demographic data: women 15 (34.1%), age 63 (42–86) years. Performance status 0: 37 (84.1%). Treatment: palbociclib 9 (20.5%), enzalutamide 7 (15.9%), ribociclib 4 (9.1%), capecitabine 3 (6.8%), nilotinib 3 (6.8%), alpelisib 2 (4.5%), bosutinib 2 (4.5%), ibrutinib 2 (4.5%). Treatment duration: 401 (7–3275) days.

Administration errors were detected in 3 (6.8%) cases. Twenty-three (52.3%) with new concomitant medication, 2 (4.5%) had potential interactions with OAA. We found 12 (27.3%) patients on alternative medicine and 5 (11.4%) presented interactions. Storage errors: 1 (2.3%). Adherence: grade 1, 35 (79.5%). Twenty-nine (65.9%) adverse effects: gastrointestinal 12 (26.7%), fatigue 12 (26.7%), central nervous system 7 (15.6%), dermatological 5 (11.1%). We resolved doubts in 15 (34.1%) cases, and 3 (6.8%) patients were scheduled for follow-up appointments.

Level of satisfaction with treatment delivery was 10 (8–10). TSQM v.II questionnaire: effectivity 75 (41–100), tolerance 100 (41–100), convenience 100 (50–100), global satisfaction 83 (25–100). Positive correlation: treatment duration with effectivity (ρ 0.308, $p=0.042$). Negative correlations: adherence with adverse effects (ρ 0.419, $p=0.005$); treatment duration with convenience and global satisfaction (ρ 0.454 and 0.350, $p=0.002$ and $p=0.020$, respectively).

Conclusion and relevance Level of satisfaction with telepharmacy and remote delivery was very high. Patients with more adverse effects presented less treatment adherence. Patients with more treatment duration thought that their treatment was more effective, but the less the duration the more the level of satisfaction.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

1ISG-004 ASSESSMENT OF CUSTOMER SATISFACTION WITH HOSPITAL PHARMACY SERVICES IN ESTONIA

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Background and importance According to the European Statements of Hospital Pharmacy, the overarching goal of the hospital pharmacy service is to optimise patient outcomes through working collaboratively within multidisciplinary teams in order to achieve the responsible use of medicines across all settings.¹ A comprehensive understanding of the satisfaction of hospital staff with the pharmacy service is necessary for improving the quality of service. However, no studies assessing contentment with hospital pharmacy services have been conducted in Estonia.

Aim and objectives The aim of the survey was to assess the satisfaction of hospital staff with hospital pharmacy services.

Material and methods A web-based survey was conducted from November 2020 to January 2021 in public hospitals in Estonia. Two regional, one central and two general hospitals were included in the study in order to cover different types of hospitals. Respondents were asked to assess the following service areas: (1) medication dispensing and distribution, (2) compounding, (3) clinical pharmacy services and medicine information, (4) clinical trials and (5) communication. A five-point rating scale was used to assess the satisfaction with services. All hospital staff were invited to participate in the study.

Results A total of 269 respondents participated in the survey; most of them were nurses (65.4%), doctors and other staff responded to a lesser extent. Overall satisfaction with hospital pharmacy services was 3.9 on a five-point scale. Satisfaction was higher in general hospitals compared to regional or central hospitals. The compounding service was rated the highest (4.2) and the medication dispensing and distribution service received the lowest score (3.7). User-friendliness of the electronic medicine ordering system, easily accessible medicine information, and communication on drug shortages were mentioned as the areas most in need of improvement.

Conclusion and relevance Although our survey showed that healthcare professionals and other specialists are generally satisfied with the hospital pharmacy service, there is room for improvement. We are planning to conduct the study in all Estonian hospital pharmacies with the aim of discovering the bottlenecks in pharmacy services throughout Estonia. This will enable the development of common standards and harmonise the provision of hospital pharmacy services.

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Conflict of interest No conflict of interest

11SG-006 ESTIMATION OF DRUG COST AVOIDANCE IN CLINICAL TRIALS OF NON-SMALL CELL LUNG CANCER

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10.1136/ejhp-2022-eahp.4

Background and importance Non-small cell lung cancer (NSCLC) is one of the most frequent oncological diseases with an important economic impact in the National Health System (NHS).

Aim and objectives To determine the avoided cost for the hospital attributable to drugs assigned to patients with NSCLC enrolled in clinical trials (CTs). It was considered as such the

cost that these drugs would mean for the NHS if the patients had not been included in a CT.

Material and methods Retrospective, descriptive study of the drug cost avoidance in CTs conducted in patients with NSCLC during the study period (January 2020–August 2021). CT title, protocol code, phase, promotor, masking and investigational drugs were collected via the software programs FarmTools and Fundanet. To calculate the avoided cost the following aspects were analysed: number of patients enrolled, scheme, dispensed drug(s), number of dispensations, duration of the treatment, standard of care and average drug prices for economic evaluation. CTs in NSCLC with included patients, with a therapeutic alternative available and those in which the sponsor provided the medicines under research, were included in the study.

Results 23 CTs with a total of 111 NSCLC patients were included in the study. A total of 43.5% were phase II, 34.8% phase III and 21.7% phase Ib/II. 82.6% belonged to the pharmaceutical industry and the rest were promoted by cooperative groups (19 and 14, respectively). 973 cycles were dispensed with an average of 17±7.5 cycles administered per patient. The total cost avoidance was € 2 314 274.25. The estimated average savings per CT was € 100 620.62, per cycle dispensed € 2378.49 and per patient € 20 849.32.

Conclusion and relevance CTs are essential for evaluating the efficacy and safety of new treatments. Furthermore, cost avoidance in investigational drugs is a tangible benefit of clinical trials, whose realisation is a source of economic benefits for the hospital as we observed in this study.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

11SG-007 ECONOMIC SAVINGS FROM WEIGHT-BASED DOSING OF PEMBROLIZUMAB: WHAT IS THE IMPACT IN A TERTIARY HOSPITAL?

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10.1136/ejhp-2022-eahp.5

Background and importance Pembrolizumab is a humanised monoclonal antibody targeting PD-1 approved by the European Medicines Agency (EMA) in 2015. Currently, it has approval for several indications and is widely used.

Aim and objectives To calculate the budget impact difference of administering pembrolizumab at a personalised weight dose of 2 mg/kg every 3 weeks (Q3W) or 4 mg/kg every 6 weeks (Q6W) instead of a fixed dose of 200 mg (Q3W) or 400 mg (Q6W) in any indication since the new dosing strategy was applied in our hospital.

Material and methods Retrospective, observational, descriptive study of all the patients treated with pembrolizumab in all indications between July 2020 and June 2021. Collected variables: sex, weight, milligrams administered, number of cycles, vials used. The cost per milligram and per cycle of pembrolizumab was evaluated and the cost for two treatment strategies was calculated: cycles of 2 mg/kg (Q3W) or 4 mg/kg (Q6W) versus 200 mg (Q3W) or 400 mg (Q6W). All dispensations were transformed to cycles of Q3W for calculations.

Results Seventy-five patients (52 men and 23 women) were included with 16 different pathologies, the majority being non-small cell lung cancer (65.3%, n=49). The mean body weight was 72±13 kg (only two patients weighed 100 kg). The average cycles Q3W administered per patient was 8.3 ±6.9 and the average dose prescribed was 145±26 mg. The cost was €1 272 068 for the weight-based dosing and it would be €1 757 000 for the fixed dosing, which means an increased cost of 38%. Vials saved with the weight-based dosing were 347, which equates to a €487 743 cost saving in 1 year. The average additional milligrams and cost per cycle per patient with a flat dose was 55.1 mg and €773. A decreased dose compared with the fixed dose that was administered in 98.7% of patients (n=75), assuming economic savings related to these patients.

Conclusion and relevance Pembrolizumab fixed dose presents practical benefits in terms of prescription and preparation, but also an extra cost regarding our patients' population in all indications, where only two patients weighed 100 kg. Weight-based dosing significantly reduces the cost of pembrolizumab and it is a good option in the era of personalised medicine.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

1ISG-008 OPTIMISATION PROGRAMME OF OMALIZUMAB TREATMENT FOR CHRONIC IDIOPATHIC URTICARIA

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Background and importance Omalizumab is a monoclonal antibody with indication for chronic idiopathic urticaria (CIU). Adequate optimisation of omalizumab use could provide an improvement of efficiency in health systems without affecting the effectiveness of this therapy.

Aim and objectives To describe the effectiveness and efficiency data of an optimisation programme about use of omalizumab for CIU.

Material and methods A descriptive retrospective study was conducted. Patients with CIU included in a programme to optimise use of omalizumab until June 2021 were selected. The prescription software program FarmaTools and electronic clinical history were used to record: duration of treatments, type of optimisation (dose reduction, therapy discontinuation or both), Urticaria Activity Score during a 7-day period (UAS7) and costs of therapies. Effectiveness of treatment was measured using UAS7 at 18 and 36 months. No response to therapy (NR) was defined as UAS7 >15. Mild disease (MD) presented UAS7 = 7–15. Adequate disease control (DC) was valued as UAS7 ≤6. Total response (TR) presented UAS7 =0. Patients with NR and presenting treatment suspension in a certain month were assumed to be NR in the following months. Optimisation of omalizumab treatment through treatment discontinuations or dose reduction was applied in patients with DC and TR. Regarding efficiency data, savings from the optimisation programme were estimated as the difference between costs of real omalizumab doses used in the

optimisation programme and the hypothetical costs with the usual dose (300 mg/28 days).

Results There were 47 patients in the study. The median duration of therapy with omalizumab was 18 months. Optimisation of omalizumab treatment was performed in 61.7% of patients: 2.1% patients only presented dose reduction, 23.4% discontinuation of treatment and 36.2% of patients had both. At baseline, all patients presented NR (UAS7 >15). At 18 months, UAS7 data were: 20% of patients had NR, 16% MD, 8% DC and 56% TR. At 36 months, results of UAS7 were: 18.7% of patients presented NR, 6.3% MD, 31.3% DC and 43.7% TR. Total economic savings associated with optimisation of treatment with omalizumab were €286 150: €113 402 saved through dose reduction and €172 747 saved through therapy discontinuation.

Conclusion and relevance Our omalizumab optimisation programme for CIU provided high efficiency, maintaining nearly half of the patients with TR at 36 months.

REFERENCES AND/OR ACKNOWLEDGEMENTS

None

Conflict of interest No conflict of interest

1ISG-012 ECONOMIC EVALUATION OF DOSE BANDING IN IMMUNOTHERAPY: NIVOLUMAB AND PEMBROLIZUMAB

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Background and importance Nivolumab and pembrolizumab are monoclonal antibodies that avoid programmed death-1 (PD-1) mediated downregulation of T-cells by binding to the receptor and blocking its interaction with ligands PD-L1 and PD-L2.

Immunotherapy fixed-dose (FD) inclusion in daily clinical practice has led to a significant economic impact. Nevertheless, some studies grant the equivalence of nivolumab¹ and pembrolizumab² at individualised-dose (ID) (nivolumab 3 mg/kg/2w, pembrolizumab 2 mg/kg/3w) and FD (nivolumab 240 mg/2w, 480 mg/4w; pembrolizumab 200 mg/3w).

Aim and objectives Evaluating the impact of dose-binding (DB) application in immunotherapy with nivolumab and pembrolizumab in terms of efficiency, clinical assistance and pharmacological exposure.

Material and methods An observational retrospective observational study including patients treated with nivolumab and pembrolizumab from January 2019 to September 2021 was conducted, specifying anthropometrical features and number of cycles administered.

Dosage adjustment intervals were designed for nivolumab (<60 kg: 170 mg, 60–70 kg: 200 mg, 70–80 kg: 230 mg, >80 kg: 240 mg) and pembrolizumab (<70 kg: 130 mg, 70–90 kg: 160 mg, >90 kg: 200 mg). Clinical application of DB was assessed according to annual saving of both therapies (efficiency), difference in cycles administered per year (clinical assistance) and dosage discrepancy between DB-FD (pharmacological exposure).

Results 195 patients were included: 68 (34.9%) nivolumab and 127 (65.1%) pembrolizumab. Mean body weight was 72.1 ±12.8 kg and 71.4 ±13.6 kg, respectively. 1849

immunotherapeutic cycles were administered: 705 (38.1%) nivolumab and 1144 (61.9%) pembrolizumab.

The annual economic impact of FD and DB was calculated at € 573 235 and € 529 556 for nivolumab and € 110 3387 and € 820 262 for pembrolizumab, respectively; estimating a potential annual economical saving for DB of nivolumab at € 43 679 and pembrolizumab at € 283 125. The application of DB in nivolumab would lead to an increase of 58 annual cycles administered, with no change in the case of pembrolizumab. In terms of drug exposure, immunotherapy with DB dosage would suppose a median dose deviation from FD of -4.17% ($-16.67-0.0$) for nivolumab and -20.0% (-35.0 to -20.0) for pembrolizumab.

Conclusion and relevance The implantation of a DB programme in immunotherapy with nivolumab and pembrolizumab would lead to an efficiency increase and a dosing reduction in comparison with FD regimens, especially in pembrolizumab, which would achieve higher annual savings without detriment of clinical assistance.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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Conflict of interest No conflict of interest

returned by physicians and 100 by nurses), 121 were included in the analyses. The majority of respondents (60%–87%) expected CPOE implementation to improve the questioned criteria, except for quality of patient care (40% expected an improvement) and time spent on documentation (76% predicted an increase). After implementation, respondents reported improvements in readability (84%) and availability of patient information (57%); 78% of respondents indicated that the amount of time spent on documentation had increased. All other criteria were reported as improved, unchanged or worsened in approximately equal proportions. When asked to rate the implementation, the mean score was 56.5 ± 30.0 before and 56.9 ± 33.2 after implementation ($p=0.809$).

Conclusion and relevance The fact that positive and negative attitudes remained unchanged suggests that the opinions of doubters and enthusiasts were not significantly affected by the implementation. It might be worthwhile to choose different implementation strategies for these two groups.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

11SG-014 ABSTRACT WITHDRAWN

11SG-013 USERS' EXPECTATIONS AND OPINIONS ON A COMPUTERISED PHYSICIAN ORDER ENTRY (CPOE) SYSTEM BEFORE AND AFTER ITS IMPLEMENTATION

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Background and importance Computerised physician order entry (CPOE) systems can enhance medication safety, but their implementation often faces hurdles, frequently due to user resistance. Implementation success depends on users' acceptance of the system. Therefore, it is important to know the users' views to tailor the implementation process and future optimisation of the system.

Aim and objectives Our aim was to examine physicians' and nurses' expectations before and opinions after the implementation of a CPOE system.

Material and methods We set up a survey combining validated tools and implementation-oriented questions to compare expectations before with opinions after CPOE implementation. The latter questions addressed quality of care, traceability of clinical decisions, readability, availability of patient information, quality of documentation, and time spent on documentation. Responses were rated on a five-point Likert scale. Additionally, respondents were asked to rate the implementation on a scale from 0 (negative) to 100 (positive). The survey was distributed to seven orthopaedic wards 4 weeks before and 3 months after implementation and anonymously collected. For the analysis of Likert responses, the number of responses of the upper and lower two Likert points was added up. Surveys with a non-response rate of $>25\%$ (excluding demographic questions) were not analysed.

Results The return rate was 36% ($N=72$) before and 26% ($N=53$) after implementation. Of the total of 125 surveys (25

Section 2: Selection, procurement and distribution

2SPD-001 HOW CAN WE BEST MANAGE SUPPLY SHORTAGES OF EXCLUSIVELY HUMAN MOLECULES FOR SUBSTITUTION? THE EXAMPLE OF IMMUNOGLOBULINS

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Background and importance Drug supply shortages that have increased over the past decade were worsened by the SARS-CoV-2 health crisis. Among the products affected are immunoglobulins (IG), essential for substitution in primary immune deficiencies in particular. In contrast with some plasmatic proteins, IG are only produced from blood donations that have decreased. Recently, IG supply was reduced, 42% in our case, mostly affecting intravenous IG (IVIG).

Aim and objectives To identify, among the existing clinical situations, those that should benefit from IG (subcutaneous IG (SCIG) preferentially in primary substitutions; IVIG treatment to as many patients as possible for whom there is no alternative).

Material and methods Meet physicians representing the most important prescribing departments. Take stock of consumption and supply. Identify ways to optimise the use of available IG.

Results The neurology, clinical haematology, internal medicine and paediatrics representatives were brought together at a Medicinal Products and Medical Devices Commission (MPMDC) session.

First 6 months of 2021, data on IVIG:

Patient number: 168. IVIG mass: 27.8 kg (70.4% of total IG). Treatment number: 510. On average: 27.6 g/patient/month; 3 cures/patient over 6 months.

IVIG use: off-label, 27.4%; immune deficiencies, 41.6% (secondary 9 times; primary 1 time); immunomodulation, 31% (of which: idiopathic thrombocytopenic purpura (ITP), 42.3%; Guillain-Barré syndrome, 9.6%; Kawasaki disease, 3.8%; chronic inflammatory demyelinating polyradiculopathy (CIDP), 38.5%; multifocal motor neuropathies, 5.8%).

Discussions at MPMDC led to the development of the following ways to cope:

1. 'Switch' as many patients as possible to SCIG.
2. As the dosage of 2 g/kg/cure is indicative, lower the doses gradually and/or space out the courses.
3. Use corticosteroids whenever possible.
4. Use IVIG for life-threatening authorised situations (eg, acute ITP).
5. Reactivate the plasma exchange pathway for immunomodulations.
6. Reduce off-label use.
7. For off-label indications, include patients in therapeutic trials of IVIG.
8. If life-threatening emergency immunomodulation off-label, treat with molecules such as rituximab and use IVIG only during the latency period.

Conclusion and relevance The implementation of these suggestions, while awaiting the publication of the IG indications' hierarchy by the relevant authorities, should optimise management of the shortage. European, or even international, recommendations would be welcome because of the globalisation of supply.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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2SPD-005 SIGNIFICANT DISCONTINUATION RATES IN PATIENTS INITIATING OR SWITCHING FROM CT-P13: A RETROSPECTIVE COHORT STUDY IN A UNIVERSITY HOSPITAL

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10.1136/ejhp.2022-eahp.11

Background and importance CT-P13 is an infliximab biosimilar that received market authorisation in the European Union in 2013. CT-P13 has undeniable cost-saving opportunities and extensive literature supporting its equivalence to originator infliximab (OI) in terms of efficacy, safety and immunogenicity. Despite these elements, CT-P13 remains largely underused in our country, either underprescribed or discontinued after its introduction.

Aim and objectives The aim of this study was to explore the reasons behind the high discontinuation rate observed among the patients on CT-P13 in a large tertiary hospital.

Material and methods A retrospective cohort study using routinely collected data was carried out. Patients were eligible if they received OI or CT-P13 between September 2017 and December 2020. They were included if they had received at least two CT-P13 infusions during the same period. Patients were excluded if their medical history was incomplete prior to or 6 months after their first CT-P13 infusion and if they had an oncological main diagnosis.

Results 156 patients were included and classified into two groups: switchers that were treated with OI and were switched to CT-P13 ($n = 85$, 54%) and initiators that did not receive OI prior to CT-P13 treatment ($n = 71$, 46%). 23 (27%) switchers and 35 (49%) initiators discontinued CT-P13 after 12 months. Main reasons for CT-P13 discontinuation were lack of efficacy ($n = 21$, 36%) and secondary loss of response ($n = 16$, 28%). Lack of active training and coordination among healthcare professionals and little patient education may have exacerbated patients' subjective complaints and increased the CT-P13 discontinuation rate.

Conclusion and relevance Lack of efficacy and secondary loss of response were the main reasons for the high CT-P13 discontinuation rate observed in a large tertiary hospital. Coordination between the various healthcare professionals involved with the patients is a prerequisite for biosimilars to achieve their maximum cost-saving potential.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

2SPD-006 DEVELOPMENT OF A PRIORITISATION PROTOCOL FOR THE USE OF IMMUNOGLOBULINS IN VIEW OF THE GLOBAL SUPPLY PROBLEM

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Background and importance Highly purified immunoglobulins (95%) are obtained from the purification of human plasma extracted from healthy donors. The mechanism of action consists of an antigen-specific activity, exerting immunomodulatory functions in addition to those of the natural immunoglobulins. The increase in demand, the dependence exclusively on plasma donations, and the pandemic situation have reduced the supply of immunoglobulins worldwide.

Aim and objectives To elaborate a protocol at regional level (seven hospitals) to prioritise, rationalise and reduce the use of immunoglobulins in view of the worldwide supply problem.

Material and methods A multidisciplinary work team was created comprising professionals involved in the use of these therapies (immunologists, haematologists, internists, neurologists, paediatricians and pharmacists). The main pathologies involved were specified.

Subsequently, the indications depicted in the technical data sheet and the available scientific evidence were reviewed, to define three priority groups:

- Priority 1: Necessary treatment, there is no other therapeutic alternative.
- Priority 2: Pathologies or clinical situations where the use of immunoglobulins is recommended.

- Priority 3: Clinical situations without sufficient scientific evidence.

Finally, the indications and dose regimen of all patients under active treatment were reviewed.

Results The work team defined Priority 1 as follows:

- Chronic treatments: primary and secondary immunodeficiencies, CAR-T hypogammaglobulinaemia in paediatrics, pure motor chronic inflammatory demyelinating polyneuropathy (CIDP) and multifocal motor neuropathy.
- Acute treatments: Kawasaki disease, primary immune thrombocytopenia (PIT) before undergoing urgent surgery or PIT with severe thrombopenia/large bleeding diathesis.

Priority 2 included: Guillain-Barré syndrome, myasthenia gravis, PIT with high risk of bleeding, CIDP (excluding pure motor), severe neonatal sepsis, alloimmune haemolytic disease in neonates, alloimmune neonatal thrombocytopenia, haemophagocytic syndrome and paediatric multisystem inflammatory syndrome due to SARS-CoV-2.

Pathologies not mentioned above were considered Priority 3, being evaluated by a multidisciplinary Experts Committee.

After reviewing the active treatments, 21% of them were temporarily suspended. Since the protocol approval, eight new cases have been assessed as Priority 3, with only one of them being denied.

Conclusion and relevance The creation of the protocol has made it possible to rationalise the use of immunoglobulins, reducing their consumption and promoting the use of therapeutic alternatives. Thus, completely necessary treatments are guaranteed through equitable and equal access throughout the region.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

2SPD-008 NETWORK META-ANALYSIS OF IMMUNOTHERAPIES IN UNTREATED ADVANCED OR METASTATIC OESOPHAGEAL SQUAMOUS CELL CARCINOMA

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Background and importance ESCORT-1st trial reported a benefit for overall survival (OS) of camrelizumab plus chemotherapy (Cam+CT) combination over chemotherapy (CT) in September 2021. Regimens with platinum agents have been the standard first-line treatment for advanced or metastatic oesophageal squamous cell carcinoma (mESCC) for decades.

Aim and objectives To develop a network meta-analysis (NMA) to provide an efficacy comparison of treatments for untreated patients with mESCC.

Material and methods A review in Pubmed and UpToDate databases was conducted on 3 October 2021. Inclusion criteria: randomised clinical trials (RCTs) including immune checkpoint inhibitor therapies (camrelizumab, pembrolizumab, nivolumab and ipilimumab) as first-line treatment of mESCC. Exclusion criteria: RCTs without a common comparator linking cited drugs. Efficacy endpoint was OS. NMA used

combined direct and indirect evidence to estimate pooled hazard ratios (HR) by Bayesian methods. Fixed and random effects were considered. Deviance information criteria (DIC) statistics were evaluated to compare models. I^2 determined the proportion of variability in outcomes due to heterogeneity.

Results Three RCTs were selected. The RCTs assessed the following regimens: Cam+CT, nivolumab plus ipilimumab (N+I), nivolumab plus chemotherapy (N+CT), pembrolizumab plus chemotherapy (Pem+CT) and CT. The common comparator was CT. Two RCTs included patients with 0–1 performance status (ECOG). Cam+CT study evaluated patients with a life expectancy of at least 12 weeks. Results of N+I and N+CT were obtained from a congress abstract. Similar values of DIC (difference <5, no minimum relevance) were estimated for fixed- and random-effects models. Fixed-effects model was selected due to the higher precision of data. I^2 was 25%. Regarding Cam+CT (therapy with the greatest magnitude of effect), HR for OS were: 1.0 (95% CI 0.76 to 1.4) vs Pem+CT, 1.1 (95% CI 0.78 to 1.4) vs N+CT, 1.1 (95% CI 0.81 to 1.5) vs N+I and 1.4 (95% CI 1.1 to 1.8) vs CT. No statistically significant differences were found among Cam+CT, Pem+CT, N+CT and N+I. All schemes with immune checkpoint inhibitor drugs were superior to CT.

Conclusion and relevance This updated NMA showed a greater efficacy benefit of combinations with immunotherapeutic agents over CT in untreated patients with mESCC. Standard first-line therapy could be modified. Safety and efficiency criteria should also be considered in the therapeutic positioning of drugs in this clinical context.

REFERENCES AND/OR ACKNOWLEDGEMENTS

None

Conflict of interest No conflict of interest

2SPD-013

INCREASE IN HEALTHCARE COSTS WITH FIDAXOMICIN VERSUS VANCOMYCIN FOR CLOSTRIDIUM DIFFICILE TREATMENT

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Background and importance *Clostridium difficile* (CD) colonises the human intestinal tract after the normal flora has been disrupted (in association with antibiotic therapy). Clinical guidelines use fidaxomicin as first-line treatment in patients at greater risk for recurrence (age >65 years, compromised immunity, severe CD infection) in accordance with 2021 Infectious Diseases Society of America (IDSA).

Aim and objectives Evaluation of the cost increase in the treatment of CD if patients are treated with fidaxomicin instead of vancomycin after the failure of first-line treatment or as first-line treatment according to the age recommendations of the IDSA.

Material and methods Retrospective observational study that included patients diagnosed with pseudomembranous colitis and treated with oral vancomycin for CD from 1 October 2020 to 30 September 2021. Clinical sources used were from FarmaTools and the Electronic Medical Record Selene.

Results 97 patients were analysed; 48.45% men, median age 72 (SD 16) years. 9 were empirically treated. 88 patients were positive for CD. 5 patients died from another pathology

during treatment (3 during the first-line and 2 during the second-line treatment).

73 patients (75.26%) (43.84% men) only needed one line of treatment with vancomycin to achieve a cure. The cost of vancomycin treatment for these patients was € 3216.

19 patients (19.59%) (63.16% men) required a second (15 patients) or third line (4 patients) of treatment after the failure of the previous lines. The cost of vancomycin treatment for these patients was € 2266. These patients could have been treated with fidaxomicin. The total cost would have been increased to € 30 300.

71 patients (73%) at the time of diagnosis were older than 65 years; 83% first line, 9.86% second line and 7.14% third line. The cost of vancomycin treatment for these patients was € 5461. Following the IDSA criteria, these patients could have been treated from the beginning with fidaxomicin. The total cost would have been increased to € 102 453.

Conclusion and relevance The use of fidaxomicin represents a very high increase in healthcare costs compared to vancomycin. In our study all the patients were cured with the use of vancomycin. It should also be noted that in clinical trials and meta-analyses, fidaxomicin achieves a modest superior efficacy compared to vancomycin.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

2SPD-014

APPROPRIATENESS OF USTEKINUMAB THERAPY PRESCRIPTION AND REAL-LIFE CONDITION USE IN CROHN'S DISEASE

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Background and importance For the patient with moderate to severe Crohn's disease, first-line options for induction therapy include a biologic agent. Tumour necrosis factor alpha antagonists (anti-TNF α) are recognised as the primary therapeutic option. Ustekinumab is an anti-IL 12/23 antibody that has been approved for use in patients who have had an inadequate response, show loss of response or are intolerant to conventional treatment or anti-TNF α or have contraindications.

Aim and objectives To describe the prescription of ustekinumab in real-life conditions in our hospital and to assess the appropriateness of ustekinumab prescription.

Material and methods All patients treated with ustekinumab were included during the period 2017–2021. Demographic variables: previous anti-TNF α agents used, dose or interval intensification, drug trough antidrug antibodies measurements, primary or secondary failure, concomitant medication, ustekinumab dose, and reason for switching (biomarkers, symptoms, mucosal inflammation) were collected. Data were obtained from the electronic medical record and prescription application. Appropriateness of prescription: therapeutic drug monitoring, intensification before switching, and contraindications to use of anti-TNF α .

Results The results are shown in Table 1.

Conclusion and relevance Given the high number of patients without therapeutic drug monitoring or with dose or interval intensification, it was decided to create an interdisciplinary commission made up of digestive and pharmaceutical experts in order to optimise drug prescribing in Crohn's disease.

Abstract 2SPD-014 Table 1

Parameter	Result
Average age (years)	46.5
Crohn's disease diagnosis	100%
Previous adalimumab and infliximab	19.5%
Previous adalimumab	50.1%
Previous infliximab	19.5%
Previous vedolizumab	4.3%
Previous anti-TNF α and vedolizumab	6.6%
Median dose ustekinumab	38.8 mg
Combination therapy azathioprine	27.1%
Combination therapy budesonide	18.6%
Combination therapy methotrexate	2.2%
Combination therapy budesonide + thiopurine	6.6%
No combination therapy	45.5%
Dose intensification	8.8%
Interval intensification	30.1%
Dose and interval intensification	6.6%
No intensification	54.4%
Drug trough concentrations/antidrug antibodies measurement (% patients)	35.2%
Monitoring not applicable	19.11%
Adalimumab <7.5	6.6%
Adalimumab <7.5 with positive antibodies	2.2%
Infliximab <5	6.6%
Infliximab <5 with positive antibodies	2.2%
Undetectable concentration	4.4%
Undetectable concentration with positive antibodies	2.2%
Primary failure	13.23%
Secondary failure	56.6%
Adverse reactions	13.23%
Refused treatment	6.6%
Unknown reason	10.34%
Symptoms reason + mucosal inflammation reason + biomarkers reason	10%
Symptoms reason	58%
Symptoms reason + mucosal inflammation reason	32%
Inappropriate prescription	56.1%

REFERENCES AND/OR ACKNOWLEDGEMENTS

Overview of medical management of high-risk adult patients with moderate to severe Crohn's disease up to date. <https://www.uptodate.com/contents/overview-of-medical-management-of-high-risk-adult-patients-with-moderate-to-severe-crohn-disease>

Conflict of interest No conflict of interest

2SPD-015 LOGISTICS AUTOMATION AND PROCESS RE-ENGINEERING: IMPACT ON INTER-HOSPITAL LOAN MANAGEMENT

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Background and importance Inter-hospital loans are part of the usual practice in the hospital Pharmacy Department.

Optimisation of this process is key to improved utilisation of resources and time by the hospital pharmacist.

Aim and objectives To evaluate the impact on pharmacist time and economic savings after the automation of the drug storage system in the Pharmacy Department and after the redesign of the inter-hospital loan requesting process (HLRP).

Material and methods Retrospective observational study in which we analysed the loan registry of a Pharmacy Service in 2016 (pre-intervention period) and 2019 (post-intervention period). Regarding the redesign of the process, in 2019 all the stages involved were defined, as well as the professional profile involved in each of them, in this case administrative assistants, pharmacy technicians and pharmacists. The cost in personnel time was estimated based on the average salary of each professional profile. For the pre-intervention period, a multidisciplinary group defined by consensus the time invested by each role involved in HLRP. For the post-intervention period, the times were measured by direct observation. A transport service cost of € 34 per loan was given by the company contracted for this purpose.

Results The number of loan requests was 83 in 2016 vs 61 in 2019, a reduction of 24.20%. There was a reduction of 13 min in the total time spent on HLRP (50 min in 2016 compared to 37 min in 2019). The cost derived from the request of each loan was € 55 in 2016 vs € 40.60 in 2019, resulting in an annual saving of € 2086.98 (45.73%). Overall expenditure was € 4563.57 in 2016 vs € 2476.59 in 2019. Finally, the time spent by the pharmacist decreased from 50 min in 2016 (100% of the activities and time spent) to 2 min in 2019 (5.4% of the time), used only in the assessment of the number of pharmaceutical units requested in the loan. In the post-intervention year this resulted in savings of up to 35.58 hours of pharmacist time spent.

Conclusion and relevance The automation of medication storage systems, together with process re-engineering, improves the efficiency of medication loan management, freeing up pharmacist time to perform more value-added tasks.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

2SPD-016 APPLICATION OF FAILURE MODE AND EFFECT ANALYSIS TO IMPROVE CYTOSTATIC DRUG STOCK MANAGEMENT

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Background and importance Drug stock management is a complex process because space, budget and other external factors such as delivery delays or demand variability must be taken into account. To manage a drug stock properly is a pharmacist's responsibility.

Aim and objectives To carry out a failure mode and effect modal analysis (FMEA) in the cytostatic drug store to improve the stock management process.

Material and methods A multidisciplinary team was assembled to perform the detection of failure modes and their causes through FMEA methodology. Then, risk priority index (RPI) was calculated: frequency (F) \times severity (G) \times detectability

(D), assigning values from 1 to 5 to each factor. Finally, corrective measures for risks were suggested.

Results Risk map was performed with the following subprocesses: realisation of the order with drugs whose stock is below the alert stock, selection of the drug presentation considering the dose for better utilisation, elaboration and administration.

Failure modes:

1. Delay in ordering medication: F:5 G:5 D:5, RPI:125.
2. Non-matching used drug presentation with the drug registered in the computer system: F:1 G:5 D:5, RPI:25.
3. Waste of remaining quantities of not used drug that day: F:3 G:1 D:3, RPI:9.
4. Issue administration on scheduled day and return to pharmacy: F:1 G:1 D:4, RPI:4.

Causes:

1. Unclaimed pending order.
2. Wrong choice of drug presentation during the preparation.
3. Lack of knowledge by the nursing staff about the stability of the vials once opened.
4. Poor day hospital-pharmacy communication flow in terms of real-time patient appointments.

Proposed actions:

1. Training sessions for nurses, orderlies and administrative staff.
2. Validation checklist implementation in the process of preparing.
3. Development of a list of drug stability once opened.
4. Real-time confirmation by day hospital of patient attendance at appointments.

Realisation of the order with drugs whose stock is below the alert stock was the subprocess with the highest number of failure modes. Delayed medication order was the failure mode with the highest RPI.

Conclusion and relevance The FMEA methodology allowed us to detect failure modes and their causes in order to redefine a process to improve its quality. Stock management process is a key element and we learned that more frequent training sessions for Pharmacy Department staff and monitoring actual stock in an exhaustive way are needed.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

2SPD-017

ANALYSIS AND MONITORING OF THE WORKLOAD AND FINANCIAL BURDEN OF DISPENSING HIGH-COST MEDICINES WITH ITEM-BASED REIMBURSEMENT IN HUNGARIAN HOSPITAL PHARMACIES

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Background and importance Certain high-cost, tendered hospital medicines, especially biologic drugs, special budget medicines of hepatitis C virus (HCV) and haemophilia are covered by item-based reimbursement in Hungary. Patients receive such therapies in clinical centres, and hospital pharmacists report use item-by-item. The National Health Insurance Fund

reimburses the product after having checked the appropriateness of the use. Accordingly, appropriateness of the administration by hospital pharmacy staff is of critical importance. The ever-expanding amount of high-cost hospital medicines with item-based reimbursement imposes an additional burden on institutions involved in the dispensing process.

Aim and objectives The aim of our study was to determine the time and cost implications of providing a safe and efficient supply of these high-cost specialty medications, and to confirm the shortages in personnel, infrastructure and funding.

Material and methods We have defined the activities related to supply of high-cost item-based medications in our institution (ordering medicines and requesting quotas, receiving goods, storing, preparing for administration, dispensing, reporting). We have conducted a prospective workload and time analysis for each related subtask (who, when, what, for how long) in June 2021. Based on these data, we calculated the mean time (\pm standard deviation) spent on the process steps and the related direct and indirect costs based on a national controlling manual for the first quarter of 2021.

Results The hospital pharmacy dispensed 50 high-cost item-based medications, 10 employees (3 pharmacists, 5 specialist pharmacy assistants, 1 administrator, 1 technical staff) were involved in the related workflow. We analysed data on 3368 preparations purchased during 263 orders, and a total of 1657 dispensing events over 3 months. The workload analysis yielded an average of 66.8 ± 7.0 hours per month equalling daily 3.23 ± 0.16 hours, which was an average of 5.68 ± 0.15 min per dispensing event. The average direct human cost was $\text{€ } 775.31 \pm \text{€ } 91.37/\text{month}$, direct non-human cost was $\text{€ } 1228.26 \pm \text{€ } 396.75/\text{month}$ and indirect non-human cost was $\text{€ } 1256.7 \pm \text{€ } 55.06/\text{month}$, which was equivalent to $\text{€ } 5.84 \pm \text{€ } 0.3$ per dispensing task

Conclusion and relevance Our findings provide valuable evidence on the workload burden and financial shortcomings of hospital pharmacies related to the dispensing and documentation of high-priced item-based reimbursed medicines in Hungary.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

2SPD-020

INTRODUCTION OF A NEW PRESENTATION OF HYALURONIC ACID FOR INTRA-ARTICULAR INFILTRATION

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Background and importance In April 2020, the protocol for the use of intra-articular injections was updated within a multidisciplinary context with Pharmacy, Traumatology and Rehabilitation. Sodium hyaluronate 60 mg/4 ml (Hyalone, high molecular weight) was included. According to the new protocol, the use of Adant One (low molecular weight hyaluronic acid) was approved for grades I-II according to the Kellgren-Lawrence index (IKL) or III-IV in cases where Hyalone is not tolerated due to pain. Hyalone was indicated for IKL grades II-III-IV.

Abstract 2SPD-020 Table 1

Parameter	Period 1	Period 2
Patients (n)	91	94
Adant One (% of patients)	85.10	52.12
Adant (% of patients)	14.89	14.89
Hyalone (% of patients)	–	32.97
Adant One cost (€)	5776.53	3367.39
Adant cost (€)	495	363
Hyalone cost (€)	–	2803.8
Total costs (€)	6271.53	6534.14

Aim and objectives To evaluate the healthcare and economic impact of the incorporation of a new presentation of hyaluronic acid in the intra-articular infiltration protocol of a regional hospital.

Material and methods Retrospective observational study and economic analysis of drugs used in intra-articular infiltration, comparing a period (period 1) prior to the update of the protocol (April 2019–April 2020), with another period (period 2) 1 year after the implementation of the protocol (April 2020–April 2021). Data were obtained from the electronic prescription program (number of patients, number of dispensations as well as cost per drug and total cost).

Results The data obtained are given in Table 1.

In period 1, the Rehabilitation Service was the service that performed the most infiltrations (52.5% of the total patients treated with Adant One) and 92.85% of the total patients treated with Adant. In period 2, Adant One was used in a similar way. In the case of Hyalone, 96.77% was used by the Rehabilitation Service.

Conclusion and relevance The introduction of the new presentation of hyaluronic acid allowed a better individualisation of the treatment of intra-articular infiltrations and did not lead to a noticeable cost increase.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

2SPD-025 ACALABRUTINIB + OBINUTUZUMAB VERSUS IBRUTINIB + OBINUTUZUMAB AS FIRST LINE IN CHRONIC LYMPHOCYTIC LEUKEMIA

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Background and importance Acalabrutinib + obinutuzumab is authorised for the treatment of previously untreated patients with chronic lymphocytic leukemia (UPCLL), such as ibrutinib. Since comparative studies are not yet available, an indirect comparison (IC) between them could be of special interest.

Aim and objectives To establish, through an IC versus obinutuzumab + clorambucil, whether acalabrutinib + obinutuzumab and ibrutinib + obinutuzumab can be considered equivalent therapeutic alternatives (ETA) in efficacy in the treatment of UPCLL.

Material and methods A PubMed search of pivotal clinical trials (CTs) responsible for the authorisation of both drugs was performed. Progression-free survival (PFS) results were taken

as the main variable for comparison. IC were performed using the Bucher method (indirect treatment comparisons calculator, Canadian Health Technology Assessment Agency) of UPCLL from both trials. The reference value used for the sample calculation in ibrutinib + obinutuzumab CT was hazard ratio (HR)=0.55 and HR=0.60 in acalabrutinib + obinutuzumab CT, therefore a delta (Δ) of 0.6 was set as the most clinically relevant value. With this value, acalabrutinib + obinutuzumab was compared with ibrutinib + obinutuzumab in PFS and the results were analysed to see if the confidence intervals (95% CI) were within the $\pm\Delta$ interval. The methodology of the Spanish ETA-Guide¹ (a tool that allows assessment of the clinical equivalence of two or more drugs and position them) was applied.

Results Two CTs were found, one with acalabrutinib + obinutuzumab and another with ibrutinib + obinutuzumab, both against obinutuzumab + clorambucil as a common comparator. Both studies had a similar methodology. However, in the ibrutinib + obinutuzumab trial, patients with small lymphocytic lymphoma were included, although they were minority (5%). This limitation for IC was accepted. After applying the Bucher method, a HR=0.435 (95% CI 0.218 to 0.866) was obtained for acalabrutinib + obinutuzumab versus ibrutinib + obinutuzumab. According to the ETA-Guide, in the comparative efficacy of both drugs, a D position was obtained: graphically, the 95% CI was positioned almost completely within the $\pm\Delta$ interval. Therefore, the difference is probably irrelevant. However, as treatment failure involves a serious prejudice for the patient, according to this guide they would be considered not ETA.

Conclusion and relevance According to the ETA criteria, acalabrutinib + obinutuzumab and ibrutinib + obinutuzumab could not be considered ETA, since after IC a greater benefit was observed with acalabrutinib + obinutuzumab. Nevertheless, safety and efficiency criteria should also be taken into account.

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Conflict of interest No conflict of interest

2SPD-027 MEDICATION STORAGE TEMPERATURES INSIDE EMERGENCY VEHICLES: A PILOT STUDY IN A TEMPERATE CLIMATE COUNTRY

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Background and importance Emergency vehicles carry crucial medicines that face the same storage conditions required by pharmaceutical regulations. Nonetheless, it has been shown, mostly in North America, that out-of-hospital storage environments tend to exceed these requirements through exposure to extreme temperatures, sunlight or vibrations leading to possible drug alterations.

Aim and objectives Our pilot study aimed to determine whether the interior of observed emergency medical and non-

medical vehicles met room temperature standards following the European Pharmacopeia (EP) and therapeutic product manufacturer requirements.

Material and methods Following European Good Distribution Practice, a temperature mapping setup in an emergency non-medical vehicle was first carried out in July 2020. Fifteen temperature recorders (Testo 184 T3, Testo, Lenzkirch, Germany) were allocated inside the vehicle following recommendations of temperature characterisation referential and monitored every minute for 48 hours. To replicate true out-of-hospital storage conditions, the vehicle was used as usual by the emergency team. During the daytime a pharmacist monitored the vehicle's status (ie, in motion, stationary, open or closed doors) and the number of people inside. Then, six emergency non-medical vehicles, one medical vehicle and storage facilities were monitored every 10 min for 6 weeks (July–August 2020) with 22 temperature recorders.

Results The first mapping stage was characterised by a mean arithmetic temperature \pm IC95% of $25.8 \pm 0.2^\circ\text{C}$ and an absolute maximal recorded temperature of 35.4°C . The United States Pharmacopeia (USP) mean kinetic temperature for each measuring point of the vehicle was between 25.4°C and 26.2°C .

Temperatures exceeding 25°C were recorded onboard all vehicles and storage areas, ranging from 47.5% to 98.1% of the total exposure time. Temperatures above 30°C represented 3 to 10 days of measurements within the vehicles with the highest absolute temperature being 38.9°C .

Conclusion and relevance Medicines carried by emergency vehicles must be stored between 15°C and 25°C . In the summer of 2020, no vehicles were consistent with the EP's and drug manufacturers' room temperature recommendations. The mapping setup showed that temperature within the vehicles is impacted by their moving state, location and air circulation. Our results endorse the implementation of periodic stock rotation, continuous vehicle temperature monitoring and the use of controlled temperature storing boxes.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

2SPD-029 STABILITY OF NIVOLUMAB SOLUTIONS AFTER TRANSPORT THROUGH PNEUMATIC TUBE SYSTEMS

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Background and importance The assessment of 'in-use' stability of biotechnological medicinal products is not typically required prior to regulatory approval. However, 'in-use' conditions (ie, handling, storage, transport) could compromise product stability and, consequently, affect safety and/or efficacy.

Aim and objectives This work aimed to investigate the stability of diluted nivolumab solution after delivery in pneumatic tube systems (PTS) and the effects of residual air inside the bag.

Material and methods Due to the complexity of nivolumab, the major stability-indicating methods – turbidimetry, size

exclusion chromatography-high-performance liquid chromatography (SEC-HPLC), dynamic light scattering (DLS), pH, osmolality, nanoparticle tracking analysis (NTA), nuclear magnetic resonance (NMR) – were applied based on the results of a previous forced degradation study. All experiments were also carried out after 7 days of storage at $2\text{--}8^\circ\text{C}$ to investigate if the mechanical stress caused by PTS could induce instability over time.

Results All samples remained clear for the duration of the study with no precipitates or particulate matter detected with the naked eye. No change in colour or turbidity was observed over the study period. The pH of nivolumab solutions ranged from 5.8 to 6.0 over time, which was within the manufacturer's recommended pH range of approximately 6.0. Also, osmolality did not undergo any variation, ranging from 283 to 297 mOsm/kg during the storage of all samples.

All SEC-HPLC chromatograms of nivolumab were characterised by a single major peak with an elution time of 11 min and a minor signal with a retention time of around 13 min. After transportation, samples with and without air presented an identical elution profile, suggesting the absence of soluble aggregates. The percentage of high molecular weight aggregates (HMWP) remained constant in samples with and without air after 7 days. These results were confirmed by DLS and NTA.

Conclusion and relevance In this study, no differences in the main physical and chemical properties were observed in compounded nivolumab solutions after a single pass in PTS for at least 7 days of storage. The presence of an air-liquid interface inside the bag was not risk-determining for protein stability. In conclusion, these results support the possible use of PTS to deliver bags to clinical services.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

2SPD-030 HOW TO ASSESS THE IMPACT OF MEDICINES SHORTAGES IN THE EUROPEAN UNION?

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Background and importance Medicine shortages have been spreading in European countries with a substantial impact on the capability of national healthcare systems to ensure continuity of care. Shortages may originate from unpredictable and multifactorial causes, either supply-related or demand-related. In 2019, the European Medicines Agency (EMA) and Heads of Medicines Agencies (HMA) Joint Task Force released two guidances on shortage notification for manufacturers and communication to the public.¹ However, rational and practical shortage risk-assessment metrics are still needed to support regulators, manufacturers and other healthcare professionals in facing the crisis.²

Aim and objectives This work aimed to propose a risk-assessment tool for health professionals, regulatory agencies and other stakeholders to triage shortages' impact on public health.

Material and methods A review of existing metrics and strategies for risk assessment of shortages revealed that most of them are designed to face specific root causes of shortages

(eg, manufacturing failures, low price, distribution problem) and cannot be applied to all types. Assuming that shortages' impact should be estimated based on the potential risks of impairing patient accessibility to therapies, relevant criteria have been identified and used to create an algorithm to triage the magnitude of shortages' impact on public health and, therefore, help to define the most appropriate mitigation strategy to be adopted.

Results The designed risk assessment procedure allowed classification of shortages' impact on three levels (high, medium, low) based on three criteria (1) type of disease to be treated, (2) availability of therapeutic alternatives and (3) market shares of the product in a specific European country.² Based on the overall score, decision trees for risk-management strategies can be built up for different settings (eg, manufacturers, wholesalers, hospitals, pharmacies) or national regulatory frameworks.

Conclusion and relevance Although further studies in a real-world setting are needed to fully validate the procedure, it is a proof of concept for promoting cooperation and harmonised solutions to medicine shortages. The most critical medicinal products can be selected in advance by competent authorities and stakeholders, improving the resilience of healthcare systems.

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2SPD-031 THE ECONOMIC IMPACT OF ANTIMICROBIAL SHORTAGES IN ANTIMICROBIAL STEWARDSHIP PROGRAMMES

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Background and importance An inadequate antimicrobial prescription is often associated with an increase in antimicrobial costs and, as a result, the antimicrobial stewardship programme (ASP) includes an absolute reduction of 9% in antimicrobial costs.

Aim and objectives To describe the economic impact of antimicrobial shortages in a hospital ASP.

Material and methods Descriptive observational study, that included all drug shortage alerts published in the Spanish Agency of Medicines between March 2020 and April 2021.

An analysis was performed for the drug alerts in pharmacological groups J01 (Antibacterials for systemic use) and J02 (Antimycotics for systemic use), and those included in the ASP. Current stock-outs in the hospital, stock-outs periods (days) and therapeutic alternatives (TA) of these drugs were recorded. The expenditure description was performed comparing the antimicrobials affected by stock-outs with the TA, using the ratio cost/defined daily dose (DDD). The incremental expenditure and expenditure proportion of these stock-outs were recorded. The cost and number of DDD were recorded from the FarmaTools computerised physician order entry (CPOE) software.

Results A total of 441 drug shortage alerts were recorded. Of these, 40 were classified into pharmacological groups J01 and

J02. 17 of these 40 shortages (42.5%) comprised 8 antimicrobials included in the ASP. No stock-outs were found for 5 of 8 antimicrobials (daptomycin, caspofungin, aztreonam, linezolid and piperacillin/tazobactam), but for 3 of 8 (anidulafungin, voriconazole and ceftolozane/tazobactam) with stock-outs periods of 9, 31 and 108 days, respectively.

The ratio cost/DDD was € 52.30 for anidulafungin and € 51.01 for the TA (caspofungin), € 20.72 for voriconazole and € 56.66 for the TA (liposomal amphotericin B) and € 264.54 for ceftolozane and tazobactam and € 268.38 for the TA (ceftazidime/avibactam). Incremental expenditure was € 6409.29, representing 3.2% of the total antimicrobial expenditure (€ 200 409).

Conclusion and relevance Antimicrobial shortages force the prescription of other drugs for the treatment of infectious diseases, which result in expenditure increases. These problems tend to reduce the impact of the pharmacists' ASP activity in the hospital, which has been shown to be an effective solution in optimising antimicrobial treatments.

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Conflict of interest No conflict of interest

2SPD-032 DRUG EXCHANGE NETWORK

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Background and importance Technology plays a crucial role in the optimisation of resources, allowing the interconnection between centres and professionals, facilitating savings strategies with great economic impact on health, such as the exchange of drugs that are not being used in one hospital to another centre that can use them, thus avoiding economic loss due to expiration.

Aim and objectives Describing the process of making exchanges of underused medicines carried out between the Pharmacy Department (PD) of the public hospitals of a region in Spain, before (pre-web phase; December 2016–October 2020) and after (web phase; November 2020–September 2021) implementing a website for that purpose.

Material and methods In November 2020, a private financing web was implemented for the exchange of medicines between PD from hospitals in a vast region of Spain. Before this, users of the different hospitals contacted each other through mailing lists where they offered the medicines (presentation, pharmaceutical form, units, batch and expiration) that were available for exchange.

Results 17 hospitals are registered on the web (2 belonging to the private health network). Of all of them, 12 hospitals are operating on the web, carrying out drug exchanges.

Total amount saved to the regional health system amounts to € 430 783.28 from the start of the project; corresponding to 115 exchanges. Savings per year: December 2016 € 6623.30, 2017 € 20 289.55, 2018 € 41 178.69, 2019 € 102 485.06, 2020 € 64 072.22, 2021 (to September) € 196 134.46. Distribution of the total drugs exchanged, in

both phases is: 30.0% chemotherapy, 19.0% antiretroviral, 11.5% drugs for pulmonary hypertension, 9.5% biological, 9.0% other, 4.5% immunosuppressants, 3.5% anti-anemic, 3.0% anti-hepatitis C, 3.0% drugs for multiple sclerosis, 3.0% antibiotics, 2.0% drugs for idiopathic pulmonary fibrosis and 2.0% fertility drugs.

Conclusion and relevance There are drugs with a high budgetary impact that are commonly used in a limited number of patients. Suspensions of this type of treatment can leave a hospital with immobilised stock without possibility of use. The establishment of a network of exchanges to share resources between various centres can be a saving strategy with significant economic impact, as drugs that are not useful in one centre can be used in another.

REFERENCES AND/OR ACKNOWLEDGEMENTS

None

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2SPD-033 MAKING THE CASE FOR PRE-FILLED SYRINGES: DEVELOPMENT AND UTILISATION OF AN ECONOMIC MODEL

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Background and importance Parenteral medication is primarily delivered via conventional vial or ampoule and syringe in hospital settings; however, prefilled syringes (PFS) offer economic and clinical advantages, including reductions in preventable adverse drug events (pADEs), drug waste and supply costs, and increases in workflow efficiencies. The benefits of converting from vials and ampoules to PFS (denoted as 'V2P' hereafter) have been elucidated in previously developed economic models; however, these models are country-specific, therefore limiting generalisability of findings.

Aim and objectives To examine the potential impact of V2P, an economic model was developed to provide hospitals with a standardised tool for use across acute and emergency clinical settings.

Material and methods The Excel-based economic model estimates the potential benefit of V2P related to four key outcomes: pADEs, labour-time efficiency, unused drug, and cost of supplies. Built-in model defaults were derived from existing peer-reviewed literature sources, expert interviews, and national datasets. The model user can input specific information related to the hospital department and drug of interest. Users may also change built-in model defaults.

To investigate model utility, a hypothetical case study was conducted focusing on atropine administration in a UK cardiac intensive care unit (ICU) administering 35 doses/day of atropine. Literature-based inputs included drug costs of £0.82/ampoule dose and £5.03/PFS dose and vial drug waste levels at 85%. The built-in assumptions were 1.39 and 0.73 pADEs per 100 administrations for vials and PFS, respectively.

Results In the hypothetical case study, annual V2P cost savings associated with reductions in pADEs, unused drug, and costs of supplies were £64 126, £59 361 and £2667, respectively.

While the annual cost of PFS was £53 783 greater than vials, the net budget savings of V2P was £72 372 per year. Additionally, preparation time decreased 893 hours per year. Full results will be presented.

Conclusion and relevance The model provides a generalisable framework with customisable inputs, allowing hospitals in any country to quantify the clinical and economic value of adopting PFS. In a hypothetical cardiac ICU switching from atropine ampoules to PFS, despite increased cost per dose with PFS, the analysis documented reductions in medication preparation time and a net budget savings owing to fewer pADEs and reduced drug wastage.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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MW, HG and TE are employees of Becton Dickinson.

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2SPD-034 METHODOLOGICAL ANALYSIS OF PHARMACOECONOMIC STUDIES IN CAR-T: A SYSTEMATIC REVIEW

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Background and importance Chimeric antigen receptor T-cell therapies (CAR-T) are based on the ex vivo modification of T-lymphocytes for the expression of an antigen receptor that provides the specific union with tumour cells for their consequent destruction. CAR-T introduction into clinical practices presents challenges from a clinical and economic perspective. Traditional pharmacoeconomic studies may be limited in their ability to act as a valid decision-making tool in the access management of CAR-T and alternative methodological approaches may have to be considered.

Aim and objectives A literature review of CAR-T pharmacoeconomic studies has been carried out with the aim of reviewing the current literature on the economic evaluation of these drugs and to determine if traditional pharmacoeconomic studies represent a valid tool for decision-making in the access management of CAR-T.

Material and methods A systematic search was carried out in Scopus, Pubmed and Cochrane Library databases, using terms related to CAR-T and Pharmacoeconomics. We included published articles and accepted manuscripts written in English or Spanish up to 15 August 2021. For the quality evaluation of the identified studies, CHEERS and Drummon checklists were used.

Results 17 pharmacoeconomic studies were identified. The most studied CAR-T drug was tisagenlecleucel for diffuse large B-cell lymphoma in adults, with a median cost per quality-adjusted life year (QALY) of € 291 924.51. CAR-T therapies represent a clinically and potentially cost-effective therapeutic alternative. The quality of the identified studies was good according to the quality assessment scores.

Conclusion and relevance Cost-effectiveness of CAR-T therapies depends on its long-term results, the duration of the study conducted, and the cure rate used of the clinical study. Because of this, pharmacoeconomic studies in CAR-T exhibit certain limitations and could not be robust tools for decision-making solely based on their findings. There is a need to develop pharmacoeconomic methods that can avoid the uncertainty of many assumptions and incorporate more data, including real-life data.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

Section 3: Production and compounding

3PC-001 CHOLESTEROL 2%/SIMVASTATIN 1% OINTMENT FOR THE TREATMENT OF POROKERATOSIS PTYCHOTROPICA: A CASE REPORT

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Background and importance Porokeratosis is a rare group of diseases characterised by annular keratotic plaques due to altered skin keratinisation. It is associated with mutations in the mevalonate pathway that cause the accumulation of toxic metabolites in the skin and the lack of the end product, cholesterol. Due to the small number of cases, therapeutic options are limited. The dual combination of cholesterol with an HMG-CoA-inhibitor (to avoid accumulation of toxic metabolites) can be a promising strategy to improve cutaneous lesions. **Aim and objectives** A 53-year-old male was diagnosed with perianal ptychotropic porokeratosis (PP) in 2012. He underwent multiple topical treatments: imiquimod, diclofenac, tacalcitol, calcipotriol, calcitriol and photodynamic therapy, all of which were unsuccessful. The pharmacy service was asked to develop a cholesterol 2%/lovastatin 2% ointment, based on a series of cases of other forms of porokeratosis, in which this formulation was successful.

Material and methods Design and validation of a topical formulation of cholesterol 2%/simvastatin 1%. Since lovastatin was not commercially available as a raw material in our setting, the equivalence was made to simvastatin (2:1).

Evaluation of the formulation's effectiveness by physician global assessment (PGA) based on clinical appearance and patient adherence and tolerance by pharmacist interview.

Results Cholesterol 2%/simvastatin 1% ointment was formulated on a petroleum jelly basis, as this provides a source of lipids to the stratum corneum and helps improve skin barrier function. The galenic validation of the preparation – organoleptic characteristics (colour, odour, occlusiveness, extensibility and consistency), homogeneity of particles and exudation – was adequate and remained stable. A shelf-life of 6 months at room temperature, protected from light, was granted.

The patient self-applied the ointment twice a day for 6 months, and then once a day for the next 6 months. The lesions improved from a PGA of 3 to 1 and discomfort decreased. The patient tolerated well the treatment and showed adequate compliance (85%). He did not experience any adverse events and his satisfaction rating was 4.5/5.

Conclusion and relevance Cholesterol 2%/simvastatin 1% ointment improved both cutaneous lesions and symptomatology in a single patient with PP that had not improved with previous therapies, showing an adequate safety profile and low cost.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

3PC-002 GLASS AMPOULES AND DRUG FILTRATION: HOW MUCH DO WE KNOW ABOUT IT?

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Background and importance Glass ampoules (GA) have many advantages but many disadvantages too, like detachment of microscopic glass particles over the drug on opening that may cause phlebitis, embolism and other side effects during administration. To prevent these problems, the use of filters is recommended before drug administration. Nevertheless, filters are priceless and are incompatible with many drugs.

Aim and objectives Identify commercialised ampoule drugs available in our pharmacy service (PS), check those contained within glass ampoules, and bibliographic review of the drugs' compatibility with filters.

Material and methods We used our informatics program Farm-aTools to obtain a list of drugs contained in ampoules available in our PS. Then we verified physically the material that these ampoules were made of. Finally, we conducted a bibliographic review of the drugs to check their compatibility with filters by using the keywords 'ampoule' and 'filter' in Microdex, the individual drug data sheets and the Handbook on Injectable Drugs (17th edn.).

Results There are 1870 drugs available in our PS, of which 136 (7.27%) are packaged in ampoules. Of these, 12.50% of the ampoules were made of plastic and the remaining 87.50% were made of glass. No report on filter compatibility was found in 75.63% of drugs contained in GA. With respect to the remaining 24.37%, only 3.36% were incompatible with filters and the remaining 21.01% were compatible with 0.22, 0.45 and 5 micron filters.

Conclusion and relevance

- Most of the drugs are packaged in ampoules made of glass.
- There is no evidence about drugs' compatibility with filters, but for those drugs that such evidence exists, the majority are compatible with filters.
- Despite the evidence about these problems related to opening GA, the information available about drugs' compatibility is limited and more studies are needed.

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Conflict of interest No conflict of interest

3PC-003 SODIUM THIOSULPHATE GEL 25% FOR THE TREATMENT OF CALCIPHYLAXIS

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Background and importance Calciphylaxis is a disease characterised by fat necrosis due to hypoperfusion from calcium accumulation in the arterioles of the skin.

In the treatment of calciphylaxis, intravenous sodium thiosulphate is usually used due to its chelating of calcium ions, a vasodilator, and antioxidant. Topical use can be an effective and well-tolerated alternative, and it also allows early treatment. This active ingredient is not marketed in any of their presentations. In these cases, a concentration of 25% thiosulphate (12.5 g in 50 mL) was recommended.

Aim and objectives To develop and validate a magistral formula of topical sodium thiosulfate and establish quality controls.

Material and methods A bibliographic search was conducted to find possible topical master formulations of sodium thiosulfate.

The galenic development and validation of the formula were achieved following the procedure for elaborating gels described in the *National Formulary* (PN/L/FF/003/00) and through quality control.

The quality control of the formula was carried out as established in the *National Formulary*: control of organoleptic characteristics (smell, colour), physical, chemical (pH controls (PN/L/CP/001/00)), and a microbiological control as Procedure 5.1.4 of the Royal Spanish Pharmacopoeia. For this purpose, five samples were taken and analysed at the beginning and after 1 month.

The risk matrix for non-sterile formulae based on the 'Guide to Good Practice in the Preparation of Medicines in Hospital Pharmacy Services' was applied to establish the validity period.

The samples were prepared in the non-sterile preparation area in the cleanroom. They were prepared following the Standard Operating Procedure (SOP).

Results A shelf-life of 30 days was established based on the risk matrix for non-sterile preparations with medium risk.

The organoleptic (smell, colour), physical (phase separation), chemical (pH) and microbiological characteristics remained stable during the study month. At the beginning the pH values obtained were 6.45 ± 0.09 and after 1 month were 7.34 ± 0.1 .

Conclusion and relevance The formula remained physical, chemical and microbiological stable for 30 days and met the requirements from the galenic point of view for topical application, serving as an alternative to intravenous administration of the active ingredient.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

3PC-004 INSULIN EYE DROP FORMULATION: EFFECTIVENESS, SAFETY AND PATIENT SATISFACTION

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Background and importance Recently, the insulin eye drops formulation 1 IU/mL has been included in the Pharmacotherapeutic Guide. Recent studies demonstrate its efficacy and safety in the treatment of keratitis and dry eye.

Aim and objectives To analyse the patient profile and describe the characteristics of insulin eye drops treatment, as well as its effectiveness, tolerance and patient satisfaction.

Material and methods Retrospective observational study in a tertiary hospital. All patients treated with insulin eye drops during the period January–September 2021 were included. The variables collected were: demographics, indication, duration of treatment, line of treatment, clinical response and adverse effects (both described in the clinical history) and patient satisfaction (using the 'Treatment Satisfaction Questionnaire for Medication' version 1.4: 14 questions, distributed in four domains: effectiveness, side effects, convenience and overall satisfaction).

A descriptive statistical analysis was performed with measures of central tendency and dispersion for quantitative variables (mean and standard deviation (SD)) and absolute frequencies for categorical variables.

Results A total of 34 patients treated with insulin eye drops 1 IU/mL were included. The mean age was 58.89 (SD 15.79) years. A total of 47.10% were women. 35.29% were diagnosed with non-herpetic keratitis, 20.59% with herpetic keratitis, 17.65% with corneal erosion, 14.71% with dry eye, 8.82% with pterygium and 2.94% others. The duration of treatment was 120.01 (SD 43.81) days. A total of 17.59% were treated in the fourth or successive lines, 17.65% in the third, 8.82% in the second and 2.94% in the first. Almost all (91.18%) the patients responded to treatment and 8.82% of patients showed toxicity (conjunctival hyperemia and ocular pain). Patients were satisfied or better with the treatment: 91.17% in terms of effectiveness, 8.53% adverse effects, 88.23% convenience and 94.12% overall satisfaction.

Conclusion and relevance The insulin eye drops formulation 1 IU/mL is a good therapeutic alternative as a rescue treatment in patients refractory to the usual treatments. The preparation, by the pharmacist, of formulas allows coverage of possible therapeutic gaps in the treatment of herpetic and non-herpetic keratitis.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

3PC-005 SELECTION OF AN OSMOLARITY VALIDATION MODEL FOR NOMINATIVE PARENTERAL NUTRITION

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Background and importance Osmolarity is one of the pharmaceutical controls carried out on the nominative parenteral nutritions (NPN) produced at the pharmacy for a given patient (magistral formula). According to a previous method validation, we use the Pereira Da Silva equation (PDS) when the theoretical osmolarity (TO) determined by this model is greater than 1000 mosmol/L and we use the manufacturers' data (MD) equation when the TO according to the PDS equation is below 1000 mOsmol/L. This method is associated with an osmolarity nonconformity (NC) rate of 7.0%.

Abstract 3PC-005 Table 1

MO class (mOsmol/L)	MO	NC	NC (PDS) C (MD)	NC (PDS) NC (MD)	C(MD) C(PDS)	C(PDS) NC (MD)
[0–700]	0.6%	30.4%	0.7%	0%	3.4%	1.1%
[700–1300]	51.5%	8.7%	68.8%	11.2%	81.1%	31.1%
[1300–1900]	37.6%	2.5%	29.3%	61.2%	14.3%	11.1%
>1900	10.3%	13.6%	1.2%	27.6%	1.1%	56.7%
Total	3795	265	2412	1118	175	90

Aim and objectives To determine the best predictive model to calculate TO of the NPN to decrease osmolarity NC rate.

Material and methods A retrospective analysis of measured osmolarities was carried out from 1 June 2018 to 7 September 2021 to determine the osmolarity classes most affected by NC. The MO (measured osmolarity) was compliant if it is between –10% and +10% of the TO. Different models (modification of the limit value; choice of the two models within a range of osmolarities) were tested and the one with the lowest NC rate was chosen.

Results A total of 3795 MO were analysed. Table 1 shows the distribution of MO, their NC rate according to the current model and their NC rate according to PDS and MD equations.

By increasing the osmolarity limit value to 1150 mOsmol/L (instead of the current 1000 mOsmol/L), the NC rate decreases to 5.2%. By allowing both equations for a TO according to the PDS equation between [900;100]; [800–1200] or [700–1300], the NC rate decreases to 4.8%; 4% and 3.5%, respectively.

Conclusion and relevance The optimal theoretical model depends on the TO PDS. Allowing both PDS and MD equations, we reduced the NC rate. Therefore, the actual TO method should be revised in favour of the MD equation for TO under 700 mOsmol/L, both MD and PDS equation for TO between 700 and 1300 mOsmol/L and PDS equation over 1300 mOsmol/L.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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3PC-006 EVALUATION OF PARENTERAL NUTRITION COMPOUNDING THROUGH A CHECKLIST

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Background and importance Parenteral nutrition (PN) is a high-risk medication. Its compounding is a complex process that must be controlled and evaluated periodically. Pharmacy staff involved must present appropriate technical skills and perfect knowledge of aseptic technique and preparation aspects.

Aim and objectives To objectively evaluate the PN compounding process by pharmacy staff, using a specifically designed checklist.

Material and methods Each pharmacy technician (PT) was evaluated by an experienced pharmacist through direct visual

Abstract 3PC-006 Table 1

	Global (average; minimum; maximum)	Aseptic technique (average; minimum; maximum)	PN compounding (average; minimum; maximum)
With experience	7.9±1.09; 5.2; 9.2	8.5±1.14; 5.9; 10	7.3±1.53; 3.6; 9.4
Without experience	7.2±1.0; 5.9; 8	8.9±0.5; 7.9; 9.7	4.8±1.5; 2.3; 7
Total	7.65±1.0; 5.2; 9.2	8.6±0.94; 5.9; 10	6.3±1.92; 2.3; 9.4

inspection, using a checklist containing 57 items: 29 related to aseptic technique and 28 regarding compounding. Each item scored 1 point; final evaluation score was calculated on a 0–10 scale.

PT were divided in two groups: with experience (PN compounding for >6 months) and without experience.

A descriptive analysis was performed using measures of central tendency, dispersion and position for quantitative variables, and frequency distribution for qualitative variables.

Results 30 operators were examined, 19 with experience and 11 without experience (the results are in Table 1).

Total number of errors was 307. Error prevalence was 18%. The most frequent errors involved: electrolyte addition sequence (10.7%); stable intermediate admixtures (7.8%); mixing after additions (7.2%); renew/disinfect gloves (5.9%); mix glucose and lipids without amino acids (5.5%); inspect intermediate/final admixtures (5.5%); mix incompatible electrolytes (phosphate-calcium, phosphate-magnesium, magnesium-calcium) (4.23%). Most relevant considered errors were related to incompatibilities/correct mixing of components, visual control, use of gloves and disinfection processes.

Conclusion and relevance Evaluation of PN compounding through a checklist containing the key elements allowed us to objectively detect errors and areas of improvement. Our study revealed a lack of training in compounding aspects, more than in aseptic technique, that was greater in those PT without experience. This study enabled us to implement a targeted training plan to improve staff qualifications and therefore quality/safety of PN.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

3PC-008 TIMES AND ERRORS FOR DISPENSING NARCOTIC DRUGS IN AUTOMATED SYSTEM VERSUS MANUAL SYSTEM

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Background and importance Narcotic drugs require a special control and monitoring by the Pharmacy Service (PS) to ensure their correct storage and dispensing. An automated dispensing system could promote a safer and more efficient process.

Aim and objectives Describe and analyse drug replacement times and errors through a manual process versus an automated process.

Material and methods A prospective 1-month observational study, divided into two periods, was carried out. In the first period (15 days), the replacement of Hospitalisation Units Dispensing System (UH-DS) was carried out through a manual process guided by the user. In the second period (15 days), after the implementation of a new automated Pharmacy Service Dispensing System (PS-DS), the replacement was carried out by computer integration between UH-DS and PS-DS.

Times were described through medians and interquartile ranges (IQRs) and were compared using a Mann–Whitney U test. Replacement errors were described through the percentage of errors with respect to the total number of units replaced and were compared using a Chi-square test.

Results A total of 1991 units were dispensed: 1082 units through the manual process and 909 units through the integrated automated process. The total time taken was 16.8 s/unit (IQR 3.6) for the manual process, while for the integrated process it was 9 s/unit (IQR 2, 4) ($p < 0.05$). The number of errors detected for the manual process was 1.57% (17/1082) compared to 0.88% (8/909) for the integrated process, which represented a reduction of 56% ($p > 0.05$).

Conclusion and relevance The implementation of an automated process integrated with a PS-DS allowed the reduction of replacement times by 46.4%, as well as replacement errors by 56%. This improvement provides a safer and more efficient drug replenishment circuit that should be implemented in routine clinical practice.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

3PC-010 ASSESSMENT OF CHEMFORT (ONGUARD, US) SYRINGE ADAPTOR LOCK FITTED WITH LUER LOCK SYRINGES TO CONTAINER INTEGRITY STANDARDS (NHS, UK) SUPPORTING DOSE BANDING OF CYTOTOXIC DRUGS

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Background and importance Disposable syringes are used as final containers in dose banding of cytotoxic products within pharmacy aseptic services. Closed system transfer devices (CSTDs) could mitigate exposure to cytotoxic drugs while maintaining drug sterility. There is a paucity of container integrity data that satisfies standards (National Health Service (NHS)) supporting the use of CSTDs as part of storage devices in aseptic services.

Aim and objectives Study aim: to satisfy container integrity requirements using *Brevundimonas diminuta* with an extended contact time of 14 days at 30°C–35°C (NHS, YCD), supporting the use of Chemfort (OnGuard) with a range of Luer lock (LL) syringe sizes as long-term storage devices in UK dose banding.

Material and methods Chemfort (Simplivia Healthcare) SAL integrity tested with Luer lock syringes: 1 mL, 20 mL and 60 mL. Each SAL+LL syringe combination ($n=20$) was filled with Tryptone Soya Broth (TSB) media puncturing the SAL septa ($n=3$). Devices were: immersed in TSB inoculated with

24-hour culture of *B. diminuta* (media:culture ratio 100:1) covering the SAL+LL syringe hub, incubated for 14 days at 30°C–35°C and inspected for growth. Each combination SAL/syringe size ($n=20$) was: filled with MilliQ water, sealed, submerged in 0.4% w/v methylene blue (MB) dye, rotated at 45 rpm for 2 hours and inspected (absorbances measured at 660 nm on a plate reader) (Epoch, Biotek UK). Limit of detection (LOD) for MB dye was 0.010 mAu at 660 nm.

Results Chemfort SAL/syringe combinations showed no microbial growth at the end of the test demonstrating container integrity. Positive controls ($n=2$) produced growth after inoculation with <100 cfu of *B. diminuta* incubated for 3 days at 30°C–35°C. Chemfort SAL/LL syringes ($n=60$) tested with MB dye had $<LOD$ absorbances at the end of the test demonstrating 100% integrity. Positive controls ($n=3$) for each syringe size resulted in dye ingress with absorbances $>LOD$ confirmed spectrophotometrically.

Conclusion and relevance Chemfort (OnGuard) SAL/LL syringe combinations ($n=120$) with septa punctures ($n=3$) prior to testing conformed to container integrity requirements (NHS) for physical and microbiological (even when submerged in *B. diminuta* with extended contact for 14 days at 30°C–35°C) syringe integrity supporting their use within pharmacy aseptic services and dose banding.

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Conflict of interest No conflict of interest

3PC-011 STUDY OF THE CONTAINER–CONTENT INTERACTION BETWEEN ETOPOPHOS POLYVINYL CHLORIDE (PVC) PERFUSION SYSTEMS

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Background and importance Etopophos is an anticancer drug inhibiting type II topoisomerase, prodrug of etoposide. It is widely used in solid and haematological cancers in paediatric and adult populations. It is administered by the slow intravenous route, in 30–60-min injections, causing a risk of interaction with the polyvinylchloride (PVC) perfusion system.

Aim and objectives To study the interaction between Etopophos and the PVC perfusion system in real-life conditions at three concentrations corresponding at the extreme dosages (38 mg and 580 mg) and the mean one (150 mg).

Material and methods Bags of three concentrations of Etopophos were prepared in sterile conditions. In real-life conditions, Etopophos was injected into the perfusion system over 60 min. Etopophos was then analysed by UV Raman spectrometry via the Qcrx system, and compared to a standard to research plasticiser traces. The intact perfusion system was analysed by Fourier transform infrared spectrometry (FTIR), then dissolved into tetrahydrofuran (THF) at 35°C, precipitated by glacial methanol and analysed by high-performance liquid chromatography (HPLC) coupled to a UV spectrometry detector. Etoposide is known for its poor solubility, its short

stability and its capacity to interact with plastic components, due to the presence of Polysorbate 80 as excipient into the formulation. The PVC perfusion system, intact of any chemotherapy administration, was analysed, as a blank sample, corresponding to a NaCl 0.9% bag.

Results HPLC analysis showed that the MS10 tubing (Fresenius Kabi) was plasticised by triethylhexyl trimellitate (TOTM), while the four route link (CAIR LGL) and the Connect-Z link (CAIR LGL) were plasticised by DINCH and TOTM. No trace of plasticiser was found after the 1-hour administration of chemotherapies. No trace of chemotherapy was found in the samples of the perfusion system used for the injection of either Etopophos or etoposide.

Conclusion and relevance No interaction between the PVC perfusion system and the chemotherapies Etopophos and etoposide was found in real-life conditions. However, further analysis, using a larger number of samples, other dosages of chemotherapies or in static conditions, to exacerbate the contact between the drug and the system may be necessary to confirm these results.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

3PC-012 IMPACT OF PRELIMINARY WIPING OF EQUIPMENT INTRODUCED INTO A CLEANROOM ON THE CONTROL OF THE ENVIRONMENT

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Background and importance Parenteral nutrition is a high-risk activity. It is necessary to master and control the preparation environment. Within our parenteral nutrition unit, a decontamination airlock (Malochet) with hydrogen peroxide (H₂O₂) (Clarus, Bioquell) is used to bring the equipment (medical devices, glass nutrient bottles) into the cleanroom. They are introduced directly from an ISO 8 area into the airlock, without systematic wiping.

Aim and objectives The goal was to improve environmental control by studying the impact of preliminary wiping of equipment entering the cleanroom before or after surface decontamination with H₂O₂.

Material and methods The same operator performed surface swabs on medical devices (paper and plastic sides) and glass nutrient bottles. The wiping method was the same for all: 1 pre-impregnated wipe (55% ethanol and quaternary ammonium propionate) per piece of equipment. The airlock was qualified (4 log decontamination, 9-min dwell phase). 6 cycles were performed for 70 samples. For each cycle, before decontamination, 3 swabs were carried out after a prior wiping (on plastic, glass and paper sides) and 4 without wiping (on plastic, glass and two paper sides), then 7 swabs on those pieces of equipment after decontamination. Inoculation on tryptocasein soy agar was performed for each swab. Agar plates were incubated for 3 days at 32°C and 4 days at room temperature. Colony-forming units (CFU) were read on days 3 and 7. Data were collected in an Excel file and analysed with Mann-Whitney and Welch tests.

Results The difference in the number of CFU at 7 days between the groups without wiping and with wiping before decontamination was significant ($p < 0.01$) but not significant

after decontamination ($p = 0.17$). The difference between the groups before decontamination with wiping and after decontamination without wiping was not significant ($p = 0.079$), but with a strong trend. Most of the contamination found after decontamination was bacteria. A mould was found after decontamination.

Conclusion and relevance This study shows that contamination brought in by equipment is possible. Wiping reduces the risk of contamination when decontamination by H₂O₂ is not possible. It seems important to limit storage inside the cleanroom to avoid a release of contamination into the air.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

3PC-013 PHARMACEUTICAL COMPOUNDING IN PAEDIATRIC PATCH TESTING: ARE WE SURE ABOUT THE ACTUAL ACTIVE INGREDIENT CONCENTRATION?

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Background and importance Large differences in active ingredient concentrations (AI) in drug patch tests, as a result of the drug source chosen, signify the need for further studies to ensure the quality of the preparations.

Aim and objectives To analyse the variability of the resulting AI concentrations in paediatric patch tests, according to the commercialised forms (CFs) used.

Material and methods A review of the recommendations for drug patch tests preparation was carried out using PubMed.

For the Allergy Department requested compounds, when no pure drug was commercially available, the CFs were used instead. In the latter case, following Spanish Society of Allergy and Clinical Immunology (SEAIC) recommendations, the CF weights were used, rather than their AI content, to obtain the prescribed drug concentration in the compounds. Finally, the actual AI concentration in each compound was calculated.

Results The SEAIC and the European Society of Contact Dermatitis recommendations were followed, whenever possible, using the pure drug, and when this was not available, resorting to the CF. Eight drugs were diluted by the Pharmacy Department at different concentrations in petrolatum. The only drugs whose manufacturers provided the pure drug were amoxicillin and doxycycline. When diluting the content of the capsules of phenoxymethylpenicillin potassium at 10%, the AI concentration obtained was 8%; however, when using the oral powder it was 1.4%. The same thing happened when diluting tablets of cefuroxime at 20%, namely the AI concentration obtained was 11%, while if using the oral powder it was 1.2%. For ampicillin at 5%, using the capsules the AI concentration obtained was 4.25%. When preparing brivaracetam at 30% and rufinamide at 3%, using the available tablets the AI concentrations obtained were 5.34% and 1.63%, respectively. However, when diluting the capsules of ethosuximide at 20%, the AI concentration obtained was 15.8%.

Conclusion and relevance The actual AI concentrations in the compounds vary depending on the CF used. Using the CF with the lowest amount of excipients allows one to obtain AI concentrations closer to those usually proposed by scientific societies. The results obtained demonstrate the need to

establish protocols with the Allergy Department in order to standardise the preparation and thereby assure quality and security in paediatric patch testing.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

3PC-014 EVALUATION OF THE MICROBIOLOGICAL QUALITY OF NON-STERILE DRUGS PREPARED IN A HOSPITAL PHARMACY

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Background and importance Pharmaceutical compounding is an integral part of the services provided by pharmacies for the specific needs of patients. For these pharmaceutical preparations the requirements of the European Pharmacopoeia (EP) regarding the microbiological quality apply, namely that in the manufacture and packaging, as well as during storage and distribution, suitable measures have to be taken to ensure their microbial quality.

Aim and objectives This study evaluated the microbiological quality of non-sterile pharmaceutical preparations of the hospital pharmacy of a University Hospital. A risk-based approach was chosen for the identification of the most microbiologically susceptible non-sterile pharmaceutical preparations.

Material and methods A risk matrix of all 42 non-sterile pharmaceutical stock preparations was created, taking into account the characteristics of the active substance and the formulation, as well as the manufacturing process risk of the individual pharmaceutical dose form. To confirm the microbiological quality, tests were conducted using membrane filtration and the surface-spread method according to EP 2.6.12. Suitability tests were carried out in the presence and absence of the selected products with five American Type Culture Collection (ATCC) test strains.

Results The risk evaluation resulted in seven non-sterile pharmaceuticals of the different pharmaceutical dosage forms with a high microbial risk: calcium glycerophosphate capsules, clobetasol adhesive gel, EEG gel, misoprostol capsules, opium tincture, propranolol solution and sucrose solution, to be tested according to EP 2.6.12. The permitted recovery rate of the test strains of 50% to 200% was fulfilled for all tested products and the chosen method was suitable for the specific products. The seven worst-case products were tested in duplicate and only the opium tincture and the EEG gel showed a microbial growth of one and three colony-forming units (CFU), respectively. These results are fully within the requirements of the pharmacopoeia.

Conclusion and relevance This study demonstrates that non-sterile production of different dosage forms (including packaging and storage) in a hospital pharmacy can guarantee the microbiological quality of pharmaceutical preparations. Only neglectable microbiological growth even of the pharmaceutical preparations with the greatest risk was observed, so that overall the requirements of the pharmacopoeia are fulfilled.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

3PC-016 VANCOMYCIN EYE DROPS AT 50 MG/ML: PHYSICOCHEMICAL STABILITY, IMPACT OF PACKAGING AND STORAGE CONDITIONS

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Background and importance Vancomycin eyedrops (VED) are unavailable in Europe and are usually compounded as extemporaneous in hospital pharmacies.

Aim and objectives To collect data on VED physicochemical stability in three different containers stored either refrigerated or frozen.

Material and methods VED at 50 mg/ml (10 mL) were aseptically compounded under a laminar flow hood from injectable vancomycin and sterile water for injection (Baxter) and stored in amber glass (n=26; Gravis), classical (n=26; CAT) or innovative Novelia (n=26; Nemera) low-density polyethylene (LDPE) bottles. Assays were performed according to GERPAC-SFPC stability studies guidelines on vials stored either at 2–8°C (analysis at days D1-D3-D7-D15-D40-D60-D90) or frozen at –20°C for 60 days, then thawed (room temperature (RT) or 2–8°C) and refrigerated once thawed (post-thaw analysis at D1-D3-D7-D20). At each time point in the study vancomycin concentration (using a stability-indicating HPLC-UV method), pH and osmolality were determined, and the visual aspect was checked. Sterility and non-visible particle count (by light obscuration particle count test) were performed at the beginning and end of the study. Non-parametric tests were used to compare containers and storage conditions ($\alpha=5\%$).

Results Vancomycin concentration (mean \pm standard deviation; expressed as a percentage of the initial value) when stored at 2–8°C from D1 to D60 was between $95.7\pm 1.6\%$ and $107.4\pm 2.1\%$ (except at D7, due to material bias) and $89.5\pm 1.6\%$ and $92.8\pm 1.9\%$ at D90. Vancomycin concentration in vials thawed at RT or 2–8°C was, respectively, between $95.8\pm 1.1\%$ and $102.2\pm 4.3\%$ and $95.3\pm 2.3\%$ and $101.1\pm 4.1\%$ at D7 and between $89.3\pm 1.8\%$ and $93.9\pm 0.6\%$ and $89.9\pm 0.8\%$ and $92.7\pm 1.2\%$ at D20 after thawing. No significant difference was found between packaging ($p=0.323$) or thawing method ($p=0.736$). pH and osmolality, respectively, 3.31 ± 0.06 and 46.12 ± 3.61 mOsm/kg, remained stable with no difference between containers ($p=0.242$ and $p=0.414$) or thawing methods ($p=0.287$ and $p=0.999$). A slight yellow colouration of VED (2–8°C) was perceived after D60. A slight increase in non-visible particles count was observed between D1 and D90 in glass and classic LDPE but values complied with the European Pharmacopoeia 2.9.19 threshold.

Conclusion and relevance VED remained stable for 2 months refrigerated or frozen, and for 7 days after thawing (RT or 2–8°C). These results will allow the preparation of a stock of VED that is available immediately. A microbiological stability study in real conditions of use should complete this work.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

3PC-017 ASSESSING THE STABILITY OF SANDOZ RITUXIMAB BIOSIMILAR AFTER EXPOSURE TO OUT-OF-FRIDGE CONDITIONS FOR 21 DAYS

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Background and importance Studies evaluating the effect of short temperature excursions on the quality of the unopened vial of Sandoz rituximab biosimilar (SDZ-RTX) stored in the original outer box at the caregiver level are lacking.

Aim and objectives This out-of-fridge (OOF) study simulated the impact of temperature excursion on the quality of SDZ-RTX.

Material and methods The OOF study was subsequently performed after 36 months of storage in long-term conditions (5 ±3°C) by exposing three batches of SDZ-RTX to two storage conditions: (i) 25±2°C/60±5% relative humidity (RH) and (ii) 30±2°C/65±5% RH, for up to 21 days. The impact of the temperature excursion was evaluated using the following parameters: purity (cation exchange chromatography (CEX), size exclusion chromatography (SEC) and non-reducing capillary electrophoresis-sodium dodecyl sulfate (nrCE-SDS)), identity (CEX and liquid chromatography-ultraviolet (LC-UV) peptide mapping) and also potency (complement-dependent cytotoxicity (CDC)-bioactivity). Other analyses are presented in the Results section.

Results No notable change was observed after 21 days at both OOF conditions (i) and (ii) for identity (charge and primary structure), pharmaceutical tests (clarity, visible and subvisible particles, container appearance, degree of colouration, pH, osmolality, extractable volume and container closure integrity testing), protein content by UV and microbiological parameters. After 21 days, slight changes were detected with SEC (decrease in purity of up to 0.4%), CEX (decrease in the main peak up to 0.8%, decrease in the sum of basic peaks up to 2.4% and an increase in the sum of acidic peaks up to 3.9%) and nrCE-SDS (decrease in purity up to 0.9%). For CDC-bioactivity, a notable change was observed in only one out of three tested batches; however, all results complied with the shelf-life specification at both OOF conditions (i) and (ii).

Conclusion and relevance The obtained stability data support the storage of SDZ-RTX for up to 21 days up to 30±2°C/65 ±5% RH. These results may be beneficial to avoid potential wastage of product and prevent distressing the patients regarding drug quality after short-term exposure to conditions outside the intended storage of 2–8°C.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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Conflict of interest No conflict of interest

3PC-018 COMPATIBILITY AND 30-DAY STABILITY OF FOUR INTRAVENOUS MIXTURES FOR MULTIMODAL ANALGESIA

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Background and importance Multimodal analgesia is based on the combination of different drugs and analgesic techniques in order to alleviate postoperative pain. One of the limitations of this technique is the lack of evidence about the stability of these mixtures in clinical practice.

Aim and objectives To evaluate the 30-day physicochemical compatibility of four analgesic mixtures of tramadol and ketamine, combined with dexketoprofen or ketorolac, ± methadone, in saline solution bags, for patient-controlled analgesia.

Material and methods Mixtures studied:

V1: tramadol-hydrochloride 7.5 mg/mL + dexketoprofen 2.26 mg/mL + ketamine 0.19 mg/mL

V2: V1 + methadone-hydrochloride 0.075 mg/mL

V3: tramadol-hydrochloride 7.9 mg/mL + ketorolac-trometamine 0.95 mg/mL + ketamine 0.4mg/mL

V4: V3 + methadone-hydrochloride 0.08 mg/mL.

Diluent: 100 mL normal saline (polypropylene bags).

Four batches of each mixture were prepared in aseptic conditions using commercially available products. Bags were protected from light, and stored at 2–8°C. The following parameters were evaluated immediately after preparation (t0), 7, 15 and 30 days after preparation (all measures by triplicate) (i) colour change and/or precipitation (visual inspection) and turbidity (nephelometry), (ii) pH (potentiometry), (iii) drug concentration (ultra-high-performance liquid chromatographic-diode array (UHPLC-DAD)) and (iv) preservation of sterility by culture in enriched soybean casein digest broth.

Two chromatographic methods were developed (M1, M2) using two different columns: Acquity-HSS-C18 (100 mm×2.1 mm×1.8 µm) (M1) and Acquity-BEH-C18 (100 mm×2.1 mm×1.7 µm) (M2). The chromatographic method consisted of a gradient with acetonitrile/water. An acidic aqueous phase was also used with a high strength silica (HSS) column (HCOONH₄/HCOOH) and a basic aqueous phase with an ethylene bridged hybrid (BEH) column (HCOONH₄/NH₃), forcing different order of drugs' elution.

Results Physical parameters and pH remained unchanged during the study; pH range for V1, V2: 7.08–7.28; V3, V4: 6.76–6.91. The chromatographic methods proved to be stable after stress tests and showed good linearity (r²>0.999) and high selectivity, with a detection limit between 0.1 and 0.3 mg/L at 215 nm. The percentage of drug recovery remained in the range 90±110% (97%–103%) of the initial concentration (t0) for all drugs in the four mixtures during the whole study period (coefficient of variation (CV) (%) 0.1–2.4). All samples preserved their sterility during the study.

Conclusion and relevance The four analgesic mixtures of tramadol and ketamine, combined with dexketoprofen or ketorolac, ± methadone, were stable for 30 days at 2–8°C in the conditions described in the study, allowing their centralised preparation at pharmacy service.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest Corporate sponsored research or other substantive relationships: study financed by the Spanish Government ISCIII FIS PI17/00826.

3PC-019 EVALUATION OF THE IMPACT OF MACHINE-AIDED DEBLISTERING IN UNIT DOSE BLISTER PRODUCTION ON THE FUNCTIONALITY OF TABLET COATING

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Background and importance Deblistering of medication is a critical step in unit dose blister production. In our setting, large quantities of push-through packs are processed by manually operated deblistering machines. Visibly damaged drugs are removed. However, it has not been investigated whether mechanical stress by deblistering machines can cause minimal, hardly identifiable damage with negative effects on functional coating.

Aim and objectives The influence of machine-aided versus manual deblistering on drugs with modified release was studied to rule out negative effects on functionality of coating. Purposely damaged tablets with tiny superficial defects served as positive controls. Enteric coating and extended release were investigated in tablets chosen for their high deblistering volume and critical active agent, respectively.

Material and methods Thrombo ASS 100 mg (acetylsalicylic acid; enteric coating) and Quilonorm retard 450 mg (lithium carbonate; retardation of release) were deblistered (A) manually, (B) with deblistering machines and (C) manually and then minimally damaged on the surface with a pointed item. Ten tablets of each group were analysed in two ways. (1) Disintegration testing was performed based on the methods of the European Pharmacopoeia. (2) Tablets were immersed into a methylene blue dye bath to visualise intactness of coating as well as damaged areas.

Results Manually and machine deblistered Thrombo ASS tablets met the required 2 hours of acid stage duration in 0.1 N HCl. The minimally damaged fraction started to disintegrate within seconds. When transferred to neutral buffer solution, manually and machine deblistered tablets showed identical disintegration behaviour. All three groups of Quilonorm retard tablets showed acid stability and disintegrated the same way in a pH-neutral environment. Cavities and grooves were visible on damaged tablets immersed into the dye bath. Tablets deblistered by hand and machine showed identical, even dying of their surfaces.

Conclusion and relevance Although minimal damage can lead to a loss of coating functionality, machine-aided deblistering showed no negative effects on coated tablets. Neither differences in disintegration tests nor in the dye bath were detected compared with manually deblistered tablets. These results were examined during a good manufacturing practice (GMP) inspection by the Austrian authority, support machine qualification and the validation of this important step in the unit dose blister process and may therefore be of interest for other production sites.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

3PC-020 CHEMICAL STABILITY AND PHYSICAL COMPATIBILITY OF INSULIN EYE DROPS USED IN CLINICAL PRACTICE

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Background and importance Insulin eye drops are an effective treatment for corneal neurotrophic ulcers due to the action of insulin as a tissue growth factor. Owing to the lack of studies on the stability of this eye drops, in clinical practice it is not possible to give them for more than 7 days of use. The purpose of this study was to assess whether the stability could be increased, making the preparation and dispensing by the Pharmacy Service easier, as well as making it more comfortable for the patient.

Aim and objectives The objective was to study the chemical stability and physical compatibility of eye drops of human insulin (Humulina and Actrapid) at 1 UI/mL, diluted in Systane, Liquifilm or 0.9% sodium chloride (0.9% NaCl), in polyethylene bottles, protected from light, at 24°C or 4.5°C, for 30 days.

Material and methods Three preparations were prepared for each condition. At the time of analysis, one sample for each preparation was analysed by high performance liquid chromatography. The time at which human insulin retained 90% of the initial concentration (T90) was obtained for each preparation. The method was validated according to the International Conference on Harmonisation Q2 (R1). Physical stability was evaluated by visual inspection, gravimetric analysis and pH measurement.

Results Humulina preparations, T90 was: (a) with Systane: 9 days at 4.5°C, 7 days at 24°C; (b) with Liquifilm: 9 hours at 4.5°C, 10 hours at 24°C; (c) with 0.9% NaCl: 1 day at 4.5°C, 15 hours at 24°C. Actrapid preparations, T90 was: (d) with Systane: 10 days at 4.5°C and 24°C; (e) with Liquifilm: 17 hours at 4.5°C, 6 hours at 24°C; (f) with 0.9% NaCl: 4 days at 4.5°C, 3 days at 24°C. During the study, neither changes in colour nor losses of weight were observed in the preparations assayed: variations of pH were higher than 5% from day 2 in all preparations with Humulina and Actrapid in 0.9% NaCl.

Conclusion and relevance Eye drops of human insulin (Humulina or Actrapid) at 1 UI/mL diluted in Systane, in polyethylene bottles and protected from light, can be used in clinical practice.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

3PC-021 DESIGN AND ELABORATION OF METRONIDAZOLE 1% TOPICAL SOLUTION FOR TREATMENT OF ULCERS INFECTED BY ANAEROBIC BACTERIA

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Background and importance The scientific literature was reviewed in order to investigate metronidazole 1% topical solution for treatment of ulcers infected by anaerobic bacteria, and whether refrigerated storage is recommended. However, the samples formulated in the Hospital Pharmacy Department presented a crystalline precipitate, which could not be redispersed. Therefore, a compounding improvement was necessary.

Aim and objectives Design and analyse, by galenic validation, different compounding improvement to increase the solubility of metronidazole in water in three storage environments.

Material and methods A bibliographic search found that metronidazole base solubility in water is 10.5 mg/mL (25°C) and 17 mg/mL (20°C) in propyleneglycol. The 1% solution in water is a saturated solution that initially presents an oversaturation stage whose intensity and duration are determined by solid particle size and its solubility increases progressively over the time.

Thereby, we formulated three metronidazole solutions in different vehicles: water (M1), water+glycerin (M2) and water+propyleneglycol (M3). They were stored in refrigeration, room temperature (RT) and $T^a > 25^\circ\text{C}$ conditions. A galenic validation was carried out, monitoring organoleptic characteristics, sedimentation time, redispersability, homogeneity, crystal growth and pH on days 0, 1, 5, 7, 11, 14, 18, 30 in a 30-day follow-up.

Results The three solutions had a pH=5.5 and showed neither colour nor odour throughout the 30-day analysis.

With refrigeration, in less than 24 hours, the three solutions crystallised and could not be resuspended. Therefore, follow-up was stopped and refrigeration was discarded.

At RT, M1 and M2 presented crystals and vigorous hand shaking and heating for several minutes was necessary to resuspend them. M3 maintained the physical characteristics and was no longer oversaturated from day 18.

At $T^a > 25^\circ\text{C}$, the three solutions started as oversaturated solutions (no crystals were observed at any time). Subsequently, M3 became a saturated solution on day 4 and M1/M2 on day 7.

Conclusion and relevance Metronidazole base in solution cannot be stored in a refrigerator due to an irreversible crystallisation. Glycerin as a humectant does not provide any advantage compared with water as a single vehicle. Propyleneglycol allows a compounding improvement because it increases the solubility of metronidazole in water, allowing the solution to be preserved at RT without crystal formation and to reach the saturation phase quickly at $T^a > 25^\circ\text{C}$. The hospital pharmacists' knowledge allows the resolution of compounding difficulties derived from the physicochemical characteristics of raw materials.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

3PC-022 PH STABILITY OF TETRACAINE SOLUTIONS FOR SURFACE ANAESTHESIA

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Background and importance Tetracaine hydrochloride is a local anaesthetic agent commonly used for surface anaesthesia, typically used in concentrations of 2%–4% for anaesthesia of the nose and throat. The substance is an ester and slowly degrades over time. Over the same time the solution, in our experience, also discolours. For this reason tetracaine solutions have been made extemporaneously in our pharmacy, with a limited shelf life.

Aim and objectives The aim of the study was to investigate the stability of tetracaine solutions as a function of pH, and from this determine the optimum stability as regards drug content and appearance.

Material and methods Tetracaine hydrochloride (Sigma-Aldrich, St Louis, Missouri, USA). Instrument: ultra-high performance liquid chromatography (UHPLC) system (Shimadzu Corp., Kyoto, Japan) with a Nexera diode array detector (DAD) detector. Analytical column: Ace Excel 2 C8, 2 μm 2.1 \times 100 mm (Advanced Chromatography Technologies Ltd, Aberdeen, GB). The analytical method was validated for linearity, precision and specificity. *pH stability study*: samples were prepared containing tetracaine hydrochloride (20.0 mg/mL), methyl parahydroxybenzoate (1 mg/mL) and sodium chloride (5.5 mg/mL) with pH values spanning 2–6. The samples were stored until visible discolouration was observed in all solutions: First for 3 days at 70°C, then at 3 days at 25°C at ambient humidity, and protected from light.

Results Upon heat stress, the drug content remained highest at pH 5: 20.5 \pm 0.1 mg/mL (97.2%) (n=3); the appearance, however, changed to yellowish brown, and the solution was unclear. The content decreased the most at pH 2: 18.2 \pm 0.0 (86.8%) (n=3); in appearance, this solution remained clear, but turned yellow.

Conclusion and relevance Using a validated UHPLC method the optimum stability for tetracaine hydrochloride is found at pH 4–5 as regards assay value. Paradoxically, however, this is not the pH at which the appearance is the most acceptable.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

3PC-023 INVESTIGATION OF LEACHABLE COMPOUNDS IN WATER FOR INJECTION USED IN HOSPITAL PHARMACY

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Background and importance Industries have been manufacturing prepackaged water for injection (WFI) and other aqueous solutes to enable simpler and practical hospital pharmacy compounding. In hospitals, the preparation of total parenteral nutrition (TPN) or other intravenous (IV) treatments like antibiotics are often administered for continuous treatment. Industrially prepackaged WFI are frequently employed to reconstitute or dilute parenteral preparations. This proves convenient due to their large volume variety availability in the market and stocking capabilities before being used in hospital compounding.

Aim and objectives However, prepackaged aqueous products could potentially leach plastic additives over time. These compounds could influence active substance stability through different physical–chemical interactions, which in turn could affect treatment efficacy. Furthermore, the patient, receiving continuous IV treatments, could get affected with potential endocrine disrupting (ED) compounds, leading to probable latent health effects.

Material and methods The Quality Control laboratory of the Pharmacy of the Lausanne University Hospital (Switzerland) has developed an analytical method using liquid

chromatography coupled to a high-resolution mass spectrometer (LC-HRMS) for the analysis of plastic additives. An innovative setup, based on post-column infusion (PCI) using 2% ammonium hydroxide in methanol, was considered to boost the signal intensity of the analytes. This method enables the screening and identification of 30 known substances due to the use of retention time, exact mass (including isotopic pattern) and MS/MS spectra.

Results A comparison was made between prepackaged industrially purified WFI (IP-WFI) and a pharmaceutical-grade distilled water (PGD-WFI). A butylhydroxytoluene (BHT) derivative compound, 3-(3,5-di-tert-butyl-4-hydroxy-phenyl)propanoic acid, and bisphenol A were identified close to 2 ppm and 30 ppb, respectively, in IP-WFI compared to PGD-WFI. This suggests that IP-WFI, once purified and packaged, is stored in warehouses, which allows these additives to leach and concentrate over time. Conversely, PGD-WFI is carried out on site and is used directly for its intended purpose. In addition, both compounds possess ED phenol moieties, making them potential xenoestrogens.

Conclusion and relevance In conclusion, PGD-WFI possesses approximately five times less of these additives than IP-WFI. These plastic additives could lead to latent health issues in patients after continuous administration of parenteral treatments. Due to a lack of toxicology information for this BHT derivative, more studies are required for ED assessment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

3PC-025 ABSTRACT WITHDRAWN

3PC-026 QUANTITATIVE AND QUALITATIVE EVALUATION OF mRNA VACCINES AFTER STERILE FILTRATION

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Background and importance The importance of mRNA-based vaccines increased rapidly due to the COVID-19 pandemic. However, little is known on the challenges linked to handling shortages and extended stability of these new types of substance. Since vaccine remnants have to be discarded according to the Summary of Product Characteristics, we hypothesise that sterile filtration after pooling is suitable to save vaccine material for clinical application.

Aim and objectives The aim of this pilot study was to compare quality parameters of remnants derived from ready-to-use mRNA vaccine solutions before and after sterile filtration. Therefore, we pooled mRNA vaccine solution remnants from Corminaty vials (BioNTech/Pfizer) and compared particle size, distribution and quantity of the lipoplexes. In addition, quantity and/or quality of the mRNA was determined.

Material and methods Measurements of invisible particulates in the range 1–50 µm were performed by light obscuration according to the European Pharmacopoeia (10th edn). The size of lipoplexes was measured with nanoparticle tracking analysis (NTA) to determine hydrodynamic diameter and particle concentration. Dynamic light scattering was employed complementarily to the NTA technique to focus on particle size from 0.3 nm to 10 µm. The concentration, purity and integrity of the mRNA was analysed by ultraviolet (UV) spectrophotometry and capillary electrophoresis after mRNA purification.

Results After pooling the remnants of the vials we found a substantial increase of particulates $>1\ \mu\text{m}$ when compared to fresh vaccine samples. This effect was likely due to contamination of the examined probes with particles from ambient air. As expected, all these particulates were eliminated by sterile filtration. Size distribution and concentration of the lipoplexes were comparable between unfiltered and filtered samples. With respect to the mRNA, we identified the fragment of interest in all examined samples. Sterile filtration did not change the concentration, purity and integrity of the mRNA.

Conclusion and relevance Our results indicate that sterile filtration of mRNA-based vaccines eliminates particle contamination from the vaccine solution while the concentration of lipoplex nanoparticles was not altered. Moreover, neither the quantity nor quality of the mRNA was affected by the filtration process. The results of our pilot study provide the first data on the stability of mRNA vaccines and help to fill knowledge gap when dealing with these substances in hospital pharmacy.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

3PC-027 DIGITALISATION SUPPORT SYSTEM FOR INTRAVENOUS MIXTURES ELABORATION IN A BIOLOGICAL SAFETY CABINET

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Background and importance We have been working with a system robot that integrates electronic prescription in our hospital pharmacy for the automated preparation of intravenous mixtures. However, some of the preparations are not candidates for robotic processing. Manual preparations should provide similar traceability and security.

Aim and objectives To describe the implementation of a digital support system (DSS) for the manual preparation in a biological safety cabinet (BSC) of intravenous mixtures.

Material and methods Retrospective descriptive study of the digitalisation of the manual preparation of intravenous mixtures in a BSC (December 2020–February 2021). Implementation phase activities comprised: (1) entering the drug density data, (2) updating drugs handling in the software and (3) staff training. The material needed (weight scale with integrated camera, screen, keyboard, code reader and printer) was situated in a BSC for cytostatic preparations.

It was decided to use the system in the following cases: (1) syringe preparations, (2) vials that are non-compatible for robot handling due to their format, (3) lyophilised powder drugs and (4) non-scheduled or emergency treatments. Verification of the precision obtained in the dosage was performed by gravimetric control based on the density of the drug. Although the pharmacopoeia allows a deviation of $\pm 10\%$ in dosage, we limited it to the same tolerance already used in the robot system, namely $\pm 4\%$.

Results Ninety drug presentations have been configured in the DSS. In the first 3 months, 1477 preparations were elaborated (22.8%), with a mean error in drug dosage of 1.51% (SD 1.41). To meet the dosage criteria, 65 preparations were rectified. DSS traces the entire process by taking pictures of the components, by recording the elaboration, and by barcode

verification or data-matrix of the final container and drug used.

Conclusion and relevance The drug density database can be applied to any system employing gravimetric dosing control. DSS represents a useful complementary tool whenever the use of a robot system is limited, providing traceability and security for the process of manual preparation of intravenous mixtures as a substantial improvement in the quality of the circuit.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

3PC-028 PHARMACEUTICAL INTERVENTIONS IN PAEDIATRIC PARENTERAL NUTRITION

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Background and importance Parenteral nutrition is needed for preterm and ill babies in the neonatal intensive care unit (NICU), neonatal medicine unit (NMU) and paediatric intensive care unit (PICU). In our centre, each parenteral nutrition (PN) prescription is analysed by a pharmacist before compounding. In cases of prescribing errors, the pharmacist alerts the prescribers and performs a pharmaceutical intervention (PI).

Aim and objectives We have implemented a tool for the routine reporting of PI for sterile preparation units for PN, 'ACTIP Nutrition'. This tool is an adaptation of the French Society of *Clinical Pharmacy* (SFPC) hospital pharmacists' reporting tool for recording the PI. This work allowed us to validate the tool ACTIP Nutrition and evaluate the rate of avoidable errors with an electronic prescriptions software package.

Material and methods The study was carried out in the sterile preparation unit over 2 months. The prescriptions of PN were analysed according to the usual practice. Each detected PI was scored according to 'ACTIP Nutrition' and recorded in the national database of PI, ACTIP.

Results A total of 627 prescriptions were analysed of which 37% required pharmaceutical intervention. 17% of the orders required two or more interventions. The intervention rate was 41% for the NICU, 31% for the NMU and 18% for the PICU. The top three interventions performed were underdosing of vitamins and trace elements ($n=71$), instability due to phosphate ($n=45$), and wrong choice of ingredient in the mix ($n=27$). The majority of PIs performed were dosage adjustments (56%).

Electronic prescribing software could eliminate 15% of errors (eg, transcription), and if a thesaurus or guidelines are incorporated into the software then an additional 14% of errors could be avoided. The PI rate would drop from 37% to 23%.

Conclusion and relevance Pharmaceutical analysis is a crucial process for limiting errors in paediatric parenteral nutrition. The ACTIP Nutrition tool allows PIs to be entered into the ACTIP database and harmonises practice between pharmacists to promote the role of the pharmacist. The American Society for Parenteral and Enteral Nutrition (ASPEN) recommends electronic prescriptions to secure patient care. In our centre, almost 30% of errors were avoidable with the use of prescriptions software. Unfortunately, our study took place over a

short period (2 months) and the PIs refused were not collected.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

3PC-029 STUDY OF PSMA11-68GA ADSORPTION ON MEDICAL DEVICES USED FOR RADIOSYNTHESIS AND MEDIA FILL TEST

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Background and importance PSMA-11 labelled with gallium-68 (PSMA11-68Ga) is a diagnostic radiopharmaceutical. Labelling is performed in a Trasis Mini all-in-one synthesiser. Sterile excipients, solvents and devices are necessary to produce a sterile and pyrogen-free injectable solution.

Aim and objectives The aim of this study was device evaluation. Two aspects were investigated: the sterility of the final preparation and the absorption of PSMA11-68Ga on the device.

Material and methods Device adsorption evaluation: radioactivity was measured with an ISOMED 2010 activity meter. PSMA11-68Ga labelling was performed and five syringes of 5 mL were filled with 1 mL from the preparation vial every 30 min after the end of the preparation. The weight activity (MBq/mg) of the preparation vial and syringes was calculated, measuring the activity and weight of each of them. At the end of the labelling process, the PSMA11-Ga68 preparation was totally filled in the preparation vial. The residual activity of different parts of the device were measured: the elution vial, the five syringes, the extraction cartridge, the synthesiser garbage, the vented filter, and three additional syringes were measured after three rinses with sodium chloride within 1 hour to 5 hours after elution. Finally, the activity of the elution vial at the end of the elution step and the activity of the final preparation vial at the end of the labelling process were compared on nine syntheses.

Final preparation sterility: media fill tests (MFT) were performed on three syntheses, replacing the excipients and solvents with tryptone-casein-soybean solution. A fertility test was performed with concentrated bacterial strains in accordance with the European Pharmacopoeia.

Results The weight activity difference between the final preparation vial and the five syringes were between 4% and 7%. Residual activities in the syringes, the vented filter, the waste garbage, the extraction cartridge and the three additional syringes were between 0.2% and 5% of the elution activity. The activity variation between the elution and final preparation vials were between -4% and +5%. The MFT did not show microbiological contamination after 14 days of incubation at 37°C. The fertility test was positive after 24 hours of incubation.

Conclusion and relevance These results show that the adsorption of PSMA11-68Ga on medical devices used for synthesis appeared to be limited. The MFT performed show that the manufacturing process was aseptic.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

3PC-030 DIFFERENT SUBSTRATES FOR ORODISPERSIBLE FILMS: YOU HAVE THE CHOICE!

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Background and importance Orodispersible films (ODF) are thin layers of a polymer that can be loaded with an active ingredient (API). This could be realised during the film-forming process or afterwards. Different polymers produce different film properties (eg, dissolution behaviour). So, you have the choice!

Aim and objectives Films of different compositions and heights were produced and investigated. The aim was to estimate whether the resulting films are appropriate candidates for further processing.

Material and methods Four formulations were chosen based on: (1) polyvinyl alcohol (PVA), (2) hydroxypropylmethylcellulose (HPMC), (3) HPMC with microcrystalline cellulose (MCC) and (4) starch.

The ODF based on starch was a commercial product, an 'edible paper'. ODF were produced with solvent casting and different heights. After drying, pieces were investigated for appearance, residual moisture and dissolution time.

Results The dried films differed in resulting thickness. Edible paper was the thickest followed by the mixture of HPMC and MCC, then PVA and finally HPMC. The very thin films of HPMC were difficult to handle.

All the films look different: PVA is white and very flexible. HPMC is colourless and flexible also. It becomes sticky when it comes into contact with water. When MCC is mixed with HPMC the films are white and too brittle to handle. Edible paper is green (colourant added) and also brittle, but is easy to handle.

Residual moisture depends especially on the formulation. PVA has ~1%–2%, HPMC MCC ~5%, starch ~7% and HPMC ~7%–10%.

Dissolution time depends on both the formulation and the height of the films. Starch takes more than 15 min and HPMC up to 3 min. Both formulations become sticky when they come into contact with water. The others predominantly show times under 1 min.

Conclusion and relevance Investigations revealed the different characteristics of the resulting films. The stickiness and prolonged dissolution time could be useful for mucoadhesive formulations. Mixture with MCC shortens the dissolution time but increases the brittleness. This formulation could be optimised. PVA and starch exhibit the easiest handling.

Incorporation of API should be possible for all formulations that were casted when API is dissolved. If the API is to be loaded after film production (eg, via inkjet printing) PVA and starch are promising candidates.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

3PC-031 PHYSICO-CHEMICAL STABILITY OF DILUTED 'THIOTEPA RIEMSER' INFUSION SOLUTIONS IN PREFILLED 5% GLUCOSE INFUSION BAGS

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Background and importance Newly formulated Thiotepa Riemser was approved in 2021 for conditioning treatment before allogeneic or autologous haematopoietic progenitor cell transplantation.

Prior to administration Thiotepa Riemser is reconstituted with water for injection and diluted with 0.9% sodium chloride or 5% glucose (G5) infusion solutions. According to the *Summary of Product Characteristics*, the ready-to-administer (RTA) infusion solutions are physicochemically stable for 24 hours stored at 2–8°C or 4 hours stored at room temperature. To our knowledge, long-term stability data have not yet been published. Of note, physicochemical stability improves when G5 infusion solutions are used as vehicle solutions.

Aim and objectives Due to lack of long-term stability data for newly formulated Thiotepa Riemser RTA solutions, the physicochemical in-use stability of diluted infusion solutions in pre-filled G5 infusion bags was investigated.

Material and methods Thiotepa Riemser 1 mg/mL, 2 mg/mL and 3 mg/mL test solutions were prepared in triplicate using pre-filled 5% glucose polyolefin bags. Test solutions were stored at 2–8°C or 25°C for 14 days. Directly after dilution and on days 1, 3, 5, 7, 14 the test solutions were inspected and samples withdrawn. Thiotepa concentrations were measured by a stability-indicating high-performance liquid chromatography (HPLC) method, adapted from the Thiotepa monographs in the British and US Pharmacopoeias. In parallel, pH and osmolality were measured. Non-visible particles were counted in the test solutions on days 0 and 14.

Results When Thiotepa Riemser test solutions were stored at 2–8°C, thiotepa concentrations remained above 98% of the initial concentration for 14 days. When stored at 25°C, thiotepa concentrations fell below 95% of the initial concentration after 3 days in 1 mg/mL solutions, 5 days in 2 mg/mL solutions and 7 days in 3 mg/mL solutions.

Peaks of unspecified impurities were detected in the chromatograms of all test solutions directly after dilution and degradation peaks increased during the storage time. Particle counts and osmolality remained unchanged in most test solutions. Values of pH increased slightly, especially when test solutions were stored at 25°C.

Conclusion and relevance Thiotepa Riemser infusion solutions diluted with G5 are physicochemically stable for 14 days when refrigerated and depending on the concentration for 3–7 days when stored at 25°C. Evaluation of the amount and relevance of unspecified impurities is ongoing.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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3PC-033

Y-SITE COMPATIBILITY OF INTRAVENOUS NEFOPAM WITH MEDICATIONS COMMONLY USED IN INTENSIVE CARE UNITS

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Background and importance Patients hospitalised in intensive care units (ICUs) often require many drug infusions. Due to limited intravenous (IV) accesses, concomitant administration

of drugs in the same infusion line is usually necessary. Compatibility studies of Y-site administrations are available in the literature, but many data are lacking. Previous work¹ identified a list of Y-site administrations without compatibility data.

Aim and objectives Nefopam, a non-opioid analgesic, is usually administered in critical care units. The aim of this study was to evaluate the physical compatibility of nefopam with other drugs used in ICUs, to secure the Y-site administration of IV drugs.

Material and methods Compatibility of nefopam with nine drugs commonly used in ICUs has been tested (calcium chloride, cefotaxime, hydrocortisone, isosorbide, magnesium, nicardipine, pyridoxine, thiamine, tramadol). These drugs were diluted in different solvents (water for injection, 0.9% sodium chloride (NaCl), 5% dextrose (D5W), 10% dextrose, Isofundine) or used pure, leading to 21 pairs being tested. For each pair, three ratios were evaluated (nefopam 80–160 µg/mL/drug B: 9/1; 1/1; 1/9). Physical compatibility examinations were performed on each mixture after preparation, and after 1-hour and 4-hour storage. This evaluation included a visual examination with the search for precipitation formation, colour change, gas formation, and a subvisual evaluation: absorbance measurements by ultraviolet (UV) spectrophotometry at 350, 410 and 550 nm, and the light obscuration particle count test. pH evaluation was performed at each analysis time point.

Results 20/21 pairs tested were compatible (95%), conforming for all items. The mixture nefopam (160 µg/mL – 0.9% NaCl) with cefotaxime (40 mg/mL – D5W) at a ratio of 1/9 revealed a subvisual incompatibility by particle counting at each time studied, while no visual change was observed.

Conclusion and relevance These laboratory tests demonstrated the compatibility of 20 pairs containing nefopam. The pair with a high concentration of cefotaxime showed particle counting, allowing the incompatibility of nefopam (160 µg/mL – 0.9% NaCl) with cefotaxime (40 mg/mL – D5W) to be concluded. New compatibility data are now available to secure IV administration. These results cannot be extrapolated for mixtures of more than two drugs.

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Conflict of interest No conflict of interest

3PC-034

DEVELOPMENT AND VALIDATION OF A METHOD FOR THE DETERMINATION OF VANCOMYCIN EYE DROPS BY ULTRAVIOLET-VISIBLE SPECTROPHOTOMETRY

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Background and importance Vancomycin is used as fortified eye drops for the treatment of bacterial keratitis. Given the absence of an available equivalent speciality, the hospital pharmacy prepares these eye drops under aseptic conditions. Content uniformity is required before each batch is released.

Aim and objectives The objective of this study was the development and validation of a method for vancomycin eye drops dosage by ultraviolet-visible spectrophotometry.

Material and methods Analyses were performed at 280 nm. The method was validated according to the International Conference on Harmonisation (ICH) Q2(R1): specificity, linearity, repeatability, intermediate precision, accuracy, limit of detection, limit of quantification. Memory effect, vial equivalence and background noise were studied. Five standard solutions were performed from 0.1 to 0.4 mg/mL and a 200th dilution to analyse the samples. A relative standard deviation (RSD) of 5% was accepted for each of the criteria.

Results The method was specific. The equivalence of vials was demonstrated with a variation of 0.58%. The background noise measured variations up to 0.00097 mg/mL. Linearity was established with the equation $y=4.6489x-0.0256$ and $R^2=0.9975$. RSD were 1.91% for repeatability and 4.65% for intermediate precision. The recovery rates varied between 98.5% and 101.9%. The limit of detection was 0.007 mg/mL and the limit of quantification was 0.021 mg/mL.

Conclusion and relevance When measuring accuracy, the prepared eye drops had a vancomycin concentration of 45 mg/mL and not 50 mg/mL as expected. After questioning our manufacturing protocol we questioned our supplier. The powder vials contained a quantity of vancomycin base equivalent to an antimicrobiological activity of 1 000 000 UI/vial. Legislation requires presentation in milligrams and UI. The amount of vancomycin base in a vial therefore varied between 850 mg and 950 mg depending on the initial content of active ingredient and was not 1 g as indicated.

The analytical method was validated. The method is suitable for routine use due to its speed and accuracy allowing a control before release of each batch of our eye drops.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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3PC-035 MINIMISING WASTE IN ONCOLOGY

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Background and importance The rise of promising new cancer therapies and their costs represents a colossal challenge for health systems. In addition, we face daily restrictions on the supply of cytotoxic drugs, while the number of patients is increasing. The Cytotoxic Centralised Units (CCUs) allow the optimised use of cytotoxics and monoclonal antibodies vials between treatments. There is, however, a significant waste of drugs, due to the impossibility to reuse the vials if they lose the sterility conditions provided by the biosafety chamber, at the end of the working day. Closed system transfer devices (CSTDs) were initially developed to minimise occupational exposure during cytotoxic preparation. They represent an important additional resource providing safety for the technician and facilitating work operations in the chamber. Recent data supporting the extent of the physical and chemical stability of drugs and the sterility provided by the CSTD in an aseptic environment allow the remaining amounts of each vial to be stored and reused.

Aim and objectives Assess the profitability of the use of CSTDs in the CCU.

Material and methods Several models of CSTDs were analysed concerning their safety performance and ergonomic design. The Tevadaptor model was the one selected. During 2020,

the daily records of wastes and savings of each oncologic drug vial were compared, as well as the comparison between the saving on opening new vials versus the annual cost for the acquisition of the CSTDs.

Results The increase in the annual budget reached the amount of € 14 934. The analysis of the number of vials that were spared with the reuse of the waste of each day resulted in a total annual savings of € 205 665.05. The balance is clearly positive for the institution, with an economic outcome of € 190 731.

Conclusion and relevance The innovation cost in oncology, combined with a context of frequent shortages, offers constant challenges to hospital budgets and makes it imperative to reduce daily waste with drugs. The use of CSTDs is a strategy that entails additional costs but allows maximisation of the use of the vial, always respecting the physical-chemical and microbiological stability of each drug, offering additional security in the working area and decreasing the risk of occupational exposure.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

Section 4: Clinical pharmacy services

4CPS-002 COVID-19 HOSPITAL VACCINATION CENTRE: PATIENT AND NURSE SATISFACTION

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Background and importance The COVID-19 pandemic has challenged all countries in a race against infection and the emergence of variants. Vaccination campaigns were the answer to this public health crisis.

In our university hospital, a multidisciplinary team was mobilised for the opening of two vaccination centres (VCs): for health professionals and for patients with high risk of severe COVID-19 illness according to national health authority guidelines.

Aim and objectives The aims of our study were to collect patient and nurse satisfaction regarding these VCs and to identify adverse events (AEs) related to vial manipulation.

Material and methods This prospective study was conducted from April to May 2021. Two satisfaction questionnaires for patients and nurses were created, each containing 13 questions subdivided into four items. Patient items were: organisation of vaccination, care, service and quality of care. Nurse items were: VC organisation, handling of vials and syringes and interprofessionalism. Responses were rated from 'poor' to 'very good'.

Results Over 1 month, 51 patient questionnaires and 4 nurse questionnaires were collected.

Regarding patient satisfaction, 82% of respondents expressed 'very good' satisfaction with their medical care. VC location and the convenience of the vaccination boxes received 61% and 65% of 'very good' ratings. Some patients mentioned low confidentiality measures.

The nurses' general satisfaction was 100% 'very good', as well as the cooperation with the pharmacy department. As for the information technology (IT) service, 50% answered 'rather bad'. The impact of the media on their activity was perceived as 'bad' for half of them and 'average' for the other half.

Nurses reported four AEs: broken vial, leakage during dilution, mishandling by some vaccinators, and defective vial.

Conclusion and relevance Patients were generally satisfied with the care received and the nurses reported a positive general satisfaction of their experience at the VC. The IT poor appreciation can be explained by network difficulties affecting data collection and certificate edition. The presence of a referring vaccination pharmacist at the VC was associated with positive feedback, which testifies to the efficiency of the pharmacist–nurse relationship. The AEs reported allowed the good manipulation pamphlets to be updated. For the continuation of COVID-19 vaccination campaigns with booster shots, these data will allow improvement of the installation of future VC.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-003 OUTPATIENT-REPORTED EXPERIENCE IN HOSPITAL PHARMACY AMBULATORY CARE DURING THE COVID-19 PANDEMIC

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Background and importance Measuring health care quality and performance is a major challenge in improving health systems' efficiency. Patient experience is an important health care quality measure; thus, use of questionnaires reporting patients' experience and perceptions while receiving care is recommended. The COVID-19 pandemic has accelerated the establishment of proximity dispensation models and ambulatory care redesign, aligned with the Anaesthesia Clinical Services Accreditation (ACSA) accreditation model, implemented in 2019 in the Pharmacy Department.

Aim and objectives Evaluate patient-reported experience regarding outpatient care in a central hospital pharmacy, during the COVID-19 pandemic.

Material and methods Single-centre cross-sectional study (March–June 2021). Ambulatory outpatients were invited to complete a survey, consisting of 14 questions on: access to care, waiting time, communication and information about medication, pharmaceutical care provider (pharmacist in charge), privacy/confidentiality and unmet needs. The survey was made available to patients in paper or digital format at the pharmacist consultation, teleconsultation, medicines home delivery and pharmadrive delivery.

Results A total of 9634 outpatients attended our ambulatory care during the study period. We carried out 1939 teleconsultations, 2194 home deliveries and 91 in-person consultations. Outpatients answered 148 surveys (1.5%). Most patients were pleased to continue picking up medication at hospital pharmacy (86%) and rated the service as good/very good. Patients considered that there was availability to listen/sympathy (99%) and privacy (96%) during the service. Information provided about medication was considered useful (89%). Waiting time

was rated as appropriate (90%). A large percentage of patients were unaware of the possibility of pharmadrive (76%) and proximity dispensation (45%). Outpatients knew their pharmacist in charge in 37% of the cases and 75% had already contacted their pharmacist, 32% were not aware of the existence of a pharmacist in charge and the remaining (30%) did not have a pharmacist in charge.

Conclusion and relevance Pharmacists' effort in pandemic times, implementing strategies to improve patient-centredness of care, ensured outpatients' continuity of pharmaceutical care and medicines. In order to engage patients and improve their experience, awareness and retention of pharmacists in charge needs to increase. As improvement measures we intend to improve our outpatient care guide with more detailed information, and will also refresh pharmacist training.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-004 IMPACT OF THE SARS-COV PANDEMIC ON THE TRAINING OF HOSPITAL PHARMACY RESIDENTS

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Background and importance The Pharmacy Service is committed to resident training. The residency programme in the Hospital Pharmacy Service covers all areas of the training programme. The high hospital demand and the weekly updates of the pharmaceutical protocols made it necessary to dedicate almost the entire working day to the hospital pharmacy residents.

Aim and objectives To evaluate the impact of the SARS-CoV pandemic on the training period of resident pharmacist interns.

Material and methods A survey was conducted among all hospital pharmacy residents in Spain. It was carried out by the Teaching and Hospital Pharmacy units. The survey was anonymous, voluntary and disinterested. Data collected: place of residence, year of training, hospital level, resident supervision, internal and external rotations missed, emotional impact and sick leave.

Results The survey was completed by 122 hospital pharmacy residents. The completion period was from 15 March to 15 April 2021. The geographic distribution of the residents was: Andalusia (48.3%), Madrid (11.7%), Catalonia (10%), Valencia (8.3%), Murcia (8.3%), Castilla y León (3%), Galicia (3%), Asturias (1.7%), Cantabria (1.7%) and the Basque Country (1.7%). The year of residence of the respondents was: 4th year (56.7%), 2nd year (18.3%), 1st year (13.3%) and 3rd year (11.7%). With respect to supervision and concern for the work: 65.6% felt adequately supervised, while 27.9% said they were deficient in the process. Regarding rotations in other services and/or hospitals: 50.8% stated that they had missed some type of rotation, of which 13.1% were irrecoverable. 63.9% recognized that the pandemic has had some emotional impact on their lives, while 34.4% stated that it has had a great impact. Of the residents, 50.81% said they had been on sick leave due to SARS-CoV.

Conclusion and relevance Pharmacy services met the demand of the hospital and associated residences with increased activity. Despite the situation, residency in a crucial stage of professional training, therefore changes must be faced in order to find the best way to meet the goals.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-005 EVALUATING PHARMACEUTICAL LOGISTICS AUTOMATED TECHNOLOGIES IN THE HOSPITAL SETTING: A HEALTH TECHNOLOGY ASSESSMENT (HTA) APPROACH

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Background and importance Automation of hospital medication management demonstrated advantages to wards manual systems, especially in error reduction, improving patient safety and ensuring drugs' traceability. Despite the existence of literature on benefits, no multidimensional evidence on automation of hospital medication management is available.

Aim and objectives The study aimed to demonstrate the value of four scenarios of automated technologies' introduction, with a comprehensive health technology assessment (HTA) approach, comparing: (1) manual dispensing, (2) presence of only centralised automated systems in the hospital pharmacy, (3) presence of only decentralised automated systems in the wards and (4) integration of scenarios 2 and 3 into a full solution, with electronic prescription.

Material and methods The HTA involved 50 healthcare professionals (pharmacists, nurses, decision-makers and other professionals) in four European countries in 2021. After a structured literature review, the nine domains of the EunetHTA Core Model were deployed using validated questionnaires (with a seven-item Likert scale). Differences among groups and scenarios were studied by ANOVA test. All analyses were conducted considering a level of significance equal to 0.05 and were performed using IBM SPSS software (Version 22.0).

Results Results from the efficacy and safety questionnaires showed that the presence of automation resulted in a decrease in dispensing errors (1.75, 1.20, 1.88, 2.19, respectively, for scenarios 1, 2, 3, 4; p value = 0.000) and consequently in adverse events (-2.13, 1.18, 1.71, 2.46, respectively, for scenarios 1, 2, 3, 4; p value = 0.000), especially if associated with electronic prescribing, confirming the literature findings. A low organisational impact of automation was registered (-0.71, 0.50, 0.49, 0.63, respectively, for scenarios 1, 2, 3, 4) due to a trade-off between technological change efforts and efficiency beneficial effects in the first year.

Ethical and social dimension results demonstrated a positive impact of automation (-0.93, 0.72, 1.03, 1.23, respectively for scenarios 1, 2, 3, 4; p value = 0.000) on patients' perceived quality of life.

The impact on drugs thefts and the identification of responsibility in cases of legal controversies were the most appreciated legal items.

Conclusion and relevance In a literature dominated by safety evidence on automated solutions, a complete HTA approach

demonstrates its validity in communicating and demonstrating multidimensional and multidisciplinary values of hospital automated dispensing solutions.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-006 EVALUATION STUDY OF THE CHANGE IN ADMINISTRATION TIMING OF FIXED COMBINATION: NETUPITANT AND PALONOSETRON IN ONCOHAEMATOLOGIC PATIENTS WITH HIGH DOSES OF CARBOPLATIN

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Background and importance Chemotherapy regimens with carboplatin AUC ≥ 4 should receive an antiemetic prophylaxis based on a triple combination of drugs. In our hospital this prophylaxis is netupitant with palonosetron (NEPA (300/0.5 mg); Akinzeo) and dexamethasone. NEPA is administered 1 hour before the chemotherapy session, so patients must take it at home before coming to hospital, with the difficulties of adherence that this implies. We evaluated shortening NEPA administration time and receiving the dose in the hospital 15 min before the chemotherapy.

Aim and objectives To evaluate the effectiveness, in terms of no acute and delayed chemotherapy-induced nausea and vomiting (CINV), of the change in administration timing of NEPA from 1 hour to 15 min before the chemotherapy.

Material and methods Single-centre, national, open-label study conducted on 129 patients from February to May 2021. The control group (NEPA 0) included ambulatory patients having NEPA + intravenous dexamethasone 1 hour and 30 min before chemotherapy, respectively. Experimental group (NEPA 1) had NEPA + intravenous dexamethasone 15 and 30 min

Abstract 4CPS-006 Table 1

	NEPA 0	NEPA 1	P
Acute phase			
Vomiting			
No (%)	80 (98.9)	47 (100)	1
Yes (%)	1 (2.3)	0 (0)	
Nausea			
No (%)	76 (93.8)	40 (85.1)	0.122
Yes (%)	5 (6.2)	7 (14.9)	
Delayed phase			
Vomiting			
No (%)	77 (100)	44 (93.6)	0.052
Yes (%)	0 (0)	3 (6.4)	
Nausea			
No (%)	64 (38.1)	38 (80.9)	0.7487
Yes (%)	13 (16.9)	9 (19.1)	

before chemotherapy, respectively. Patients completed the MASCC Antiemesis Tool (MAT) questionnaire 24 hours and 120 hours after the chemotherapy session, to measure acute and late CINV, respectively. Differences in the proportion of acute and delayed CINV between NEPA 0 and NEPA 1 were analysed using Chi-square test.

Results A total of 129 patients participated in the study: 82 patients received NEPA 0 and 47 patients NEPA 1 (Table 1). 66 (51.2%) were female with a mean age of 66.5 years. The most frequent diagnosis was lung cancer (n=83, 64.3%). No statistically significant differences (p value >0.05) were found in either acute or delayed CINV, so both treatments can be considered similar in terms of efficacy. 13 patients started in NEPA 0 and then moved to NEPA 1; the results of the inpatient study showed that developing CINV is more related to personal features than to NEPA administration timing.

Conclusion and relevance The change of NEPA administration timing has showed similar effectiveness to the standard one. It has beneficial implications for patients, as it allows NEPA to be administered at onco-haematological day hospital before the chemotherapy session rather than having to be taken at home. Simplifying the antiemetic prophylaxis regimen for patients is expected to increase adherence while maintaining treatment effectiveness.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-008 THE ROLE OF THE PHARMACIST IN THE MANAGEMENT OF INTRAVENOUS FLUIDS AND ELECTROLYTES IN ADULT PATIENTS

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Background and importance Many patients in our hospitals require intravenous (IV) fluid therapy to avoid or address imbalances of either fluid and/or electrolyte balance. One in five patients who receive IV experience increased morbidity or complications relating to fluid administration. The National Institute of Clinical Excellence (NICE) recommend that fluid prescribing should be treated with the same consideration as that of medication, and that it is the responsibility of the multi-professional team.

Aim and objectives To ascertain the current role of hospital pharmacists in the management of IV fluids and electrolytes.

To determine the advantages and limitations of existing training on IV fluids and electrolytes.

To explore potential roles for pharmacists in relation to the management of IV fluids and electrolytes.

Material and methods In July 2021 a pre-piloted 20-item questionnaire developed was emailed to all pharmacists working in secondary care in (n=739). A mix of multiple-choice, Likert-style as well as free-text questions were included. Descriptive statistics were used. Free-text comments were evaluated using thematic analysis.

Results A total of 198 pharmacists responded, representing a 27% response rate. Just over half the respondents had

experience managing IV fluids (54%) but only 3% defined themselves as 'very experienced' in this area. Most respondents do not review IV fluids (71%). In relation to a desire to learn how to review IV fluids, 84% of respondents expressed a desire to learn, 7% were already actively learning and 9% felt no desire to learn this skill. Most respondents (65%) were not confident in their ability to support junior doctors in the prescribing of IV fluids; however, 65% of respondents completely agreed or agreed that the pharmacist has a role in the management of fluids at ward level, with 67% agreeing that the pharmacist has a role in the prescribing of IV electrolytes and 65% in the prescribing of IV fluids.

Conclusion and relevance Pharmacist respondents believe that pharmacists have a role in the management of IV fluids and electrolytes; however, most have identified a gap in their knowledge and skills. There is also a need to resource this additional task appropriately so that other roles of the pharmacist are not neglected.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-011 ASSESSMENT OF KNOWLEDGE, ATTITUDES AND PRACTICES REGARDING ANTIBIOTIC RECONSTITUTION AMONG HEALTHCARE PROFESSIONALS IN 12 SOUTHEASTERN EUROPEAN HOSPITALS: A MULTICENTRE CROSS-SECTIONAL STUDY

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Background and importance Preparation and administration of intravenous medicines, especially antibiotics, have many steps or aspects that are usually interrelated, which makes these medicines most commonly involved in medication errors in hospitals.¹ Therefore, it is important to focus on contextual aspects of antibiotic use in hospitals especially in terms of antibiotic reconstitution/dilution.

Aim and objectives The aim of this study was to explore the knowledge, attitudes and practices (KAP) regarding antibiotic reconstitution/dilution among healthcare professionals in 12 Southeastern European hospitals.

Material and methods The study was conducted using interviewer-administered questionnaires or self-administered questionnaires mailed to healthcare professionals. Information on demographic characteristics and KAP regarding antibiotic reconstitution/dilution were collected from May to September 2021.

Results More than 90% of physicians consult pharmacists for advice concerning stability of reconstituted antibiotics, incompatibilities with other medicines or solvents, or preparation and administration of parenteral antibiotics for special patient groups. Conversely, medical nurses/technicians consult with

their colleagues (up to 56.10%) rather than asking pharmacists for information concerning antibiotic reconstitution/dilution (up to 36.90%). More than 53% of 565 healthcare professionals considered the database within the hospital information system to be the most trusted source of information. Electronic resources, such as e-journals, online databases and websites, were the least trusted information source by more than 61% of healthcare professionals. The study revealed that knowledge depends on the educational level, since physicians had a higher percentage of correct answers (52.05%–88.10%) in comparison to medical nurses/technicians (33.33%–68.42%). Furthermore, there was a statistically significant difference in knowledge level among healthcare professionals from different hospitals.

Conclusion and relevance The study indicates the need for a database within the hospital information system regarding antibiotic reconstitution/dilution in order to decrease the inappropriate preparation and administration of parenteral antibiotics in hospitalised patients. Moreover, it is important to raise awareness about this issue as a part of the everyday practice of hospital pharmacists. There is a need to introduce specific training on preparation and administration of parenteral antibiotics among healthcare professionals in hospitals.

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Conflict of interest No conflict of interest

4CPS-013 MERGING THE MEDICATION RECONCILIATION AND THE HOSPITALISATION REPORT TO FORM THE LIAISON LETTER IN A DEPARTMENT OF OTOLARYNGOLOGY

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Background and importance Since 1 January 2017, the liaison letter (LL) has been mandatory (Decree No. 2016–995, 2016). To optimise patient care and allow better coordination between health professionals we wanted to merge the hospitalisation report (HR) and the medication reconciliation (MR) to form a common document LL. We first implemented this document in May 2020 for digestive surgery and in December 2020 for orthopaedic surgery. Since March 2021 we continued this implementation in otolaryngology.

Aim and objectives The objective was to assess changes in practice and satisfaction among hospital staff (HS) in the otolaryngology department.

Material and methods A prospective observational study was conducted from 1 March to 1 April 2021, including all otolaryngology patients with an overnight hospital stay, to identify which document (MR, HR or LL) was created. Information about the patients was also collected in a table. A survey with eight questions was distributed to collect knowledge, use and satisfaction with the HS.

Results The data collection included 42 patients: 21 males and 21 females. The median age was 61.5 range (17–89) years.

The average length of stay was 4.77 (range 1–16) days. Surgeries were scheduled in 10% of cases. The main reasons for hospitalisation were parotidectomy, laryngectomy and thyroidectomy. For these 42 patients, 18 HR, 1 MR and 33 LL were created.

Of the 45 questionnaires sent to HS, we received 30 responses. 90% of the HS stated that they knew about the MR, and 47% used it. 90% had been aware of the LL (by verbal and written communication). 43% of them were informed by a pharmacist. 90% considered that the presentation of the LL is satisfactory. 87% of HS were satisfied with this creation and 83% said they had not encountered any difficulties.

59% of doctors found this implementation very useful, 27% indispensable and 14% somewhat useful. 75% of doctors said they use the LL frequently; 17% rarely consider using it and 8.5% said they never use it.

Conclusion and relevance HS are mostly satisfied by this new communication tool. However, this study shows the difficulty in changing practice since duplication of documents was observed. A remote assessment would allow a conclusion to be reached about the robustness of the use of the LL.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-014 CLINICAL RELEVANCE OF PHARMACISTS' INTERVENTIONS IN THE ACUTE WARD

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Background and importance Clinical pharmacists assist physicians in the medication process when performing Clinical Pharmacist Services. Clinical pharmacist interventions (PI) to medication-related problems are conveyed to the physician through pharmacist notes in the patient record. The attending physician will accept and act on the interventions found to be clinically relevant. Previous studies have measured the acceptance rate of PI, and found varying rates from low to high, but not always reflecting on the reason for the resulting rates.

Aim and objectives The purpose of this study was to investigate the clinical relevance of the PI assessed by the attending physician.

Material and methods Clinical pharmacists at acute wards in Region Zealand, Denmark perform Clinical Pharmacy Services including medication history, medication reconciliation and medication review.¹ Data for this study were collected during the period January–February 2020. After concluding the pharmacist note in the patient record, the written interventions were copied to a separate sheet of paper, excluding patient- or physician-specific data. The attending physician was asked to assess each intervention for clinical relevance/significance using the Eadon score.² The Eadon classification ranges from 1 (Intervention is harmful to the patient's well-being) to 6 (Intervention is potentially life-saving). The physician made the assessment in private and returned the sheet in a sealed mailbox for later analysis. The analysis took place after the end of data collection to avoid affecting the PI during the project period. At the end of the study period, the mailbox was opened and data manually transferred to Microsoft Excel for descriptive statistics.

Results A total of 50 PI were assessed. None of the interventions were considered harmful to the patient, while 6 of the interventions (12%) were assessed as insignificant in relation to the patient's current treatment. The majority of the interventions (64%) were assigned an Eadon score of 4–6, interpreted as significant (40%), very significant (12%) or potentially life-saving (12%).

Conclusion and relevance In general, clinical pharmacists' interventions were well accepted by physicians, who classified 64% of interventions as resulting in better treatment, prevention of major organ failure, or potentially life-saving, interpreted as clinically relevant.

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PCNE Classification for Drug-Related Problems V9.1.

Conflict of interest No conflict of interest

4CPS-015 SATISFACTION AND INDIRECT IMPACT OF AN OUTPATIENTS' TELEPHARMACY PROGRAMME

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Background and importance A telepharmacy programme (TPP) started in December 2019 delivering medication to primary healthcare centres through a pharmaceutical telephone care service from Hospital Pharmacy. Outpatients from all pathologies were included except onco-haematology, and erythropoietin patients.

Aim and objectives To evaluate outpatients' satisfaction with the TPP and its indirect impact on work and family conciliation.

Material and methods A random survey was conducted from 15 September 2020 to 1 October 1 2021 to patients included in the TPP. Inclusion criteria were being an adult aged over 18 years old and a TPP user for 6 or more months. Information regarding sociodemographic data (sex, age, studies, work situation), Likert-type questions about satisfaction with the TPP, most and least valued TPP feature, frequency of dispensing prior to inclusion, and time spent on face-to-face consultations at the hospital pharmacy was collected. In order to evaluate the indirect impact of the TPP service, the working time gained per patient and year was calculated, especially the time gained in labour-active patients.

Results 97 (34.1%) of 284 patients were included in the TPP. 53.6% men, 59.8% aged over 50 years, 73.2% with basic studies or without studies, 35% in employment. 75.3% patients attended the pharmacy service on a monthly basis before inclusion in the TPP; once included, 56.7% had received medication at the primary care centre four times or more at the time of the study. 92.7% of the surveyed patients rated TPP satisfaction with the highest score (ie, 5/5 points). The most valued features were time and/or economic saving (62.9%), pharmaceutical care received (20.6%) and family or work conciliation (both 13.4%). The worst valued features were days and time slot established to dispense medication in primary healthcare centres (18.5%) and the confidentiality of the delivery (6.2%). Surveyed patients required

on average 89.5 min to go and come back from hospital; furthermore, among labour-active patients the average on face-to-face consultation was 87 min. Inclusion in the TPP allows an average of 17.4 hours/patient/year working time gained.

Conclusion and relevance TPP achieves a high degree of satisfaction in hospital outpatients, showing a saving on indirect costs between employed patients, where time and economic trip saving were the benefits most valued by users. However, delivery schedule assignment of medication was the least popular feature.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-016 FACTORS INFLUENCING THE ATTITUDES AND OPINIONS OF CZECH PHYSICIANS AND CITIZENS TOWARD INFLUENZA VACCINATION IN CZECH PHARMACIES

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Background and importance Pharmacists are health professionals who have the skills and logistic ability to vaccinate. Pharmacy-based vaccination (PBV) has already shown widespread success. Czech Republic has low influenza vaccination rate with currently no PBV.

Aim and objectives The objective of this study was to determine physicians' and citizens' attitudes and opinions toward influenza vaccination in Czech pharmacies.

Material and methods A representative sociological cross-sectional study was conducted from November to December 2020 through face-to-face structured interviews. A questionnaire was used for this purpose. The first part was focused on sociodemographic variables (eg, gender, age). The second part examined the attitude of physicians and citizens to influenza vaccination in pharmacies (positives, negatives, utilisation of PBV). The third part was composed of statements (whether citizens and physicians agree with influenza vaccination in pharmacies). For the characteristics of the tested cohort, descriptive statistics were expressed as either absolute and relative frequencies. Pearson Chi-square test was processed for correlation analysis by SASD 1.5.8.

Results Of 1348 physicians, 1093 (611; 55.9% women) with mean age 48 ± 0.8 years participated. Of 2302 citizens, 1769 (902; 51.0% women) with mean age 47 ± 0.1 years agreed to participate in the study. Citizens as well as physicians mostly disagreed with vaccination against influenza in pharmacies (41.1% vs 56.3%) and more than a third of citizens could not express an opinion on this issue (33.7%). According to citizens, this vaccination will allow greater availability of influenza vaccination (22.7%) and relief for general practitioners (24.3%). About half the citizens (50.3%) did not perceive any positives, mainly those with lower education ($p < 0.001$). As a negative, one-third of citizens (31.0%) perceived the pharmacy as an inadequate place for vaccination. In the physicians' opinion, pharmacists are unable to deal with adverse drug reactions after vaccination (46.6%). Conversely, 41.8% of physicians also perceived vaccination in pharmacies as a positive relief for general practitioners.

Conclusion and relevance Almost half of citizens and physicians currently disagree with vaccination in pharmacies in the Czech Republic. The physicians' main concern is the inability of pharmacists to deal with adverse drug reactions. For citizens, the major disadvantage is locating PBV in a pharmacy.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-017 THE DECISION-MAKING PROCESS IN HEALTH POLICY IMPACTS CLINICAL PRACTICES: A QUALITATIVE STUDY

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Background and importance The setting up of the free policy in caesarean sections is spreading in sub-Saharan Africa. In our country, since 2009, a free kit as a guideline, containing the required materials and antibiotics, has been available.¹ An agency was set up to manage the policy. Unfortunately, some contradictions were noted in antibiotic prophylaxis practices.

Aim and objectives We aimed to identify bottlenecks for appropriate antibiotic prophylaxis practices.

Material and methods Using a semi-structured interview guide, we explored in the stakeholders involved their opinions on the mechanism used in the setting up with a focus on the choice of the antibiotics. The data were analysed by content analysis.

Results From the emerged themes, the stakeholders expressed positive opinions about the kit, intended for the patient's safety and protection, and good practices in caesarean sections. The choice of the antibiotics in the kit was based on pharmacological and non-pharmacological criteria. However, the non-involvement of certain socioprofessional categories such as microbiologists in the decision-making and the top-down approach showed that the engagement and opinions of all stakeholders has been little considered. Moreover, there appeared to be a low evidence-base and mixed-consensual opinions, which revealed a poor relevance in the choice of the antibiotics. These aspects that have received little consideration in this decision-making are contrary to the two important principles described by Formoso *et al* in the methodology of guidelines. In effect, they emphasised that health-care decisions can and should be made through the participation and balanced judgment of specific stakeholders, and scientific evidence should be highly relevant, be gathered systematically and be appraised critically at the patient and policy levels.²

Conclusion and relevance The inappropriate practices in prophylaxis can be explained by the bottlenecks found in our study. Local stakeholders' opinions and engagement coupled with evidence-based decision-making are essential to ameliorate antibiotic prophylaxis in caesarean sections.

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Conflict of interest No conflict of interest

4CPS-019 REACTOGENICITY OF THE BNT162B2 (PFIZER-BIONTECH) MRNA VACCINE AGAINST COVID-19 IN TERTIARY HOSPITAL WORKERS

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Background and importance Although clinical trials of the BNT162b2 mRNA vaccine against COVID-19 (Pfizer-BioNTech) have shown acceptable levels of safety, continuous monitoring of the reactogenicity of the vaccine outside of controlled settings in clinical trials can provide additional information for patients, health professionals and the general population on local and systemic reactions after vaccination.

Aim and objectives To analyse the reactogenicity of the first and second doses of the mRNA vaccine against COVID-19 BNT162b2 (Pfizer-BioNTech) in a sample of tertiary hospital workers.

Material and methods 295 tertiary hospital workers who received the BNT162b2 vaccine against COVID-19 between January and March 2021 answered a questionnaire on socio-demographic variables, previous COVID-19 infection, and local and systemic reactions after the first and second doses of the vaccine.

Results 291 completed the questionnaire after the first and second doses of the vaccine (response rate of 95.4%), which constituted the final sample of the study. Of these, 200 were women (68.7%), and the mean age was 48.46 (SD 11.77) years. 81.8% and 84.0% of the participants indicated having experienced at least one adverse reaction after the first and second doses of the vaccine, respectively. The most commonly reported reaction was pain at the injection site, being more frequent after the first dose of the vaccine. Systemic reactions evaluated were reported more frequently after the second dose of the vaccine. The most frequent reactions to the first dose were pain at the injection site (74.6%), headache (11.3%) and fatigue (9.3%). In the second dose, the most frequent reactions were pain at the injection site (64.8%), general malaise (30.7%) and headache (26.8%). Women, younger adults and people with a previous COVID-19 infection reported increased reactogenicity. Furthermore, a high reactogenicity after the first dose was related to a higher number of adverse reactions after the second dose of the vaccine.

Conclusion and relevance The distribution of reactogenicity in the present study is consistent with the data reported in the studies conducted with the BNT162b2 vaccine, especially in terms of association with the characteristics of the participants. These findings can facilitate the identification of people with a higher probability of having a high reactogenicity to the vaccine, allowing them to anticipate its appearance.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-020 COMPARISON OF DEPRESCRIBING STRATEGIES: LESS-CHRON CRITERIA VERSUS THE GOOD PALLIATIVE-GERIATRIC ALGORITHM IN A NURSING HOME

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Background and importance Polypharmacy and the use of potentially inappropriate medication are frequent in nursing homes and are associated with adverse health outcomes. Deprescribing has been proposed as a way to curtail this problem; however, the best way to implement deprescribing and its real impact are still unclear.

Aim and objectives To compare two different deprescribing strategies and to assess the impact of their application in a nursing home.

Material and methods Quasi-experimental study of pre-post design in a nursing home July–September 2020. Inclusion criteria: inpatients aged >65 years and >5 medications. The pharmacist applied the LESS-CHRON criteria (LCs) and the good Palliative-Geriatric algorithm (gPG) to the same population to assess the differences. If the individual met the criteria for deprescription an intervention was made. Gender, age, number of drugs, intervention, organ system involved and interventions accepted were registered. The reduction of LCs was evaluated. The main variable was the impact on the average number of medications per patient according to the strategy used if all the interventions were accepted.

Results The treatment of 33 residents was reviewed. Median age was 74 years and 40.7% were men. The average number of medications per patient was 9.4.

LCs: 28 criteria were detected in 17 different residents. 32.1% involved cardiovascular system (55.5% regarding anti-hypertensives) and 28.5% nervous system. 8/28 proposed interventions were accepted, reducing the number of LCs by 28.5%.

gPG algorithm: 21 recommendations were added resulting in a total of 49 in 25 patients. Of these 21, 80.9% were aimed at suspending drugs not included in the LCs and 14.2% at reducing doses. 66.6% of the proposed interventions were accepted. Encompassing the two strategies, 44.8% of the interventions carried out were accepted.

Acceptance of all interventions would have meant a reduction of 1.27 medications per resident on average applying the gPG versus a reduction of 1.03 according to the LCs.

Conclusion and relevance The LCs are a tool to help deprescription in individuals with multimorbidity, especially those related to the cardiovascular system; however, it is necessary to validate whether they are useful in patients with a longer life expectancy, where an algorithm such as gPG may be preferable.

REFERENCES AND/OR ACKNOWLEDGEMENTS

LESS CHRON: tool for deprescribing in patients with multimorbidity.

Conflict of interest No conflict of interest

4CPS-021 POST-STERNOTOMY MEDIASTITIS: A MEDICOECONOMIC STUDY COMPARING TWO PREVENTIVE STRATEGIES IN CARDIAC SURGERY

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Background and importance Causing excess mortality and prolonged hospitalisations, mediastinitis is a serious sternal wound infection that can occur after open heart surgery. With an incidence of 4.2% in 2020 in our hospital which specialises in thoracic and cardiovascular surgery, its occurrence must be prevented.

Aim and objectives To compare the cost-effectiveness of standard treatment with Collatamp G, a gentamicin-impregnated implant, and negative pressure therapy with Pico 7.

Material and methods Cost-effectiveness study comparing one retrospective control arm (standard sternal dressing – July to September 2019) and two prospective intervention arms (Collatamp G and Pico 7 – November 2020 to February 2021). Patients with at least one risk factor (RF) for postoperative mediastinitis were included. The primary endpoint was the incidence of mediastinitis at 1 month after surgery (M1). From the medical record, postoperative hospital costs were collected to calculate the incremental cost-effectiveness ratios (ICER).

Results A total of 82 patients were included. The mean number of RF/patient was 1.7 (83/48) in the control arm, 1.8 (46/25) in the Collatamp G arm and 2.4 (22/9) in the Pico 7 arm ($p < 0.05$). The incidence of mediastinitis at M1 was 8% (4/48), 4% (1/25) and 11% (1/9), respectively ($p > 0.05$). Two cases of air leak making the Pico 7 system ineffective were noted. The postoperative hospital costs were €12 860/patient (control), €10 451/patient (Collatamp G) and €13 127/patient (Pico 7). The ICER is €55 583/mediastinitis avoided with Collatamp G versus €9616/mediastinitis avoided with Pico 7.

Conclusion and relevance The difference in the incidence of mediastinitis was not significant. Both strategies are more cost effective than standard sternal dressing. The ICER is in favour of Collatamp G, but the Pico 7 arm population has more RF and the observed leaks can be resolved. Pico 7 should be re-evaluated with the addition of a sealing patch when there is a risk of leakage. By supporting surgical teams in the evaluation of preventive strategies, the hospital pharmacist contributes to optimise treatments at the best cost.

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Conflict of interest No conflict of interest

4CPS-026 OPTIMISATION OF DIRECT ORAL ANTICOAGULANT TREATMENTS: ANALYSIS OF PRESCRIPTIONS AND PHARMACEUTICAL INTERVIEWS

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Background and importance In a multidisciplinary hospital with 426 beds, anticoagulant treatments have a high risk of iatrogenism and prescription error. We decided to focus on the direct oral anticoagulant (DOAC) treatments.

Aim and objectives We analysed prescriptions to evaluate the rate of correct prescription. We wanted to assess the level of patient knowledge and impact of a pharmaceutical interview (PI) on this degree of knowledge.

Material and methods A prospective study including 38 patients from 1 July 2020 to 31 August 2020 was conducted. First, we evaluated the relevance of dosage of DOAC during pharmaceutical analysis. Then, patients' knowledge of DOACs was assessed by a questionnaire before and after PI. This questionnaire comprised nine items concerning: general notions about DOAC, drug administration, over- and under-dosing and drug interactions. A statistical test was performed to compare the data ($\alpha = 2.5\%$).

Results The mean age of the 38 included patients was 83 years and the sex ratio was 1. Patients received apixaban (53%), rivaroxaban (45%) and dabigatran (2%). DOAC were used to prevent stroke in adult patients with non-valvular atrial fibrillation for 95% of them. Data were lacking to allow a correct pharmaceutical analysis: patient weight was not indicated in the patient file in 90% of prescriptions of apixaban. A dosage error was noted in 9 prescriptions and 4 prescriptions were changed following pharmaceutical intervention. Knowledge assessment was carried out in 31 patients. For 7 patients, communication difficulties, cognitive and psychiatric disorders made this assessment impossible. Therapeutic knowledge before and after PI was 52% and 67%, respectively. We observed a statistically significant improvement in patients' knowledge of their DOAC treatment concerning general notions about the drug (+10%), administration (+24%), over- and under-dosage (+13%) and drug interactions (+23%).

Conclusion and relevance This study reveals patients' poor knowledge of their DOAC treatment. However, performing PI statistically improves patient knowledge. It would therefore be interesting to systematically carry out these PI. It would also be interesting to develop a city-hospital link in conjunction with pharmacists for optimised patient follow-up.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-028 EFFECTIVENESS AND SAFETY OF CENOBAMATE: EXPERIENCE IN A THIRD-LEVEL HOSPITAL

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Background and importance More than one-third of patients with epilepsy have uncontrolled seizures despite being treated

with two or more anti-seizure medications (ASM); this condition is known as refractory or drug-resistant epilepsy. Cenobamate is a new ASM that has been recently approved by the European Medicines Agency for the adjunctive treatment of focal-onset seizures in adults with drug-resistant epilepsy. In the Spanish system, cenobamate is a drug that is dispensed in hospitals and, since August 2020, access to it has been made through the compassionate use programme. Because of its newness, real-world data regarding cenobamate use are currently very limited.

Aim and objectives The aim of this study was to evaluate the effectiveness and safety of cenobamate in real-world practice.

Material and methods We conducted a single-centre, retrospective study of patients who received cenobamate in our hospital between September 2020 and September 2021. The patients included in the study must have received cenobamate for at least 3 months. Demographic and clinical variables were collected by reviewing medical records. The efficacy outcome was the proportion of patients who exhibited a 50% or greater reduction in the monthly seizure frequency from baseline (50% responder rate). We also recorded adverse events (AEs) and estimated the rate of discontinuation of treatment.

Results All the patients included in the study (n=30) were adults with focal-onset epilepsy who had uncontrolled seizures despite a history of treatment with ASMs. Patients were treated with one to five concomitant ASMs during the study period and 43.3% of them reduced the number of ASMs with one or two. The daily dose of cenobamate ranged from 50 to 400 mg/day. The 50% responder rate was 53.3%, with a median of 50% (IQR 31.2; 73.3) in the reduction of monthly seizure frequency. 73.3% of patients had nervous system disorders (somnolence, dizziness, dysarthria, etc.), 16.67% had gastrointestinal AEs and 6.67% showed skin disorders (one of them had rash erythematous). The discontinuation rate because of AEs was 13.3%.

Conclusion and relevance The effectiveness and safety data obtained are similar to those of the clinical trial. We found that adjunctive treatment with cenobamate allows a reduction in the number of concomitant ASMs in an important proportion of the patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-030 SELECTIVE DECONTAMINATION OF THE GASTROINTESTINAL TRACT IN PREVENTING VENTILATOR-ASSOCIATED PNEUMONIA IN AN INTENSIVE CARE UNIT

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Background and importance Ventilator-associated pneumonia is related to hospital complications and economic costs.

Aim and objectives To describe the implementation in the intensive care unit (ICU) of a tertiary level hospital of a 'Selective Decontamination of the Digestive Tract (SDD)' protocol for preventing ventilator-associated pneumonia (VAP); to study the evolution of VAP incidence over two consecutive years, and to evaluate the economic cost of the protocol.

Material and methods The SDD protocol is a strategy included among the specific optional measures in the Pneumonia Zero Project (PZ) whose aim is to contribute to reducing the incidence of VAP in those critical care units where rates are above the recommended levels. Its application is intended to prevent and/or eradicate the oropharyngeal and gastrointestinal carrier state of potentially pathogenic microorganisms. It consists of applying an oropharyngeal paste in the oral cavity and a solution introduced through a nasogastric tube four times a day in patients on mechanical ventilation.

We prepared the paste and solution in the Pharmacy Service and incorporated their criteria for use as an ICU pharmacotherapeutic protocol for both intravenous antibiotic prophylaxis and SDD formulations in the electronic prescription programme. We applied the protocol to all the mechanically ventilated patients who met the selection criteria.

We compared VAP data between February and December 2019 with the same period in 2018.

Results In 2018, the VAP rate per 1000 days of mechanical ventilation was 12.34. After performing the SDD protocol in 2019, the rate of VAP per 1000 mechanical ventilation days decreased to 5.75. Between the two periods the overall incidence of pneumonia decreased from 5.8% to 2.7%.

We estimated a production cost in 2019 of € 5.37 per SDD paste and € 2.20 per SDD solution. We produced 610 units of SDD paste and 850 units of SDD solution in 2019 with a total estimated production cost of € 5145.70.

Conclusion and relevance SDD applied with other recommended VAP control measures gave preliminary positive results in reducing the rate of VAP infections. We need to extend the study period to confirm these findings.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-031 EFFICACY AND SAFETY OF HIGH-DOSE TWICE-WEEKLY SEBELIPASE ALFA IN SEVERE-ONSET WOLMAN DISEASE: A CASE REPORT

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Background and importance Lysosomal acid lipase (LAL) deficiency is a rare metabolic disease (0.2:10 000) characterised by lysosomal accumulation of cholesterol esters and triglycerides, with a severe and rapidly progressive form known as Wolman disease (WD), usually fatal in the first 6–12 months of life. Sebelipase alfa (SA) is a recombinant human LAL authorised as enzyme replacement. According to the technical data sheet, it is administered weekly and should be started at low doses (1 mg/kg) with a gradual increase according to response, thus avoiding serious hypersensitivity reactions. Dosing twice-weekly with rapid dose escalation had not been previously described in the literature.

Aim and objectives To describe the efficacy and safety of high-dose SA administered twice-weekly in severe WD.

Material and methods We describe the case of a 3-month-old baby diagnosed with WD with secondary haemophagocytic syndrome, admitted to the paediatric critical care unit. Since

admission, she presented anaemia, thrombopenia, hyperferritinaemia, altered liver function tests and lipid profile, and massive hepatosplenomegaly. Given the rapid deterioration and critical situation, with severe respiratory and kidney failure, treatment with SA was started at high doses twice-weekly.

Results To date, the patient received 11 doses of SA over 35 days. The first dose was administered at 3 mg/kg, and the subsequent doses at 5 mg/kg, twice-weekly as an intravenous infusion over 240 min. She required mechanical ventilation and continuous haemodialysis for 2.5 weeks; and red blood cell and platelet transfusions repeatedly up to day +24 after the start of SA. Initially, ferritin was 9438 ng/mL, decreasing to 1583 ng/mL at day +35. Transaminases reached a peak (AST: 3×ULN, ALT: 2×ULN) at day +10, being within normal values at day +21, with a slight subsequent elevation without clinical relevance. Bilirubin also reached a peak of 14.7 mg/dL at day +10, being at 6.3 mg/dL at day +35. Lipid profile has not yet reached normal values. A reduction in hepatosplenomegaly was noticeable after 1 month. No adverse effects were reported.

Conclusion and relevance After the diagnosis of WD with aggressive and severe presentation, treatment with high-dose twice-weekly SA has been an effective and well-tolerated treatment so far in our case, although it will be necessary to maintain enzyme replacement for life.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-033 DEVELOPMENT AND EVALUATION OF AN AMITRIPTYLINE TOPICAL FORM FOR THE TREATMENT OF CANCER-RELATED NEUROPATHY

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Background and importance In France, 6.9% of the general population suffer from neuropathic pain.¹ Among the causes are surgery (20%), including cancer surgery, and chemically induced paresthesia (4.1%).² There are few treatments developed for this indication, and patients quickly find themselves in a therapeutic impasse. In addition, oral treatments could possibly cause undesired systemic effects.

Aim and objectives The aim was to develop and evaluate a topical form of amitriptyline at 10% for second-line treatment of patients.

Material and methods A galenic development was carried out following the recommendations of the International Council for Harmonisation (ICH) Q2 and 3 that addressed the galenic, physicochemical and microbiological parameters. Different types of topicals have been designed, from the cream to the thermogel with poloxamer.

Once the form was judged satisfactory on the pharmaceutical criteria, the preparation was assessed in the clinical context. Pain evaluation was carried out according to a visual analogue scale (VAS). A reduction of at least 30% was considered clinically relevant according to the recommendations of the French Society of Evaluation of the Treatment of the Pain.

Results The best compromise found was a 10% amitriptyline cream made in Versatile with urea at 2% as an emollient agent. This cream retains its diffusion properties, its organoleptic characteristics but also its physicochemical and microbiological stability for more than 6 months (stability data are still ongoing) in a PVC/ALU packaging.

81 patients were included (February–November 2020). For 49 patients (60.5%), the cream was effective. The etiologies for which the cream seems to be the most effective are post-chemotherapy pain (64% efficiency with taxane-based chemotherapy, 70% efficiency with platinum-based chemotherapy).

Conclusion and relevance The development of this topical has allowed neuropathic patients to gain relief. These data are very encouraging and will be confirmed through the implementation of a clinical trial.

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Conflict of interest No conflict of interest

4CPS-034 DEPRESCRIBING ORAL IRON IN ELDERLY PATIENTS: EXPERIENCE FROM A NURSING HOME ASSOCIATED WITH A THIRD LEVEL HOSPITAL

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Background and importance Oral iron is prescribed to elderly patients as the treatment for episodes of iron deficiency anaemia. Inadequate follow-up and chronic prescription in patients who no longer benefit from it is common.

Aim and objectives To identify potentially inappropriate prescriptions (PIP) for oral iron (OI) in institutionalised elderly patients, as well as describing the deprescribing process in consensus with the centre's medical team.

Material and methods Demographic (age, sex), clinical (pathologies), analytical (haemoglobin, ferritin and serum iron) and pharmacological variables (dosage, possible adverse reactions) were collected from all patients undergoing oral iron treatment at the centre under our care. The Selene medical record and the Mira electronic prescription were used for data collection.

Chronically prescribed treatments without evidence of iron deficiency anaemia and non-iron deficiency analytical profile in elderly patients (Hb >12 g/dL, ferritin >100 ng/mL) were ruled as cut-off points for PIP. Data were collected prior to and 3 months after the intervention.

Results Out of the 129 institutionalised patients, a total of 27 patients (21%) followed a chronic treatment with different presentations of OI (10 iron lactate, 17 sulfate). With a median age of 88 years, the majority (74%) were women. 56% of the patients in treatment had chronic constipation, possibly exacerbated by OI.

Of the 27 patients with OI, 16 PIPs (59%) were found. 12 patients (75%) had high iron reserve values (ferritin and

haemoglobin) and 4 patients followed a chronic prescription without adequate analytical testing.

We proposed to the medical team to study the possibility of suspending OI treatment in those 12 patients with high iron reserve values, as well as assessing those 4 patients without previous blood tests, and to reevaluate after 3 months. The pharmaceutical deprescribing recommendation was accepted in 10 patients (63%).

Three months after the withdrawal, 4 patients had normal values of iron reserve tests, 3 were deceased, 2 had no analytical data, and 1 patient restarted a 3-month course of OI treatment.

Conclusion and relevance Oral iron treatments are prone to inadequate chronic prescription; these drugs commonly cause gastrointestinal adverse effects. Deprescribing efforts by pharmacists in a nursing home as part of a multidisciplinary team is a effective way of optimising treatment in polymedicated, elderly patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-035 PHARMACIST-LED MEDICATION RECONCILIATION AT DISCHARGE SHALL NOT BE SUFFICIENT TO REDUCE UNPLANNED HEALTHCARE UTILISATION: HEAR THE PATIENT EXPERIENCE!

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Background and importance Older patients often experience adverse drug events (ADEs) after discharge that may lead to unplanned readmission. Pharmacist-led medication reconciliation at discharge (MRD) is known to reduce medication errors that lead to ADE but results on healthcare utilisation are controversial.

Aim and objectives The main aim of this study was to evaluate the MRD's effect provided to patients aged over 65 years on their unplanned rehospitalisation for ADE within 30 days. A secondary objective was to assess the impact of the pharmacist's presence on patient experience and knowledge about their treatment.

Material and methods An observational, multicentre prospective study, in medical and rehabilitation wards in 5 hospitals in Brittany, France. Included patients were aged 65 years and over who received MR at admission (MRA). A pharmacist-led MRD was the intervention. The primary endpoint was the proportion of patients experiencing death, unplanned rehospitalisation and/or visit to an emergency department within 30 days after discharge. Secondary endpoints encompassed the patient's experience of discharge and knowledge about their medication changes.

Results Patients who received MRA and MRD did not have significantly fewer deaths, unplanned rehospitalisations and/or emergency visits related to ADE or other (p=0.960) 30 days after discharge than patients receiving MRA alone.

The discharge from hospital seemed well organised for these patients (p=0.003) and they reported more frequently

that their community pharmacist and general practitioner received information about their hospital stay ($p=0.036$).

In the intervention group ($n=221$), 74.9% of patients had an interview with a pharmacist but only 47.8% reported any conversation with a healthcare professional about their medication.

41% of patients who received MRA did not have MRD ($n=153$), mainly because the pharmacist was not notified of the patient's discharge or because of a lack of time.

Conclusion and relevance This study found no effect on MRD on healthcare utilisation 30 days after discharge on patients aged over 65 years. MRD significantly improved the patient's experience of seamless care after discharge. Patients' knowledge about their medications still offers scope for improvement. A better integration of pharmacists in care services seems necessary to improve the process, and the best time for the patient's interview remains under discussion.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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<https://ejhp.bmj.com/content/25/2/100.long> <https://ejhp.bmj.com/content/23/4/207.long>

Conflict of interest No conflict of interest

4CPS-037 THE 5P-STUDY: PATIENT AND HEALTH CARE PROVIDER PERSPECTIVES ON POTENTIAL PREVENTABILITY OF HOSPITAL ADMISSION FOR ACUTE EXACERBATION OF CHRONIC OBSTRUCTIVE PULMONARY DISEASE

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Background and importance Chronic obstructive pulmonary disease (COPD) is a highly prevalent chronic disease partly characterised by the occurrence of exacerbations. The main treatment goal for COPD consists of reduction of symptoms and future risk and severity of exacerbations. A part of the hospital admissions for COPD exacerbations could theoretically be preventable with timely and appropriate outpatient care or self-management. It is important to consider and understand patients' and health care providers' (HCP) perspectives on potential preventability of hospitalisations to implement strategies directly influencing underlying factors. Different perspectives and beliefs between patient and HCP about the potential preventability can affect treatment efficacy.

Aim and objectives The aim of this study was to explore patients' perspectives on the potential preventability of their hospital admission for an acute exacerbation of COPD (AECOPD) and to compare these with their HCPs' perspectives.

Material and methods Semi-structured interviews were conducted with patients admitted for a COPD exacerbation ($N=11$), their HCP on the respiratory ward ($N=11$) and their treating pulmonologist ($N=10$). Interviews were transcribed verbatim and analysed using thematic content analysis.

Abstract 4CPS-037 Table 1

		Pulmonologist		Kappa
		Yes	No	
Patient	Yes	0	3	-0,18
	No	1	6	
		HCP (respiratory ward)		Kappa
		Yes	No	
Patient	Yes	1	2	-0,28
	No	6	2	
		HCP (respiratory ward)		Kappa
		Yes	No	
Pulmonologist	Yes	1	0	0,14
	No	5	4	

Results The results of the perspectives on the potential preventability of AECOPD hospitalisation are shown in Table 1.

Different patient and caregiver factors for optimisation were identified: calling help, recognition and taking action on symptoms and instruction on COPD, treatment and action plans. Furthermore, treatment adherence and inhalation technique were not frequently assessed. However, both HCPs and patients felt the need for regular feedback.

Conclusion and relevance Patients and their HCPs have different beliefs about the potential preventability of AECOPD hospitalisation. Although not all patients and HCPs believed that hospitalisation was preventable, most did mention factors that could have led to a different outcome for the current exacerbation or for the patient's health status and treatment of exacerbations in the future. The factors show that shared decision-making is crucial to bring to light the perspective of the patient and their individual needs to timely treat or even prevent AECOPD and thereby decrease admission rates.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-038 INTRAPLEURAL COLISTIN FOR PLEURAL EMPYEMA CAUSED BY EXTENSIVELY DRUG-RESISTANT PSEUDOMONAS AERUGINOSA: A CASE REPORT

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Background and importance Pleural empyema (PE) is a collection of pus in the pleural space, with high morbimortality if it is caused by multidrug-resistant (MDR) bacteria. The most common cause of empyema is a primary pneumonic process. The intrapleural administration of antimicrobials makes it possible to reach therapeutic concentrations in the pleural cavity, limiting the adverse effects associated with systemic treatment.

Aim and objectives Our aim was to describe the use of intrapleural colistin (IpC) in one patient.

Material and methods We describe a 22-year-old woman who was admitted to the Intensive Care Unit after a lung transplant.

Results She presented a respiratory failure, clinically and radiologically compatible with necrotising pneumonia, for which she underwent retransplantation. Multiple cavitations were observed in the explant and the culture was positive for *Pseudomonas aeruginosa*; treatment with intravenous (IV)

ceftazidime 2 g every 8 hours was initiated. Two weeks later, PE was confirmed by growth of *P. aeruginosa* resistant to carbapenems in the pleural fluid and treatment was escalated to IV ceftolozane/tazobactam 2 g/1 g every 8 hours.

After subsequent microbiological control, *P. aeruginosa* resistant to ceftolozane/tazobactam and ceftazidime-avibactam (minimum inhibitory concentration (MIC) >250 µg/mL) was observed and, therefore, IV ciprofloxacin 400 mg/12 hours and IV amikacin 15 mg/kg/24 hours were initiated. Nebulised colistin 5 million units (MIU)/8 hours was added. IpC was added due to the persistence of extensively drug-resistant (XDR) *P. aeruginosa* in the pleural fluid. The decision was based on a case report in which IpC was used for MDR *Acinetobacter baumannii* PE, with positive results; 0.5 MIU of colistimethate sodium were diluted in 50 mL 0.9% physiological saline and instilled through the pleural drains every 12 hours (clamped for 2 hours).

The patient presented episodes of desaturation and sweating associated with the administration of IpC, forcing the suspension of IpC after 9 days of treatment. Finally, she died in the context of infectious disease as a consequence of refractory hypoxaemia.

Conclusion and relevance The persistence of XDR *P. aeruginosa* in our patient motivated the search for alternatives and IpC was chosen on the basis of a single case. However, the efficacy could not be determined due to its poor tolerance. Despite the limited amount of published data, the administration of intrapleural antibiotics may constitute a therapeutic option.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-039 EFFECTIVENESS OF ERENUMAB AND GALCANEZUMAB IN THE TREATMENT OF MIGRAINE

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Background and importance Migraine is a neurological disorder characterised by episodic and recurrent seizures. Erenumab and galcanezumab are two monoclonal antibodies (MA) indicated for the prophylaxis of migraine in adults. They are recently marketed drugs, so it was necessary to determine their effectiveness.

Aim and objectives This study analysed the effectiveness of these MA in a series of patients in a third-level hospital.

Material and methods Retrospective observational study. Study period: January 2020–April 2021.

To start treatment, patients must be diagnosed with chronic or episodic migraine, having at least 8 migraine days per month and after having failed three or more previous treatments, one of them being botulinum toxin in the case of chronic migraine. This treatment is dispensed in the outpatient consultation service of the Hospital Pharmacy after a clinical interview in which all variables are recorded. To evaluate the effectiveness, we analysed the number of days with migraine attacks per month and the consumption of concomitant-related medication.

Results 53 patients (49 women, 4 men). Median age: 50 (range 21–77) years.

Diagnosis: chronic migraine: 41 patients; episodic migraine: 12 patients.

Treatment: erenumab 140 mg: 46 patients; erenumab 70 mg: 5 patients; galcanezumab 120 mg: 2 patients.

Received doses: galcanezumab: 6 doses: 2 patients; erenumab: 12 or more doses: 10 patients; 6–11 doses: 27 patients; 3–5 doses: 11 patients; fewer than 3 doses: 3 patients.

The median number of monthly episodes suffered pre-treatment was 20 (9–30). After 3 months, the median was 9 (1–30): 45% of episodes. After 6 months: 7 (0–28): 35% of episodes. After 12 months: 13 (4–28): 65% of episodes. 4 patients suspended treatment due to lack of effect.

The rest of the antimigraine drugs consumed prior to the use of MA, at the beginning, after 3 months and after 6 months of treatment were:

Beta-blockers: 22.22%, 1.85%, 0%, 0%.

Calcium antagonists: 20.37%; 1.85%, 0%, 0%.

Antiepileptics: 38.89%; 1.85%, 1.96%, 0%.

Nonsteroidal anti-inflammatory drugs (NSAIDs): 25.92%; 29.63%, 45.09%; 16.21%.

Triptans: 38.88%; 62.96%, 50.98%, 18.91%.

No interactions with MAs were identified.

Conclusion and relevance The use of subcutaneous MA reduced the median of seizures per month significantly at 3 and 6 months. Although a rebound is observed at 12 months, the result of this is difficult to assess due to the small number of patients (10). The consumption of other antimigraine drugs was also reduced.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-040 INTERINDIVIDUAL VARIABILITY OF LINEZOLID IN CRITICALLY ILL PATIENTS

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Background and importance A high variability in linezolid plasma concentrations (Cp) has been observed when administered at the standard dosage recommended in the technical data sheet (600 mg/12 hours), which is directly related to the effectiveness of the treatment and the appearance of haematological toxicity.

Aim and objectives The main objective was to describe the Cp values of linezolid obtained in critically ill patients, as well as the recommendations made during pharmacokinetic monitoring.

Material and methods Retrospective observational study carried out in a third-level general hospital. Patients >18 years old admitted to the critical care units between September 2019 and May 2021, in which at least one Cp determination of linezolid was performed, were analysed. Demographic, clinical, therapeutic and pharmacokinetic monitoring-related variables were collected. Cp determination of linezolid was analysed by homogeneous enzyme immunoassay (Indiko™ Plus kit). The target therapeutic interval of linezolid was established between 2 and 8 µg/mL and statistical analysis was performed using R software.

Results 92 patients were analysed, 67% men and 33% women, with a median age of 67 and 68 years and a mean body mass index (BMI) of $30 \pm 7.74 \text{ kg/m}^2$ and $30 \pm 6.98 \text{ kg/m}^2$, respectively. Linezolid was administered intravenously (IV), 86 started treatment with the standard dosage (600 mg/12 hours), 5 with an intensified regimen (600 mg/8 hours) and only 1 patient with a regimen below that recommended in the technical data sheet (600 mg/24 hours). After the first control: 34 patients (37%) Cp = 2–8 $\mu\text{g/mL}$, 37 (40%) Cp <2 $\mu\text{g/mL}$ and 21 (23%) Cp >8 $\mu\text{g/mL}$. The median Cp at first control was 3.1 $\mu\text{g/mL}$, with a wide range of distribution (0.2 to 30 $\mu\text{g/mL}$). A modification of the dosage was recommended in 70% of the reports made and 47% achieved Cp within the therapeutic interval at the second control. A total of 2.4 determinations per patient were performed, recommending an individualised dosage in 60% of the reports. The recommended dosing was between 400 and 2400 mg/day, in intermittent infusion every 6, 8, 12 and 24 hours; and in 5 patients, 1200–1800 mg/day by continuous infusion. A significant reduction in platelet count from baseline (>25%) was observed in 46% (42) patients and 22% (20) developed thrombocytopenia, with a platelet count below $100 \times 10^3/\mu\text{L}$.

Conclusion and relevance There is high variability in the Cp of linezolid obtained in the critically ill patients analysed in our study, with a low percentage of patients being within the established optimal therapeutic interval. In 60% of the pharmacokinetic reports, a modification of linezolid dosage was recommended.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-041 SACUBITRIL/VALSARTAN PRESCRIPTION PRACTICE IN PATIENTS WITH CHRONIC HEART FAILURE

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Background and importance Sacubitril/valsartan (SV) is a drug for chronic symptomatic heart failure (HF) with reduced left ejection fraction (LVEF). The PARADIGM-HF study demonstrated that SV was superior to standard treatment, reducing the absolute risk of cardiovascular death or hospitalisation for HF by 4.7%.

Aim and objectives The objectives of this study were to evaluate the adherence of clinicians to the recommendations of the Pharmacy and Therapeutics Committee (PTC) for the prescription of SV, as well as to estimate the number of patients who were readmitted due to decompensation of HF and the number who died from any cause.

Material and methods A prospective study that included patients treated with SV was carried out from February to August 2020. Variables considered were: sex, age, LVEF, N-terminal pro B-type natriuretic peptide (NT-proBNP), standard treatment, New York Heart Association (NYHA) classification and mortality and/or hospitalisations due to HF at 6 months.

Recommendations approved by the PTC for the prescription of SV were: LVEF $\leq 35\%$, NT-proBNP >400 pg/mL, NYHA class II-III and standard therapy (angiotensin-converting enzyme inhibitors or angiotensin II receptor blockers plus beta-blockers and mineralocorticoid antagonists).

Results A total of 54 patients were included (89% men) with a median age of 72 (32–87) years. 23 patients (43%) started treatment during their hospital admissions, while 31 (57%) received the drug before admission.

Overall adequation to the first prescription of SV was achieved in 5/23 patients (21.7%). Adequation for each individual item was as follows: LVEF $\leq 35\%$ in 18 patients (74%), NT-proBNP >400 pg/mL in 23 (100%), NYHA II-III in 17 (74%) and just 8 patients were successfully treated with standard therapy.

72% (39/54) of patients continued treatment after being discharged from hospital and 64% (34/53) continued with this drug 6 months later. Four patients were readmitted once, and another four twice, as a consequence of decompensation of the HF during the 6 months of follow-up. Eight patients died during this period.

Conclusion and relevance Clinicians mostly adapt to the utilisation criteria established by the PTC except for the recommended standard treatment, and the percentage of readmissions due to decompensation of HF in our cohort of patients is higher when compared to the clinical trial.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-042 PHARMACOKINETIC MONITORING OF TACROLIMUS IN RENAL TRANSPLANT PATIENTS

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Background and importance Tacrolimus (TAC), a calcineurin inhibitor, is indicated in renal transplantation, and its monitoring is important due to its pharmacokinetic variability.

Aim and objectives To describe the demographic, clinical and pharmacokinetic characteristics of patients in immediate post-renal transplantation in treatment with TAC.

Material and methods Retrospective observational study carried out in a third-level general hospital. All patients with renal transplantation between September 2019 and September 2021 were included. The following variables were collected at immediate transplantation: demographic (sex, age), anthropometric (weight, height, body mass index (BMI)), monitoring-related (TAC concentration, ConTAC, corresponding to the first monitoring and at which optimal levels are reached, time relapsed from the start of TAC to the first level and the optimal level, number of determinations), clinical (creatinine (Cr) and renal clearance (ClCr) on the day of transplantation and day +7) and pharmacotherapeutics (antibody administered). Two protocols depending on the immunological risk were applied. Low-risk protocol (LR): basiliximab 20 mg on day 0 (day of transplantation) and on day +4, with immediate release TAC (single pre-transplant dose and maintenance dose). High-risk protocol (HR): thymoglobulin 1–1.5 mg/kg/day for 5–7 days and at the end, start with TAC. The target therapeutic interval of TAC in the first month post-renal transplant used was 10–15 ng/mL and the TAC dosage used was 0.15 mg/kg/day orally. The data collected were extracted from the GestLab and OrionClinic12 computer programs.

Results Thirty five patients were analysed, 57% men and 43% women with a mean age of 60 ± 13 and 57 ± 11 years,

respectively. Demographic variables, men: mean weight 78 ± 11 kg, height 1.69 ± 0.08 m and BMI 27 ± 3 kg/m², women: mean weight 67 ± 12 kg, height 1.52 ± 0.12 m and BMI 30 ± 7 kg/m². Eighteen patients (51.43%) were considered LR, receiving basiliximab + mean pre-transplant TAC dose of 10 mg and 17 patients (48.57%) as HR, receiving thymoglobulin. Mean TAC dosing regimen until first monitoring, with a mean time of 2 days: 7.25 mg/12 hours in LR and 6.14 mg/12 hours in HR. Mean total dose of TAC up to first monitoring: 33.47 ± 13.42 mg in LR and 19.29 ± 8.03 mg in HR. At first monitoring: LR, mean ConTAC of 22.89 ± 8.04 ng/mL (83.3% >15 ng/mL, 11.11% <10 ng/mL, 5.55% 10–15 ng/mL); HR, mean ConTAC of 14.59 ± 8.87 ng/mL (47.05% >15 ng/mL, 35.3% <10 ng/mL, 17.65% 10–15 ng/mL). Mean number of determinations to reach target level: 3 in LR and HR, with a mean time of 6 days in LR and 7 days in HR. Mean Cr value on transplant day and day +7: 5.9 ± 2.7 mg/dL and 3.48 ± 2.1 mg/dL, with mean ClCr of 10.73 ± 5.14 mL/min and 26.8 ± 19.76 mL/min, respectively.

Conclusion and relevance Pharmacokinetic monitoring of TAC is useful in immediate renal transplantation since a high percentage of patients present concentrations outside the target therapeutic range in the first determination. Further studies are needed to optimise the initial TAC dosage in this type of patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-043 EFFECTIVENESS, SAFETY AND ADHERENCE OF GUSELKUMAB IN MODERATE TO SEVERE PSORIASIS

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Background and importance Treatment with biologic drugs is indicated in patients with moderate to severe psoriasis, and the therapeutic goal is an improvement equal to or greater than Psoriasis Area and Severity Index (PASI) 75.

Aim and objectives To analyse the use of profile guselkumab in a tertiary hospital and to evaluate the effectiveness, safety and adherence of the treatment in clinical practice in moderate-severe plaque psoriasis

Material and methods Observational, retrospective, descriptive study including all the patients who were prescribed guselkumab from 2019 to October 2021.

Demographic (sex, age) and clinical data (previous biological treatment, date of initiation of treatment and subsequent doses administered, adverse effects and reason for ending treatment) were collected from the digital medical record and the electronic prescription programme.

Effectiveness was derived from PASI levels and recorded over an average of 56 weeks. Safety was measured by the rate of adverse effects.

Results 33 patients (48.5% male and 51.5% female) with a mean age of 49 years. 6.1% received guselkumab as the first line of treatment, 48.9% as the second line and 45.4% as the third or more lines. The biological drugs which were previously used were etanercept (63.6%), adalimumab (30.3%), ustekinumab (30.3%), secukinumab (27.3%), ixekizumab (12.1%) and apremilast (3%).

An average of 57.53 days of difference between medication administration dates was recorded, confirming good adherence to the treatment (100 mg subcutaneous every 56 days).

In terms of effectiveness evaluation, the mean baseline PASI was 10.6 and the mean PASI over a 56-week period was 2.17. This represents an average reduction of 79.5% in PASI levels.

26 patients achieved a decrease in PASI, and of these 12 reached PASI 100.

Adverse effects were detected in 3 patients (9%): diarrhoea, candida spp infection and suppurative outbreak. Treatment discontinuation occurred in 5 patients (15.1%) due to the appearance of adverse effects (2) inefficiency of treatment (2) and desire for pregnancy (1).

Conclusion and relevance The use of guselkumab is an appropriate therapeutic option in patients diagnosed with moderate-to-severe plaque psoriasis after failure of at least one biologic treatment. The achievement of a PASI 79, as well as the few adverse effects that made it necessary to discontinue treatment, demonstrate its therapeutic effectiveness and safety.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-044 PATIENTS' PERCEPTIONS OF HEALTHCARE ASSOCIATED-INFECTIONS AND USE OF ANTIBIOTICS IN A SURGICAL CONTEXT

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Background and importance Surgical patients are exposed to infections, especially surgical site infections, which is a burden for public health. To prevent and cure these infections, surgical teams and patients refer to antimicrobials whose inappropriate use leads to an increase in antimicrobial resistance.

Aim and objectives We interviewed some patients who had undergone surgery to explore their perceptions of healthcare-associated infections and antibiotic use.

Material and methods Data were collected by two socio-anthropologists over a period of 2 months in 2019 using semistructured individual interviews. Patients in the digestive and obstetric wards of two hospitals were included. Data analysis was performed by three pharmacists using content analysis. Coding was realised in pairs and in-depth analysis.

Results Thirty patients were interviewed. The knowledge of healthcare-associated infections by patients was variable. Some of them knew that they can contract an infection in hospital, others did not. The majority of the patients, whether they were educated or not, attested that antibiotics are used for avoiding the suppuration of surgical wounds, cicatrising or healing of wounds. Others argued that antibiotics fortify them after surgery. Moreover, antibiotics utilisation without healthcare workers' prescription was spread in our patients. The patients interviewed did not have any appropriate knowledge about the relation between irrational use of antibiotics and the occurrence of antimicrobial resistance.

Moreover, communication about patients' care was poor in view of our interviewees' declarations.

Conclusion and relevance Patients' perception of the role of antibiotics in general or in surgical use is imprecise, and is related to their perception of infections associated with care. It is therefore essential to strengthen a clear dialogue between healthcare professionals and patients in relation to care.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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Conflict of interest No conflict of interest

4CPS-045 HEALTHCARE EVALUATION OF HOSPITAL PHARMACY SERVICES BY PATIENTS WITH IMMUNE-MEDIATED INFLAMMATORY DISEASES: A MULTICENTRE STUDY

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Background and importance Immune-mediated inflammatory diseases (IMIDs) are a group of disabling chronic diseases.

Aim and objectives To assess the satisfaction with healthcare by patients with the most prevalent IMIDs, inflammatory bowel disease (IBD), psoriasis (Ps), psoriatic arthritis (PsA), rheumatoid arthritis (RA) and spondyloarthropathies (ESART), and to determine the factors that influence patients' satisfaction.

Material and methods Observational, prospective, multicentre, real-world evidence study, conducted in four Spanish hospitals. Patients with IMIDs who had attended at least three visits to the Pharmacy Department were included. Sociodemographic, clinical and pharmacotherapeutic data were collected from medical records. Care satisfaction was assessed using the Instrument for the Evaluation of the Experience of Chronic Patients (IEXPAC) questionnaire. Responses to IEXPAC are grouped into three factors: productive interactions, new relational model, and patient self-management, scored from 0 (worst) to 10 (best experience). Health-related quality of life (HRQoL) was assessed using the EQ-5D-5L questionnaire.

Results A total of 578 patients were analysed (IBD=25.3%; Ps=19.7%; ESART=18.7%; RA=18.5%; Ps=17.8%); mean age 49.8 (12.3) years and 50.7% were male. The mean score for IEXPAC was 6.6 (1.9). RA obtained the lowest score, 5.83 (2.0), with statistically significant differences observed versus Ps (7.01 ± 1.7; p=0.003), IBD (6.83 ± 1.9; p=0.012) and ESART (6.80 ± 1.6; p=0.001). Productive interactions (8.5 ± 1.8) and patient self-management (7.3 ± 2.3) were the highest scoring factors and the new relational model the lowest (3.2 ± 2.7). Male versus female gender (7.0 (1.7 vs 6.1 (1.9), p<0.001), longer interval between medication intake (Pearson correlation coefficient (PCC)=0.133, p<0.002) and higher HRQoL (PCC=0.176, p<0.001) were significantly related to better patient satisfaction. Current biologic therapy also significantly influenced patients on treatment with tumour necrosis factor inhibitors (6.6 (1.9)) and interleukin inhibitors (6.7 (1.8)), who expressed higher satisfaction than those on selective immunosuppressants (5.7 (1.9)) (p=0.025).

Conclusion and relevance The results of IEXPAC show a high overall satisfaction with the quality of care by patients with IMIDs seen in the pharmacy service. However, there are areas for improvement to offer better quality of care, namely to inform about health and social resources, access to information via the internet about their disease, and fostering and facilitating relationships with patients in similar conditions.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-046 CARDIOVASCULAR RISK OF HIV PATIENTS

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Background and importance Patients with HIV infection have greater risk for cardiovascular diseases (CVD) compared to the general population, being the main cause of morbidity/mortality. Factors that contribute to this increase are both those of the infection and the classical cardiovascular risk factors (CRFs).

Aim and objectives The aim was to observe the prevalence of CRFs, to estimate the cardiovascular risk of HIV patients and to analyse pharmaceutical interventions which were carried out to control the risk.

Material and methods Observational and prospective study carried out from February to June 2021.

The main unmodifiable (age, sex) and modifiable CRFs (smoking, arterial hypertension (≥140/90 mmHg), diabetes mellitus, elevated low-density lipoprotein-cholesterol (LDL-c) (>100 mg/dL), low high-density lipoprotein-cholesterol (HDL-c) (<40 mg/dL), elevated total cholesterol (≥200 mg/dL) and physical inactivity) were identified. The patient's cardiovascular risk was measured using the Framingham Scale (2008). Data were collected through electronic clinical history and the interview with the patient in a pharmaceutical care clinic.

Results 63 patients were included. Median age was 53 (IQR 45–57) years and 67% were men.

The CVRFs analysed were: (a) tobacco use 50.7% (median: 10 cigarettes/day (IQR 9–20)); (b) arterial hypertension 31.7% (70% were treated pharmacologically but only 25% had their blood pressure controlled); (c) diabetes mellitus 8%; (d) 50.8% had high total cholesterol, 63.40% high LDL-c and 17.4% low HDL-c (27% were under pharmacological treatment) and (e) 61.9% carried out regular physical activity.

According to the Framingham Scale, 23.4% had a high risk of CVD in the next 10 years and 28.5% a moderate risk.

92 pharmaceutical interventions were carried out. The most relevant were: recommendation to quit smoking habits and/or monitoring adherence and tolerance of varenicycline (44%), advice on nutritional habits (41.3%) and the suggestion to start or increase weekly physical activity (32%).

Conclusion and relevance CRFs are common in these HIV patients and a large proportion of them have a moderate–high risk of CVD. The main role of the pharmacist in this study has been aimed at modifying heart-healthy lifestyle habits. The approach of cardiovascular risk should be considered as part of the integral follow-up of HIV patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-048 IMPROVING SAFETY IN THE USE OF MONOCLONAL ANTIBODIES IN PATIENTS WITH MIGRAINE: AN INTERDISCIPLINARY STUDY

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Background and importance Erenumab and galcanezumab are two subcutaneously administered monoclonal antibodies (MAs) indicated for migraine prophylaxis in adults.

These MAs are newly marketed drugs. The integration of the hospital pharmacist (HP) in interdisciplinary teams (IT) has been shown to reduce the complications of these treatments. In addition, it improves monitoring of health outcomes, reduces unnecessary medication, treatment costs and minimises hospital admissions.

Aim and objectives To analyse the outcomes after the creation of an MA dispensing circuit and an IT composed of neurologists, nutritionists and HPs. This team focused on the treatment of migraine and the early detection, treatment and prevention of adverse reactions (AR).

Material and methods Retrospective observational study conducted from January 2020 to September 2021. Patients diagnosed with chronic or episodic migraine under treatment with MA were included.

These treatments are exclusively prescribed by the neurologist and are dispensed in the outpatient consultation services by an HP. The HP conducted the clinical interview, recorded effectiveness data, AR and other clinical data of interest, and generated the corresponding report in the patient's medical record. In addition, the HP provided pharmaceutical advice and all necessary information to the patient. The nutritionist prepared the nutritional recommendations for the treatment and prevention of constipation.

Results During the study period 77 patients (85.7% female) were attended, with a median age of 51 (22–79) years.

The occurrence of constipation was detected in 30 patients (38.96%), substantially higher than that described in the pivotal trials (PT) of reference: erenumab 70 mg: 1.3%; 140 mg: 3.2%. Galcanezumab 120 mg: 1%; 240 mg: 1.5% and in the erenumab therapeutic positioning report (TPR): 3.3%.

The occurrence of hypertension was also detected in 7 patients (9.09%), not described in the PT or TPR.

All AR were reported. Oral and written information was provided to the patient.

Conclusion and relevance The creation of the IT brings value in the quality of healthcare and fosters cooperation between physician, nutritionist and HP. Furthermore, it favours early detection, prevention and treatment of AR.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-049 MANAGEMENT OF PAN-RESISTANT *STENOTROPHOMONAS MALTOPHILIA*

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Background and importance The detection and dissemination of pan-resistant bacteria in hospitals is relatively frequent. It is necessary to know new therapeutic alternatives available to eradicate them.

Aim and objectives The aim of this study was to evaluate the effectiveness and safety of cefiderocol in the management of pan-resistant *Stenotrophomonas maltophilia* (SM) isolated in a retroperitoneal collection.

Material and methods Description of a clinical case. The microbiological cure, defined as the eradication of SM in the material extracted from the abdominal abscess, was established as the effectiveness criteria and the non-presentation of adverse effects (AE) as the safety criteria.

Results A 72-year-old man with a history of acute lithiasic pancreatitis, chronic liver disease, and cholecystectomy was readmitted to the intensive care unit due to sepsis caused by acute lithiasic pancreatitis. During admission, the patient received several antibiotics: piperacillin/tazobactam, meropenem and linezolid. Day +30, he presented an episode of septic shock whose focus was a retroperitoneal collection in the pararenal space. It was drained percutaneously and SM resistant to cotrimoxazole (drug of choice) and sensitive to levofloxacin was isolated. He was treated for 20 days with levofloxacin 500 mg/12 hours and meropenem 2 g/8 hours. Day +60, he presented a second episode of septic shock (leukocytes: $40.57 \times 10^3/\mu\text{L}$, neutrophils: $38.58 \times 10^3/\mu\text{L}$, C-reactive protein (CRP): 274.5 mg/L). In the extracted material, SM resistant to all marketed antibiotics was isolated. The compassionate use of cefiderocol was requested and approved. SM was sensitive to cefiderocol. He was treated with cefiderocol 2 g/8 hours in monotherapy for 21 days. Day +3 of the start of treatment, a surgical drainage was performed to control the focus. SM was not isolated in the extracted material. Day +7 of treatment, once the focus was controlled, the patient remained afebrile, improving clinically and analytically (leukocytes: $8.8 \times 10^3/\mu\text{L}$, neutrophils: $7.13 \times 10^3/\mu\text{L}$ and CRP: 71.3 mg/L). SM was not re-isolated during the 113-day admission. He was admitted on day +250 for collagenitis and day +377 for septic shock, not isolating SM. He did not present any AE related to cefiderocol.

Conclusion and relevance New therapeutic alternatives must be available for pan-resistant bacteria. Cefiderocol in monotherapy was effective and safe in the treatment of pan-resistant SM.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-051 PHARMACOKINETICS ALTERATIONS IN TWO CRITICALLY ILL PATIENTS ON EXTRACORPOREAL MEMBRANE OXYGENATION RECEIVING ISAVUCONAZOL

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Background and importance Extracorporeal membrane oxygenation (ECMO) can modify drug pharmacokinetics and pharmacodynamics. We report two cases of critically ill patients on ECMO receiving isavuconazole.

Aim and objectives Primary aim: to assess the correlation between the dose of isavuconazol administered and its plasma drug concentrations (IsaPlasmConc). Secondary aim: to analyse differences in IsaPlasm at different points in the ECMO circuit to study drug sequestration.

Material and methods Prospective study in critically ill patients treated with intravenous isavuconazol and receiving ECMO in the intensive care unit (ICU) from August to October 2021. Isavuconazol area under the curve (AUC_{isa}) was calculated using the trapezoidal method. Blood samples were drawn from an arterial catheter and from ECMO circuit pre- and post-oxygenator at 0 (predose) and 1 hour (end of infusion), and from an arterial catheter at 2, 4, 6 and 12 hours after isavuconazol infusion.

A therapeutic goal of IsaPlasmConc 2.5–10 µg/mL was established. The analytical method used was high-pressure liquid chromatography. Differences greater than 10% on ECMO sites were considered as possible drug sequestration.

Results Both patients received a loading dose of isavuconazole 200 mg/8 hours over 48 hours. No relevant drug interactions were identified.

Patient 1: male, 61 years, 65 kg. Pulmonary aspergillosis treated with isavuconazole 200 mg/24 hours intravenously (IV). On day 4, IsaPlasmConc (arterial, pre-oxygenator and post-oxygenator) were: C0h: 1.39, 1.36 and 1.34, respectively; C1h: 2.83, 2.64 and 3.02; C2h: 2.28; C4h: 1.6; C6h: 1.61; C12h: 1.06 µg/mL. AUC_{isa} was 36.8 µg/hour/mL. It was considered infra-therapeutic, so the isavuconazol dosage was increased to 200 mg/12 hours. On day 10, IsaPlasmConc were: C0h: 2.16, 2.17 and 2.09; C1h: 3.17, 2.99 and 2.96; C2h: 3.10; C4h: 2.67; C6h: 2.41; C12h: 2.24. AUC_{isa} was 144.3 µg/hour/mL. The patient achieved negative cultures and clinical improvement.

Patient 2: male, 65 years, 84 kg. Pulmonary aspergillosis treated with isavuconazole 200 mg/12 hours IV. On day 4, IsaPlasmConc (arterial, pre-oxygenator and post-oxygenator) were: C0h: 2.00, 1.95 and 1.86, respectively, C1h: 3.01, 3.34 and 3.21; C2h: 3.00; C4h: 2.44; C6h: 2.34; C12h: 3.09. AUC_{isa} was 125.2 µg/hour/mL. The patient died due to external causes.

Conclusion and relevance In our patients there was not a significant sequestration of isavuconazole in the ECMO circuit. However, patients required higher isavuconazole doses to achieve IsaPlasmConc therapeutic goals. Therapeutic drug monitoring during ECMO is appropriate to assure therapeutic efficacy and security.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-053 GALCANEZUMAB IN PROPHYLAXIS OF REFRACTORY HIGH-FREQUENCY EPISODIC MIGRAINE IN CLINICAL PRACTICE

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Background and importance High-frequency episodic migraine (HFEM) represents an important health problem due to its high prevalence and to the loss of quality of life. The

therapeutic approach is based on prophylactic and symptomatic treatment.

Galcanezumab has been authorised by the European Medicines Agency (EMA) for the prophylaxis of migraine in adults with at least 4 days of migraine per month (MDM).

Aim and objectives To study the effectiveness and safety of galcanezumab in the prophylaxis of HFEM in real-life clinical practice.

Material and methods Observational, retrospective study of patients with HFEM who initiated treatment with galcanezumab between June 2020 and June 2021. Demographic data, number of prophylactic treatments received, date of diagnosis, mean MDM, and HIT-6 scale score at baseline and 3 months after treatment initiation were collected from the electronic medical record.

Results In the study period, 48 patients (81%, 39 women) with HFEM started treatment with galcanezumab. The median age was 47 (24–68) years. The time since diagnosis was 71 months. 52% had received more than five prophylactic drugs. Topiramate was used in 90% (43) of the patients, and was contraindicated in the remainder; it was discontinued in 56% (27) of the cases due to lack of response and in 33% (16) due to poor tolerance. Other treatments used were: amitriptyline (79%, 38); off-label botulinum toxin (77%, 37), flunarizine (75%, 36), propranolol (46%, 22), metoprolol (33%, 16) or valproic acid (38%, 18).

Three-month follow-up was carried out in 94% (25) of the patients. The median MDM at baseline was 10.5; and after treatment, 4; implying a median reduction in MDM of 58%. The median HIT-6 score at baseline was 68 (56–79). Variation in HIT-6 could not be assessed due to lack of data.

The median treatment duration at cut-off was 8 (3–15) months. Treatment was discontinued in 6 cases due to lack of response (3), adverse effects (2) or the patient's decision (1). Adverse effects were reported in 23% (11) of the patients, the most frequent being dizziness and instability (4) and constipation (2).

Conclusion and relevance Galcanezumab appears to be an effective treatment in patients with multidrug-refractory HFEM. Further studies are needed to assess these results in the long term. Galcanezumab has an acceptable safety profile, with the incidence of dizziness and constipation being higher than described in clinical trials, but rarely leading to treatment discontinuation.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-054 ANALYSIS OF REAL-WORLD DATA FOR ERENUMAB UTILISATION AND PATIENT-RELATED OUTCOMES

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Background and importance Erenumab was approved for migraine prophylaxis shortly before the COVID-19 pandemic. After 18 months, there was enough data to conduct several studies.

Aim and objectives Evaluate effectiveness and safety of erenumab using real-world data and compare the results with clinical trials.

Material and methods A retrospective, observational study was performed in a second-level hospital. Evaluation of patients with migraine being treated with erenumab for at least 6 months. Data extraction from clinical histories and prescription software. Patient-related outcomes filled in their clinical history by the neurologist and pharmacist.

Results 55 patients recruited to commence treatment with erenumab between January 2020 and April 2021. 48 patients included (7 patients excluded due to lack of follow-up). 44 women, average age 49.7 years, and 21 days per month with migraine (MMD).

26 patients reached a reduction of MMD of $\geq 50\%$, and 10 of $\geq 75\%$ (54.2% and 20.8%, respectively) after a follow-up of between 3 and 9 months. Of the 22 patients that did not reach at least 50% reduction in MMD, 7 patients tried a dosage increase, with 5 of them achieving an average 61% reduction in MMD. All patients mentioned having softer migraine pain.

Regarding safety, only 11 patients experienced adverse reactions, mostly constipation. Three patients needed to cease treatment.

Conclusion and relevance Erenumab has established a new treatment in migraine prophylaxis that works even better than in the clinical trials. According to clinical trials results, erenumab can reduce MMD by 50% in about 40% of patients regardless of the dosage, and by 75% in about 18.9% of patients. In our findings, erenumab achieved a 50% reduction in 54.2% of patients, and a 75% reduction in 20.8% of patients, achieving better results in real life than in the clinical trials.

Our study has as a limitation the follow-up being carried out by physicians and not by pharmacists, which could improve patient-related outcomes and experiences as hospital pharmacists dispense medication every 2 months in our hospital. The hospital pharmacist's role can be useful for evaluating treatments results described by patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-055 SUCCESSFUL SOFOSBUVIR/VELPATASVIR TREATMENT IN A HEPATITIS C PATIENT RECEIVING CHRONIC ANTIPILEPTIC THERAPY: A CASE REPORT

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Background and importance Co-administration of direct-acting antivirals (DAA) with strong cytochrome P-450 (CYP)-inducing drugs, such as some antiepileptic medications, is contraindicated because it can result in loss of efficacy and virological failure.

The majority of interactions between DAA and the concomitant medication are manageable since the interacting drug can temporarily be stopped or substituted. However, there is usually some reluctance to modify chronic antiepileptic therapy in patients with well-controlled seizures.

This case report contributes to the limited literature regarding co-administration of sofosbuvir/velpatasvir and antiepileptic drugs since there are only two reported cases.¹

Aim and objectives The objective was to assess the efficacy of sofosbuvir/velpatasvir for 12 weeks in a patient taking

the strong CYP-inducing drugs carbamazepine and phenobarbital.

Material and methods Descriptive and retrospective clinical case. Data were obtained by review of electronic medical records.

Results A 54-year-old woman was diagnosed with chronic hepatitis C infection. Ultrasound transient elastography showed F3 stage liver fibrosis and she was naïve to hepatitis C antiviral agents. The patient was receiving treatment with carbamazepine, clonazepam, phenobarbital, topiramate, folic acid and omeprazole.

The use of the pangenotypic antivirals glecaprevir/pibrentasvir and sofosbuvir/velpatasvir was contraindicated with carbamazepine and phenobarbital. Elbasvir/grazoprevir was also contraindicated.

It was recommended not to stop or change the patient's anticonvulsant drugs, so it was decided to commence treatment with sofosbuvir/velpatasvir for 12 weeks with viral load measurement at 4 weeks, 12 weeks and 24 weeks post-treatment initiation. Treatment success was defined as an undetectable hepatitis C virus RNA level 24 weeks post-treatment initiation, that is, 12 weeks after completion of therapy (sustained virologic response, SVR12).

Concomitant use of omeprazole can reduce sofosbuvir and velpatasvir concentrations, so omeprazole was administered 4 hours after the antiviral drug.

Treatment adherence to sofosbuvir/velpatasvir was correct according to the dispensing records. No adverse effects were reported during antiviral therapy, and the patient has remained seizure-free.

Viral load was undetectable at every point of measurement and SVR12 was achieved.

Conclusion and relevance Sofosbuvir/velpatasvir administered for 12 weeks in a patient receiving treatment with carbamazepine and phenobarbital achieved SVR12 despite the enzyme-inducing effect of these antiepileptic drugs on the hepatitis C antiviral concentrations.

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Conflict of interest No conflict of interest

4CPS-057 DISCONTINUATION OF PROTON PUMP INHIBITORS DURING HOSPITALISATION: A RANDOMISED CONTROLLED TRIAL

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Background and importance Many patients take proton pump inhibitors (PPIs) even though the drugs are no longer needed.¹

² We know that there are side effects to long-term PPI treatment.³ No previous studies have examined whether it is possible to reduce or discontinue treatment during hospitalisation and continue it successfully after discharge.

Aim and objectives The aim of the study was to investigate if PPIs can be discontinued or reduced through counselling by pharmacy staff during hospitalisation.

Material and methods A prospective randomised controlled study was performed in the Emergency and Medical Department. Patients were included if they had received PPIs for at least 2 months and were aged 18 years or older.

Patients were excluded (1) if they were diagnosed with gastric ulcer within 6 months, eosinophilic oesophagitis, gastroesophageal reflux disease (GERD), Barrett's oesophagus, gastrinoma and (2) if they were aged over 50 years and on treatment with non-steroidal anti-inflammatory drug (NSAIDs) except low-dose acetylsalicylic acid, steroids and/or platelet inhibitors, anticoagulants.

The intervention was performed by pharmacy staff and included counselling on discontinuation or reduction of the use of PPIs, and also included a strategy to cope with rebound symptoms.

The primary outcome was the proportion of patients who successfully discontinued or reduced their use of PPIs at follow-up telephone call 30 days after discharge. The data were tested with Fisher's exact test (small samples).

Results 31 adults were included; 4 withdrew at their own request or because they could not be reached on follow-up telephone calls. 69.2% (95% CI 38.6% to 90.9%) (9/13 patients) in the intervention group successfully discontinued or reduced their PPI compared to 7.1% (95% CI 0.2 to 33.9) (1/14 patients) in the control group. The difference between groups was statistically significant ($p=0.001$).

Conclusion and relevance Statistically significantly more patients discontinued or reduced their use of PPI after counselling by the pharmacy staff. The pharmacy staff is capable of identifying patients for whom PPI dose reduction or discontinuation is relevant and performing a successful counselling on discontinuation or reduction of the use of PPIs.

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Conflict of interest No conflict of interest

4CPS-059 CASE REPORT OF SEVERE HYPERBILIRUBINAEMIA IN A PATIENT CARRYING POLYMORPHISMS IN CES1P1, CDA, SLC22A7 AND ENOSF1 TREATED WITH FLUOROPYRIMIDINES

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Background and importance Capecitabine (Xeloda) is an oral fluoropyrimidine used for the treatment of colorectal neoplasms. Common adverse drug reactions (ADRs) during capecitabine monotherapy are gastrointestinal toxicity, hand-foot syndrome and asthenia. Haematological toxicity and hyperbilirubinaemia are also frequently reported. Currently, the genotyping of four *DPYD* variants is a standard practice for the prediction of capecitabine toxicity occurrence and severity. However, numerous studies have shown that other genes present in the pharmacokinetics and pharmacodynamics pathway of capecitabine may also be related with toxicity

Aim and objectives To describe a severe hyperbilirubinaemia case of a 63-year-old woman under capecitabine treatment with *DPYD* normal metaboliser status and genetic variants in *CES1P1*, *CDA*, *SLC22A7* and *ENOSF1*.

Material and methods Retrospective case report. Clinical data were obtained from patient medical records. The causal relationship between capecitabine and hyperbilirubinaemia was assessed using the Naranjo algorithm. Genetic variants were analysed using real-time polymerase chain reaction (PCR) with TaqMan probes.

Results A 60-year-old woman diagnosed with stage IIIB rectal mucinous adenocarcinoma initiated neoadjuvant radiotherapy + capecitabine (1450 mg/12 hours). After cycle 1, the patient presented grade II diarrhoea and leukopenia, bilirubin of 4.50 mg/dL (VN 0.3–1.20 mg/dL), and grade I thrombocytopenia, which led to capecitabine suspension and the re-establishment of normal laboratory values. After tumour resection surgery, it was decided to initiate adjuvant capecitabine (1500 mg/12 hours) after *DPYD* status evaluation and with strict monitoring of bilirubin values. Genotyping analysis stated *DPYD* normal metaboliser profile, so treatment was initiated. 7 days later, bilirubin increased from a baseline of 0.7 to 3.5 mg/dL. Capecitabine was suspended. The patient underwent rigorous follow-up without pharmacological treatment and was diagnosed with Gilbert's syndrome. Naranjo's algorithm determined the ADR as probable. Exploratory genotyping was performed of >20 genes that have been previously associated with capecitabine toxicity, revealing that the patient carried *CES1P1* rs7187684-CT and rs11861118-AG, *CDA* rs532545-TT, *CDA* rs602950-CC, *SLC22A7* rs4149178-AA and *ENOSF1* rs2612091-CT, variants that currently have a lower evidence level than *DPYD* and are not analysed in clinical practice.

Conclusion and relevance This case suggests that capecitabine toxicity may be influenced by other genetic variants involved in drug pharmacokinetics and pharmacodynamics beyond *DPYD*. However, prospective studies are required to validate these findings.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-060 INFLUENCE OF GENETIC POLYMORPHISMS ON THE RESPONSE AND TOXICITY OF CAPECITABINE THERAPY IN PATIENTS WITH BREAST CANCER

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Background and importance The response and the toxicity profile associated with capecitabine treatment shows great interindividual variability. The study of genetic polymorphisms of genes involved in the metabolism of capecitabine could help to predict the response and toxicity to breast cancer treatment.

Aim and objectives To evaluate both the response and toxicity of patients with breast cancer treated with capecitabine, as well as its relation to some genetic polymorphisms of genes involved in the metabolism of capecitabine (*UMPS*, *TYMP* and *UPB1*).

Material and methods A prospective observational study was conducted during 2021 in a third-level hospital. The study

had been approved by the Ethics and Clinical Research Committee of the Hospital with the prior informed consent of the patients for their inclusion in the study. Clinical and demographic characteristics were obtained by reviewing the clinical history of the patients. The response was evaluated according to the RECIST 1.1 criteria and toxicities were categorised according to version 5.0 of the CTCAE. A DNA extraction was performed from swabs with saliva samples using a QIAamp DNA Mini Kit. Genetic markers were analysed via OpenArray by QuantStudio 12K Flex System using the 'TaqMan PGx Express' array. The relation between demographic and clinical variables and polymorphisms with response and toxicity to treatment with capecitabine were studied using bivariate analysis with R software 4.1.1 version.

Results 63 patients were treated in 2021. The evaluation of the response (n=38) resulted in complete response: 13.16% (n=5), partial response: 10.53% (n=4), stable disease: 10.53% (n=4) and progressive disease: 65.79% (n=25). An association was observed between the nulliparity (p=0.037, OR 7.2, IC95% 0.96 to 67.19) of the patients and the response to capecitabine, as well as between estrogen (p=0.024, OR 4.11, IC95% 1.15 to 15.22) and progesterone (p=0.006, OR 5.71, IC95% 1.62 to 23.84) receptors with the appearance of toxicity after treatment. No association was found between any of the studied polymorphisms with response or toxicity to capecitabine therapy.

Conclusion and relevance The results suggest that there is no relevant relation between the genetic variants analysed with the response and toxicity to capecitabine therapy. However, this result partly resembles that reflected by other studies. A larger study with a bigger patient cohort is required in order to obtain meaningful results.

REFERENCES AND/OR ACKNOWLEDGEMENTS

None

Conflict of interest No conflict of interest

4CPS-061 IMPACT OF PHARMACOGENETICS ON THE TOXICITY OF HIGH-DOSE METHOTREXATE IN A PAEDIATRIC POPULATION

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Background and importance High-dose methotrexate (HDMTX) is the most widely used systemic treatment in paediatric cancer due to its high effectiveness, easy administration and low cost. The great interindividual variability in relation to toxicities derived from HDMTX treatment may be caused by genetic variants in genes involved in the metabolism and transport of methotrexate (MTX). The study of these variants involved in the MTX pathway could help to predict the toxicity profile associated with HDMTX treatment.

Aim and objectives To evaluate the influence of polymorphisms in *MTR*, *MTRR*, *MTHFR*, *MTHFD1*, *ATIC* and *SLCO1B1* genes on the development of toxicity during treatment with HDMTX in paediatric oncology patients.

Material and methods A multicentre retrospective study was carried out during 2021 in two third-level hospitals. The study was approved by the Ethics and Clinical Research

Committee of the Hospital with the prior informed consent of the patients for their inclusion in the study.

Data: DNA extraction was performed from swabs with saliva samples using a QIAamp DNA Mini Kit. The polymorphisms were studied by via OpenArray by QuantStudio 12K Flex System using the 'TaqMan PGx Express' array. Clinical-pathological characteristics and toxicities were obtained by reviewing the clinical history of the patients. Relation between pathological-clinical features, polymorphisms and toxicities were studied using bivariate analysis with Software R 4.1.1 version.

Results A total of 64 patients aged between 0–14 years which were treated with HDMTX in the last 10 years were studied. Patients carrying the allele G of *MTR* rs3768142 variant had a higher probability of presenting hepatotoxicity (p=0.007, OR 4.25, IC95% 1.45 to 12.42), gastrotoxicity (p=0.00001, OR 9.18, IC95% 2.96 to 29.46) and haemotoxicity (p=0.0195, OR 9.5, IC95% 1.04 to 86.97). The analysis showed that patients with the allele G of *MTRR* rs3768142 variant had a higher incidence of hepatotoxicity (p=0.05, OR 3.1, IC95% 0.95 to 10.11). In addition, the presence of the allele A in *MTHFR* rs1801133 gene polymorphism indicated the presence of haemotoxicity (p=0.037, OR 5.73, IC95% 9.95 to 34.55).

Conclusion and relevance The results obtained in this study suggest that patients who present some of the polymorphisms indicated above may present a higher rate of toxicity in paediatric oncology patients with HDMTX treatment. This would allow us in the future to carry out an individualised therapy that provides greater efficacy and less toxicity associated with the treatment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-063 ERENUMAB VERSUS GALCANEZUMAB, EFFECTIVENESS IN REAL-LIFE EXPERIENCE

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Background and importance Erenumab and galcanezumab have been the first prophylaxis option in migraine since the arrival of calcitonine gene-related peptide inhibitors (CGRPi). In clinical trials, their effectivity has been set after 12 weeks of treatment.

Aim and objectives Evaluate the efficacy difference between both treatments using real-world data.

Material and methods A retrospective, observational study was performed from January 2020 to July 2021. Patients with more than 12 weeks of treatment were analysed. Evaluation of response on patients' interviews with neurologists and pharmacists, extracting data from clinical history. Comparison with the other drug and the clinical trial results.

Results Of 95 patients with migraine on treatment with CGRPi, 77 were included in our study. They were 67 women, with an average of 50.6 years. 29 patients received galcanezumab, and 48 erenumab. Most patients started treatment with 70 mg.

After 12 weeks of treatment, clinical trials obtained a reduction in monthly migraine days (MMD) of $\geq 50\%$ and $\geq 75\%$ in 58.3% and 20.8% of patients receiving erenumab

and 72.4% and 37.8% in those receiving galcanezumab. Their clinical trials showed an MMD reduction of $\geq 50\%$ and $\geq 75\%$ in 39.9% and 17.0% with erenumab and 62.3% and 38.8% with galcanezumab.

Comparing both treatments with their clinical trials, erenumab gets better results in the real world, although both treatments get similar results as in clinical trials with a reduction of 75%. Confronted with both treatments, galcanezumab has better results in real life, reducing MMD in $\geq 50\%$ (72.4% vs 58.3%).

Conclusion and relevance Erenumab and galcanezumab seem to achieve better results in real patients, but galcanezumab appears better than erenumab, although both treatments are better than their clinical trials. Facing them, galcanezumab seems to achieve a better response, so further studies are required to check this observation out.

These new treatments can improve a patient's quality of life, so their use should be reviewed and follow up should be collaborative between neurologists and pharmacists to see the real effect of this medication.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-064 QUALITY OF LIFE STUDY: GALCANEZUMAB IN THE TREATMENT OF MIGRAINE

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Background and importance Galcanezumab is a monoclonal antibody used for migraine prevention. Its approval was based on demonstrated efficacy through reduction of migraine days and impact on quality of life. However, this last variable is not routinely monitored in real practice

Aim and objectives To determine the improvement of the quality of life of patients with migraine in treatment with galcanezumab and correlate this with effectiveness in real practice.

Material and methods Prospective study between February 2020 and September 2021. To determine quality of life we used the Migraine-Specific Quality of Life Questionnaire version 2.1 (MSQ). MSQ comprised three domains: role function restrictive (RR) (7 items related to limits on social/work activities), role function preventive (PR) (4 items connected with preventing activities) and emotional function (EF) (3 items associated with emotional state). Score 0–100, such that a higher score indicates a greater quality of life. The questionnaire was carried out in weeks 0, 4 and 12, and the mean of the differences with respect to week 0 was determined. Response for RR domain was defined as a change from baseline to week 12 of ≥ 17 points according to trials. To evaluate effectiveness we used the number of episodes per month, defined as a change from baseline of $\geq 25\%$ migraine days, and discontinued treatment due to ineffectiveness.

Results Thirty patients were enrolled, 90% women. 73% chronic migraine and 27% episodic migraine. Treatment duration was 10 (4–18) months. The mean score of the questionnaire at week 0 was 41 (7;98), at week 4 was 56 (16;98) and at week 12 was 57 (26;98). The mean difference between weeks 0 and 4 was 1 (–15;+98) and between weeks 0 and 12 was 8 (–14;+60). At week 12, 27% patients presented

negative differences with respect to baseline, worsening quality of life. 17% patients obtained response for RR. Median number of episodes was 10 (8–17) at the beginning and 9 (1–17) after 12 weeks. 33% reduced $\geq 25\%$ migraine days, 27% patients reduced to 50%. 13% patients discontinued treatment due to ineffectiveness.

Conclusion and relevance After 12 weeks only 17% patients obtained response for the RR domain; and 1 of 4 patients experienced worsening quality of life. Effectiveness was obtained in a few patients which appears to correlate with quality of life. Therefore, quality of life questionnaires should be one more tool used to evaluate treatment effectiveness.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-065 SAFETY OF BEVACIZUMAB BIOSIMILAR IN CLINICAL PRACTICE IN NEW AND SWITCHED TREATMENTS

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Background and importance Efficacy and safety of emerging biosimilars is ensured by the comparative studies required for their centralised approval by the European Medicines Agency. However, there is a lack of studies of biosimilars safety in clinical practice. Recently a new biosimilar bevacizumab, Zirabev, has been commercialised.

Aim and objectives To assess the safety of bevacizumab biosimilar Zirabev in clinical practice.

Material and methods We conducted a prospective observational study of a cohort of patients who started treatment with bevacizumab biosimilar between February and July 2021 at the Oncology Service of the health organisation Barrualde-Galdakao in a Basque health institution.

Eligible patients: new bevacizumab treatments, treatment restarts, changes in line of treatment and ovarian, cervix and brain carcinoma pathologies maintenances. Switching has done in treatments already started from Avastin to Zirabev.

Information was collected in a database from medical records. Adverse reactions were measured according to National Cancer Institute of the United States toxicity criteria.

Results Between February 2021 and July 2021, 27 adult patients started bevacizumab biosimilar treatment in our centre. Baseline characteristics of the patients (N = 27): female 22 (81.5%); age 57.5 ± 13.7 years (mean \pm SD); baseline blood pressure (mmHg) $124.3 \pm 18.2/78.0 \pm 7.2$. Neoplasia ovarian 8 (29.6%), cervix 2 (7.4%), colon 9 (33.3%), brain 3 (11.1%), breast 5 (18.5%). Days with bevacizumab biosimilar treatment: 112.7 ± 46.9 . Switching from reference medicine to biosimilar: 11 (40.7%). New bevacizumab treatments: 16 (59.3%).

Adverse events (G = grade) in switching patients (N=11): G1 epistaxis 2, G1 gingival haemorrhage 1.

Adverse events in starting treatments: G1 arterial hypertension 1, G2 arterial hypertension 3, G3 venous thrombosis 1, G3 arterial thromboembolism (pulmonary) 2.

Most frequent adverse event was hypertension (14.8%, N=27, G1–2). Thrombotic-like events were the most serious reactions (11.1%, N=27, G3).

Only one patient stopped bevacizumab treatment due to toxicity (G3 pulmonary embolism and G3 deep vein thrombosis).

Conclusion and relevance Initiation of use of bevacizumab bio-similar in our centre has shown a positive safety profile. Thrombotic-like reactions were more severe compared to the literature. Nevertheless, there were no serious adverse events (G4–5).

REFERENCES AND/OR ACKNOWLEDGEMENTS

Common Terminology Criteria for Adverse Events (CTCAE) Version 5.0. 27 November 2017.

Conflict of interest No conflict of interest

4CPS-067 PHARMACIST INTERVENTIONS IN SEQUENTIAL ANTIMICROBIAL THERAPY INSIDE AN ANTIMICROBIAL STEWARDSHIP PROGRAMME (ASP)

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Background and importance Early switching of intravenous (IV) to oral (PO) antimicrobials is not only possible but highly recommended. Once patients are clinically stable it can reduce the risk of infection of the IV catheter, increase comfort and mobility for the patient, decrease the risk of thrombophlebitis, and reduce the length of hospitalisation and lower associated costs. Changes from IV to PO antimicrobial therapy resulted in equal clinical efficacy compared with patients administered the full parenteral course.

Aim and objectives Encourage and register pharmacists' interventions in sequential antimicrobial therapy inside an antimicrobial stewardship programme.

Material and methods The study was an interventional, prospective study conducted in a 405-bed academic hospital in Spain from January to May 2021. Using an app called WASSP we preselected patients eligible for IV–PO switch: in treatment with good absorbed antimicrobials (levofloxacin, ciprofloxacin, amoxicillin/clavunate, metronidazole, clindamycin, linezolid, trimethoprim-sulfamethoxazole, fluconazole, voriconazole, isavuconazole) for 3 or more days. Then, each individual case was studied with these criteria: aged 18 years and above, IV–PO switch diagnosis (upper urinary tract infection, bacteraemia, intra-abdominal infection, skin and soft tissue infection, febrile neutropenia, osteoarticular infection, community-acquired pneumonia, pelvic inflammatory disease), received an IV antibiotic for more than 72 hours, body temperature $<37.8^{\circ}\text{C}$ for the past 24 hours, tolerating orally and showing clinical improvements from signs of infection. Finally, we communicated to doctors which patients were appropriated for the switch using an emergent note in our electronic prescription system and we followed-up those patients.

Results In this study, from all the patients individually analysed (292) pharmacists informed that 18.15% of all patients who started on IV antibiotics were candidates for an early IV–oral switch. Doctors agreed on early switch in 33/53 cases, which constitutes 62.26% of the acceptance rate of the intervention. Broken down this represents 37.14% to metronidazole, 17.14% to ciprofloxacin, 14.28% to linezolid, 8.57% to levofloxacin, 5.71% to amoxicillin/clavunate, 2.85% to clindamycin and 2.85% to trimethoprim-sulfamethoxazole.

Conclusion and relevance We must highlight the metronidazole IV–oral switch because surprisingly few prescribers knew that almost 100% of the drug is orally absorbed.

This study may be used as a template for the introduction of further pharmacist-led antimicrobial stewardship initiatives.

Recommendations initiated by pharmacists do improve the timeliness of the IV–PO switch.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-068 IMPACT OF PHARMACOGENETICS IN SEVERE ALLERGIC ASTHMA PATIENTS TREATED WITH OMALIZUMAB

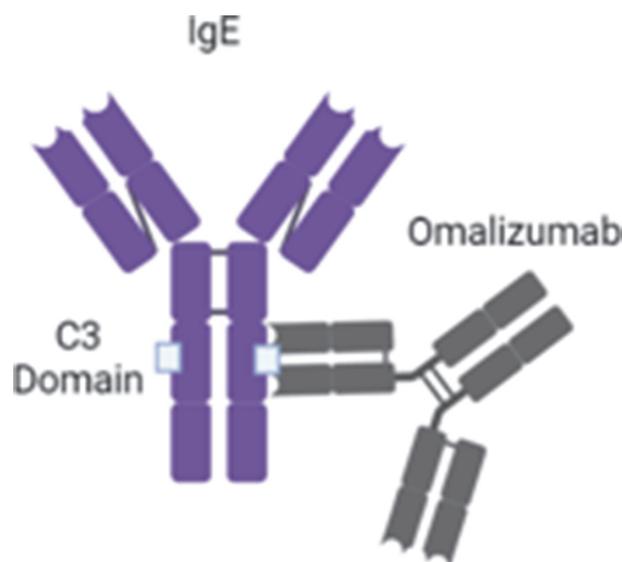
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Background and importance The main difficulty in the treatment of severe allergic asthma lies in its heterogeneity. Currently, therapies have improved with the use of monoclonal antibodies such as omalizumab (Xolair), which acts by binding to the C ϵ 3 domain of immunoglobulin E (IgE), so that it cannot bind to the Fc ϵ R receptor and consequently the amount of free IgE responsible for the allergic response is reduced (Figure 1). Despite this, there is variability in the response to treatment and one of the possible causes is the presence of genetic polymorphisms.

Aim and objectives The objective was to determine if there is an association between Arg102Gly gene polymorphism of the C ϵ 3 domain and omalizumab response.

Material and methods A retrospective cohort study was performed in a third-level hospital, including 70 patients with severe asthma who had received treatment with omalizumab for at least 1 year. Clinical variables were obtained using the ATHOS-Prisma clinical software and the polymorphism was



Abstract 4CPS-068 Figure 1 Omalizumab mechanism of action

analysed by real-time polymerase chain reaction (PCR) with TaqMan probes and Sanger sequencing. Response was evaluated according to the indications of the Spanish Guide for the Management of Asthma (GEMA) and the statistical analysis was carried out with R 3.0.1.

Results 70 patients were included in the study, of whom 64% were women (45/70) and 36% men (25/70). Average patient age was 52±15 years with a median treatment duration of 4 (2,6) years. 57% of the patients responded to the treatment according to the GEMA Guide compared to 43% who did not get a response. The bivariate analysis between response and Arg102Gly gene polymorphism of C \square 3 domain showed that patients carrying Arg102Gly-C allele ($p=0.0384$; OR 2.97; 95% CI 1.07 to 8.94) presented better response to treatment with omalizumab. Specifically, the response was increased by 30% in patients with Arg102Gly-C allele.

Conclusion and relevance The use of biological drugs has led to a significant improvement in these patients' quality of life. However, identification of the correct therapy is a prognosis critical point. In this study, an allelic variant in C3 gene was positively associated with omalizumab treatment response. This discovery makes possible the approach to a personalised medicine that allows the improvement of prognosis in severe allergic asthma patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-069 INFLUENCE OF GENETIC VARIANTS IN THE VITAMIN D HYDROXYLATION PATHWAY AS A RESPONSE FACTOR TO PLATINUM-BASED CHEMOTHERAPY IN NON-SMALL CELL LUNG CANCER

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Background and importance Chemotherapy based on platinum compounds is the standard treatment for non-small cell lung cancer (NSCLC) patients with EGFR wild type and is also used as second line in mutated EGFR patients. Vitamin-D may influence chemotherapy response by inhibiting tumour progression, suppressing metastasis, cell proliferation, and angiogenesis, or promoting apoptosis. Therefore, gene polymorphisms in the vitamin D signalling pathway might have an impact on chemotherapy response. Recent studies reported that genetic background plays a key role in the chemotherapy response. However, little is known about the implication of *CYP2R1* and *CYP27B1* gene polymorphisms, which regulate the activation of circulating vitamin D through hydroxylation, in the response to platinum-based chemotherapy.

Aim and objectives The aim of this study was to evaluate the influence of polymorphisms in the *CYP2R1* and *CYP27B1* genes on the platinum-based chemotherapy response in patients with NSCLC.

Material and methods A prospective cohort study was conducted. 165 patients diagnosed with NSCLC between 2003 and 2019, followed-up until December 2020. *CYP27B1* (rs4646536, rs3782130, rs703842, rs10877012) and *CYP2R1* (rs10741657) polymorphisms were analysed by real-time PCR

using TaqMan probes. Response (CR: complete response, PR: partial response) and no response (SD: stable disease, PD: progressive disease) were evaluated.

Results Patients' median age at NSCLC diagnosis was 62 (53–67) years; 73.3% (121/165) men; 69.09% (114/165) stage IIIB-V; 59.39% (98/165) adenocarcinoma; 58.18% (96/165) family history of cancer; 24.24% (40/165) previous lung disease; EGFR status: 52.73% (87/165) wild type, 10.91% (18/165) mutated, 36.36% (18/165) unknown; 22.56% surgery; 31.52% radiotherapy; chemotherapy agents: 18.29% (30/164) gemcitabine; 21.34% (35/164) paclitaxel; 24.39% (40/164); 35.98% (59/164). 65.85% (108/164) response; 34.15% (56/164) no response.

Patients carrying the *CYP2R1*-rs10741657-G alleles were associated with better response ($p=0.017$; OR 3.17; 95% CI 1.19 to 8.42; G vs AA). However, for *CYP27B1* (rs4646536, rs3782130, rs703842, rs10877012) we did not find a statistically significant association.

Conclusion and relevance Our results suggest that *CYP2R1* rs10741657 G-allele influences response in platinum-based chemotherapy in NSCLC patients. Therefore, this polymorphism could be used as a response biomarker in NSCLC patients undergoing treatment with platinum-based chemotherapy.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-071 CYP27B1 GENETIC VARIANTS' INFLUENCE IN NEPHROTOXICITY DUE TO PLATINUM-BASED CHEMOTHERAPY IN NON-SMALL CELL LUNG CANCER

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10.1136/ejhp-harm-2022-eahp.108

Background and importance Platinum-based doublet-chemotherapy is the standard treatment for non-small cell lung cancer (NSCLC) for epidermal growth factor receptor (EGFR) wild-type patients, which presents high percentages of severe adverse events, such nephrotoxicity (20%–30%).

Nephrotoxicity is characterised by high morbidity and mortality. Cisplatin is one of the major causes of nephrotoxicity. Several studies have shown that vitamin D activation through *CYP27B1* and *CYP2R1* enzymes is protective against chronic kidney disease among other pathological pathways. However, few studies have focused on the role of vitamin D pathway genetic polymorphisms in nephrotoxicity.

Aim and objectives The aim of this study was to evaluate the influence of *CYP27B1* and *CYP2R1* gene polymorphisms on nephrotoxicity due to platinum-based chemotherapy in NSCLC.

Material and methods Prospective cohort study. 165 patients diagnosed with NSCLC between 2003 and 2019, followed up until December 2020. *CYP27B1* (rs4646536, rs3782130, rs703842, rs10877012) and *CYP2R1* (rs10741657) polymorphisms were analysed by real-time polymerase chain reaction (PCR) using TaqMan probes. Nephrotoxicity was evaluated according to the Common Terminology Criteria for Adverse Events (CTCAE) v.4.0.

Results Patients' median age at NSCLC diagnosis was 62 (53–67) years; 73.3% (121/165) men; 69.09% (114/165) stage IIIB-V; 59.39% (98/165) adenocarcinoma; 58.18% (96/165) family history of cancer; 24.24% (40/165) previous lung disease; EGFR status: 10.91% (18/165) mutated. Chemotherapy agents: 18.29% (30/164) gemcitabine; 21.34% (35/164) paclitaxel; 24.39% (40/164); 35.98% (59/164). Nephrotoxicity: 17.58% (29/165).

Patients carrying the *CYP27B1*-rs4646536 ($p=0.0312$; OR 0.32; CI_{95%}0.10 to 0.84; AG vs AA); *CYP27B1*-rs3782130 ($p=0.0247$; OR 0.22; CI_{95%}0.05 to 0.85; CC vs G); *CYP27B1*-rs703842 ($p=0.0121$; OR 0.15; CI_{95%}0.03 to 0.67; CT vs CC) and *CYP27B1*-rs10877012 ($p=0.0239$; OR 4.50; CI_{95%}1.17 to 17.2; TT vs G), were associated with nephrotoxicity. However, for *CYP2R1*-rs10741657 we did not find a statistically significant association.

Conclusion and relevance Our results suggest that rs4646536, rs3782130, rs703842 and rs10877012 influence nephrotoxicity in platinum-based chemotherapy. *CYP27B1* is the only enzyme capable of activating vitamin D. Therefore, genetic study of these polymorphisms could be used as a toxicity prediction biomarker in NSCLC patients undergoing platinum-based chemotherapy.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-072

BEZLOTOXUMAB FOR THE PREVENTION OF CLOSTRIDIODES DIFFICILE RECURRENCE: STUDY IN THE REAL WORLD

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Background and importance *Clostridioides difficile* is the most common cause of infectious diarrhoea in hospitalised patients and causes great morbidity due to the high percentage of recurrence. Bezlotoxumab is a monoclonal antibody against toxin B, intended to prevent relapse. Due to its high cost, it is used in a population and under conditions slightly different to those referred to in the MODIFY clinical trials. Due to the scarcity of real-life studies, it is necessary to collect data on the effectiveness of bezlotoxumab in daily hospital practice.

Aim and objectives To determine the effectiveness of bezlotoxumab in preventing recurrences of *C. difficile* infection (CDI) in patients from a tertiary hospital in Spain.

Material and methods We conducted a longitudinal, retrospective study of a cohort of patients treated with bezlotoxumab between 2 August 2018 and 31 March 2021. All patients received a single infusion of bezlotoxumab at 10 mg/kg. The main variable was the percentage of clinical cure within 12 weeks. As secondary variables, this percentage was analysed in terms of different risk factors.

Results 52 patients were included in the study. The median age was 73.5 years, 32 (61.5%) were women and the median Charlson index was 5.16. ?? (42.9%) patients received bezlotoxumab during the first CDI episode, 22 (30.8%) during the first recurrence and 14 (26.4%) during the second or later recurrences. 32 patients (61.54%) received vancomycin at standard dose during recurrence, 16 (30.77%) used

vancomycin tapering and 4 (7.69%) fidaxomicin. There were 9 (18.4%) recurrences within 12 weeks of bezlotoxumab infusion. It should be noted that 6 patients died during the inpatient stay and 3 others did so during the 12 weeks of follow-up, so they were excluded from the calculation of the recurrence ratio. The main risk factor for recurrence identified was severe infection (77.8% of recurrences) followed by age above 65 years and immunosuppression, which were present in 66.7% and 44.4% of the recurrences, respectively.

Conclusion and relevance The recurrence ratio at 3 months of bezlotoxumab administration was 20.9%, which is similar to that found in the pivotal clinical trials (16.5%). The highest prevalence of recurrences was identified in the subgroup of patients with severe CDI.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-075

EVALUATION OF THE COST OF MANAGING ADVERSE EVENTS RELATED TO CYTOTOXIC DRUGS IN CHILDREN

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Background and importance Despite the public health importance of the problems posed by cancer, there are few studies focusing on the economic aspects, particularly those devoted to second-line treatment, to manage the secondary events associated with cytotoxic drugs.

Aim and objectives The objective of this study was to estimate and evaluate the cost of the management of secondary events following chemotherapy treatments in children.

Material and methods This was an 'indirect cost of illness' study conducted by the analysis of 63 medical records of children with eight different types of cancer who all received cisplatin in their chemotherapy protocols and who were being treated in the paediatric hemato-oncology department of Rabat.

Results We analysed 45/63 medical records because of their unavailability at the time of the analysis. 80% of the patients were still undergoing treatment, 7% were under palliative treatment, and 13% died. Median age was 5 years.

Cancer type: neuroblastoma 51%, malignant germ cell tumour 13%, medulloblastoma 11%, osteosarcoma 9%, nasopharyngeal undifferentiated carcinoma 7%, hepatoblastoma 5%, and 2% each for metastatic rhabdomyosarcoma and sacrococcygeal teratoma.

Only sacrococcygeal teratoma and metastatic rhabdomyosarcoma, which showed 127 managements in front of the appeared side effects, in 88% of cases the drugs were administered to correct adverse effects, in 5.5% the cures were shifted, in 4.7% the cures were stopped and in 1.8% the dosages were reduced.

Based on the cost of the drugs administered to treat and correct the side effects of these two types of cancer, we noted a total of € 4500 in addition to the cost of chemotherapy.

Conclusion and relevance According to our results, the cost of management of secondary events related to cytotoxic drugs is considerable, so it is necessary to focus on other studies to evaluate the pharmacoeconomic impact of the indirect costs of these diseases.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-077 GENETIC VARIANTS AFFECTING BISOPROLOL RESPONSE IN CARDIOVASCULAR DISEASES

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10.1136/ejhp-2022-eahp.111

Background and importance β -Blockers are commonly prescribed to treat multiple cardiovascular (CV) diseases, but, frequently, adverse drug reactions and intolerance limit their use in clinical practice. Interindividual variability in response to β -blockers may be explained by genetic differences. In fact, pharmacogenetic interactions for some of these drugs have been widely studied, such as metoprolol. But studies that explore genetic variants affecting bisoprolol response are inconclusive, limited or confusing because of mixed results with other β -blockers, different genetic polymorphisms observed, endpoint studied, and so on.

Aim and objectives The aim of this study was to perform a systematic review in order to find relevant genetic variants affecting bisoprolol response and to perform a meta-analysis.

Material and methods Systematic review of genetic variants affecting bisoprolol. We performed a search in Pubmed on 15 January 2021 using MESH terms in the following argument: ('Bisoprolol' OR 'Metoprolol' OR 'Adrenergic Beta antagonist') AND ('Pharmacogenetic' OR 'Single Nucleotide Polymorphism (SNP)' OR 'Polymorphism'). We included 'metoprolol' and 'adrenergic beta antagonist' to detect research with combined results of various β -blockers.

We conducted a random-effects meta-analysis in recessive, dominant, codominant and overdominant models for the G risk allele in order to assess the association between *ADRB1* A389G (rs1801253) and bisoprolol.

We used R statistics software, version 3.6.2, package 'meta' to conduct the meta-analysis (<https://CRAN.R-project.org/package=meta>) and Harbord's test in order to quantitatively assess publication bias, considering a p value < 0.1 as significant statistical publication bias.

Results We found 13 publications studying the association of genetic polymorphisms with patients' response to bisoprolol (Figure 1). Most of them focused on *ADRB* variants, and even though the *ADRB1* Arg389Gly variant seems to have an influence on bisoprolol efficacy, the results are inconclusive and our meta-analysis did not find any statistically significant results in this regard.

Conclusion and relevance Many genetic polymorphisms have been assessed with respect to their influence on patients' response to bisoprolol and *ADRB1* Arg389Gly (rs1801253) seems the most relevant genetic polymorphism in this regard but the results have not been confirmed with a meta-analysis.

Our results support the need of further studies about the impact of genetic variants on bisoprolol response, considering

different genetic polymorphisms, conducting single and multiple single nucleotide polymorphisms (SNPs) analysis, including other clinical parameters in a multivariate study.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-078 MOTIVATIONAL INTERVIEWING IN CLINICAL PHARMACIST INTERVENTIONS: A SYSTEMATIC REVIEW OF RANDOMISED CONTROLLED TRIALS

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Background and importance The role of clinical pharmacists in delivering services with patient-focused care is growing. Motivational interviewing (MI) is an effective intervention for changing patient behaviour; however, the role of MI in clinical pharmacist interventions has not yet been well established.

Aim and objectives The aim of this systematic review was to investigate the existing evidence on the effect of MI in clinical pharmacist interventions in hospitals, primary care practices and specialised outpatient clinics. The types of MI interventions, their characteristics and outcomes were examined.

Material and methods A systematic literature search using the databases PubMed, PsycINFO, EMBASE and The Cochrane Library was conducted. Randomised controlled trials (RCTs) about MI interventions performed by clinical pharmacists in hospitals, primary care practices and specialised outpatient clinics working in close collaboration with physicians were included. Studies performed in community pharmacies were excluded. No restriction criteria were applied for the population type, delivery mode of the intervention, the comparator, or outcome. A bias assessment was performed by two reviewers according to the Cochrane collaboration risk of bias tool.

Results The literature search yielded eight RCT studies. More than 10 different outcome variables were reported across the studies. Four of eight studies showed a statistically significant effect on primary outcomes like medication adherence, hospital readmissions, and emergency department visits. Five studies reported training of pharmacists in MI, and three studies reported fidelity assessment.

Conclusion and relevance The main limitation of the study was the small number of studies and their heterogeneity. Beneficial effects of MI were found in some clinical pharmacist interventions. These interventions could have a positive impact on medication adherence and other health outcomes; however, more trials are needed to establish the effects of MI and determine MI characteristics and training associated with the success of the intervention.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-079 ANALYSIS OF CURRENT RESEARCH IN WEARABLES: TOWARDS GREATER DIGITAL HEALTH

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Background and importance Digital health is the concept that incorporates information and communication technologies into healthcare services. Nowadays, and favoured by the SARS-CoV-2 pandemic, hospital pharmacy has been forced to adopt digital technologies and tools to improve patient care.

Aim and objectives If any area of hospital pharmacy has gained prominence in recent years, it is the area of digital health. Therefore, it was decided to analyse current clinical trials in relation to technological devices or wearables.

Material and methods Descriptive study of current clinical trials on technological devices from the pharmacological aspect. The following filters were applied: active trials, devices in digital pharmacy, all phases, all ages and both sexes. The type of device was analysed as intervention, pathology, location, and study topic. Both observational and interventional studies were included. The tool used for evaluation was the ClinicalTrials.gov clinical trials registry.

Results Nineteen current active phase clinical trials were analysed. The phases of the projects were: phase I-7, phase II-3, phase III-2 and phase IV-7. The main pathologies of the clinical trials were: musculoskeletal disorders (6), chronic obstructive pulmonary disease (3), Parkinson's neurodegenerative diseases (3), oncology (2), autism (1), renal system (1), cardiac system (1) and self-injection devices (1). The main countries conducting clinical trials were: United States (13), Europe (4), Asia (1) and Oceania (1). Seven projects were detected in the patient recruitment phase.

Conclusion and relevance Although the use of wearables in the field of hospital pharmacy is a little known topic, it is increasingly gaining prominence in the literature and in scientific research. Digital health is the driver of change towards new models of care between patients and healthcare professionals. Therefore, it is necessary to continue with research and clinical trials to promote digitisation in hospital pharmacy.

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Conflict of interest No conflict of interest

4CPS-080 EFFICACY AND SAFETY OF THE CONTINUOUS INFUSION OF VANCOMYCIN IN PAEDIATRIC PATIENTS: A SYSTEMATIC REVIEW

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Background and importance In adults, continuous infusion of vancomycin (CIV) has been evaluated as an alternative to intermittent infusion (IIV) with potential advantages. The limited evidence in the paediatric population has not allowed the routine use of CIV.

Aim and objectives To identify and assess the available evidence on the safety and efficacy of CIV in paediatric patients.

Material and methods A systematic review of the literature indexed in PubMed and EMBASE databases and published before November 2020 was conducted, in accordance with the PRISMA Statement. The search terms included: 'Vancomycin' AND 'Paediatric OR Child OR Children OR Infant' AND 'Continuous infusion'. The inclusion criteria were: clinical

trials (CTs) and observational studies that assessed the clinical efficacy and/or attainment of plasma concentrations of vancomycin (pharmacokinetic efficacy) in paediatric patients treated with CIV. The exclusion criteria were: adults and the neonatal population and studies in a language other than English or Spanish. The data collected included: year of publication, type of study, characteristics of population, as well as efficacy and safety data on CIV.

Results A total of 359 articles were identified, of which 7 met the inclusion criteria. The studies included were published between 2012 and 2019. Regarding the type of study, there was 1 CT, 3 case series studies, 2 retrospective studies and 1 prospective study. The analysed population (n=460) consisted of critical paediatric (n=34), cystic fibrosis (n=3), onco-haematological (n=94), and osteomyelitis and pneumonia (n=15) patients, as well as various subpopulations (n=314). All the articles (n=7) assessed the attainment of plasma concentrations of vancomycin. The percentage of patients with concentrations within the therapeutic range varied among the different studies from 0% to 100% of the total study population. Only 3 studies assessed clinical efficacy, but none of them were designed for this purpose. Only 2 of the 6 studies observed cases of nephrotoxicity with 11% (n=10) and 12% (n=3) of the total population, respectively.

Conclusion and relevance The best administration method for this antibiotic within the paediatric population is still unknown due to limited evidence. However, studies conducted thus far suggest pharmacokinetic advantages for CIV. Further investigation is required, in particular CTs comparing IIV with CIV for clinical efficacy and safety outcomes

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-081 SUBCUTANEOUS FUROSEMIDE INFUSION USING ELASTOMERIC INFUSION PUMPS IN A TERTIARY HOSPITAL

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Background and importance Congestive heart failure (CHF) management in outpatients is often complicated. Increasing oral diuretics or combining drugs to improve a patient's symptoms is not always effective enough. To avoid hospital admissions, furosemide subcutaneous administration has been proposed as a useful alternative. Comparing intravenous with subcutaneous infusion of furosemide, the latter is supposed to increase diuresis using lower furosemide doses, reduce hospital stays and minimise re-entry rates.

Aim and objectives Our aim was to describe furosemide subcutaneous infusion by portable pump (FPP) use in a tertiary hospital.

Material and methods Retrospective study in which all outpatients treated in 2020 and 2021 with FPP, monitored by the cardiology unit, were included. Pumps which provided an infusion flow rate of 0.5 mL/hour were used. Length of infusion was 7 days/pump. The formulation's pH was 8.7. Once prepared, FPP could be stored for 84 days at room temperature or in a refrigerator and protected from light. Demographic data, diagnosis and clinical results were collected.

Efficacy was measured by the N-terminal pro B-type natriuretic peptide (NT-proBNP), body weight and plasma sodium descent. Security was measured by changes in glomerular filtering (GF).

Results 46 FPP were prepared for 31 patients (19 males, 12 females; medium age 69 (30–90) years). 7/31 received two, 1/31 three and 3/31 four cycles of FPP. Medium length of treatment was 10 (5–28) days. 30/31 received 120 mg/day furosemide (final concentration 10 mg/mL) per pump and 1/31 80 mg/day furosemide with serum saline (6.6 mg/mL) per pump. Pumps were prescribed for decompensated CHF (31/31), 2 of them after heart transplantation and 1 due to transthyretin amyloidosis.

Mean weight loss was 2.6 ± 2.9 kg. NT-proBNP was reduced in 12/31 patients, and unknown in 6/31 patients. Mean NT-proBNP reduction was 280.81 pg/mL. Plasma sodium decreased in 12 patients and the average reduction was 0.85 ± 6 mEq/L.

There was worsening GF in 18/31 patients (medium change in GF was -6.50 mL/min). No patient experienced local infection, rash irritation or flow problems with administration.

Conclusion and relevance FPP allowed patients to improve some CHF measures outside the hospital. Our study supports the use of FPP, being safe and effective.

Pharmacists have a key role by checking the dose, ensuring physical–chemical stability and sterile conditions in preparation, and instructing patients in the use of FPP.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-082 ENVIRONMENTAL POLLUTION WITH QUINOLONES IN SPAIN

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Background and importance Concern about emerging pollutants, including pharmaceuticals, has been growing in recent decades. Antibiotics receive particular attention because of the problem of antibiotic resistance. Hospital pharmacists play an important role in the antibiotic stewardship programme, aiming to reduce antibiotic resistance.

Wastewater treatment plants (WWTPs) were not designed to eliminate pharmaceuticals. In fact, the effluent from these WWTPs frequently shows the presence of several antibiotics, including quinolones. The presence of human pathogens and a wide diversity of environmental bacteria provide the opportunity for transferring resistance factors between bacteria.

Among the quinolones, ciprofloxacin has received preferential attention. It is one of the substances included in the Surface Water Watch List under the European Union Water Framework Directive.

The predicted no-effect concentration (PNEC) is the concentration of a chemical which marks the limit at which below no adverse effects are expected. The PNEC for ciprofloxacin is 0.064 µg/L and 0.5 µg/L for norfloxacin. When concentrations exceed the PNEC, the water is denoted as being ‘at risk’ for resistance selection.

Spain is the European country ranked fourth in terms of consumption of quinolones.

Aim and objectives In this study we aimed to review the presence of quinolones in WWTP effluent (treated) in Spain.

Material and methods We used the pharmaceutical database published by the German Environment Agency, Umweltbundesamt, which collects all published information about the presence of pharmaceuticals in different environmental matrices.

The database was downloaded on 28 September 2021. We selected data regarding quinolones in WWTP effluent (treated) samples from Spain. We looked to see if measured concentrations were above the PNECs.

Results We found 25 reports of norfloxacin (2 above PNEC) and 47 for ciprofloxacin (31 above PNEC). The highest concentration for ciprofloxacin was 5.69 µg/L (Madrid) and 0.98 µg/L for norfloxacin (Seville). There were no data for levofloxacin or other quinolones.

Conclusion and relevance In Spain, 65% of ciprofloxacin and 8% of norfloxacin samples leaving WWTPs show a concentration >PNEC, and thus may be contributing to the development of quinolone-resistant bacteria. More data are needed to describe the effects and fate on the environment. It is necessary to increase awareness about quinolone pollution among hospital pharmacists to help reduce its consumption.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-083 COST-EFFECTIVENESS ANALYSIS OF ADALIMUMAB AND ITS CLINICAL ALTERNATIVES IN IMMUNE-MEDIATED INFLAMMATORY DISEASES IN SPAIN

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Background and importance Immune-mediated inflammatory diseases (IMIDs) present a high burden of illness, as they are chronic conditions with associated comorbidities and high indirect costs. In Spain, IMIDs prevalence is around 6% and rheumatoid arthritis (RA) (1%) is one of the most common among them. The introduction of biological treatments, like adalimumab (ADA), has contributed to improve RA's clinical outcomes. The high cost of these biologics used to be a hurdle for their prescription until the appearance of biosimilars. Cost-effectiveness analysis can help in decision-making for this pathology.

Aim and objectives Our objective was to assess the cost-effectiveness of ADA and its clinical alternatives in RA.

Material and methods We built a cost-effectiveness model based on meta-analyses (direct or indirect) conducted between 2015 and 2021. We gathered all the effectiveness information (American College of Rheumatology (ACR)) through a PICO-S strategy including infliximab, etanercept, certolizumab, tocilizumab, golimumab, tofacitinib and upadacitinib. Two reviewers evaluated the inclusion of the studies and assessed their quality using the PRISMA-NMA Checklist. Efficiency score was cost per number needed to treat (NNT) versus placebo (PLC). The model was designed from a hospital perspective (only direct costs) and with a 1-year horizon. Cost data (€ 2021) were obtained from Spanish datasets and literature review. Using all this information, a cost-effectiveness analysis between ADA and the suitable alternatives was performed. A probabilistic sensitivity analysis (PSA) was performed.

Results Two meta-analyses met the inclusion criteria and fulfilled on average 70.6% of the 32 points on the PRISMA-NMA Checklist of items. Tarp *et al* (2017) showed no statistically significant difference in NNT between infliximab, ADA, etanercept, certolizumab, tocilizumab and golimumab for ACR-50. Song *et al* (2019) showed no significant difference in NNT between ADA, tofacitinib and upadacitinib for ACR-20.

Total annual cost was € 4529 ADA versus € 4650–€ 10 001 for the other treatments. As no effectiveness difference was seen, a cost minimisation analysis was performed. Hence ADA was the most cost-effective treatment. In the PSA, only ADA and infliximab performed as the best alternative, with ADA showing the highest probability of being cost-effective.

Conclusion and relevance According to our model, ADA was the most cost-effective option for RA treatment in Spain.

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4CPS-084 MANAGING BREAST CANCER TREATMENT PATHWAYS IN THE COVID-19 ERA

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Background and importance Over the last 2 years the COVID-19 pandemic (C-19) has severely impacted the diagnosis and treatment of patients suffering from cancer. Considering breast cancer (BC) as a case study; fewer women than expected have been diagnosed, predicting a backlog of cases that could overwhelm the current infrastructure. In addition, measures directed at reducing viral spread such as social distancing or increased sanitary practices limit current resource utilisation.

Targeted measures are advised to offset these constraints to assure that affected women are effectively cared for in a timely manner, despite health care budgets that have been severely impacted by the pandemic, for example, by managing treatment toxicity to limit emergency hospital attendance or admissions.

Aim and objectives To identify evidence of possible interventions that could favourably impact (1) treatment capacity, (2)

planned and unplanned attendance at hospitals and clinics and (3) the overall costs of treatment.

Material and methods The key steps in the patient journey through BC systemic adjuvant therapy were identified. At each step a systematic and structured literature search using PubMed, Clinical Trials Registries and Google Advanced Search was conducted to identify candidate interventions, the level of evidence, quantifiable risks and benefits and statistical significance.

Results Safer care during C-19 requires increased separation of patients and staff, impacting treatment capacity. A broad range of possible effective interventions were identified including validated patient reassessment tools, shortened treatment schedules, rapid infusion delivery, dose-banding, enhanced toxicity monitoring and prevention, the subcutaneous and co-administration of therapeutics, home delivery of treatments and wider use of cost-effective treatment options created by generic and biosimilar products. Each step is identified on the patient pathway map of the poster.

Conclusion and relevance Hospital pharmacists have a catalogue of targeted, evidence-based measures at their disposal to assure that women with breast cancer can be effectively cared for in a timely manner despite the impact of C-19 and resulting challenges in treatment capacity and health care budgets.

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4CPS-086 INHALED SEDATION WITH HALOGENATED AGENTS IN THE INTENSIVE CARE UNIT: A LITERATURE MINI-REVIEW

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Background and importance Sedatives are administered to reduce anxiety and stress in mechanically ventilated, critically ill patients. Midazolam and propofol are the sedatives of choice, but their behaviour is difficult to predict in this type of patient. Inhaled sedation with halogenated agents has emerged as an alternative because of their speed of action and elimination.

Aim and objectives To review the available evidence on the use of sedative inhaled gases in the intensive care unit (ICU).

Material and methods A literature search was conducted through the medical databases PubMed and Google Academics using the terms 'Inhaled sedation' and 'Critical care'. Articles comparing inhaled sedation directly with conventional sedation, or describing pioneering uses of inhalation sedation, were selected. Another search with the same keywords was performed using TripDataBase and UpToDate to locate meta-analyses and clinical practice guidelines.

Results 236 articles were located and 25 were selected. No randomised clinical trials were found. Four meta-analyses were located.

Inhaled sedation is described to be effective to achieve deep sedation and to reduce sedation and extubation time; it also favours a decrease in troponin levels. Its use is also relevant in patients who do not achieve adequate sedation with conventional sedation. The gases used were isoflurane and sevoflurane.

There are clinical practice guidelines developed by different societies: American Society of Anesthesiologists, National Institute for Health and Care Excellence, Spanish Society of Intensive Care Medicine and The American Society of Intensive Care Medicine. They consider inhaled sedation as an alternative in patients with bronchospasm and in patients who are difficult to sedate.

Conclusion and relevance It can be concluded that the use of inhaled gases reduces the extubation and awakening time in critically ill patients. A reduction in troponin concentration is observed. However, these are not 'hard' variables that demonstrate an important clinical impact.

Their use may be of interest in patients with bronchospasm or in those who do not achieve an adequate sedation with conventional high-dose sedatives.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-087

THE USE OF PATIENT-REPORTED OUTCOME INSTRUMENTS IN IMMUNE CHECKPOINT INHIBITOR THERAPY FOR CANCER IN CLINICAL PRACTICE: A SYSTEMATIC REVIEW

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Background and importance Immune checkpoint inhibitors (ICI) have shown significant clinical benefit for patients diagnosed with varied types of cancer. With an increasing use of these therapies, it is of urgent interest to achieve a comprehensive understanding of the overall patient experience and to confirm if the results of patient reported outcome (PROs) in clinical ICI trials are reflected in clinical practice.

Aim and objectives We conducted a systematic review of the published literature to identify and categorise PRO instruments and examine related utility and measurement issues in studies reporting on ICI.

Material and methods Literature was searched using PubMed and Embase (October 2021). Search terms included controlled vocabulary and specific keywords related to: (1) ICI, (2) PRO and (3) Oncology. Two reviewers independently screened titles/abstracts followed by a full-text selection based on predefined criteria. We included qualitative and quantitative studies in clinical practice.

Results We screened 235 references and included 14 publications in our analysis: 6 reported PRO data from cross-sectional survey, 4 were prospective observational studies, 2 were case-control studies, 1 was a randomised controlled pilot trial and 1 as a qualitative study. 10 were single-centre and 4 were multicentre studies. The median number of patients included was 67 (range 6–412), 7 focused on melanoma patients, 2 on lung cancer, 1 on genitourinary cancer and 4 included various diagnostics. Regarding treatment, 7 studies were carried out in patients undergoing treatment and 7 in long-term survivors. The most frequent questionnaires used were cancer-specific (6

EORTC-QLQ-C30, 2 FACT-G), although the variability between the studies was very important, with 16 different scales identified, of which 9 were evaluated in a single study.

Conclusion and relevance Cancer-specific or generic quality-of-life (QoL) questionnaires are the most widely used PRO measures in clinical practice ICI studies. As ICI therapies exhibit unique characteristics different from conventional cancer therapies, such broad instruments may not capture the specific ICI-related symptoms, toxicities, and impact on the patient's QoL. Hence, the adaptation or development of ICI-specific PRO tools should be further investigated.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-088

INDIRECT COMPARISON OF NIVOLUMAB, PEMBROLIZUMAB AND CAMRELIZUMAB IN PATIENTS WITH UNRESECTABLE AND/OR ADVANCED SQUAMOUS CELL CARCINOMA OF THE OESOPHAGUS IN A SECOND-LINE SETTING

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Background and importance Established treatment for advanced, recurrent or unresectable oesophageal squamous cell cancer (ESCC) includes systemic therapy, definitive chemotherapy and/or palliative treatment depending on the stage of the cancer. These drugs increase the therapeutic options available.

Aim and objectives To determine if nivolumab, pembrolizumab and camrelizumab can be considered equivalent second-line therapeutic alternatives (ATE) by using a common comparator, for patients with unresectable and/or advanced ESCC.

Material and methods A bibliographic search was conducted to select phase III randomised clinical trials of second-line treatments for ESCC. Indirect comparisons were made by using the Bucher method using nivolumab as the reference drug and overall survival (OS) as the main variable. The maximum acceptable difference as a clinical non-inferiority standard Delta (Δ), and its inverse were set at 0.65 and 1.54, respectively. They were established by ESMO-Magnitude of Clinical Benefit Scale.

Results Three similar clinical trials were selected: ATTRACTION-3, KEYNOTE-181 and ESCORT, one for each drug evaluated.

Limitations found: chemotherapy used as comparator: ATTRACTION-3 nivolumab vs paclitaxel/docetaxel; KEYNOTE-181 pembrolizumab vs paclitaxel/docetaxel/irinotecan; ESCORT camrelizumab vs docetaxel/irinotecan.

KEYNOTE-181 study divides OS in patients with PDL-1 >10%, with ESCC and in all patients, with higher statistical significance ($p < 0.008$) for the population with ESCC.

After applying the Bucher method, the following hazard ratio (HR) values (95% CI) were obtained for OS: nivolumab 0.77 (0.62 to 0.96), pembrolizumab 0.77 (0.63 to 0.96) and camrelizumab 0.71 (0.57 to 0.87).

The results of the comparison with nivolumab were adjusted pembrolizumab HR=1 (0.738–1.355) and adjusted camrelizumab HR=0.922 (0.694–1.225). The HR of OS for both drugs is within the limits of Δ and its 95% CI does not exceed the neutral value and the equivalence margin.

According to the ATE Guide, it would fit with a type A therapeutic positioning, assuming that the OS variable studied for pembrolizumab does not meet statistical significance for patients with squamous histology.

Conclusion and relevance Nivolumab, pembrolizumab and camrelizumab could be considered ATE. It is necessary to take into account that there is a certain degree of uncertainty in this positioning result.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-089 RISANKIZUMAB IN REFRACTORY HIDRADENITIS SUPPURATIVA TO ANTI-TNF α : A CASE REPORT

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Background and importance Hidradenitis suppurativa (HS) is a skin condition, especially in areas of constant friction, characterised by painful subdermal lesions that generally worsen over time and that have serious repercussions on the quality of life of patients. Risankizumab is a new anti-IL-23 (IgG1) monoclonal antibody authorised and used for moderate to severe psoriasis and with a potential effect on HS refractory to adalimumab (anti-tumour necrosis factor alpha (anti-TNF α)).

Aim and objectives To evaluate the evolution and response of risankizumab after combined treatment with adalimumab and resorcinol 15% cream in a severe and refractory HS in a 63-year-old man during 24 months of treatment.

Material and methods To evaluate the efficacy of risankizumab, the clinical response was monitored through the resolution of the lesions in the affected areas at 1, 3 and 6 months.

Results The patient was diagnosed in early 2019. After starting treatment with adalimumab (loading dose: 160 mg day 0, 80 mg day 14 and 40 mg weekly) for 2 years, adjuvant treatment with topical resorcinol 15% (twice a day) was started for the last 6 months. Finally it was decided to start treatment with risankizumab subcutaneous in January 2021 (loading dose: 150 mg day 0, 150 mg day 28 and 150 mg after every 12 weeks). Only adalimumab stopped before starting risankizumab. After 1 month of dual treatment (risankizumab and resorcinol), the patient showed a significant improvement in the skin lesions produced by HS. Two cycles after starting risankizumab the lesions had resolved by 80%. The patient was followed for the first 6 months with risankizumab.

Conclusion and relevance Risankizumab has proven to be a therapeutic alternative for the treatment of HS beyond glucocorticoids, methotrexate and anti-TNF α . The combination with resorcinol 15% cream seems to have enhanced the effect of risankizumab, although larger population studies are needed to establish itself as a therapeutic alternative. The role of the hospital pharmacists was to advise the Local Commission on the choice of anti-IL-23 among risankizumab, guselkumab and tildrakizumab, according to the reports reported. This is the first documented case in Andalusia, Spain.

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Conflict of interest No conflict of interest

4CPS-090 EFFICACY AND SAFETY OF PANGENOTYPIC TREATMENTS IN HEPATITIS C VIRUS (HCV) PATIENTS

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Background and importance Hepatitis C virus (HCV) is one of the leading causes of progressive liver damage, cirrhosis and hepatocellular carcinoma. The emergence of pangenotypic regimens presents new opportunities for HCV treatments, regardless of genotype, minimising the need for virological testing services.

Aim and objectives To describe the use of different pangenotypic treatments in HCV patients to evaluate efficacy and safety.

Material and methods Observational and retrospective study in all adult HCV patients who received treatment with pangenotypic treatments between January and December 2020 in a regional hospital of 300 beds. Hospital pharmacist-dispensed treatment monitoring adherence and tolerance. Data collected were age, sex, genotype, degree of fibrosis, type of patients (naïve, relapse or non-responder), HCV treatment, treatment duration, basal viral load (VL), VL at 12 weeks after treatment completion and adverse reactions. As an indicator of efficacy, sustained viral response (SVR) was used.

Results 42 patients (76.9% men) were analysed. Median age 50.8 (range 27–79) years. A patient (2.4%) had genotype 1a, 2 (4.8%) had genotype 1b, 5 (11.9%) had genotype 2, 1 (2.4%) had genotype 3, 3 (7.1%) had genotype 4, 1 (2.4%) had genotype 5 and the genotype was not determined in 29 patients (69%). Regarding the degree of fibrosis, 17 patients (40.5%) were F0-F1, 6 (14.3%) were F2, 5 (11.9%) were F3 and 14 (33.3%) were F4. 34 (80.9%) were naïve patients, 5 (11.9%) failed prior treatment based on interferon and 3 (7.1%) were non-responders to treatment with direct-acting antivirals (DAA). 15 patients (35.7%) were treated with glecaprevir/pibrentasvir for 8 weeks, 24 patients (57.1%) with sofosbuvir/velpatasvir for 12 weeks and 3 (7.1%) with sofosbuvir/velpatasvir/voxilaprevir for 12 weeks. Median baseline VL was 3 125 159.6 IU/mL (range 3130–55 800 000), with 22 patients (52.4%) having >800 000 UI/mL. SVR was achieved in 38 patients (90.5%). VL was not determined in 3 patients. Regarding safety, 6 patients (14.3%) suffered at least one adverse reaction: headache (3), fatigue (2), gastrointestinal discomfort (2) and insomnia (1).

Conclusion and relevance Pangenotypic regimens probably represent the latest stage of development of treatment for chronic hepatitis C, and they have extremely high efficacy regardless of genotype, subtype, treatment history, or fibrosis status. They are well-tolerated drugs with a good safety profile.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-092 BIOLOGICAL THERAPIES FOR THE TREATMENT OF PSORIASIS: EFFECTIVENESS, SAFETY AND ECONOMIC IMPACT OF OPTIMISATION STRATEGIES

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Background and importance The goal of psoriasis treatment is to achieve and maintain the widest possible clearance of lesions and control of systemic inflammation over the long term. Biological therapies (BT) are only indicated moderate-severe psoriasis (MSP) refractory to conventional systemic therapy. In patients with sustained total clearance of lesions (TCL), dose reduction (DR) and dose spacing (DS) are optimisation strategies used in clinical practice to reduce the risk of the appearance of adverse effects (AE) and optimise resources. **Aim and objectives** Describe the effectiveness and safety of BT in MSP, and measure the economic impact of optimisation strategies in clinical practice.

Material and methods An observational and retrospective study was performed in MSP patients treated with BT from 12 January to October 2021. We registered: sex, age, responders patients (RP): Psoriasis Area and Severity Index (PASI) $\geq 75\%$ reduction in baseline PASI, time to loss of response (TTLOR), patients with TCL: PASI-100, patients with loss of response (LOR), duration of TCL (DTCL), causes of end of treatment (EOT) and AE due to BT. Patient data were obtained from the corporate prescription programme and electronic medical history.

Direct costs between the use of DS instead of optimised dose were compared in order to calculate the economic saving. **Results** During the study period, 36 patients were included (51.42% male). Mean age was 53 (28–77) years. The proportion of RP was 94.29% and 48.57% achieved TCL with a mean DTCL of 35.5 months. 25.71% of patients had LOR with a mean of 31 months. The main causes of EOT were: no response (2.86%), LOR (25.71%) and pregnancy (8.57%). Physicians used optimisation strategies in 11 patients (31.42%) meaning an expenditure reduction of €116,386, while in 3 patients (8.3%) the dose was intensified due to lack of disease control. Regarding safety, 3 patients suffered SE: erythema (2) and weight gain (1).

Conclusion and relevance BT was effective in most cases with an acceptable safety profile. Moreover, optimisation strategies meant an expenditure reduction with a huge optimisation of the resources available in our hospital.

Correct follow-up of the patients is very important to detect which patients might benefit from optimisation strategies, treatment change or intensification.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-093 DRUG-INDUCED SOMNOLENCE IN FRAILTY PATIENTS ATTENDING AN EMERGENCY DEPARTMENT

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Background and importance Drug-induced somnolence is an important cause of emergency department (ED) visits in frailty patients.

Aim and objectives To describe the drugs involved in ED visits due to drug-induced somnolence in frailty patients and to evaluate the risk factors involved in ED revisits 30 days after discharge.

Material and methods Retrospective observational study. Patients admitted to the frailty area of an ED who consulted for drug-induced somnolence were included (October 2020–March 2021). Patients admitted due to suicide attempts were excluded.

To evaluate the risk factors associated with 30-day revisits, a multivariate analysis was performed using logistic regression, including in the model those variables related to the comorbidities, destiny at discharge, polypharmacy (>9 drugs), treatment modification and number of central nervous system (CNS) depressant drugs prescribed at discharge with a p value <0.2 in a previous univariate analysis.

Results 80 patients were included (mean age 80.1 (SD 13.1) years). Median number of drugs at admission was 9 (range 3–20), being the median of chronic pathologies 6 (range 1–12). Of these patients, 35 (43.7%) had dementia, and a moderate-severe dependence was found in 32 (40.0%).

Median number of CNS depressant drugs on admission was 3 (range: 1–6). Antidepressants (63.7% of patients), benzodiazepines (58.6%), antipsychotics (47.5%) and opioids (45.0%) were the drugs most frequently prescribed on admission. The combination of benzodiazepines and opioids was present in 20 (25.0%) patients. At hospital discharge, CNS depressant drugs prescriptions were modified in 44 (55.0%) patients.

Eighteen (25.0%) patients revisited the ED 30 days after discharge, 16 (22.2%) of them due to episodes related to the use of CNS depressant drugs. The presence of chronic kidney disease, dementia, and more than three CNS depressant drugs at discharge were included in the multivariate analysis (p<0.2), observing a trend towards a higher risk of revisits in patients with chronic kidney disease (OR (95% CI): 2.87 (0.80 to 7.27)), without reaching a statistically significant association.

Conclusion and relevance Frailty patients who visit the ED due to drug-induced somnolence frequently have multiple contributing drugs. Nearly 25% of patients revisited the ED 30 days after discharge, most of them due to new episodes related to these drugs. Chronic renal failure may be associated with an increased risk of 30-day revisits.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-094 NON-RECOMMENDED DRUGS IN PATIENTS ATTENDING AN EMERGENCY DEPARTMENT DUE TO DECOMPENSATED CHRONIC HEART FAILURE

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Background and importance Decompensated chronic heart failure (CHF) is one of the main causes of emergency department (ED) visits.

Aim and objectives To assess the frequency of prescription of non-recommended drugs in patients admitted to the ED for decompensated CHF, and its impact on the frequency of 90-day revisits to these units.

Material and methods Retrospective observational study. Patients >18 years diagnosed with CHF who attended the ED of a tertiary hospital due to decompensated episodes were included (December 2020–February 2021).

Potentially inappropriate chronic drugs from the primary care electronic prescription programme according to the review of Page *et al*¹ were recorded, including those classified with evidence A (assessed in multiple populations) or evidence B (limited populations). To evaluate the impact of these groups of drugs on ED revisits for new decompensated episodes, a multivariate analysis was performed using logistic regression, including those variables related to the patient's comorbidity with a *p* value <0.2 in a previous univariate analysis.

Results 135 patients were evaluated: 5 (3.7%) were younger than 65 years, 63 (46.7%) were 65–85 years and 67 (49.6%) were older than 85 years. Regarding left ventricular ejection fraction was <40% in 21 (15.6%) patients, having an unknown value in 41 (30.4%) patients. 121 (89.6%) patients had hypertension, 80 (59.3%) atrial fibrillation, 29 (21.5%) chronic obstructive pulmonary disease, 47 (34.8%) diabetes, 41 (30.4%) ischaemic heart disease and 55 (40.7%) chronic kidney disease (CKD).

75 (54.9%) patients were taking ≥ 10 drugs at the time of the ED visit. 90 (66.7%) patients were taking beta-blockers, 83 (61.5%) angiotensin-converting enzyme (ACE) inhibitors, 26 (19.3%) potassium-sparing diuretics and 101 (74.8%) loop diuretics. 32 (23.7%) patients were taking potentially inappropriate drugs. 52 (39.7%) patients returned to the ED 90 days after hospital discharge due to new decompensated episodes. In the multivariate analysis, CKD was significantly associated with a higher risk of revisit (OR 3.29, 95% CI 1.43 to 7.55), observing a non-significant increased risk in those patients with non-recommended drugs (OR 2.12, 95% CI 0.85 to 5.34).

Conclusion and relevance The prescription of non-recommended drugs is a frequent phenomenon in patients with CHF who visited the ED with decompensated episodes. Those patients undergoing treatment with these drugs may have a greater risk of 90-day revisits.

REFERENCES AND/OR ACKNOWLEDGEMENTS

- Page RL. *Circulation* 2016;**134**:6.

Conflict of interest No conflict of interest

4CPS-096 TACROLIMUS VARIABILITY AND COMORBIDITIES IN LUNG TRANSPLANTATION

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Background and importance In solid organ transplant patients, inpatient variability in tacrolimus levels >30% is related to the appearance of specific de novo donor antibodies (dn-DSA) and rejection.

Aim and objectives We wanted to determine if in a cohort of 71 lung transplant patients in 2018 and 2019 this variability

is also related to the appearance of post-transplant complications: diabetes, osteoporosis, renal failure, dyslipidaemia and if the sex of the patients and their pre-transplant diagnosis has an influence.

Material and methods Through the hospital's own lung transplant patient management programme and the hospital's assisted electronic prescription, the following data were retrospectively analysed: tacrolimus levels from the second post-transplant month and its percentage coefficient of variation (% CV) until December 2020 (% CV: (standard deviation/mean)*100); tacrolimus, prednisone and mycophenolate mofetil dose; onset of diabetes and the drug being treated; glomerular filtration rate (GFR) <60 mL/min/1.73 m²; onset of osteoporosis; appearance of dyslipidaemia; sex; age; and pre-transplant diagnosis. For the statistical analysis, SPSS v.22 was used.

Results Of the 71 lung transplant patients in 2018, 8 died, 21 (30%) were women, 38 (54%) had a% CV of tacrolimus >30%, 32 (45%) had GFR <60 mL/min/1.73 m², 28 (39%) had osteoporosis, 47 (66%) had dyslipidaemia and 21 (29%) had diabetes.

The drugs used in the treatment of osteoporosis were: zoledronic acid, denosumab and teriparatide; dyslipidaemia: atorvastatin; and diabetes: metformin and insulin.

After the statistical analysis performed using the CHI2 test, no statistically significant differences were obtained between the% CV of tacrolimus and the remainder of the variables. The statistical significance in each case was: GFR <60 mL/min (*p*=0.111), osteoporosis (*p*=0.202), dyslipidaemia (*p*=0.353), diabetes (*p*=0.361), pre-transplant diagnosis (*p*=0.455), age (*p*=0.720) and sex (*p*=0.812).

Conclusion and relevance The% CV of tacrolimus >30% is not related to the appearance of post-transplant complications in a statistically significant way in this cohort of 71 lung transplant patients. There is a positive trend towards the development of kidney failure. More studies are needed and with a larger number of patients to be able to draw more precise conclusions.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-097 ROLE OF THE PHARMACIST IN THE CARE OF THE LUNG TRANSPLANT PATIENT

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Background and importance After a lung transplant, patients must have knowledge about pharmacological treatment and healthy lifestyle habits.

Aim and objectives To evaluate the effectiveness of pharmaceutical care for lung transplant patients from 2017 to 2020 aimed at increasing their knowledge about pharmacological treatments and healthy lifestyles and its influence on unscheduled readmissions in the first 90 days after transplantation.

Material and methods 129 lung transplant patients received, by the transplant pharmacist, information sessions 2 or 3 weeks after transplantation, during the hospital stay, on medicines and healthy lifestyles and the delivery of an informative book prepared for the occasion by the multidisciplinary team. The knowledge acquired was evaluated with the completion of a

questionnaire before and after the information sessions. The score of their satisfaction with the information received before and after the sessions was also collected.

Fifteen days after discharge, the patients were telephoned and a further survey was carried out.

The reasons for unscheduled readmissions in the period were mainly worsening of the respiratory function test and fever.

Results Of the 129 lung transplanted patients in the period studied, 114 completed both questionnaires.

70 were men and the average age was 55 years. The causes of transplantation were: diffuse interstitial pulmonary disease: 58, chronic obstructive pulmonary disease: 29; bronchiectasis/cystic fibrosis: 17; other causes: 7; pulmonary hypertension: 3.

99 transplants were double-lung, 20 left single-lung and 10 right single-lung.

The percentage of correct answers varied from 70% in the pre-questionnaire to 85% in the post-questionnaire ($p=0.000$).

The score of the patients' satisfaction with the information received was 6.6 points in the pre-questionnaire and 9.3 in the post-questionnaire ($p=0.000$).

114 telephone calls were made to patients' homes in order to complete the post-questionnaire.

In the first 90 days after transplantation, 27% of the transplanted patients were readmitted unscheduled in 2020 compared with 38.2% in 2016 (control group) ($p=0.225$).

Conclusion and relevance Pharmaceutical care for lung transplant patients statistically significantly improved their knowledge about medicines and healthy lifestyles as well as their degree of satisfaction with the information received, and statistically significantly improved the unscheduled readmissions in the first 90 days after transplantation.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-099 CLINICALLY RELEVANT DRUG-DRUG INTERACTION EVENTS IN PATIENTS WITH ABIRATERONE, ENZALUTAMIDE OR APALUTAMIDE TREATMENT

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Background and importance Cytochrome P enzymes play a key role in drug metabolism and it is essential to understanding some interactions.

Aim and objectives Optimising pharmacotherapy in prostate cancer patients through the identification of drug interactions between anti-androgenic therapy and the patient's usual medication.

Material and methods Patients on abiraterone, enzalutamide or apalutamide treatment were identified through the pharmacy computerised record of dispensations. Their usual medication was obtained from the pharmacotherapeutic history.

The evaluation of abiraterone and enzalutamide interactions was performed with Liverpool and Uptodate databases. For apalutamide, Micromedex and Uptodate were used because apalutamide is not registered in Liverpool. Clinically relevant interactions were reported to the urologist, performing the pertinent pharmaceutical interventions.

Results 32 prostate cancer patients were identified; 21 (65.6%) were treated with abiraterone, 8 (25%) with enzalutamide and 3 (9.4%) with apalutamide. The median of age was 79 (53–90) years and the median of concomitant treatments was 7 (3–13).

18 relevant interactions were detected; 2 (11.1%) with abiraterone, 10 (55.6%) with enzalutamide and 6 (33.3%) with apalutamide. The drugs with relevant interactions belonged to the following therapeutic groups:

- Cardiovascular system (61.1%). In the co-administration of bisoprolol with abiraterone or apalutamide we recommended reducing the bisoprolol doses. In treatments with enzalutamide and doxazosin, lecardipine, torasemide or nebulolol we advised changing the therapy to hydralazine, angiotensin-converting enzyme inhibitors, furosemide or atenolol. Statins should be replaced by ezetimibe or fibrates in enzalutamide or apalutamide treatment.
- Antithrombotics (16.7%). Dabigatran, apixaban or acenocoumarol are contraindicated with anti-androgenic therapy. We proposed the use of heparins or oral anticoagulants with strict international normalised ratio (INR) control.
- Proton pump inhibitors (PPIs) (11.1%). In patients treated with enzalutamide, pantoprazole or ??? changing to an anti-H2 was suggested.
- Analgesics (11.1%). Metamizole and tramadol are not recommended in cases of concomitant administration with abiraterone or apalutamide.

In the consulted databases a discrepancy of 25% was found, which illustrates the need to compare at least two databases to obtain an optimal review of interactions.

Conclusion and relevance Abiraterone, apalutamide and, mainly, enzalutamide suffer a large number of interactions, which may modify a treatment's efficacy and/or its safety. The use of multiple concomitant medications is a risk factor that increases the possibility of hospitalisation and mortality. The pharmacist must achieve the correct review of drug interactions with reference to at least two databases.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-101 BIOLOGIC AGENTS IN RHEUMATOLOGICAL DISEASES: IMPACT OF 'TREAT TO TARGET' IN CLINICAL PRACTICE

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Background and importance The aim of rheumatological diseases (RD) treatment should be clinical remission (CR) or alternatively a state of low level of clinical activity. The treatment of RD with a 'treat to target' (T2T) strategy consists of measuring and recording disease activity at each visit. If the patient has not reached the desired goal, therapeutic adjustments should be made to achieve it, and if the patient reaches CR then optimisation strategies (OS) can be performed: spacing or dose reductions.

Aim and objectives Measure the impact of T2T strategy in terms of effectiveness, safety and economic saving in rheumatological patients (RP) treated with biological agents (BA).

Material and methods A retrospective analysis was conducted in RP treated with BA with at least 3 months of treatment since April 2009 to August 2021. We registered: sex, age, type of RD, responder patients: DAS-28 <3.2, BASDAI <4; patients with CR: DAS-28 <2.6, BASDAI <2, median duration of treatment (DOTm), adverse events (EA), proportion of patients with OS, intensifications, adherence and economic saving obtained with OS. Direct costs between the use of standard dose instead of optimised dose were compared to calculate the economic saving.

Results 86 patients were included: 51% were male, median age was 58 years (IQR 28–84 years). The most prevalent pathology was rheumatoid arthritis (RA) with 60.56% of patients, followed by spondyloarthritis (SpA) in 22% and psoriatic arthritis (PA) in 17.44%. 93% (80/86) were responders with a DOTm of 50.7 months: CR was achieved in 73.75% (59/80) of responders and 4.65% (4/86) required dose intensification. Adherence was adequate in 95% of the patients.

Of all responders, 30% (24/80) were optimised: 70.83% (17/24) RA, 16.66% (4/24) PA and 12.5% (3/24) SpA. T2T has allowed an overall cost reduction of 27.4% compared with treatment with standard guidelines, meaning a total saving of €392 495 in the study period. AE was detected in 11.63% (10/86) of the patients, the most frequent being: infections (4.65%; 4/86) and local reactions (2.33%; 2/86).

Conclusion and relevance The T2T strategy in RP means an expenditure reduction with a huge optimisation of the resources available in our hospital guaranteeing the patient's health results.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-102 DRUG-RELATED HOSPITAL ADMISSIONS IN OLDER ADULTS: COMPARISON OF THE NARANJO ALGORITHM AND AN ADJUSTED VERSION OF THE KRAMER ALGORITHM

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Background and importance Drug-related admissions (DRAs) are an important cause of preventable harm in older adults, in particular in those aged 85 years and older. Characterisation and prevention of incident DRAs in older adults requires a standardised approach for DRA causality adjudication. Multiple algorithms exist to assess causality of adverse drug reactions, including the Naranjo algorithm and an adjusted version of the Kramer algorithm. The performance of these tools in assessing DRA causality has however not been robustly demonstrated.

Aim and objectives This study aimed to evaluate the ability of the adjusted Kramer algorithm to adjudicate DRA causality in geriatric inpatients. The secondary objectives were to characterise DRAs in this patient population and to identify independent determinants for a DRA.

Material and methods DRAs were assessed in a convenience sample of patients admitted to the acute geriatric wards of an academic hospital. DRAs were identified by expert consensus and causality was evaluated using the Naranjo and the

adjusted Kramer algorithms. Positive agreement with expert consensus was calculated for both algorithms. A multivariable logistic regression analysis was performed to explore determinants for a DRA.

Results A total of 218 geriatric inpatients were included of which 65 (29.8%) experienced a DRA. Positive agreement was 72.3% (95% CI 59.6% to 82.3%) and 100% (95% CI 93.0% to 100%) for the Naranjo and the adjusted Kramer algorithm, respectively. Diuretics were the main culprits and most DRAs were attributed to a fall ($n=18$; 27.7%). A fall-related principal diagnosis was independently associated with a DRA (OR 20.11; 95% CI 5.60 to 72.24).

Conclusion and relevance The adjusted Kramer algorithm demonstrated a higher positive agreement with expert consensus in assessing DRA causality in geriatric inpatients compared to the Naranjo algorithm. Our results support implementation of the adjusted Kramer algorithm as part of a standardised DRA assessment approach in older adults. Cardiovascular agents and central nervous system drugs were the main perpetrators for DRAs, underlining the need for preventive initiatives targeting these drug classes. In our geriatric inpatient population, a fall-related principal admission diagnosis was identified as an independent determinant for a DRA. Additional research, focusing on identification of older adults at risk for a DRA and implementation of preventive strategies, is needed.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-103 IMPROVING MEDICATION RECONCILIATION REPORTS: EVALUATION THROUGH QUALITY AUDITS

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Background and importance Medication reconciliation (MR) before a scheduled surgical procedure (SSP) improves patient safety, but the quality of this process must be taken into account. In our centre, the MR protocol includes hospital pharmacists' reports (RR) that encourage the process.

Aim and objectives Evaluate the evolution of quality of pharmacists' MR reports after annual audits.

Material and methods The study was performed in a 350-bed hospital.

According to MR protocol, before a SSP a pharmacist prepares an MR report that contains patients' data, medical service, the medications or dietary supplements that they take (active ingredient, dose, posology), and an individualised MR proposal for surgeons to adapt their medication during hospitalisation, according to availability of drugs and adequacy of prescription. MR proposals can be 'maintain', 'suspend', 'evaluate' or 'replace for'.

Subsequently, another protocol was developed to evaluate the quality of the MR report. Five relevant items were selected: item I: percentage of reports with empty medication list; II: percentage of reports with at least one item from column 'medication' written by commercial name; III: percentage of reports with at least one item from column 'medication' empty; IV: percentage of reports with at least one item from column 'dosing' empty; V: percentage of reports with at least one item from column 'reconciliation proposal' empty. Results were considered optimal if item errors were $\leq 10\%$ and

excellent if $\leq 5\%$. From 2016 to 2019 an audit was carried out annually, selecting a random sample of 30 patients and establishing an annual improvement plan according to the results (Table 1).

The improvement proposals established for each year were: 2016, include a week rotation in the reconciliation area for the first-year resident; 2017, extend MR rotation of the third-year resident from 2 to 5 months; 2018, establish a supervision/review circuit by the reference pharmacist of the RRs performed.

Results

Abstract 4CPS-103 Table 1 Results

Item	2016	2017	2018	2019
I	10%	10%	7%	0%
II	26%	9%	10%	4%
III	0%	0%	0%	0%
IV	0%	4%	0%	0%
V	10%	0%	0%	0%

Conclusion and relevance After each improvement proposal introduced, especially the review of the RRs, an improvement in the quality of the RRs was observed over the years. After the last audit, all the indicators were at excellent levels of achievement.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-104 PERSISTENCE WITH DISEASE-MODIFYING THERAPY IN MULTIPLE SCLEROSIS PATIENTS

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Background and importance Pharmacists are well positioned to improve clinical outcomes for patients by assisting with individualised patient in the outpatient setting. Given the difficulty of measuring the health outcome of disease-modifying therapies (DMTs) in patients with relapsing–remitting multiple sclerosis (RRMS), persistence to DMTs could be a good indirect measure.

Aim and objectives Our purpose was to analyse persistence and time to discontinuation (TD) of DMTs in patients with RRMS in a tertiary hospital.

Material and methods Retrospective, observational study in patients with RRMS who started DMTs with interferon- β (INF- β), glatiramer-acetate (GA), teriflunomide, dimethylfumarate (DF), fingolimod, natalizumab and alemtuzumab between 2016 and 2019. Persistence was calculated until April 2020 and defined as the length of time on the drug. Variables analysed: sex, age, Expanded Disability Status Scale (EDSS) at baseline, previous DMTs, TD, global persistence, persistence to DMT and causes of discontinuation.

Results 492 subjects were followed for a median time of 19.6 months, 69.3% women and median age 40 years. Median EDSS was 1 (0–6) in naïve patients and 2 (0–7) in pretreated

patients. 250 patients were naïve (50.8%) and 242 pretreated (49.2%). 31.1% of patients had used one DMT before. DMTs prescribed were 113 DF, 108 teriflunomide, 87 INF- β , 76 GA, 49 fingolimod, 34 natalizumab and 25 alemtuzumab. Median TD (months (range)) of DMTs was 14.1 (1–43) being longer in pretreated patients (16.8 (1–41)) than in naïve patients (13.9 (1–43)). Median TD per drug was natalizumab 27 (1–40), fingolimod 17 (3–32), INF- β 16 (1–43), teriflunomide 15 (1–41), DF 11 (1–38) GA 10 (1–27) and alemtuzumab 9 (8–10). Global persistence was 66.2% and per drug: 92.0% alemtuzumab, 73.5% DF, 73.5% natalizumab, 68.4% AG, 67.3% fingolimod, 61.1% teriflunomide and 50.6% INF- β . Main reasons for discontinuation were ‘intolerance’ 46.9% and inefficacy 39.8%. Discontinuation due to intolerance was INF- β 58.1%, GA 54.2%, DF 50%, teriflunomide 42.9% and fingolimod 37.5% and due to inefficacy fingolimod 50%, teriflunomide 50%, DF 43.3%, INF- β 34.9% and GA 29.2%. 88.9% atalizumab discontinuations were due to risk of progressive multifocal leukoencephalopathy (PML). The only reason for alemtuzumab discontinuation was inefficacy.

Conclusion and relevance Our cohort showed a high persistence rate. The main cause of discontinuation was ‘intolerance’. Patients with alemtuzumab, DF and natalizumab remained under treatment for longer. INF showed the lowest persistence. Low persistence may be related to intolerance.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-106 SAFETY OF ADJUVANT TRASTUZUMAB EMTANSINA FOR RESIDUAL INVASIVE HER2-POSITIVE EARLY BREAST CANCER

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Background and importance Trastuzumab-emtansine (T-DM1) is a treatment approved by the European Medicines Agency (EMA) in 2020 as a single agent for the adjuvant treatment of adult patients with HER2-positive early breast cancer (EBC) who have residual invasive disease, in the breast and/or lymph nodes, after neoadjuvant taxane-based and HER2-targeted therapy, in which it demonstrated a significant improvement in invasive disease-free survival compared with trastuzumab.¹

Aim and objectives Aim: to describe our experience with T-DM1 adjuvant for EBC treatment in real-world conditions (RWC). We analysed the T-DM1 safety profile and compared it with a pivotal trial (PT).¹

Material and methods Retrospective study in a tertiary hospital. 100% patients with EBC treated with adjuvant T-DM1 between 2019 and 2021.

Demographic data, basal Eastern Cooperative Oncology Group (ECOG), neoadjuvant therapy schedule, T-DM1 cycles received, adverse events (AEs), pegfilgastrim use, intentional dose delays, treatment interruptions and dose reductions were collected.

Results 29 patients received T-DM1. 100% women, average age 52 (range 27–75) years. 2/29 basal ECOG ≥ 1 .

20/29 received neoadjuvant treatment based on doxorubicin (lyposomal or conventional) and cyclophosphamide followed

by taxanes (19/20 paclitaxel, 1/20 docetaxel) with trastuzumab and pertuzumab. 24/29 presented toxicities to neoadjuvant treatment (15/29 thrombocytopenia).

T-DM1 starting dose: 3.6 mg/kg/21 days in 28/29 patients. In 1/29, 3 mg/kg due to persistent thrombocytopenia. 10/29 receiving therapy at the time of the study. 8/19 received <14 cycles, 5/8 discontinued due to toxicities.

19/29 experienced ≥ 1 AE. Grade ≥ 3 thrombocytopenia was the most common (12/29), followed by increase in liver enzymes (ILE) (6/29), grade ≥ 2 neuropathy and grade ≥ 2 asthenia (5/29).

2/29 received pegfilgrastim.

3/29 patients had dose reduction (2/29 one, 1/29 two dose-level reductions). 7/29 experienced dose delays due to toxicities.

Comparison RWC vs PT: any grade AE 65.5% vs 98.8%; grade ≥ 3 thrombocytopenia 41.4% vs 5.7%; grade ≥ 2 neuropathy 34.5% vs 1.5%; ILE 20.7% vs 5.6%; discontinuation due to toxicities 17.2% vs 18.0%; dose reductions 10.3% vs 10.4%. Dose delays and reduced initial dose were not considered in the PT.

Conclusion and relevance Safety profile of T-DM1 in RWC is consistent with the PT results. Overall AEs in RCW were lower than in the PT. Grade ≥ 2 AEs were higher in RWC but not related to increased discontinuations or dose reductions. Our results should be interpreted with caution due to the sample size.

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Conflict of interest No conflict of interest

4CPS-107

IMMUNOTHERAPY IN SEVERE UNCONTROLLED ASTHMA: EFFECTIVENESS AND SAFETY IN CLINICAL PRACTICE

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Background and importance Immunotherapy is used in those patients with severe uncontrolled asthma (SUA) despite treatment with inhaled glucocorticoids (IGC) and beta2 adrenergic agonists (LABA) at high doses, and/or oral glucocorticoids (OGC), but it seems that its effectiveness is lost over time.

Aim and objectives The aim of this study was to measure the effectiveness and safety of immunotherapy in SUA in clinical practice.

Material and methods A multicentre and retrospective study was performed in SUA patients from two Spanish centres who received treatment with immunotherapy (omalizumab, mepolizumab or benralizumab) since March 2017 to October 2021. We registered: sex, age, patients that maintained response after 2 years of treatment, loss of response, median follow-up (mFU). Effectiveness was evaluated as a reduction in OGC, exacerbations and/or urgency visits. Safety in terms of side effects (SE) and patient-reported outcomes with Asthma Control Test (ACT) score (<19 points = poor control) was also assessed. A dispensation program and the Diraya clinical station were used as sources of information.

Results 56 patients were included, 46 females, with a median age of 60 (7–86) years. The mFU was 60. 21 and 15 months with omalizumab, mepolizumab and benralizumab, respectively. The treatment was effective in 82% of all patients. 21%, 15% and 15% of patients were non-responders with omalizumab, mepolizumab and benralizumab, respectively.

65%, 50% and 23% of patients maintained the response after 2 years with omalizumab, mepolizumab and benralizumab, respectively. 30%, 15% and 7.6% of the patients experienced loss of response with omalizumab, mepolizumab and benralizumab, respectively, after a median of 60, 18 and 14 months.

ACT score was collected in 17 patients in our pharmacist consultation. Patients with ACT score <19 (n=5) were recommended to advance their medical appointment to evaluate whether to continue with treatment. Regarding safety, 9 patients suffered SE, the most frequent being recurrent respiratory infections.

Conclusion and relevance Immunotherapy was effective in most cases with an acceptable safety profile. Due to loss of response over time, we must take advantage of the monthly or bimonthly visits of these patients to the pharmaceutical consultation to carry out a more exhaustive follow-up and thus collaborate with pulmonologists and allergists in the management of these patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-108

BIOMARKERS EVOLUTION IN PATIENTS WITH SARS-COV-2 PNEUMONIA TREATED WITH BARICITINIB

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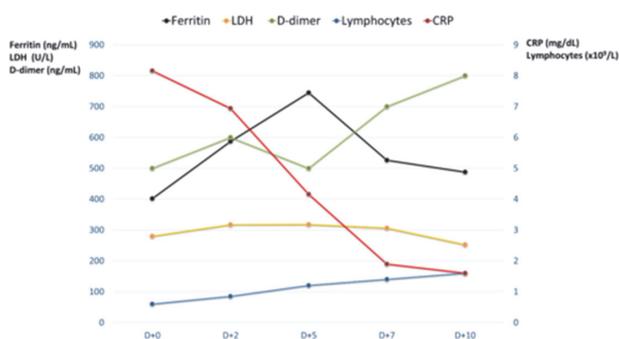
Background and importance A randomised clinical trial has demonstrated that baricitinib reduces the mortality of patients with SARS-CoV-2 that require hospitalisation. However, the evolution of biomarkers that predict the patients' outcome is not well described.

Aim and objectives To analyse the evolution of biomarkers in hospitalised adults with SARS-CoV-2 pneumonia treated with baricitinib.

Material and methods We conducted a retrospective observational study in a tertiary university hospital (760 beds). We included 31 patients positive for SARS-CoV-2 between January and February 2021. All received baricitinib 4 mg daily for ≥ 5 days (2 mg daily if glomerular filtration <60 mL/min).

We evaluated five biomarkers: lymphocytes, C-reactive protein (CRP), ferritin, lactate dehydrogenase (LDH) and D-dimer. The results were obtained on the day of admission (D +0) and on days 2 (D+2), 5 (D+5), 7 (D+7) and 10 (D +10) after starting baricitinib.

A pharmacist was involved in the multidisciplinary team taking part in COVID-19 protocol drafting, validation of treatments, dose adjustments, interactions, and monitoring of adverse effects.



Abstract 4CPS-108 Figure 1 Evolution of biomarkers from day 0 (D +0) to day 10 (D+10) after initiation of baricitinib treatment

The REDCap database was used for data collection and the G-STAT-2.0.1 for statistical analysis (paired t-test/Holm–Bonferroni correction).

Results A total of 31 patients were included: 6 women and 25 men. Median age (IQR) was 64 (55;75) years.

Main comorbidities were dyslipidaemia (39%), hypertension (35%), pulmonary disease (29%), diabetes (16%) and cardiopathy (16%). During admission, 15 (48%) received corticosteroids and 18 (58%) remdesivir, 7 (23%) needed high-flow oxygen, 5 (16%) required intensive care unit (ICU) admission and 2 (6%) died.

Baseline biomarkers, as median (IQR), were: CRP 8.2 (5;11) mg/dL, ferritin 402 (176;794) ng/mL, LDH 280 (237;340) U/L, lymphocytes 0.6 (0.4;0.9) 10⁹/L and D-dimer 500 (300;700) ng/mL.

The change in the biomarkers is shown in Figure 1. There was a decrease in CRP which was statistically significant from D+5 ($p=0.0144$) onwards and an increase in lymphocyte count significant from D+2 ($p=0.0148$) onwards. LDH, ferritin and D-dimer did not significantly improve. No patient had thromboembolic complications or other adverse reactions associated with treatment.

Conclusion and relevance Patients with severe SARS-CoV-2 pneumonia treated with baricitinib showed a significant increase in lymphocyte counts as well as a significant decrease in CRP shortly after baricitinib treatment. This fact, together with the low mortality, and good tolerance supports the use of baricitinib for patients with COVID-19 pneumonia.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-109

DESCRIPTIVE ANALYSIS OF PATIENTS CO-INFECTED WITH HIV AND HEPATITIS C VIRUS (HCV) TREATED WITH ANTIVIRALS FOR HCV AND ITS EFFICACY IN A PRISON FROM 2002 TO 2020

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Background and importance The prevalence of patients with hepatitis C virus (HCV) viral load in national prisons was 3% in 2018, 2.5 times lower than the one obtained 10 years ago. In fact, since patients started to be treated with interferon-free-based treatments in 2015, a drastic decrease in HCV viral load prevalence was observed.

Aim and objectives To evaluate the response to treatment in inmates of a prison presenting HIV-HCV co-infection and that following treatment with HCV antiviral drugs.

Material and methods A descriptive observational study was conducted. The electronic clinical history and prescriptions of patients receiving HCV antivirals between 1 November 2002 and 31 December 2020 were reviewed. Moreover, the following data were collected: age, gender, HIV serology, discontinuation or not of the treatment and sustained viral response (SVR) at 12–24 weeks after treatment end. This response was defined as undetectable HCV-RNA 12–24 weeks after treatment compliance. The role of the pharmacist was adherence and adverse effects monitoring and to undertake an educational work.

Results During the study 251 patients were treated, of which 33.4% were co-infected with HIV-HCV. Their average age was 43 years and 86.9% were males.

From 2002 to 2014, 33% of the 127 patients treated with interferon-based regimens were co-infected, and 50% of them obtained SVR, in contrast with mono-infected individuals, of whom 70.5% obtained SVR. Moreover, 28.5% co-infected patients did not respond to the treatment, 9.5% discontinued, 7.1% relapsed, 2.3% abandoned treatment because of intolerance and 2.3% were moved to another prison.

However, between 2015 and 2020, from the 34.4% co-infected patients (from a total of 125) treated with interferon-free regimens (DDA), 95.2% obtained a SVR, meanwhile 92.5% of the mono-infected individuals obtained SVR. One of the co-infected patients relapsed and another obtained a response of breakthrough.

Conclusion and relevance The efficacy of antivirals in co-infected patients has increased due to the implementation of improved treatment guidelines, reaching more than 95% SVR with DDA, which approximates to the rates in the rest of the population. Treatment access for all patients and high treatment efficacy has led to 0% prevalence in this prison.

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Conflict of interest No conflict of interest

4CPS-110

INITIAL EXPERIENCE OF THE USE OF CEFIDEROCOL FOR MULTIDRUG RESISTANT INFECTIONS IN A UNIVERSITY HOSPITAL

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Background and importance Recently new antibiotics were introduced in our hospital formulary for the treatment of serious infections caused by multidrug-resistant (MDR) organisms (CRE, ESBL, MDR-PA, CRA-AB). Cefiderocol, thanks to its

structure and mechanism of action, may play a unique role in patients who have limited or no alternative treatment options.

Aim and objectives The aim of this study was to describe the first cases of prescriptions of cefiderocol used in the 5 months following its availability in Italy, and the hospital pharmacist interventions in assisting clinicians from microbiology select a safe and appropriate antibiotic treatment.

Material and methods A standardised prescription form was sent to the infectious disease specialist to collect patients' characteristics, infection type, reasons for cefiderocol use, doses and duration of treatment (concomitant treatments, adverse events and outcome). A susceptibility testing kit (30 µg cefiderocol disc) was provided to the microbiology specialist in order to reserve this new antibiotic for patients with cefiderocol-susceptible isolates. A retrospective study was performed to collect the data of adult patients who received cefiderocol.

Results A total of 30 patients with mean age of 56 (23–90) years received cefiderocol (9 females, 21 males). Of these, 19 patients were treated in intensive care units, with the most common regimen of 2 g three times/day tid (n=6), while 3 patients with acute renal failure required a regimen of 750 mg twice daily. The main sites of infection were respiratory tract (n=16), urinary tract (n=3), intra-abdominal (n=4) and bloodstream (n=5). 5 patients had multisite infections.

The duration of therapy was in the range 6–16 days. The most common pathogens were *Acinetobacter baumannii* (n=13), *Klebsiella pneumoniae* (n= 8), *Pseudomonas aeruginosa* (n=10) and *Enterobacter* spp (n=5). 10 patients had superinfections. The most concomitant therapy was colistin (n=9). No severe adverse events were reported. 7 patients with septic shock died.

Conclusion and relevance Our study describes real-life experience of the use of cefiderocol as a salvage option in critical patients, providing additional data on its benefit, safety and limits in both empirical and targeted treatment of multidrug-resistant Gram-negative bacteria (MDR-GNB) infections, and it confirms the need for a multidisciplinary team.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-111 RUXOLITINIB FOR REFRACTORY GRAFT-VERSUS-HOST DISEASE IN PAEDIATRIC PATIENTS

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Background and importance Ruxolitinib has shown efficacy in the treatment of steroid-refractory graft-versus-host disease (GVHD) after haematopoietic stem cell transplantation (HSCT) in adults, but the evidence in children is still scarce.

Aim and objectives To evaluate the effectiveness and safety of ruxolitinib in paediatric patients with steroid-refractory GVHD.

Material and methods A retrospective observational study including all patients treated with ruxolitinib in our paediatric hospital (January 2017–September 2021) was carried out.

Variables collected from electronic medical records and the pharmacy dispensing program were: age, sex, weight, previous treatments for GVHD, length of treatment, dose, treatment response, reasons for discontinuation and adverse events (AEs) related to ruxolitinib. Effectiveness was assessed by the clinical resolution of GVHD.

Results 31 patients (64.5% male, n=20; median age 13.5 (1–19) years; median weight 36.9 (10–85) kg) received treatment during the period of the study in 34 episodes. In 15 episodes (44.1%) the treatment was for acute GVHD (aGVHD) and in 19 (55.9%) for chronic (cGVHD).

The median number of previous lines was 2 (1–4); all patients had previously received steroids. The median length of treatment was 7.4 (1.4–52.3) months. The median initial dose of ruxolitinib was 11.8% 2.5 mg/12 hours (n=4, weight <15 kg); 58.8% 5 mg/12 hours (n=20, weight 15–60 kg) and 29.4% 10 mg/12 hours (n=10, weight 47–85 kg).

4 episodes of cGVHD were not included in the effectiveness analysis: follow-up was continued in another centre (n=2) and 2 patients died while on treatment from other causes. Complete response rate in aGVHD and cGVHD was 86.7% (n=13) and 60.0% (n=9), respectively. 2 (13.3%) patients with cGVHD showed partial response and treatment was switched to other lines. 2 (13.3%) patients with aGVHD and 1 (6.7%) with cGVHD showed treatment failure. 3 (20.0%) patients were receiving ruxolitinib at the time of the analysis for cGVHD showing stable response (n=2) and improvement (n=1).

AEs related to ruxolitinib were: increased serum alanine aminotransferase and aspartate aminotransferase 8.8% (n=3), herpes zoster infection 5.9% (n=2), hypertension 2.9% (n=1) and anaemia 2.9% (n=1). 1 patient required dose reduction due to grade 4 hepatic toxicity, that was resolved.

Conclusion and relevance In our study, ruxolitinib has shown effectiveness for refractory GVHD in most of the patients. The safety profile in our population is consistent with the literature. Further studies in paediatric patients are warranted.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-112 VORICONAZOLE THERAPEUTIC DRUG MONITORING: RELATIONSHIP WITH LIVER TOXICITY

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Background and importance Serious fungal infections are a subject of concern in hospital medicine. Voriconazole is one of the most used antifungal agents to treat these situations. Voriconazole therapeutic drug monitoring (TDM) may help to avoid treatment failures or adverse events.

Aim and objectives This study aimed to evaluate the impact of voriconazole TDM in dose or drug changes and seek a relationship between voriconazole plasma levels and liver toxicity.

Material and methods TDM was performed in patients treated with voriconazole. Plasma levels were measured once a steady state was achieved and immediately before administering the drug (though drug concentration).

Voriconazole concentrations were analysed by a validated reverse phase-high performance liquid chromatography-ultra-violet (RP-HPLC-UV) method.

Liver enzymes and cholestasis markers concentrations (aspartate aminotransferase (AST), alanine aminotransferase

(ALT), gamma glutamyl transferase (GGT), alkaline phosphatase (ALP) and total bilirubin (TB)), dose, diagnosis, age and sex were registered.

Microsoft Excel was used for the statistics calculation.

Results 68 determinations in 38 patients (73.75% men; aged 64.84 ± 11.29 years).

Diagnosis: probable disease 21 (55.28%), possibility 12 (31.57%), prophylaxis 5 (13.15%).

6 (15.8%) patients needed a change in treatment. 5 (83.33%) had the dose changed in order to maintain plasma levels between 1 and 5.5 µg/mL. In 1 patient (16.66%) voriconazole was substituted.

28 (73.7%) started treatment with the dose of 200 mg/12 hours, whereas the rest (26.3%) has a higher dose. 60% of dose changes were in patients taking 200 mg/12 hours.

A positive correlation existed between plasma levels of voriconazole and liver enzymes as well as with cholestasis markers (AST: $r^2=0.1817$; ALT: $r^2=0.1118$; GGT: $r^2=0.2528$; PA: $r^2=0.2444$ and TB: $r^2=0.4637$).

The Chi-square statistic was significant at $p<0.05$ for plasmatic levels over 3 µg/mL and AST/ALT over physiological range (35 U/L).

The relative risk of presenting ALT over the physiological range is 3.12 and for AST 2.31 in patients with plasmatic levels of voriconazole >3 µg/mL respects the ones whose plasmatic levels were <3 µg/mL.

Conclusion and relevance Voriconazole TDM is a tool that can help to avoid treatment failure and adverse events. Its relationship with liver toxicity, which shows our data, TDM would help to prevent these side effects.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-113 REAL-LIFE DATA ON THE USE OF ABIRATERONE/ENZALUTAMIDE IN CASTRATION-RESISTANT PROSTATE CANCER

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Background and importance Abiraterone and enzalutamide are used for treating castration-resistant prostate cancer (CRPC). The lack of direct comparisons makes the selection and positioning of these drugs difficult.

Aim and objectives To compare abiraterone and enzalutamide use in metastatic CRPC, and to provide real clinical data on effectiveness and safety.

Material and methods Retrospective observational study conducted in a tertiary hospital in patients with metastatic CRPC.

Patients evaluated and treatment initiated between January 2015 and September 2021.

The primary effectiveness variable was progression-free survival (PFS). Overall survival (OS) and survival probabilities were also estimated. Survival parameters were estimated with the Kaplan–Meier test and compared by the log-rank test using R-software (v.4 - 2021).

As safety variables, the percentage of patients with adverse events (AE) and grade according to the Common Terminology Criteria for Adverse Events (CTCAE) were collected.

Results 99 patients were included (abiraterone=70 and enzalutamide=29; disproportionality due to the prospective design). No significant differences were observed in the patients' baseline characteristics: mean age (75.6±9.1 years vs 75.8±7.5, respectively) and number of metastases at baseline. These were mainly bone (36.34%) and lung (6%). Gleason at baseline was ≥8 in 45.7% of those treated with abiraterone and 31% with enzalutamide. 92.9% in the abiraterone group had Eastern Cooperative Oncology Group (ECOG) 0–1 and the comparable figure was 89.7% for enzalutamide.

62.9% with abiraterone presented ≥1 AE. Most frequent AE were G1-asthenia (22.3%) and G1-hypertension (12.3%). 8.6% were AE≥G2. In the enzalutamide group, 69% presented ≥1 AE(10.3% ≥G2). Common were G1-asthenia (62.1%) and G1-headache (13.8%).

Median PFS for abiraterone was 31 months (95% CI 20 to NA) and for enzalutamide 42 months (95% CI NA to NA); with no significant differences ($p=0.5$). Median OS was not reached in either group, with no significant differences ($p=0.7$). For overall survival, at month 13, 92.2% of patients did not reach the event in the abiraterone group and 81.5% in the enzalutamide group.

The power of the study for PFS was 0.038 and for OS 0.042, indicating that the power to detect differences is low.

Numerical disproportion between individuals makes enzalutamide more sensitive to events; however, the number of events remained proportional, with both curves being practically superimposable.

Conclusion and relevance Statistical differences in PFS were not found. Median OS was not reached in either group; AE were mild to moderate for both groups. We cannot affirm that there are differences in effectiveness and safety between these treatments.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-114 INTEGRATION OF A PHARMACIST INTO A GERIATRIC DEPARTMENT

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Background and importance Elderly chronic patients are usually pluripathological and polymedicated, which makes them vulnerable and complex to deal with. The review of their pharmacological treatment and their interactions, deprescribing and managing medications provides safety and improves their quality of life in a context of pharmacotherapy optimisation.

Aim and objectives To create a healthcare resource between the services of geriatrics and hospital pharmacy which facilitates clinical management of arranged patients for a medical consultation in outpatient geriatric clinic.

Material and methods Prospective study which included patients arranged for a geriatric consultation for the first time between May 2021 and August 2021. All these items were considered: pharmacotherapy, adherence to medical treatment, medical history, final analysis and last hospital admission. Treatment optimisation recommendations were mentioned to the geriatric physician. Primary care, specialised and

emergency consultations were recorded the month following the aforementioned changes.

Results 33 patients were included, of whom 64% were women, mean age 86 (SD 4.4) years. 113 interventions were carried out (3.4 per patient), most of which were due to therapeutic optimisation (23%), excessive treatment duration (21%) and medical interactions (13%). Also, no specific therapeutic indications (11%) and incorrect dosage (4%) were noted. A dose adjustment was proposed in 40% of the interventions and the modification of therapeutic agents in 14%. Changes were accepted in 65% of the proposals. 26 pharmacotherapeutic groups were involved in the interventions, with antihypertensives, lipid-lowering drugs and benzodiazepines being the most affected ones. The month following the intervention, only 3 patients needed to go to the doctor due to the changes made: high blood pressure (n=1) and insomnia (n=2) were the problems reported. None of the patients required emergency assistance.

Conclusion and relevance The introduction of the figure of the hospital pharmacist into a multidisciplinary approach for elderly, fragile patients enables an optimisation of their pharmacotherapy in order to achieve an effective detection of medical problems, all of which results in an improvement of their quality of life.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-115 NABPACLITAXEL PLUS GEMCITABINE VERSUS FOLFIRINOX IN METASTATIC PANCREATIC CANCER: REAL-WORLD DATA EXPERIENCE

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Background and importance Pancreatic cancer (PC) is a highly lethal malignancy although palliative systemic chemotherapy can improve disease-related symptoms and prolong survival. In our hospital the most used treatment regimens for this pathology are nabpaclitaxel plus gemcitabine (GemNab) and FOLFIRINOX. There are no studies that directly compare the two schemes, making the choice empirical.

Aim and objectives To assess the effectiveness and safety of GemNab versus FOLFIRINOX in metastatic PC.

Material and methods A descriptive retrospective study from January 2016 to September 2021 was conducted. Variables collected were age, sex, Eastern Cooperative Oncology Group (ECOG) stage, treatment regimen, and number of cycles. As efficacy endpoints, progression-free survival (PFS) and overall survival (OS) were used. Analysis was performed using the Kaplan–Meier curve (SPSS Statistics v.24 program). Security was evaluated based on adverse effects (AEs), delays of therapy, reductions of doses, and suspensions associated with the treatment scheme.

Results Forty-one patients were included with median age 61.5 (47–79) years. There were 75.9% men and 24.1% women. ECOG stage was 0–1 in all cases. Twenty-eight patients received GemNab and thirteen FOLFIRINOX scheme. The median number of cycles was 4 (1–14) in GemNab group and 6 (1–18) in FOLFIRINOX population. Median PFS was 8 months (95% CI, 4 to 11) in GemNab group and 8 months (95% CI, 3 to 12) in FOLFIRINOX arm. Median OS was 7

months (95% CI, 2 to 11) in GemNab group and 8 months (95% CI, 3 to 12) in FOLFIRINOX population. The main AEs observed were asthenia (64.3%), neurotoxicity (25%) and diarrhoea (25%) for GemNab. This combination drug presented delays and reductions of doses in 60.7%, respectively, including suspensions due to AEs in 17.9%. Neurotoxicity (38.5%), diarrhoea (30.8%) and neutropenia (23.1%) were the AEs frequently reported in patients with the FOLFIRINOX scheme. Regarding tolerance of FOLFIRINOX, 84.6% delayed the cycle, 61.5% reduced the doses and 38.5% had treatment suspended.

Conclusion and relevance In our metastatic PC population, GemNab and FOLFIRINOX showed similar effectiveness. With respect to safety profile, more than half of the patients presented delays of therapy and reductions of doses in both groups and more patients discontinued treatment with the FOLFIRINOX regimen due to AEs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-116 ASSOCIATION OF DIHYDROPYRIMIDINE DEHYDROGENASE DEFICIENCY WITH CAPECITABINE TOLERANCE

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Background and importance Dihydropyrimidine dehydrogenase (DPD) is the first of the enzymes in the fluoropyrimidine metabolic pathway. It is the rate-limiting enzyme in the catabolism of fluoropyrimidine drugs. Patients with partial or total deficiency in DPD activity can not adequately degrade fluoropyrimidines, increasing the risk of serious toxicity.

Aim and objectives To assess the rate of deficiency of the metabolising enzyme DPD in our population and describe the management of these patients in clinical practice.

Material and methods The study was conducted between January 2020 and August 2021. Patients diagnosed with colorectal cancer receiving capecitabine were included. Age, gender, Eastern Cooperative Oncology Group (ECOG), regimen treatments and number of cycles were collected from the electronic clinical history. To determine the variants of DPD, a pharmacogenomics analysis was performed using a real-time polymerase chain reaction (PCR) technique. The polymorphisms studied were rs3918290, rs55886062, rs67376798 and rs56038477. Regarding the management of patients, the doses reduction, adverse events (AE), and withdrawal treatments were recorded.

Results A total of 35 patients in treatment with capecitabine were selected for the analysis of DPD activity. The study population comprised 24 men (68.6%) and 11 women (31.4%). The average age was 60 (27–87) years. ECOG 0–1 was observed in 97.1% of cases. Oxaliplatin plus capecitabine was the initial cancer therapy in 74.3% of patients, and 25.7% were treated with capecitabine in monotherapy. A mutated allele heterozygote was detected in 11.4% of patients: rs67376798 (8.6%) and rs56038477 (2.9%). A 50% dose reduction was prescribed initially according to pharmacogenetics recommendations in DPD deficiency and this dose was maintained throughout the entire treatment. In patients without mutation a dose reduction was required in 22.9%. All

patients with DPD mutation and 41.9% without DPD mutation presented AE. The most common AE in this population were gastrointestinal such as nausea (25.7%), constipation (14.3%), diarrhoea (11.4%) and vomiting (11.4%). No withdrawal treatments were registered.

Conclusion and relevance Patients with DPD polymorphisms in our population completed treatment with 50% of the dose. AE were more prevalent in DPD mutation group. Determination of variants of DPD can help avoid serious or fatal EA.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-117 APPROPRIATENESS OF ANTIBIOTIC PRESCRIPTIONS IN A LONG-TERM CARE FACILITY

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Background and importance Antimicrobials are the most frequently prescribed drugs in long-term care facilities (LTCF). Antibiotic prescriptions may be unnecessary; but even when necessary, the antibiotics prescribed are often excessively broad-spectrum or longer duration.

Aim and objectives To evaluate appropriateness of antibiotic prescriptions in a LTCF and analyse possible factors related to inappropriateness.

Material and methods An 18-month prospective study was conducted in a 264-bed LTCF. Antibiotic prescriptions for suspected lower respiratory tract infection (LRTI), skin and soft tissue infection (SSTI) or urinary tract infection (UTI) initiated for LTCF residents were included. We excluded confirmed positive COVID-19 infections without suspected bacterial/fungal co-infection and prophylactic antibiotic prescriptions. We obtained demographic and clinical characteristics of residents, variables related to infection and antibiotic prescription, microbiology data and setting of prescription initiation. Each antibiotic prescription was assessed for appropriateness and classified as unnecessary, inappropriate and suboptimal antimicrobial use.¹ Associations of variables with inappropriate antibiotic prescribing were estimated using logistic regression.

Results We included 416 antibiotic prescriptions (out of 489) corresponding to 159 residents, 43.6% women, mean age 83.2 (SD 9.6) years. Fosfomicin-tromethamine was the most commonly prescribed antibiotic (25.0%), followed by cephalosporins (18.8%), amoxicillin-clavulanic acid (15.9%) and fluoroquinolones (13.0%). Polytherapy: 2.6% of episodes. Infections: UTI (43.3%), LRTI (34.6%), SSTI (22.1%). Targeted therapy: 16.8%. Median treatment duration: 5 (IQR 1–7) days; 9.4% prescriptions for >7 days. Sample collection was carried out in 29.6%. Positive result: 82.9% of cultures. The most prevalent microorganisms isolated were the Gram-negative bacteria (87.3%). The majority of antibiotic prescriptions were initiated within the LTCF (84.1%), with 12.7% by the emergency department (ED) and 3.2% by hospital or primary care (HPC). Overall, 46.6% of antibiotic prescriptions were judged unsuitable: unnecessary (16.9%), inappropriate (70.6%), suboptimal (12.5%). Multivariable analysis showed that empirical therapy, some classes of antibiotics (cephalosporins, fluoroquinolones, fosfomicin calcium,

macrolides) and prescription initiation in the emergency department were independent predictors of antimicrobial inappropriateness.

Conclusion and relevance Almost half of antimicrobials prescriptions are inappropriate. Antibiotics initiated in the ED constitutes a small but not unimportant percentage of all prescriptions. Antimicrobial stewardship programmes should include interventions in this setting because of the high inappropriate use.

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4CPS-119 REAL-WORLD EXPERIENCE WITH PCSK9 INHIBITORS PROTOCOL FOR HYPERCHOLESTEROLAEMIA

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Background and importance PCSK9 inhibitors (PCSK9i) are drugs that reduce low-density lipoprotein (LDL) levels. Due to their high cost and restrictive indications, a drug use evaluation (DUE) was performed.

Aim and objectives Evaluate a protocol for PCSK9i use and patients' follow-up developed in our centre.

Material and methods Our PCSK9i protocol establishes criteria for new prescriptions and clinical monitoring according to European guidelines. After doctor prescription and hospital pharmacist (HP) validation, patients have an appointment with the HP to review whole treatment, dietary and exercise habits. LDL-levels are reviewed by the HP after 1 month of treatment, and annually.

Patients not reaching the desired outcome are cited with the HP, to check causes of treatment failure (lack of adherence, ineffective dosing, change of habits, etc.) and referred to the doctor to evaluate treatment optimisation if needed.

All patients with PCSK9i were included. We recorded sex, age, last appointment with the doctor, LDL-levels before treatment (LDL-1), LDL-levels after 1 month (LDL-2) and, in patients with more than 1 year of treatment, date and results of the last LDL analytic (LDL-3). A descriptive analysis was performed using measures of central tendency, dispersion and position for quantitative variables, and frequency distribution for qualitative variables.

Results 161 patients were included, 67.7% male. Medium age was 60±8,7 years. Follow-up ranged from 2 months to 5 years. Treatment regimens were: evolocumab 140 mg biweekly: 30 patients (18.6%); alirocumab 75 mg biweekly: 96 (59.6%) and 150 mg biweekly: 35 (21.7%).

Abstract 4CPS-119 Table 1 LDL results

	Minimum (mg/dL)	Maximum (mg/dL)	Medium (mg/dL)
LDL-1 (n=161)	66	344	132.5 ±47.3
LDL-2 (n=158)	8	188	60.49 ±34.04
LDL-3 (n=122)	7	160	61.59±33.96

Medium LDL levels improvement after 1 month was 71.7 ± 41.2 mg/dL (Table 1).

17 patients (10.55%) did not have an analytic in the last year, and 10 patients (6.21%) had not had an appointment with their doctor in more than a year. 38 patients (23.6%) had LDL levels over the objective. According to guidelines and protocol, these patients were referred to the physician for revision.

Conclusion and relevance Although some patients do not reach the desired outcome and/or their monitoring may be improved, our data show that PCSK9i causes a great reduction of LDL levels that is maintained over time.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-120 ADVERSE DRUG REACTION (ADR) NOTIFICATIONS' IMPACT ON PATIENTS FOLLOWED AT AN AMBULATORY CARE PHARMACY UNIT

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Background and importance Pharmacovigilance aims to improve drug efficacy and patients' safety through detection, notification and prevention of adverse drug reactions (ADR).¹ The intervention of Ambulatory Care Pharmacists, who directly assist the patient, is very important because, by detecting and notifying ADR, they will greatly improve patients' treatment and life quality.

In Portugal, Ambulatory Care Pharmacy drugs are prescribed and purchased by international non-proprietary names (INN) and never by their commercial denomination, whether generic or not. One of the purchases' award criterion is the most economically advantageous proposal. The ADR notifications allow the Hospital Pharmacy to purchase therapeutic alternatives for the patients.

Aim and objectives Retrospective study to analyse ADR notifications registered between 2020 and 2021 in an Ambulatory Care Pharmacy Unit. The ADR occurred in patients followed at these Ambulatory Care Pharmacy facilities.

Material and methods ADR notifications analysis occurred between 2020 and 2021 (January–September) in patients followed at the Ambulatory Care Pharmacy.

Results There were 41 ADR notifications in 2021 (January–September) and 7 ADR notifications in 2020. 27 of the ADR notified were for generic drugs, of which 16 occurred with anastrozole, 7 with imatinib, 1 with bicalutamide, 1 with emtricitabine/tenofovir, 1 with letrozole and 1 with tenofovir.

Generic drugs were related to the majority of the notified ADR. In almost every case, patients were given the same active substances produced by different generic pharmaceutical laboratories which were effective in controlling the notified ADR.

Conclusion and relevance It was verified that the majority of the notified ADR occurred with generic drugs (the majority occurred with anastrozole – a breast cancer treatment drug), which can be linked to the tablet's pharmaceutical formulation or excipients, given that when patients were dispensed a different brand of the same drug, their symptomatology improved.

It is also appropriate to emphasise that ADR related to Imatinib Farmoz were notified, which are fundamentally related to its tablet coating, according to the patients' complaints.

The ADR notifications' execution by the pharmacist allowed the Hospital Pharmacy to acquire the best tolerated drugs by the patients, despite the higher costs, contributing to better patient compliance, treatment efficacy and patients' quality of life.

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Conflict of interest No conflict of interest

4CPS-121 EMERGENCY MEDICINE CLINICAL PHARMACIST'S INTERVENTIONS AND THEIR IMPACT ON PREVENTABLE ADVERSE DRUG EVENTS

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Background and importance Emergency departments (ED) with established emergency pharmacist programmes have reported on both cost savings and a perception among physician and nursing staff that medication safety and quality of care are improved. Thence, in ED, the involvement of clinical pharmacists can play an important part in the identification and reduction of preventable adverse drug events (ADEs).

Aim and objectives Evaluate the type and frequency of an emergency medicine (EM) clinical pharmacist's intervention (CPI) on physicians' prescribing and their effect on preventable ADEs.

Analyse the acceptance of CPI. These interventions were related to identifying, preventing and resolving drug-related problems.

Material and methods Retrospective observational study of all CPI completed on ED lodged (inpatient) adult (≥ 16 years old) prescriptions over 4 months in an academic hospital of 400 beds.

The National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) Index for Categorising Medication Errors Algorithm was used to categorise interventions. An ADE has been defined as "any harm associated with any dose of a drug".

Results A total of 645 CPI were collected in 607 patients (mean average of 1.23 ± 1.89 CPI per patient). Mean age was 77 ± 10.4 years and 69% were men. The acceptance rate was 90.4%; all CPI were conducted face-to-face with a physician. CPI most often pertained to anti-infective agents (40%), cardiovascular agents (17%), insulin (10%) and anticoagulants and thrombolytics (10%). The predominant intervention type were dose adjustment (35%), omission of regular medication on admission (30.5%), therapeutic substitutions (30%), initiating drug therapy (16.5%) and changes in route of drug administration (11%).

Of overall CPI, 42% were categorised as potential ADEs. The most common preventable ADEs intercepted were improper dose (56%) and frequency and route (23%).

The most common outcomes for interventions were reduction of preventable ADEs (45%) and optimisation of the therapeutic effects of the drugs that were administered (29%).

Conclusion and relevance This study demonstrated that adding EM pharmacists to the ED decreased significantly the rate of medication errors and potential ADEs. Also, working side-by-side would explain the good acceptance of the CPI by ED physicians. However, further study is needed to demonstrate the clinical pharmacist's contribution to the improvement of clinical and economic outcomes more comprehensively.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-122 OVERVIEW OF THE IMPACT OF PENICILLIN ALLERGY LABELS ON ANTIBIOTIC USE IN THE EMERGENCY DEPARTMENT

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Background and importance Many patients claim to be allergic to penicillin (Pen-A); however, only 10–25% of these are truly penicillin-allergic. It needs to be established if they are truly allergic (type-1 allergy) in order to indicate alternative antibiotics. Moreover, patients who do not have a type-1 allergy can safely receive cephalosporins or carbapenems, but having a label of Pen-A may be associated with prescription of broad-spectrum antibiotics (BSA), hospital stay duration and readmission.

Aim and objectives Assess the impact of Pen-A labels on antibiotic in an emergency department (ED).

Identify patients who remain appropriate candidates to receive beta-lactam therapy or cephalosporins, are mislabelled or may be dis-labelled with penicillin allergy skin testing (PST).

Material and methods Retrospective cohort study with ED cases treated with BSA from January 2020–January 2021.

Pen-A were identified by assessing all allergies in the electronic medical record. Each patient with a Pen-A label was matched for age, gender, BSA prescribed in ED and previous exposures to penicillin or cephalosporins.

PST may be considered if they meet any of the criteria recommended: history of Pen-A >10 years ago, frequent antibiotic use required, immunosuppressed state and history of infections caused by multidrug-resistant (MDR) bacteria.

Results A total of 287 patients (mean age 62 years; SD 16 years; 53% men) were enrolled.

The main antibiotic prescribed in Pen-A patients were quinolones (49%) and macrolides/lincosamides (21%). In 88% cases, antibiotic hospital guides suggested treatments with a cephalosporin.

Of 46 patients with Pen-A, 24 had non-type 1/non-severe reaction, 6 type 1 allergy/severe reaction, 4 without reaction (mislabelled) and 12 not documented. 37(80.4%) patients were treated previously with cephalosporins, whereas only 2 patients presented cross-reactivity. 30 (65.2%) patients met criteria to consider referring to PST, of which 67% had history of Pen-A >10 years ago, 60% required frequent antibiotic use, 13% were immunosuppressed and 9% had infections caused by MDR bacteria.

Conclusion and relevance Most patients, around 80% would have been spared the use of BSA if the Pen-A label had been assessed. Furthermore, most patients who had received cephalosporins did not have cross-reactivity. The introduction of PST could help correctly verify Pen-A in 65.2% patients. Hereinafter, ED pharmacist will be prepared to evaluate possible Pen-A to reduce the use of BSA and de-label when necessary.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-123 PERFORMANCE OF MOST COMMONLY USED EQUATIONS TO ESTIMATE GLOMERULAR FILTRATION RATE IN CRITICALLY ILL PATIENTS

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Background and importance Estimating glomerular filtration rate (GFR) in critically ill patients is challenging due to fluctuations in kidney function and creatinine production. Creatinine clearance computed from a 24-hour ($\text{CrCl}_{24\text{h}}$) urine collection cannot always be performed. Therefore, equations based on serum creatinine are commonly used to estimate GFR. However, it is still questionable which formula performs best in this setting.

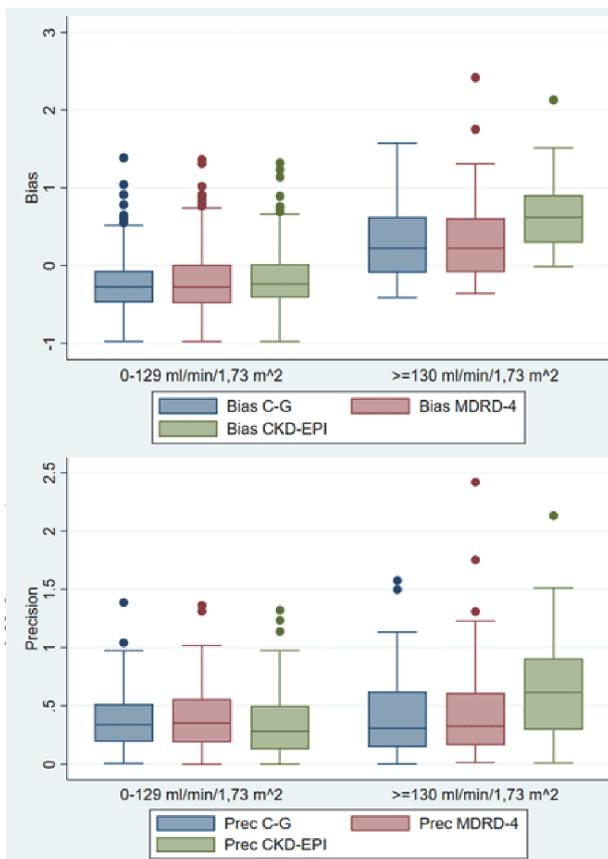
Aim and objectives We aimed to assess the performance of different serum creatinine-based equations to estimate GFR in critically ill patients.

Material and methods Observational retrospective study conducted in four intensive care units of a tertiary hospital from January to September 2020, consecutive patients with a measured $\text{CrCl}_{24\text{h}}$ were included. $\text{CrCl}_{24\text{h}}$ was compared to the most commonly used GFR estimating equations: Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI), Modification of Diet in Renal Disease (MDRD-4) and Cockcroft–Gault (CG). Pearson coefficients were estimated to evaluate the relationship between $\text{CrCl}_{24\text{h}}$ and CKD-EPI, MDRD-4 or CG. Bland and Altman plots, bias and precision were performed to contrast $\text{CrCl}_{24\text{h}}$ values with estimated GFR. Data were stratified into patients with $\text{CrCl}_{24\text{h}}$ between 0 and 129 mL/min/1.73m² and patients with an augmented renal clearance (ARC) ($\text{GFR} \geq 130$ mL/min/1.73m²).

Results 261 patients were included in the study (60.2% male, with a mean±SD age of 62±15 years and a serum creatinine of 1.23±1.00 mg/dL).

For the subgroup with GFR between 0 and 129 mL/min/1.73m², Pearson coefficients estimated for CKD-EPI, MDRD-4 and CG were 0.729, 0.637 and 0.680, respectively. Bland and Altman plots showed homogenous distribution for CKD-EPI and CG but were less homogenous for MDRD-4. No statistically significant differences were found between equations in terms of bias and precision.

For the subgroup with $\text{GFR} \geq 130$ mL/min/1.73m², Pearson coefficients estimated for CKD-EPI, MDRD-4 and CG were 0.312, 0.329 and 0.388, respectively. Bland and Altman plots showed homogenous distribution for CG and more heterogeneous distribution for CKD-EPI and MDRD-4. Bias was statistically different between CKD-EPI and both CG and MDRD-4 ($p=0.0032$) but precision was not (Figure 1).



Abstract 4CPS-123 Figure 1

Conclusion and relevance According to the data, no differences were found between formulas to estimate GFR for critically ill patients with a CrCl_{24h} between 0 and 129 mL/min/1.73m²; whereas for patients with ARC, CG and MDRD-4 seemed to be more appropriate for estimating GFR.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-124 COST OPTIMISATION PLAN IN IMMUNOTHERAPY

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Background and importance Three years ago, posology of nivolumab 3 mg/kg was modified in the Summary of Product Characteristics (SmPC) for a fixed dose (flat-dose) of 240 mg every 2 weeks or 480 mg every 4 weeks after showing equivalence.

Aim and objectives The aim of the study was to assess the potential cost savings if we used individualised dose by weight (3 mg/kg) and apply flat-dose (240 mg or 480 mg) in those patients weighing 80 kg or more.

Material and methods Retrospective study conducted in a second-level general hospital that included all patients treated with nivolumab during 1 year (2020).

A database was designed with the following variables: age, sex, weight, diagnosis, dosage regimen and drug costs expressed in laboratory sale price.

After applying the cost optimisation plan, the dosage of the patients was grouped according to weight: ≥80 kg use of flat-dose and <80 kg use of individualised dose of 3 mg/kg.

Costs of administering nivolumab according to an individualised dose of 3 mg/kg and the flat-dose regimen were calculated.

Results During the study period, 37 patients were treated with nivolumab, 29 received a fixed dose of 240 mg every 2 weeks and eight fixed doses of 480 mg monthly. Patients' mean weight was 71.1 kg (range 52–119). Drug's total cost was € 1 258 560 per year.

Applying the individualised dose of 3 mg/kg in all patients, the cost would be reduced to € 1 177 620, generating a saving of € 80 940.

Applying the individualised dose of 3 mg/kg and scheduling treatment administration on a single day a week, the cost would be € 1 116 558.75, obtaining a saving of € 142 002.

In addition to the above measures, setting the dose at 240 mg in those patients weighing ≥80 kg, the cost would be reduced to € 1 090 096.50, generating a saving of € 168 463.50. Applying this method, based on body weight, only six patients would maintain flat-dose while 31 would require an individualised dose.

Conclusion and relevance The use of individualised nivolumab doses may be a good strategy for optimising treatment costs. The combined use of flat-dose with individualised dose based on patients' weight would reduce the cost associated with nivolumab by 13.4%, corresponding to about € 168 000 per year.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-127 THERAPEUTIC DRUG MONITORING WITH BIOLOGICAL DRUGS IN THE TREATMENT OF INFLAMMATORY BOWEL DISEASE

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Background and importance Inflammatory bowel disease (IBD) is characterised by a chronic inflammation of the gut mucosa. About one-third of patients show primary non-response to biological agents, and up to 50% after an initial clinical response discontinue therapy due to secondary loss of response or a serious adverse event.

Therapeutic drug monitoring (TDM) plays an important role in optimising therapy for these patients.

Aim and objectives Assessing the outcome of optimising biologic drug therapy regimens based on serum dosing results in IBD patients.

Material and methods An observational, descriptive and retrospective study was conducted from 1 April 2018 to 31 August 2021. It included all the patients with IBD treated with biological agents (adalimumab, infliximab and vedolizumab), and this study was based on information contained in pharmaceutical records and clinical files.

A total of 71 patients were included. The study analysed the average treatment times of each drug in patients considered primary non-responders (PNR), as well as patients with secondary loss of response (SLR) to biological agents and the

subsequent therapeutic optimisation (dose escalation, interval reduction or therapeutic switch).

Results 58 patients remained in the first line of treatment. 12 patients needed one switch and 1 patient underwent 2 switches. The average number of drugs administered per patient was 1.2.

The overall mean times, in weeks of treatment, were 187 for adalimumab, 94 for infliximab, and 58 for vedolizumab. Patients who remained on the same drug showed a mean treatment time of 193 weeks for adalimumab and 106 for infliximab.

Regarding PNR, it only occurred with infliximab, in 8.1% (3/37) of patients, after an average of 35 weeks of treatment.

20 patients (28%) had undergone 23 therapeutic optimisations by SLR, distributed as follows: 6 increased doses, 2 reduced time interval and 15 therapeutic switches. The time to SLR was, in weeks, 189.5 for adalimumab, 53.3 for infliximab and 18 for vedolizumab.

Conclusion and relevance TDM allowed therapeutic optimisation of biological agents, enabling the maintenance of patients on the selected regimen for more time, and an early switch in PNR.

Serum determination of drug concentrations and antidrug antibody levels may be a good strategy for maintenance and/or optimisation of therapy.

REFERENCES AND/OR ACKNOWLEDGEMENTS

1. DOI: 10.1016/j.cgh.2019.03.037

Conflict of interest No conflict of interest

4CPS-131 SWITCHING AND DISCONTINUATION OF DISEASE-MODIFYING TREATMENTS IN MULTIPLE SCLEROSIS PATIENTS: EXPERIENCE IN A UNIVERSITY HOSPITAL

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Background and importance Currently, there are many approved disease-modifying treatments (DMTs) for the management of multiple sclerosis (MS) with variable potencies (first-line and second-line therapies), different schedules, mechanism of action, route of administration and side effect profile. None of them are curative. Modification between first-line DMTs or switching to second-line are proposed when the disease progresses, and no universal guidelines exist for switching therapies.

Aim and objectives To describe the reasons that brought about treatment modification in routine clinical practice with reference to: switch, temporary interruption or permanent discontinuation.

Material and methods During the retrospective study period (December 2019–December 2020) patients with relapsing MS were analysed.

Collected data were: age, sex, DMT before and after switch, reason for treatment modification, duration of initial therapy, number of changes.

Results Of 200 analysed patients, 106 had treatment modification, 69 were women, mean (SD) age was 39.9 (9.47) years.

82 patients had received one previous treatment with median duration 58 months, and 24 received at least two treatments.

8 patients had temporary interruptions (4 for pregnancy and 4 for other personal reasons) and none had permanent discontinuation. The main drugs used before the modification were the *interferons* IFN β -1a (50%) and IFN-1b (38%), and after the modification teriflunomide (33%) and natalizumab (44%). Reasons for treatment switch were unacceptable breakthrough disease activity (60 patients), treatment intolerance (35 patients) and JC virus (JCV) activation with progressive multifocal leukoencephalopathy risk (11 patients).

Of the patients with a suboptimal response, unfortunately 9 patients with duration of treatment more than 20 years converted to secondary progressive MS with permanent disability.

Regarding treatment intolerance, the most remarkable reasons were IFN-related flu-like symptoms, depression and injection site reactions.

Conclusion and relevance Modification between first-line DMT or escalation to higher potency therapies was a common occurrence during our study. Most patients were treated with first-line drugs before and after the modifications.

Lack of efficacy remains the main driving force behind switching. These results confirmed that some patients can experience disease activity despite injectable or oral DMTs, which necessitates escalating to a more potent treatment for preventing worsening of disability. Determining which DMT is best for which patient and when to switch remains a major challenge, and the patient's personal preferences should be considered.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-133 ANALYSIS AND EVALUATION OF PHARMACEUTICAL INTERVENTIONS PERFORMED IN THE EMERGENCY DEPARTMENT

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Background and importance The emergency department (ED) has been described as a dynamic and complex environment vulnerable to medical errors.

The clinical pharmacist (CP) has proven to be a key part of the multidisciplinary team for improving the quality and safety of patient care.

Services provided by pharmacists in the ED include traditional clinical pharmacy services, responding to medical emergencies, providing consultations on medication issues and identifying drug-related problems.

Aim and objectives To analyse and evaluate the CP's interventions in the ED.

Material and methods A descriptive prospective study of the CP's interventions performed in a 2-month-work rotation period in the ED was performed. The study was conducted in a 400-bed hospital that serves a population of 250 000 inhabitants.

The following variables were collected: type of pharmaceutical intervention, pathology associated with IP, proactive intervention (yes/no) and acceptance of the intervention (yes/no).

A database was designed to record the interventions that were carried out during the study period and data were processed with Microsoft Excel.

Results A total of 308 interventions were recorded in the period of study classified as:

- – Prescription suggestion (n=2).
- – Adequacy of treatment (n=46): dose or pharmaceutical presentation adjustments (n=20), antibiotic therapy (n=26).
- – Prevention of adverse reactions (n=11): contraindication (n=1), inappropriate doses (n=2), duplications (n=3), interactions (n=2), analytical monitoring recommendation (n=3).
- – Support tasks (n=244): medication reconciliation (n=242), drug information to the physician (n=2).
- – Others (n =5).

90.5% were proactive interventions and 99% of them were accepted by the physician.

The main pathologies involved were: psychiatric (18.8%), cardiovascular (16.5%: hypertension (9.8%) and atrial fibrillation/heart failure (6.7%)), endocrine (11.2%: diabetes (5.8%), dyslipidaemia (3.6%), hypothyroidism (1.8%)), respiratory (10.3%), gastrointestinal (5.4%), non-classified pain (5.4%), glaucoma (4%), onco-haematological (2.7%), neurological (2.2%) and dermatological (1.8%).

Conclusion and relevance The number of CP's interventions carried out during the study period is optimal, when compared with data from other studies carried out. The major part of the CP interventions were based on medication reconciliation. In a very high percentage of cases, the pharmacist works proactively and his interventions are almost always accepted.

This study demonstrates the role and importance of the pharmacist incorporated into the ED multidisciplinary team.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-134 OPTIMISATION OF DENOSUMAB PRESCRIPTION IN OSTEOPOROSIS PATIENTS

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Background and importance Bisphosphonates should be the first choice for osteoporosis treatment, with lower cost and no less benefit than denosumab.

Aim and objectives To evaluate the indication for treatment with denosumab and to develop proposals for optimising osteoporosis treatment.

Material and methods Cross-sectional study in a primary care area (8 centres). Data from the ECAP digital medical record of denosumab-treated patients during January 2020 were reviewed by the Pharmacy Service. Variables: demographic (age and sex), diagnosis, bone mineral density (BMD) and previous fractures, indication, previous treatment and adherence.

Results A total of 394 denosumab-treated patients, aged 74.9 ± 9.6 years, 92.6% women, were included. BMD T-score was ≤ -2.5 (indicative of osteoporosis) in 48.3% of men and 64.1% of women, while it was > -2.5 in 6.9% of

men and 14.8% of women. There was no densitometric test in the remaining patients. The most prevalent previous fracture in men was hip fracture (31%), while previous fracture was not present in most women (49.6%). Other fractures in men: 27.6% none, 24.1% vertebral, 17.3% ≥ 2 vertebral. In women: 16.7% ≥ 2 vertebral, 13.7% vertebral, 13.4% hip, 6.6% peripheral. Therefore, 80.8% of patients actually suffered from osteoporosis, while 19.2% had no true diagnosis. Osteoporosis patients receiving denosumab without a clear indication were 47.1%. Some 63% received prior treatment and 72.6% were adherent. Regarding those with an indication, 54.9% were due to ≥ 2 previous vertebral or hip fractures, 21.3% to adverse effects or poor adherence to bisphosphonates, 7.9% to chronic corticosteroid therapy, 7.4% to incident hip fracture or increased risk of fracture with age between 65 and 70 years, 5% to digestive alteration that contraindicates the use of therapeutic alternatives, and finally 3.5% to glomerular filtration < 35 mL/min/m². Denosumab should be withdrawn in 22% of patients and it should be changed to bisphosphonate in 25.1%, thus leading to a theoretical €75 100 annual saving.

Conclusion and relevance Denosumab should be withdrawn or replaced in 47.1% of patients. The proposals of the clinical pharmacist contribute to safe drug use and health system efficiency. It would be necessary to know the final implementation of the proposals by rheumatologists, which were pending due to the COVID-19 pandemic.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-137 PROSPECTIVE ANALYSIS OF CLINICAL PHARMACIST INTERVENTIONS FOR QT DRUG-DRUG INTERACTIONS ALONGSIDE CLINICAL DECISION SUPPORT

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Background and importance Drug-drug interactions leading to QT prolongation and potentially fatal torsades de pointes arrhythmias (QT-DDIs) are very common. Clinical decision support (CDS) triggers alerts for such QT-DDIs to warn physicians while prescribing. An additional safeguard mechanism is real-time follow-up of all alerts by clinical pharmacists who intervene by telephone when necessary.

Aim and objectives The first objective was the evaluation of the alert acceptance of QT-DDIs and QT interventions over a period of 5 years (2016–2020). The second objective was to evaluate the risk profile of patients with a QT intervention.

Material and methods In a tertiary hospital, QT-DDIs and pharmacist interventions were prospectively registered in a Microsoft Excel database. Possible interventions were electrocardiogram (ECG) or electrolyte monitoring, therapy change (eg, drug switch), the choice between monitoring and therapy change, and drug (re)initiation. Measured risk factors were female sex, age > 65 years, impaired renal function (creatinine clearance < 60 mL/min), electrolyte disturbances (potassium, calcium or magnesium), structural heart disease, number of

QT prolonging drugs, bradycardia, no recent ECG, recent prolonged QT interval. Three types of acceptance were evaluated: CDS alert acceptance, telephone acceptance (ie, oral confirmation by physician) and intervention acceptance. Chi-square tests were used to compare frequencies.

Results In total, the CDS triggered 11 084 QT-DDIs, of which 2679 (24.2%) alerts were accepted. Pharmacists intervened for 192 QT-DDIs (1.7% of all QT-DDIs) with a telephone acceptance of 177 (92.2%). When verified in the patient records, the true intervention acceptance was significantly lower (145, 75.5%; $p=0.037$). Of 192 interventions, monitoring was advised for 85 (44.3%), therapy change for 51 (26.6%), and re/initiation for 31 (16.1%). There was no significant difference in intervention acceptance between the intervention types ($p=0.087$). On average, patients with a QT intervention had five risk factors. The most prevalent risk factors were age >65 years (121, 63.0%), structural heart disease (120, 62.5%), female sex (88, 45.8%) and prolonged QT interval (88, 45.8%).

Conclusion and relevance Telephone acceptance was very high, which can be interpreted as the pharmacist interventions being highly appropriate and complementary to CDS alerts. However, reasons for the difference between telephone acceptance and intervention acceptance need to be explored.

REFERENCES AND/OR ACKNOWLEDGEMENTS

K Muylle and S Wuyts contributed equally.

Conflict of interest No conflict of interest

4CPS-138 THERAPEUTIC DRUG MONITORING OF INTRAVENOUS BUSULFAN IN PAEDIATRIC PATIENTS

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Background and importance Busulfan is a chemotherapeutic drug used in preparative regimens for hematopoietic stem cell transplantation in adults and children for different diseases. Its efficacy and safety could be affected by its narrow therapeutic range and its pharmacokinetic variability, making therapeutic drug monitoring essential to optimise treatments.

Aim and objectives To analyse the impact of therapeutic drug monitoring on busulfan treatments in our centre during the last 10 years.

Material and methods We conducted a retrospective observational study in paediatric patients treated with intravenous busulfan between 2010 and 2020 in a bone marrow transplantation unit.

We recorded demographics (age, sex, weight, baseline disease), treatment (type of conditioning protocol, dose by weight), drug monitoring (need for dose modification, number of necessary adjustments, percentage of variation between received dose and theoretical dose), efficacy (incidence of implant failure) and safety variables (incidence of sinusoidal obstruction syndrome).

For pharmacokinetic studies we applied a nonlinear regression method and used ID3 software. Area under the curve target was 55 000–95 000 ng/mL×hour, depending on the conditioning protocol (reduced intensity or myeloablative).

Abstract 4CPS-138 Table 1

	Myeloablative (N=39)	Non-myeloablative (N=6)	Global (N=45)
Patients with dose variation	33	6	39
Reductions	21	3	24
Median change (IQR)	-7.5% (-15.1 to -4.2%)	-6.8% (-10.6 to -3.8%)	-7.1% (-15.0 to -4.0%)
Increases	12	3	15
Median change (IQR)	11.4% (9.1 to 17.5%)	10.7% (9.3 to 11.7%)	11.4% (8.9 to 14.8%)

Results We included 45 patients with ages between 4 months and 16 years. They received 43 allogeneic and two autologous transplantations. Baseline diseases in the allogeneic group were 23 malignant and 20 non-malignant haematological diseases while in the autologous group there were two neuroblastomas. Regarding the conditioning regimen, 38/45 were myeloablative and 7/45 non-myeloablative.

Busulfan initial doses ranged from 3.2 and 5.1 mg/kg/day (related to adjusted body weight), according to the protocol and the weight band. All patients received seizures prophylaxis.

Eight patients presented implant failure (five received myeloablative conditioning). Four patients presented sinusoidal obstruction syndrome (all received myeloablative conditioning).

Conclusion and relevance These data show high variability in the direction and magnitude of adjustments made to assure a busulfan exposure within the desired range. Busulfan monitoring is an essential tool to optimise treatments and to improve its efficacy and safety.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-139 ADEQUACY ANALYSIS OF PROPHYLACTIC TREATMENT OF EPISODIC AND CHRONIC MIGRAINE IN PATIENTS WHO START ANTIMIGRAINE BIOLOGICALS

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Background and importance After the appearance of migraine biological drugs, some criteria have been established for their rational use and efficiency. There are many drugs for migraine prophylaxis but there are very few for which clear evidence has been presented, so we will try to provide data in this regard.

Aim and objectives To determine the adequacy of prophylactic treatment and compliance with the financing conditions for antimigraine monoclonal antibodies in our hospital.

Material and methods Retrospective observational study involving all the patients that had started treatment in our hospital with any of the monoclonal antibodies: erenumab, fremanezumab and galcanezumab. The duration and tolerance of all migraine prophylaxis treatments were recorded. Prophylactic treatments were considered adequate according to whether or not they had a therapeutic indication in the technical sheet in

Spain. Being consider as low evidence drugs the rest of them. Finally, compliance with the funding criteria set by the Health Ministry to start monoclonal antibody treatment was determined: having 8 or more days of migraine/month and having failed at least three prophylactic treatments for at least 3 months, one of them being botulinum toxin in the case of chronic migraine.

Results A total of 38 patients (79% women) started treatment with antimigraine biologics. The average number of prophylactic treatments was 3.9 and only one patient did not receive the minus 3. 10.5% reported some type of intolerance with any of the treatments. The duration of treatment reached at least 3 months in 78% of the patients and exceeded 6 months in 48%. 43% of the drugs used in prophylaxis had an indication. In the 57% of patients that received drugs without indication, the following were used: pregabalin (5), valproic acid (4), diazepam (2), candesartan (1), levetiracetam (1), citalopram (1), zonisamide (1), tizanidine (1) and Lisinopril (1). 14 patients (37%) did not meet the funding criteria: 8 for not having reached 3 months of treatment, 3 for presenting less than 8 MMD and 2 for presenting chronic migraine and not having received botulinum toxin A.

Conclusion and relevance More than half of the patients (57%) received drugs without indication for migraine prophylaxis and more than a third (37%) did not meet the funding criteria for these biological drugs. The work of the hospital pharmacist could improve the adequacy of treatment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-142 EFFECTIVENESS AND SAFETY OF ATEZOLIZUMAB IN METASTATIC UROTHELIAL CARCINOMA

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Background and importance Few options exist for patients with metastatic urothelial carcinoma (MUC). Atezolizumab, an anti-PD-L1 immune checkpoint inhibitor, has been shown to reduce tumour size in patients who have been treated with platinum chemotherapy or who are not eligible for such treatment in MUC.

Aim and objectives To evaluate the effectiveness and safety of atezolizumab in MUC in real clinical practice, comparing the results with the pivotal clinical trial IMvigor211.

Material and methods This was a retrospective observational study including all patients with MUC treated with atezolizumab, between January 2018 and October 2021. Variables included were age, sex, smoking status, Eastern Cooperative Oncology Group (ECOG), line of treatment, cycles received, duration and causes of treatment discontinuation (progression, toxicity, death). Effectiveness was assessed by the Kaplan–Meier method (SPSS v25.0) in terms of progression-free survival (PFS) and overall survival (OS). Adverse effects (AE) were collected and classified according to the *Common Terminology Criteria for Adverse Events* (CTCAE) scale v5.0.

Results 33 patients (87.9% men) were included. Median age was 67 (53–85) years. 24.2% were smokers and 66.7% former smokers. All patients had ECOG \leq 1 at the beginning of

treatment. Treatment line of atezolizumab: 12.1% firstline, 72.7% secondline, 12.1% thirdline and 3% fourthline. 87.9% received at least one previous platinum-based line. Median of cycles received and duration of treatment were 5 (1–21) and 4 months, respectively. 81.8% of the patients discontinued therapy: 21.2% due to death and 60.6% due to progression. Median PFS and OS were 5 months (95% CI 3.9 to 6.1) and 15 months (95% CI 1.7 to 28.3), respectively. In IMvigor211, median PFS and OS were 2.1 and 8.6 months, respectively. 39.4% of patients had AE only grade 1–2. The most common AE were pruritus (n=6), asthenia (n=3), oedema (n=3), constipation (n=2) and neuropathy (n=2). In IMvigor211, 95% had AE (55.8% \geq grade 3) and the most common of any grade were fatigue, pruritus and asthenia.

Conclusion and relevance The effectiveness results observed in real clinical practice appear to be superior to those obtained in the pivotal study, although our sample size and design are limited. The safety profile appears to be better than IMvigor211 with a similar toxicity profile.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-145 EFFECTIVENESS AND SAFETY OF BARICITINIB AND TOFACITINIB IN RHEUMATOID ARTHRITIS IN CLINICAL PRACTICE

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Background and importance Baricitinib and tofacitinib are Janus kinase inhibitors indicated in rheumatoid arthritis (RA) with a demonstrated effectiveness and safety in various clinical trials.

Aim and objectives To evaluate the effectiveness and safety of baricitinib and tofacitinib in patients diagnosed with RA in clinical practice.

Material and methods Retrospective descriptive study that included patients with RA treated with baricitinib or tofacitinib between September 2018 and September 2021. The data were obtained from the review of clinical and analytical histories in Diraya. The variables collected were: age, sex, previous treatment, C-reactive protein (CRP), erythrocyte sedimentation rate (ESR) and follow-up time. To evaluate the effectiveness, the decrease in the value of the inflammatory parameters (ESR and CRP), the reduction in the number of painful joints, the remission of the disease, the dose reduction and the treatment changes were taken into account. Safety was determined based on the adverse reactions (ARs) described.

Results 32 patients with a median age of 55 years were evaluated. 21 received treatment with baricitinib (15 women) and 11 with tofacitinib (10 women). The median treatment time was 18 months. The median of previous treatments in patients with baricitinib was 2 biologics and for patients with tofacitinib of 1 biological. In 13 patients with baricitinib and in 4 with tofacitinib there was a reduction in inflammatory parameters. Baricitinib decreased the number of painful joints in 15 patients and tofacitinib in 11. There was remission in 15 patients treated with baricitinib (of which 5 reduced doses) and in 10 with tofacitinib. 6 ARs related to the use of baricitinib (2 weight gains, 1 neutropenia, 1 herpes zoster, 1

interstitial pneumonia and 1 anxiety attack that forced a change in treatment) and 5 with the use of tofacitinib (1 herpes zoster, 1 dry lip, 1 tinnitus, 1 oedema and 1 dyslipidaemia). Of the 21 patients with baricitinib, 4 changed treatment due to ineffectiveness (2 to tofacitinib and 2 to biologics), and of the 11 treated with tofacitinib 2 switched to biologics and 1 suspended treatment due to cardiovascular risk.

Conclusion and relevance In our clinical experience, baricitinib and tofacitinib are shown to be effective in the treatment of RA, with a good safety profile.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-146 DEVELOPMENT AND VALIDATION OF A RAPID HIGH-PERFORMANCE LIQUID CHROMATOGRAPHY METHOD (HPLC) FOR THE DETERMINATION OF TRIAZOLES IN HUMAN PLASMA

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Background and importance The incidence of invasive fungal infections has increased significantly. Triazoles are the antifungals of choice for pulmonary aspergillosis, but they have a high intra- and interindividual variability in pharmacokinetics and are associated with a large number of interactions, thus requiring analytical techniques that allow therapeutic drug monitoring to ensure the effectiveness and safety of these drugs.

Aim and objectives The aim of this study was the development and validation of a high-performance liquid chromatography (HPLC) method for measuring voriconazole, isavuconazole and posaconazole in human plasma using tioconazole as an internal standard.

Material and methods The system consisted of an Agilent 1260 Infinity chromatograph with an ultraviolet diode array detector (UV-DAD). The column used was a Kinetex F5 4.6 × 150 mm, 5 µm (Phenomenex, USA). The method was validated according to the Food and Drug Administration (FDA) bioanalytical method validation guidance. The analysis run time for all drugs was 7.5 min. The chromatographic conditions are shown in Table 1. To process the samples were taken 100 µL of internal standard, 200 µL of plasma and 300 µL of acetonitrile. Then, they were homogenised for 30 s and centrifuged at 15 000 g for 5 min.

Results The results are shown in Table 2.

Conclusion and relevance A method has been validated for the determination of triazoles by HPLC in human plasma that

Abstract 4CPS-146 Table 2 Validation parameters according to FDA guidance

Analyte	Rt (min)	Equation	R ²	Within-day mean (µg/mL) (%VC)			Between-day mean (µg/mL) (%VC)		
				Low	Medium	High	Low	Medium	High
Voriconazole	3.7	y= 0.2363x-0.0083	0.9992	1.56 (3.6)	3.47 (1.3)	6.57 (0.6)	1.56 (4)	3.43 (1.5)	6.51 (0.6)
Isavuconazole	5.8	y= 0.6567x+0.0326	0.9999	1.38 (0.6)	4.82 (0.1)	9.19 (0.1)	1.43 (1.2)	5.14 (0.2)	9.12 (0.6)
Posaconazole	4.1	y= 0.6485x+0.0008	0.9989	0.51 (0.8)	1.04 (1.27)	1.39 (0.8)	0.47 (1.23)	0.91 (2.3)	1.29 (1.24)

will allow therapeutic drug monitoring to be performed in target patients.

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Conflict of interest No conflict of interest

4CPS-147 EXPERIENCE OF USE OF BIOLOGICAL ANTIMIGRAINE TREATMENTS IN CLINICAL PRACTICE

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Background and importance The comparative efficacy and safety of antimigraine monoclonal antibodies (mAb) is not known in clinical practice.

Aim and objectives Describe the clinical experience of using mAb in migraine management.

Material and methods Retrospective descriptive research of patients with migraine treated with erenumab, fremanezumab or galcanezumab between October 2019 and September 2021. All patients had 8 days of migraine monthly and 3 failures to prophylactic treatments, one of these being botulinum toxins. In all cases, the administration was monthly with a dose of 70 or 140 mg for erenumab, 225 mg for fremanezumab and 120 mg for galcanezumab (after a single dose of 240 mg the first month). Efficacy was evaluated at 12 weeks and considered: reduction of monthly headache days, reduction to 50% of the number of attacks, decrease in the consumption of symptomatic medication, and discontinuation.

Abstract 4CPS-146 Table 1 Chromatographic conditions of methods

Analyte	Mobile phase	λ (nm)	Calibration range (mg/mL)	Flow (mL/min)	Temperature (°C)	Injection volume (mL)
Voriconazole	60% Buffer (KH ₂ PO ₄ 0.05 M pH=3.5)/40% acetonitrile	254	1–7	1	25	40
Isavuconazole	50% Buffer (KH ₂ PO ₄ 0.05 M pH=3.5)/50% acetonitrile	260	0.5–10	1	25	50
Posaconazole	50% Buffer (KH ₂ PO ₄ 0.05 M pH=3.5)/50% acetonitrile	260	0.3–1.5	1	25	50

Results We included 37 patients, 33 with chronic migraine and 4 with episodic. 81% were women, with an average age of 51 ± 9 years, 13 received erenumab, 20 fremanezumab and 4 galcanezumab. Erenumab reduced the number of headache days by an average of 18 days in 7 patients, and the number of attacks halved in 8 and the consumption of symptomatic medication in 7. Only 14 patients with fremanezumab reached 12 weeks of therapy, 13 decreased the number of migraine days/month by an average of 11 days, 3 reduced the number of attacks by half, and 5 the consumption of symptomatic medication. Only 2 of 4 patients treated with galcanezumab decreased the number of days of migraine an average of 16 days, halved the number of attacks and the consumption of symptomatic medication. Treatment was discontinued for ineffectiveness in 12 patients (7 with erenumab, 3 with fremanezumab and 2 with galcanezumab). The most frequent adverse effects common to the three mAb were constipation and administration-related reactions. Erenumab also produced paresthesia (23%) and asthenia (8%).

Conclusion and relevance Taking into account that the number of patients was similar in both groups, fremanezumab has a better clinical benefit in reducing the number of days of migraine, and erenumab in reducing the number of attacks by half, and decrease the consumption of symptomatic medication, being generally well-tolerated drugs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-148 USE OF REMDESIVIR IN SEVERE SARS-COV-2 PNEUMONIA IN CRITICALLY AND NON-CRITICALLY ILL PATIENTS

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Background and importance Severe SARS-CoV-2 pneumonia (COVID-19) is causing an increasing number of deaths worldwide because no effective treatment is currently available. Remdesivir has shown *in vitro* activity against coronaviruses and is being used as an antiviral treatment for COVID-19.

Aim and objectives To evaluate the use and results of remdesivir treatment in hospital settings.

Material and methods A retrospective study was conducted at an 800-bed hospital and involved patients with COVID-19, between March 2020 and June 2021, aged over 18 years, and undergoing treatment with remdesivir. We extracted information from the hospital files, Soarian and Hosix VB and the database was analysed using Excel 5.0, using descriptive and inferential statistics.

Results The 199 patients enrolled in the study were mainly men, staying in medical wards and intensive care units (ICU) and with an age average of 65 years. Of the 84% patients that finished the treatment with remdesivir, 157 completed a 5-day course and 11 patients completed a 10-day course. Of the 16% patients that interrupted the treatment, all due to adverse events, most were in medical wards and, of these, 67% were discharged and 25% died. In those staying in ICU that suffered adverse events, 20% were discharged and 40% died. Overall, the main adverse events were hypertransaminasemia, bradycardia and acute kidney injury. All patients with hypertransaminasemia improved, but half of the patients that stopped the treatment with remdesivir due to bradycardia

died. Of all the patients, 77% were discharged, but 20% died. Of the group of patients who died, 77% were in ICU and 21% had adverse events with remdesivir. We found a significant relationship between ICU stay and patients who completed the treatment ($p=0.022$, $p<0.05$) and also with age above 75 years ($p=0.027$, $p<0.05$).

Conclusion and relevance As expected, most of the patients who died were in ICU and 16% suffered adverse events. Nonetheless, our data suggest that remdesivir can benefit non-critically ill patients with COVID-19, where clinical improvement was observed in 77% of the patients with discharged. Adverse events were less frequent, but when they occurred, they were mainly hypertransaminasemia and bradycardia. It is expected that ongoing randomised controlled trials will clarify its real efficacy and safety, and who and when to treat.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-149 HOSPITAL AT HOME COVID UNIT: MULTIDISCIPLINARY STRATEGIES

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Background and importance The COVID-19 pandemic has had a dramatic impact on worldwide health services. Clinical treatments, hospitalised patient management and the need to guarantee the quality of care for COVID-19 patients were the main challenges.

The Hospital at Home (HaH) Unit has already demonstrated efficacy, safety and economic advantage compared to conventional hospitalisation. To reduce the pressure of care in hospitals caused by the pandemic, the HaH COVID Unit was created.

Structuring a multidisciplinary team is essential to ensure the best results, reduce mortality and ensure the response in the control of the pandemic. In this sense, pharmacists were involved in developing COVID-19 treatment protocols (C19TP) for patients transferred to the HaH COVID Unit to finish their therapy (corticotherapy and antibiotherapy) at home.

Aim and objectives Characterise C19TP and strategies implemented to optimise medication dispensing for COVID-19 patients.

Material and methods Clinically stable COVID-19 patients were admitted to complete home C19TP between April 2020 and August 2021. On average, medication was dispensed for 5 to 7 days. The developed strategies were:

- Multidisciplinary cooperation in monitoring COVID-19 patients mostly through telemonitoring and telephone consultations
- Ensure availability and safe use of drugs
- Perform protocols for therapeutic management of COVID-19 patients.

Results 165 patients were admitted to the HaH COVID Unit (21 in 2020 and 144 in 2021) to complete the C19TP.

The therapy mostly included corticosteroid therapy (28.6% in 2020 and 70.8% in 2021) and antibiotherapy (85.7% in 2020 and 22.9% in 2021), highlighting the recommended

therapeutic changes throughout the pandemic. It should be noted that 2 patients completed antiviral therapy with remdesivir at home. Strategic implementation of home visits clearly impacts on the hospital beds' capacity.

Conclusion and relevance HaH COVID Unit is a safe and effective option in carefully selected patients with COVID-19.

Collaborative and multidisciplinary management could have a great impact on the improvement of healthcare provided to COVID-19 patients.

Pharmacists should actively participate in therapeutic decisions, in the formulation and adjustment of therapeutic regimens for COVID-19 patients, ensuring the monitoring, evaluation of the safety of the medication, efficacy and management of drug interactions.

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4CPS-150 ABILITY TO ASSESS ACUTE KIDNEY INJURY IN PATIENTS ADMITTED TO HOSPITAL

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Background and importance Different criteria were created to identify acute kidney injury (AKI) based on serum creatinine (SCr) levels, namely AKIN, KDIGO, RIFLE.

Aim and objectives To assess the ability to monitor AKI occurrence based on the availability of timely measured SCr levels in a retrospective cohort of patients admitted to hospital.

Material and methods Data from patients admitted to hospital between 1 June 2018 and 31 December 2020 were collected. AKI stage was calculated for each patient based on the AKI staging cut-offs using the three major guidelines (RIFLE, AKIN and KDIGO) and five criteria. In a first analysis, time to reach the SCr cut-off was ignored. In a second analysis, patients reaching any AKI stage were re-evaluated considering the time recommended between SCr tests: 48 hours AKIN and 7 days RIFLE and KDIGO. Descriptive analyses of the AKI stage allocation were performed.

Results During 31 months, 25 777 admissions occurred corresponding to 18 935 patients (4112 patients with more than 1 admission; range 1–18). Mean age of admissions was 60 years (SD 27), 14 146 (54.9%) were female and the mean length of stay was 10 days (SD 16); 63 admissions had a duration <24 hours. During 263 969 bed-days, 81 892 SCr tests were recorded, representing 1 test per 3.22 bed-days. In 4407 admissions (17.1%) no SCr test was recorded. The first SCr test was done on average 2.2 days (SD 2) after admission. A total of 6958 tests increased 0.3 mg/dL from baseline and 1500 tests increased 1.5–2 times their value (stage 1); of these, 1689 and 323 exceeded the 48 hours, and 103 and 29 the 7 day-interval, respectively. In 1618 tests, baseline increased 2–3 times (stage 2) with 363 over 48 hours and 33 over the 7-day interval. In 477 tests, baseline increased more than three times and in 166 increased 4.0 mg/dL (stage 3),

where 105 and 39 were over 48 hours and 10 and 4 were over the 7-day interval, respectively.

Conclusion and relevance To accurately monitor AKI, hospital pharmacists need access to SCr levels of inpatients measured at least every 48 hours.

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Conflict of interest No conflict of interest

4CPS-151 EVALUATION OF CASPOFUNGIN USE IN THE PAEDIATRIC HAEMATOLOGY WARD OF THE NATIONAL BONE MARROW TRANSPLANT CENTRE

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Background and importance Invasive fungal infections are becoming frequent in hospitals and present a major mortality cause for transplanted patients. With the systemic emergence of these fungemia, caspofungin consumption is increasing greatly and consequently so are the pharmaceutical expenses in our establishment.

Aim and objectives To evaluate caspofungin prescriptions in the National Bone Marrow Transplant Centre (NBMTTC), the indications, treatment duration and estimates of the treatment cost.

Material and methods A 5-month retrospective study from March to July 2021 in the paediatrics ward of 545 prescriptions for 19 patients where a data collection sheet was elaborated and validated for each new prescription. Data were processed afterwards and the results explored with Microsoft Excel Professional Plus 2016.

Results 95% of prescriptions adhere to the drug marketing authorisation (MA) approved indications (neutropenic fever, *Candida* and *Aspergillus* documented infections) and 5% use outside the MA, a mucormycosis. Average treatment duration was 25 days, with a 15-day average neutropenic fever and invasive candidiasis and a 63-day average for documented invasive aspergillosis. 32% of the treatment cost was attributed to post-transplant complications while 63% were costs for non-transplanted chemotherapy patients' 'complications'. In total the use of caspofungin cost € 290 580, 51% of which were expenses to be paid by the National Health Insurance Fund and 49% to be paid in full by the NBMTTC.

Conclusion and relevance With the high cost of caspofungin treatment and the type of patients treated at the NBMTTC (immunosuppressed, transplanted, undergoing chemotherapy) a better optimisation of caspofungin use seemed inevitable and indispensable, starting by implying guidelines for a stricter control of the empirical treatment prescriptions and the regular follow-up of treatment durations and necessity of use of caspofungin.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-153 REMDESIVIR USE AND EFFICACY IN PATIENTS WITH SEVERE SARS-COV-2 PNEUMONIA

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Background and importance Remdesivir is a viral RNA polymerase inhibitor. After the NIAID ACTT-1 study results, it currently is an antiviral medicine used to treat coronavirus disease 2019.

Aim and objectives Describe use of remdesivir based on current epidemiological trends.

Describe results of use of remdesivir in clinical practice.

Compare our research results with those of the NIAD ATCC-1 study.

Material and methods Retrospective observational study, all patients treated with remdesivir were included for two study periods: first stage (July–December 2020) and second stage (January–March 2021). Demographic and clinical variables were collected. Data were obtained from electronic medical records and prescription applications. Nineteen patients were included in the study.

Results

At the beginning (n (%))		1st stage (n=14)	2nd stage (n=5)
Median age (years)		57.2	56.8
Sex	Female	5 (35.7)	2 (40)
	Male	9 (64.3)	3 (60)
Prescription	ICU	6 (43)	1 (20)
	No ICU	8 (57)	4 (80)
Charlson Comorbidity Index		2.94	2.90
Symptom days		6.1	5.9
Days of treatment		5	5
Treated with dexamethasone		10 (71.4)	4 (80)
Oxygen saturation		90.7	92.6
Respiratory support		14 (100)	3 (60)
Type of respiratory support	Vmask (30–60%)	3 (21.4)	1 (20)
	Nasal prongs	11 (78.6)	2 (40)
Total admission days		11.5	10
At 28 days (n (%))		1st stage (n=14)	2nd stage (n=5)
Respiratory support		3 (21.4)	0 (0)
Died		1 (7.14)	0 (0)
Not hospitalised		9 (64.3)	5 (100)

Conclusion and relevance In both stages remdesivir was used in a similar way in patients with similar basal characteristics. Treatment days were 5, instead of 10 days as in the pivotal study, due to regulation of Spanish health officials' instructions in patients who did not require mechanical ventilation.

Patients treated with remdesivir presented a recovery time with an average of 11.5 and 10 days, respectively. These data matched those of the previous study.

Similar to previous research, lack of a control group and the small sample size must be mentioned, and because of this the magnitude of clinical benefit could not be estimated.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-154 STEVENS–JOHNSON SYNDROME IN A PREGNANT WOMAN CAUSED BY PYRIMETHAMINE AND SULFADIZINE

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Background and importance Stevens–Johnson syndrome (SJS) is a rare and serious skin drug reaction and the pathogenesis includes genetic factors. If it occurs in pregnant women, both conditions can simultaneously affect the mother and the fetus.

Aim and objectives To determine the contribution of the pharmacist in the treatment of rare side effects of drugs.

Material and methods Small cystic images were identified in a 42-year-old pregnant woman (28+1 weeks) by ultrasonography and neurosonography. A transplacental amniocentesis was offered to rule out infections and *Toxoplasma gondii* polymerase chain reaction (PCR) in amniotic fluid was positive. The patient began oral treatment with pyrimethamine tablets 50 mg/24 hours, sulfadiazine 1500 mg/12 hours and folic acid 7.5 mg/24 hours orally.

12 days after starting treatment, the pregnant woman attended the emergency department of our hospital due to the appearance of a skin rash on the abdomen and lower extremities, skin irritation and fever, and therefore admission was decided.

Results The patient presented feverish peaks during admission with worsening of the rash and painful laterocervical lymphadenopathy. In addition, she had anaemia, leukopenia, and thrombocytopenia attributed to this treatment. She was suspended from treatment with pyrimethamine and sulfadiazine due to suspected toxicity. The diagnosis was oriented to SJS secondary to pyrimethamine and sulfadiazine. Due to the worsening and the clinical dermatological severity of the patient, after consulting the pharmacist, it was considered necessary to start cyclosporine 120 mg every 12 hours (2 mg/kg/12 hours) intravenously (off-label use). She was finally referred to another hospital due to the worsening of the SJS. During admission, treatment with cyclosporine was not maintained, there was a progressive improvement in the skin lesions, and she was discharged due to a favourable evolution of the skin lesions.

Conclusion and relevance The pharmacist validated the treatments during the patient's hospital stay and reviewed the interactions and adverse reactions associated with the prescribed treatments, confirming the possible causality of SJS by pyrimethamine and sulfadiazine. The pharmacist performed a bibliographic search and the benefit–risk balance of medications in special situations was evaluated. Finally, it should be noted that few cases of SJS have been reported during pregnancy, so the pharmacist notified the Spanish Pharmacovigilance System for Medicinal Products for Human Use.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-155 APPROPRIATENESS OF PHARMACOTHERAPY IN NURSING HOMES: PHARMACY AND GERIATRICS SERVICES COORDINATION PROJECT

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Background and importance Potentially inappropriate prescriptions (PIPs) in elderly persons lead to increased morbidity and mortality, greater number of hospital admissions and use of healthcare resources. The periodic clinical review of the prescriptions is necessary to adapt the pharmacotherapy to the current situation of the patient, and the incorporation of the pharmacist in the multidisciplinary team is therefore essential.

Aim and objectives Appropriateness of pharmacotherapy (AP) and analysis of the interventions carried out in elderly patients from nursing homes (NHs) with polypharmacy.

Material and methods Prospective study carried out from October 2020 of a programme of AP in polymedicated patients of NHs, through the implementation of a project for the coordination of Geriatrics, Pharmacy and NHs from a university hospital. The pharmacist carried out a pharmacotherapeutic review of the active prescriptions of the patients, and subsequently prepared an individualised report with proposals for therapeutic optimisation and sent it to the geriatrician for evaluation. PIPs were identified by explicit/implicit criteria (STOPP/START, BEERS, LESS-CHRON, MAI) and CheckTheMeds software, and were classified according to the Third Granada Consensus on Medication-Related-Problems (MRPs). The economic impact was calculated from the direct costs of the discontinued drugs.

Results 102 patients (74.5% women) were revised with feedback from 10 NHs. Median age 88 (IQR 84–93) years. Average of pathologies per patient: 8. Median of prescribed drugs: 13 (IQR 11–15).

495 prescriptions with possible MRPs were detected, the main ones being: unfavourable risk–benefit balance according to the functional situation (29.3%), probability of adverse events (17.6%), inadequate duration of therapy (18.4%), inadequate dose/regimen (16.4%) and duplication (5%). 41% corresponded to PIPs according to STOPP/BEERS or LESS-CHRON criteria. According to the therapeutic group, MRPs have been detected mainly in drugs from group A: 30%, N: 24.2%, C: 18.4% and M: 14%.

81% of the detected MRPs were intervened, with a degree of acceptance of 73%. The main interventions were: suspension or deprescription of drugs (67%) and dose reduction or change of frequency of administration (24%).

23% reduction in the number of drugs prescribed/patient, with an economic saving of € 2550/month and € 15 700/6 months.

Conclusion and relevance Deprescription strategy in our NHs has been efficient, since a high number of interventions with a high degree of acceptance have been detected. AP supposes great support to clinicians, promoting the rational use of the drugs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-156 ANTIMICROBIAL STEWARDSHIP PROGRAMME IN A GENERAL SURGERY SERVICE: ROLE OF THE PHARMACIST

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Background and importance The aim of antimicrobial stewardship programmes (AMS) is to improve clinical outcomes, minimise associated adverse events and avoid the potential emergence of resistance. The General Surgery Service (GSS), given its complexity, heterogeneity and need to treat varied and complex infections, is a service potentially benefitting from these interventions.

Aim and objectives Our objective was to analyse the recommendations issued by the pharmacist and evaluate the degree of acceptance by surgeons.

Material and methods A prospective study was carried out between February and April 2021. Patients with antimicrobial treatment for ≥ 4 days were included. Recommendations were: duration of treatment, dosage optimisation, early sequential therapy (EST) (at 72 hours if clinical stability criteria, availability of oral route and existence of antimicrobial for oral administration). Recommendations were made after reviewing the clinical course and microbiological data. They were considered accepted if the prescription was modified after 24 hours. The variables were: gender, age, previous intensive care unit (ICU) stay and initiation of treatment, isolated microorganism, empirical versus targeted treatment, drug, recommendation category and their acceptance, mean of days from discontinuation of treatment to discharge and need to restart antimicrobial therapy at 7 days.

Results 75 recommendations were made. 58 patients were included with a mean age of 69 (SD 15.8) years and 58.7% men. 36% were admitted from the ICU where antimicrobial treatment was started in 66.8%. The most frequent microorganisms were *Escherichia coli* (13.4%), *Enterobacter cloacae* (10.4%) and *Enterococcus faecium* (8.9%). Treatment was empirical in 68%. Recommendations were: duration of treatment (84%), EST (9.3%), dosage optimisation (6.7%). 66.6% of them were accepted. Most drugs prescribed were: piperacillin/tazobactam (34.7%), amoxicillin/clavulanic acid (16.0%), meropenem (13.3%). Mean of 5 days from discontinuation of treatment to discharge. Need to restart antimicrobial therapy at 7 days (4%).

Conclusion and relevance The duration of antimicrobial therapy was one of the main reasons for inappropriate use in the GSS. A third of patients came from the ICU. All of these make the participation of the pharmacist as a cornerstone of ASP essential. Recommendations were well accepted; however, periodic communication between pharmacists and physicians could be a strategy to optimise treatment, improving efficiency and security.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-157 IMPACT OF COVID-19 PANDEMIC ON PATIENTS TREATED WITH BIOLOGICAL DRUGS AND ENZYME REPLACEMENT THERAPIES

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Background and importance After the arrival of the pandemic, visits to the hospital were considerably reduced. This, added to the quarantine that patients could suffer, led to the discontinuation or delay of scheduled administrations in outpatients treated with biological drugs (BD).

Aim and objectives To evaluate the impact of the pandemic on patients treated with BD and enzyme replacement therapies (ERT).

Material and methods A retrospective observational study in which the incidents detected during 13 months (March 2020–April 2021) in the administration of vedolizumab, infliximab, ustekinumab, ocrelizumab, natalizumab, patisiran, dupilumab, abatacept, belimumab, reslizsaumab, sebelipab, agalsidase alpha and alpha-1 antitrypsin were collected.

All outpatient therapies with BD and ERT during the study period were included. The patients' clinical data in the electronic medical records and the data of preparation of the treatments of the Farmis-Oncofarm were analysed. Finally, the reason for the incidence in the administration of the treatment was analysed.

Results Incidences were registered in 178 patients in active treatment with BD and ERT and 530 administrations during the periods March–April 2020 and January–February 2021. 40 (7.5%) incidences were detected in 35 (19.7%) patients in whom there was delay or discontinuation of treatment. Delay in the administration of treatment was observed in 27 patients with an average delay of 3 weeks; 2 patients died from complications of their disease; and the remaining 6 patients discontinued treatment. Among the reasons for the delay or discontinuation in the treatments we observe the following: 5 patients could not receive the treatment due to active infection with COVID-19 and 2 patients because they had been in contact with another infected person; 17 did not come for fear of contagion; and the remainder did not do so for personal reasons. A worsening of the clinical situation associated with the disease was found in 10 patients during the delay or discontinuation of treatment.

Conclusion and relevance The global pandemic has had an impact on outpatients with chronic diseases who need intravenous treatment, and a delay or discontinuation of BD and ERT in 7.5% of scheduled administrations has been observed, the main causes being fear of contagion and personal motives.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-158 EVALUATION OF MEDICINE-RELATED INCIDENTS IN THE NATIONAL BONE MARROW TRANSPLANT CENTRE

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Background and importance The Sterile Compounding Centralised Unit (SCCU) at the National Bone Marrow Transplant Centre (NBMT) prepares an average of 9000 sterile injectable preparations yearly. Many medicine-related incidents (MRI) with various levels of therapeutical and economic repercussions have been documented either in the clinical or the pharmacy departments.

Aim and objectives Evaluation of MRI in the NBMT and economic analysis of medication losses.

Material and methods An 8-month retrospective study from January to August 2021. A MRI incident sheet was elaborated to document each incident for data collection and analysis.

Results A total of 35 incidents were reported during the study period. The main causes were: stopping the drug prescription by the treating doctor without informing the pharmacist in charge (42.85%), medication administration omission by the treating staff (20%) and cold chain breach (11.42%).

Of the 242 medication units' loss (instability after compounding or cold chain breach), the pharmacy department is responsible of 69.8% of losses, of which 98.8% were caused by the cold chain breach. The adult haematology department is responsible of 22.7% of the total units' loss whereas 7.4% of the losses are attributed to the paediatric haematology department. The most involved drug families in these incidents are anticancer drugs (45%) and antifungal drugs (20%). 43.3% of the MRI are non-hospital nomenclature drugs.

The cost evaluation of the incidents revealed a loss of an equivalent of € 37 615 representing 2.06% of the total medicines budget of the NBMT and 3.2% of the sterile preparations prepared by the SCCU. An 85.9% cost loss was caused by a technical error in the NBMT power monitoring system.

Conclusion and relevance Establishing corrective solutions such as optimising medicine conservation and supply chain quality limits the occurrence of further MRI. The first step towards a more pertinent improvement in the prevention of the occurrence of further MRI is the total digitalisation of patient files.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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4CPS-161 BUDGETARY IMPACT OF PCSK9I DOSES REGIMEN OPTIMISATION

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Background and importance Hypercholesterolaemia produces a higher risk of atherosclerosis and cardiovascular events. The proprotein convertase subtilisin kexin type 9 inhibitors (PCSK9i), evolocumab and alirocumab, were approved by the European Medicines Agency in 2015, and they are available to manage patients who have not achieved the target cholesterol levels or who are intolerant to the standard treatment with statins or ezetimibe. Nevertheless, due to their high budgetary impact, it is crucial to find measures to optimise their use.

Aim and objectives The aim of the study was to analyse the effectiveness and costs of the optimised PCSK9i regimen compared to the standard dosage regimen.

Material and methods A retrospective cohort study was conducted in patients who began using PCSK9i between September 2017 and September 2021. In patients with a reduction

in low-density lipoprotein cholesterol (LDLc) greater than 50% or who have reached their target value, alirocumab 150 mg/4 weeks or evolocumab 140 mg/21 days were proposed for optimisation of the dosage. Demographic, clinical and pharmacotherapeutic data were collected. Treatment efficacy was calculated as percent reduction in LDLc from baseline at treatment initiation to the end of the study period. The collected data were analysed using a Student's test through the SPSS programme.

Results Twenty-two patients were included, 9 males, with a median age of 62 (range 42–82) years, median treatment time was 22.52 (1.27–49.30) months and initial LDLc values of 161 (101–237) mg/dL. Fifteen patients (68%) were treated with alirocumab. Two patients discontinued treatment. Two patients were excluded because the treatment was not effective. Nine patients (45%) were proposed to optimise doses. In these patients the mean LDLc value was 75.66 ± 41.21 mg/dL and a reduction of $48.33\% \pm 26.87$, while in patients on standard doses it was 90.72 ± 59.70 mg/dL and $51.52\% \pm 26.72$, respectively. The difference was not significant ($p > 0.05$). The optimised doses involve a saving of € 2040.97/patient/year in alirocumab and € 1417.65/patient/year in evolocumab.

Conclusion and relevance The optimised use of PCSK9i is an effective measure and would mean a reduction in the direct costs in the treatment of hypercholesterolaemia.

It is necessary to search for strategies that help to reduce the budgetary impact to optimise health resources without damaging treatment effectiveness.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-162 CYTOKINE RELEASE SYNDROME IN ONCO-HAEMATOLOGICAL PATIENTS TREATED WITH TOCILIZUMAB

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Background and importance Cytokine release syndrome (CRS) is a common and life-threatening toxicity directly related to new targeted therapies for onco-haematological diseases. Although the optimal therapy for CRS remains unknown, tocilizumab has demonstrated success.

Aim and objectives To assess the efficacy of tocilizumab in onco-haematological patients with CRS. Relationship between CRS and targeted therapies was also reviewed.

Material and methods Retrospective cohort study in a single centre. Cases of onco-haematologic patients who received tocilizumab for CRS treatment from 2019 to 2021 were studied.

Patient demographics, onco-haematological diagnosis and targeted therapy, CRS-related symptoms and tocilizumab treatment were collected from electronic patient files. CRS resolution after tocilizumab treatment was reviewed in order to evaluate the efficacy of therapy.

CRS severity based on the American Society for Transplantation and Cellular Therapies grading scale for CRS was compared between the groups of patients with different onco-haematologic diagnoses and targeted therapies.

Results A total of 47 patients received tocilizumab (46 hematologic and 1 oncologic) for CRS. Main onco-haematological diagnoses were multiple myeloma (75.5%), lymphoma (10.2%)

and acute myeloblastic leukemia (8.2%). Targeted therapy consisted of *chimeric antigen receptor T-cells* (CAR-T-cells) in 29 patients (61.7%), bispecific antibodies in 16 (34.0%) and haematopoietic stem cell transplantation (HSCT) in 2 (4.3%).

Nineteen patients (40.4%) developed CRS grade 1, 26 (55.3%) grade 2 and 2 (4.3%) grade 3.

Tocilizumab median dose was 8.0 (5.3–10.4) mg/kg. Twelve patients (25.5%) required a second tocilizumab dose. CRS resolution occurred in all patients.

CRS was more severe in the group of patients with a diagnosis of lymphoma, developing CRS grade 3 in 25% of patients versus 0% in the other groups ($p < 0.05$). In the group of patients with multiple myeloma, CRS grade 1 occurred more frequently (48.5% vs 2.3%, $p < 0.05$).

Severe CRS (grade 2 and 3) was more frequent in patients treated with bispecific antibody or HSCT than in those who received CAR-T-cell therapy (77.8% vs 51.9%, $p < 0.05$).

Conclusion and relevance Tocilizumab is an effective treatment in CRS after new targeted therapies in onco-haematological patients.

Severity of CRS seems to be higher in patients with diagnosis of lymphoma and in those treated with bispecific antibodies and HSCT.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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4CPS-163 EARLY EXPERIENCES IN SWITCHING BETWEEN MONOCLONAL ANTIBODIES IN CHRONIC MIGRAINE PREVENTIVE THERAPY

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Background and importance Monoclonal antibodies targeting the calcitonin gene-related peptide (CGRP-mAbs) have been introduced into the therapeutic arsenal of chronic migraine (CM) prophylaxis. Clinical trials report similar efficacy between them. Some patients with CM and multiple treatment failures do not respond to a first treatment with CGRP-mAbs, but there is no evidence for switching to a second CGRP-mAbs. These treatments are dispensed in hospital pharmacies, where pharmacists follow up these patients and the efficacy of these treatments.

Aim and objectives We aimed to describe the effectiveness of CGRP-mAbs (erenumab and galcanezumab) switching in preventive treatment for CM in clinical practice.

Material and methods A retrospective case series including patients with CM treated with CGRP-mAbs and switched to another CGRP-mAb between August 2020 and September 2021 in a third-level hospital in Spain. Effectiveness was established with $\geq 50\%$ reduction of monthly migraine days (MMD) in respect to baseline, or $\geq 30\%$ reduction of MMD and ≥ 5 points reduction of the HIT-6 with respect to baseline.

Results Twenty patients were included: 14 were treated with erenumab as first CGRP-mAb and were switched to galcanezumab; 6 were treated with galcanezumab and were switched to erenumab. The median duration of the first CGRP-mAb treatment was 7.8 (5.0–9.7) months. The reason for treatment switching was non-response in 15 cases and adverse events in

5 cases. The adverse event was in all cases severe constipation in patients treated with erenumab.

Thirteen patients improved their response after CGRP-mAb switching with a median of 22.6% (12%–40%) reduction of MMD in respect to baseline; 4 patients had a worse response after CGRP-mAb switching with a median of 14.7% (12.5%–17.8%) increase of MMD with respect to baseline; and 3 patients did not respond to any CGRP-mAb treatment. Response to the second CGRP-mAb was observed in 10 patients switched from erenumab to galcanezumab and 3 patients switched from galcanezumab to erenumab. No patient presented unacceptable toxicity to the second CGRP-mAb treatment.

Conclusion and relevance Some patients with CM may benefit from switching between mAbs with the same mechanism of action. More studies are needed to describe which patients will respond to CGRP-mAb switching.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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4CPS-165 HAS COVID AFFECTED THE TREATMENT OF ONCOLOGY PATIENTS?: A DESCRIPTIVE STUDY OF TREATMENTS FROM 2019 TO 2021

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Background and importance The COVID-19 pandemic has had a significant impact on cancer diagnosis and treatment worldwide.

Aim and objectives To describe patients in oncology treatments comparing 2019, 2020, and 2021 to September 2021.

Material and methods A descriptive study was conducted in a tertiary hospital from January 2019 to September 2021. Inclusion criteria were patients undergoing parenteral and oral oncology treatment. Variables were: gender, age, diagnosis, patients with oral and parenteral oncology treatments dispensed by the Pharmacy Service. Data were collected from the electronic medical record (FarmaTools).

Results During the study period, 1010 patients were treated with parenteral and 402 with oral antineoplastics. The average age was 67 ± 23.7 years (51.6% male). In the group of parenteral treatments the main diagnoses in 2019 were: vesical carcinoma (VC) (14%), metastatic non-small cell lung cancer (mNSCLC) non-squamous (NS) noALK noEGFR (7.1%) and metastatic KRAS and NRAS mutated colorectal cancer (mCC) (6%); in 2020 were VC (13%), mNSCLC NS noALK noEGFR (6.2%) and adjuvance in breast cancer (mBC) noHER2 and positive hormonal receptor (+HR) (5.6%); and in 2021 (to September) VC (9%), metastatic NSCLC NS noALK noEGFR (5.9%) and KRAS and NRAS mutated mCC (5.9%). In treatment with oral antineoplastics in 2019: adjuvance CC (27.6%), mBC noHER2 +HR (20%) and metastatic castration-resistant prostate cancer (mCRPC) (10.5%); in 2020 mBC noHER2 +HR (20%), adjuvance CC (12.5%) and mCRPC (10.5%); and in 2021 mBC noHER2 +HR (21%), adjuvance CC (11.8%) and mCRPC (7.8%). 364 patients were treated by an intravenous route in 2021, 356 in 2020 and 290 in 2021. 105 patients were treated by oral treatment in 2019, 144 in 2020 and 153 in 2021. Patients treated in

metastatic stages were 241 in 2019, 254 in 2020 and 234 in 2021.

Conclusion and relevance In 2020, there was a decrease in patients treated with KRAS and NRAS mutated mCC and an increase in adjuvance BC. Regarding oral treatment, patients on adjuvant treatment with colorectal cancer decreased in 2020. The increase in the number of patients on oral treatments from 2019 to 2021 is notable, and the important role that telemedicine has had from 2020 and the home delivery of medication by pharmacy services, thus reducing hospital visits. Further studies are needed to confirm this.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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4CPS-166 ASSOCIATION BETWEEN IMMUNE-RELATED EFFECTS AND EFFECTIVENESS OF FIRST-LINE PEMBROLIZUMAB IN ADVANCED NON-SMALL-CELL LUNG CANCER

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Background and importance Pembrolizumab in monotherapy (in patients with PD-L1 expression $\geq 50\%$) or in combination with platinum-based chemotherapy (CT) (PDL-1 $< 50\%$) is the new standard therapy in first-line treatment of advanced or metastatic non-small cell lung cancer (mNSCLC).

Aim and objectives The aim of this study was to determine whether the incidence of immune-related adverse events (irAEs) following the use of pembrolizumab in first-line mNSCLC is associated with clinical outcomes in real-world practice.

Material and methods An observational, retrospective study was carried out, including patients with mNSCLC treated with pembrolizumab in first-line, between 1 January 2017 and 1 January 2021. Baseline patient characteristics were collected. To assess treatment effectiveness, the overall survival (OS) and progression-free survival (PFS) were measured. irAEs were categorised. OS and PFS were calculated for the population with any irAEs of any grade (irAEs+) and compared to patients without irAEs (irAEs-) in order to test our hypothesis.

Results The study included 62 patients with the following characteristics: mean age 67.44 years, majority of men (77.42%), smoking history (47% former smokers, 45% smokers), adenocarcinoma (87%), ECOG/PS-1=50%, ECOG/PS-0=38% and ALK/ROS-1/EGFR negative (89%), PD-L1 $\geq 50\%$ (N=31), PDL-1 $< 50\%$ (N=27) and unknown (N=4). Half of the patients received pembrolizumab alone and half received pembrolizumab in combination with CT. Most patients discontinued treatment due to progression (75.81%). irEAs (N=164) were observed in 77.4% of patients. In Kaplan–Meier analysis, median OS for overall, irAEs+ (N=48) and irAE- population (N=14) were as follows: 10.6 (95% CI 8.2 to 13.05), 10.9 (95% CI 8.6 to 13.2) and 4.4 months (95% CI 0 to 15.3), respectively. Median PFS for overall, irAEs+ and irAE- population were: 7.4 (95% CI 4.6 to 10.3), 8.7 (95% CI 5.9 to 11.6) and 2.3 months (95% CI 0 to 11.7), respectively. There were no significant differences in PFS and OS among the different populations.

Conclusion and relevance Our population did not reach statistical significance in the association between the presence of

irEAs and clinical benefit. This may be due to the limited sample size.

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Conflict of interest No conflict of interest

4CPS-167 SODIUM AND MAGNESIUM ALTERATIONS IN THE CRITICAL PATIENT WITH SARS-COV-2 AND PARENTERAL NUTRITION

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Background and importance Severe SARS-CoV-2 infection requiring management in the critical care unit (CCU) involves long hospital stays with the need for artificial nutritional support and sometimes, depending on the clinical course, parenteral nutrition (PN).

Aim and objectives The aim of this study was to analyse sodium and magnesium electrolyte disturbances associated with mechanical ventilation in critically ill patients with COVID-19 requiring PN.

Material and methods Retrospective observational study including 50 patients with SARS-CoV-2 admitted to CCU for 4 months (January–April 2021) who required PN.

We analysed the variables of sex and age and the analytical values of sodium and magnesium during PN supplementation, as well as the contribution of these ions during PN supplementation. Na and Mg ions were not supplemented in PN, in patients with high levels.

Results Age: average 67 years. Sex: 62% male; 38% female. Died: 54%. The results obtained are shown in table 1.

46% of patients had hypermagnesaemia at the start of PN, and about 30% started with hypernatraemia; in both cases it was maintained throughout the period of PN.

Of the total number of patients, 5 developed hypermagnesaemia and 3 hypernatraemia during PN supplementation

Conclusion and relevance Critically ill patients with SARS-CoV-2 had a high percentage of sodium and magnesium levels, 32% and 46%, respectively, at the time of starting PN, mainly associated with the use of mechanical ventilation. These alterations continued during PN supplementation in most cases.

Abstract 4CPS-167 Table 1 Sodium and magnesium alterations, before and during the PN supplementation

	Na (meq/L)	N° patients (%)	Mg (mg/dL)	N° patients (%)
Before NP	↑ 150,3 (145-165)	16 (32)	↑ 2,5 (2,2-3,4)	23 (46)
	↓ 134	1 (2)	↓	0
	normal	33 (66)	normal	27 (54)
During NP	↑ 150,7 (146-159)	15 (30)	↑ 2,4 (2,2-2,8)	24 (48)
	↓ 132	1 (2)	↓ 1,4	1 (2)
	normal	34 (68)	normal	25 (50)

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-170 REVIEW OF NEW BIOMARKERS THAT PREDICT THE PHARMACOKINETICS OF BIOLOGIC DRUGS IN INFLAMMATORY BOWEL DISEASE

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Background and importance Adalimumab is an anti-TNF α monoclonal antibody used in inflammatory bowel disease (IBD). Its efficacy can benefit from therapeutic drug monitoring (TDM). Certain biomarkers can be useful in future pharmacokinetics adjustment model designs.

Aim and objectives To study the correlation between plasmatic concentrations of adalimumab and the plasmatic concentrations (Cp) of prealbumin and albumin in patients with IBD.

Material and methods An observational, retrospective study was carried out from September 2020 to September 2021.

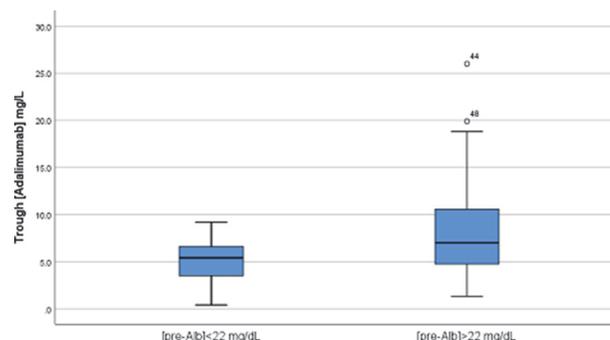
Inclusion criteria: (1) patients older than 18 years with diagnosis of IBD (Crohn's disease or ulcerative colitis); (2) patients receiving treatment with adalimumab maintenance therapy; and (3) having a trough Cp of adalimumab, albumin and prealbumin obtained the same day.

Exclusion criterion: (1) the presence of anti-adalimumab antibodies.

The following variables were collected: gender, age, diagnosis, adalimumab trough concentration, albumin and prealbumin. The analytical determinations of adalimumab were made by ELISA technique (Theradiag) with a test range 0.3–16 μ g/mL. The statistical analysis was made using R 4.1.1 statistical software.

Results In this study, 39 patients were included, of which 34 (87.2%) were diagnosed with Crohn's disease and 5 (13%) suffered from ulcerative colitis; 53.8% were women. The mean age and weight were: 35.9 years (95% CI 31.3 to 40.5) and 68.5 kg (95% CI 61.9 to 75.1), respectively.

A positive and statistically significant correlation was found between the adalimumab trough Cp and the Cp of prealbumin (R^2 0.113; p : 0.019). In those patients with prealbumin levels higher or equal to 22 mg/dL, the mean adalimumab trough Cp in maintenance therapy was significantly higher than those obtained in patients that had prealbumin levels lower than 22 mg/dL (adalimumab trough concentration: 8.73 mg/L (95% CI 6.03 to 11.43) vs 5.16 mg/L (95% CI 3.74 to 6.58), respectively ($p=0.043$)) (figure 1). There was no correlation between the Cp of adalimumab and those of albumin.



Abstract 4CPS-170 Figure 1

Conclusion and relevance In the studied population sample of patients with IBD, a positive correlation between the concentration of adalimumab and prealbumin was observed. To our knowledge this is the first study to find this association, and as prealbumin is a protein with a smaller half-life than albumin, it could be used as a predictive biomarker of adalimumab clearance modification.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-171 EFFECT OF LIPIDIC COMPOSITION OF PARENTERAL NUTRITION ON THE DEVELOPMENT OF HYPERTRIGLYCERIDAEMIA AND CHOLESTASIS

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Background and importance The lipid type of parenteral nutrition (PN) may influence the development of cholestasis and hypertriglyceridaemia. Custom PN (CPN) contains medium-chain triglycerides (MCT) and fish oil, rich in omega-3, in contrast to the three-chamber bag PN (3CB) which lacks these lipids.

Aim and objectives This work aimed to compare the relationship between the different lipidic compositions of CPN and 3CB and the outcome of hypertriglyceridaemia and cholestasis. **Material and methods** An observational, longitudinal, retrospective, and descriptive study was performed. It included hospitalised non-critical patients aged from 18 to 80 years, without liver diseases, with baseline triglycerides (TG) lower than 200 mg/dL, and gamma-glutamyl transferase (GGT) and alkaline phosphatase (ALP) lower than three times their upper limit of normal values. These patients had received parenteral nutrition with at least 40 grams of lipids per day for more than 5 days.

Data for TG, GGT and ALP were recorded for patients receiving either CPN or 3CB. The increase in these values was evaluated during the administration of PN.

Presence of cholestasis is established if GGT and/or ALP exceeded three times the upper limit of normal, and of hypertriglyceridaemia when TG exceeded 200 mg/dL.

Quantitative statistical analysis was performed using the Student's t-test (p value <0.05) whereas the Chi-squared test was used for qualitative analysis.

Results 41 patients, who received PN for 10 days on average, were included in this study: 20 with CPN and 21 with 3CB.

Table 1 shows the results obtained for TG, GGT and ALP both baseline and increased.

Results show that there was a higher risk of hypertriglyceridaemia in patients with 3CB (62% with 3CB vs 25% with CPN; OR 4.87; p<0.05). No significant difference was observed in the development of cholestasis (48% with 3CB vs. 40% with CPN; OR 1.36; p>0.05).

Conclusion and relevance The absence of fish oil and MCT in the lipid composition of 3CB is associated with an increase in TG values. Although GGT and ALP levels are seen to rise as well, further studies are needed in order to prove this correlation.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-172 POSACONAZOL THERAPEUTIC DRUG MONITORING IN A PAEDIATRIC TERTIARY HOSPITAL

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Background and importance Invasive fungal infections (IFI) are a major cause of morbidity and mortality in immunosuppressed patients. Posaconazole is used for prophylaxis and treatment of IFI in immunocompromised patients, although there are scarce data on its pharmacokinetics and posology in children. Posaconazol dosing schedule of our institutional protocol for IFI prophylaxis is 4 mg/kg (max 400 mg) three times a day and 6 mg/kg (max 300 mg) once daily (twice daily on day 1) for oral suspension and tablets, respectively.

Aim and objectives Determine the number of patients who achieved therapeutic plasma concentrations at steady state (ssCp) (0.7–3.75 µg/mL) with the dosing schedule of our institutional protocol. Describe and analyse the pharmaceutical interventions necessary to achieve optimal ssCp and avoid toxicities or treatment failure.

Material and methods Retrospective, observational, single-centre study including 103 immunocompromised patients receiving prophylactic posaconazole from April 2020 to September 2021, with a treatment duration of at least 1 week. Variables collected: age, weight, formulation and trough ssCp.

Results The patients had a median age of 9 (2–23) years and a mean weight of 33.6±18.3 kg. 57/103 (55.3%) of the patients received suspension and 46/103 (44.7%) tablets. 71/103 (68.9%) of the patients had ssCp within the therapeutic range after the first draw (suspension, 31/71; tablets, 40/71), 23/103(22.4%) had a ssCp value <0.7 (suspension, 12/23; tablets, 11/23) and 9/103 (8.7%) had a ssCp value >3.75 (suspension, 4/9; tablets, 5/9).

356 pharmaceutical interventions were performed, 151 in patients taking oral suspension and 205 receiving tablets. In the first group, the dose was decreased in 10.6% of interventions, increased in 23.2% and 61.6% did not require dose changes; treatment was discontinued in 4.6% due to drug interactions, toxicity or change of therapy. Regarding those receiving tablets, the recommendation was to reduce the dose in 11.7%, not to change in 76.1%, increase in 7.8% and stop in 4.4%. In some cases dose modifications were made for clinical circumstances.

Conclusion and relevance Most patients achieved therapeutic ssCp after the first determination according to our scheme.

Abstract 4CPS-171 Table 1

	CPN (mean±SD)	3CB (mean±SD)	P value
Baseline TG	123.5±39.4	110.2±38.4	0.28
Increased TG	50.7±53.9	112.9±76.3	0.004
Baseline GGT	43.8±36.2	31.5±21.4	0.22
Increased GGT	91.3±104.7	160.1±170.4	0.15
Baseline ALP	90.7±55.2	90.04±48.04	0.97
Increased ALP	46.6±53.8	82.2±90.8	0.14

The need for dose adjustments was more frequent among the suspension group in order to achieve a correct ssCp, which is consistent with adult and paediatric population studies. Hence, it shows the relevance of pharmacokinetics studies of posaconazole in paediatric populations and the lack of evidence to ensure its efficacy and safety.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-173 PHARMACEUTICAL INTERVENTION IN BROAD-SPECTRUM ANTIBIOTIC PRESCRIPTION IN HOSPITALISED PATIENTS

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Background and importance Indiscriminate use of broad-spectrum antibiotics implies a threat to public health and may cause multidrug-resistant pathogen infections. In this sense, data from the Infectious Disease Society of America (IDSA) revealed that >60% physicians have detected at least one case of pan-resistant and intractable bacterial infection during the previous year.

Aim and objectives The aim of this study was to analyse the quality of antibiotic prescription (indication and duration of treatment) based on the recommendations of our Antibiotic use Optimisation Program (AOP).

Material and methods A retrospective study (January 2020 to April 2021) of hospitalised patients taking carbapenems, ureidopenicillins, quinolones, cephalosporins or glycopeptides was carried out. We collected demographic information, antibiotic regimen, type and site of the infection and microbiological data from the clinical history management program (SAP). Pharmaceutical interventions over antibiotic prescriptions were mainly associated with starting, interrupting, broadening the spectrum or switching to oral therapy.

Results We included 75 patients (64% men, mean age 67.7 ±13.4 years) with an average stay of 10.3±4.1 days. Most common sites of infection were: soft tissue (25%), intra-abdominal (16.3%), urinary (10%), respiratory (10%) and meningeal (5%). Main pathogens isolated were: Gram-positive cocci (49.4%), Gram-negative bacilli (39.3%), anaerobic cocci (5.7%) and fungi (5.6%).

We implemented 142 pharmaceutical interventions such as withdrawing (33.1%), changing (26.8%) or starting (20.4%) a new antibiotic. In addition, switching and/or changing to oral therapy (18.3%) and continuing the treatment (1.4%). Almost all pharmaceutical interventions were accepted for other specialists. Conversely, glycopeptides (22.5%), carbapenems (19.8%), ureidopenicillins (18%), cephalosporins (11.7%) and quinolones (4.5%) were the main antibiotics that we had an impact on.

Conclusion and relevance Our study shows that hospital pharmacists and the Infectious Control Group play an important role in optimising antibiotic regimes in a variable clinical context. Pharmaceutical recommendations have good acceptance and should be particularly targeted at specific antibiotic classes. All these measures may contribute to decreasing the incidence of multiresistant bacterial infections in the hospital.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-174 EFFECTIVENESS OF OBETICOLIC ACID TREATMENT IN PATIENTS WITH PRIMARY BILIARY CHOLANGITIS

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Background and importance Primary biliary cholangitis (PBC) is a disease with few therapeutic options. Currently the main drug used is ursodeoxycholic acid (UDCA), although approximately 35% of patients will have an inadequate biochemical response after 1 year of treatment. In these patients, the association of UDCA and obeticholic acid (OCA) is indicated, while in cases of intolerance to UDCA, OCA is used as monotherapy.

Aim and objectives To evaluate the efficacy of OCA in patients with PBC based on different biochemical response parameters.

Material and methods An observational, descriptive and retrospective study was carried out in three third-level hospitals in the Canary Islands. Based on the FarmaTools e-prescribing program, a total of 30 patients with a diagnosis of PBC undergoing OCA treatment for at least 3 months were selected. Clinical data were collected: sex, age, date of initiation with OCA. To evaluate the efficacy, the analytical data were extracted from the electronic medical record (Drago AE and SAP): alkaline phosphatase (AF), total bilirubin (BT), gamma glutamyltransferase (GGT), aspartate aminotransferase (AST) and alanine aminotransferase (ALT) at the beginning and every 12 weeks of treatment. Statistical analysis was performed using Microsoft Excel.

Results Thirty patients (90% women) with a mean age of 55 years were included. All previously treated with UDCA for at least 1 year without good response and, subsequently, it remained concomitant with OCA. After 3 months of treatment, the following results were obtained: AF was reduced in 77% of the patients by 31%±22%; in 50% the BT was reduced by 23%±15%; in 83% the GGT decreased by 43%±27%; in 63% the AST decreased by 24%±17% and in 70% the ALT values were reduced by 27%±18%. Of the 30 patients, 19 reached 1 year of treatment of which: in 79% AF and AST were reduced by 46%±265 and 28%±20%, respectively; 32% decreased BB by 30%±24%; GGT decreased in 84% of patients by 68%±37% and ALT decreased in 100% by 38%±23%.

Conclusion and relevance According to the literature, OCA has improved the analytical parameters of the analysed sample, demonstrating its effectiveness in the treatment of PBC in patients who have not previously responded to UDCA therapy.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-175 MEDICATION REGIMEN COMPLEXITY INDEX AMONG SOLID ORGAN TRANSPLANT PATIENTS IN A TERTIARY HOSPITAL

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Background and importance Complex medication regimens (MR) are associated with worse treatment adherence. The Medication Regimen Complexity Index (MRCI) is a validated tool used to quantify complexity of MR and it is the sum of the score in three sections: dosage forms (A), dosing frequency (B) and additional directions (C).

Aim and objectives To assess the relative MR complexity among solid organ transplant patients (SOT; kidney, heart, lung and liver) in a tertiary hospital through the validated MRCI Spanish version.

Material and methods Transplant patients who collected medication in the Hospital Pharmacy between January and March 2021 were selected. A total of 40 patients (10 per transplant) were chosen randomly through Excel, and a macro with a template of MCRI was created. The qualitative variables were age, sex and type of transplant; the quantitative ones were months from transplant, the total amount of medications, sections A, B, C and total MRCI. All prescribed medications documented in medical records at the hospital ambulatory clinics and the electronic medication list were included. Patients were excluded if they were followed up in other hospitals, had died or MR dosage or frequency was missed/unclear. Subgroup analysis was made to assess MRCI among the type of transplants through ANOVA. All data analysis was made with SPSS version 23, with a <0.05 significance level and a confidence interval of 95%.

Results Sample median age was 56.6±14.7 years (95% CI 51.9 to 61.3), a 40% (16/40) were women, median of time from trasplant was 92.7±69.9 months (95% CI 70.4 to 115.0) and number of medications 11.1±4.6 (95% CI 9.6 to 12.6). Subgroup median MCRI were 23.3±10.2 (kidney; 95% CI 16.0 to 30.5), 46.2±12.8 (lung; 95% CI 37.1 to 55.3), 28.5±11.1 (heart; 95% CI 20.6 to 36.4) and 18.7±5.4 (liver; 95% CI 14.8 to 22.5). Section B was the greatest contributor to MCRI (16.6±8.2; 95% CI 14.0 to 19.2), followed by C (6.6±4.3; 95% CI 5.2 to 7.9) and A (5.7±3.7; 95% CI 4.5 to 6.9). Tukey test showed a statistically significant MCRI in lung transplant with p<0.001 when compared to kidney and liver transplants, and p=0.002 compared to heart transplant.

Conclusion and relevance The medication regiment of our sample was more complex in lung patients than in any other SOT, therefore these patients could benefit more from pharmaceutical interventions. Further studies with larger samples are required to confirm differences among kidney, liver and heart transplants.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-176 ORAL IVERMECTIN EFFECTIVENESS IN THE TREATMENT OF PERMETHRIN-RESISTANT SCABIES: A DESCRIPTIVE AND RETROSPECTIVE OBSERVATIONAL STUDY

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Background and importance Ivermectin is used as a therapeutic alternative for permethrin-resistant scabies. The recommended treatment consists of administering two single doses (SD) separated by 7–14 days. An increased incidence and resistance to permethrin was observed in late 2020 possibly influenced by the SARS-CoV-2 pandemic.

Aim and objectives To assess the effectiveness of oral ivermectin as a treatment for topical 5% permethrin-resistant scabies in patients from a tertiary hospital and to analyse the characteristics of the sample and the treatment.

Material and methods An observational, retrospective and descriptive study was done including patients who collected ivermectin 3 mg tablets in the Hospital Outpatient Pharmaceutical Care Unit between April 2020 and April 2021. All patients were previously treated with topical 5% permethrin and treatment had failed. Ivermectin was considered effective in patients who were discharged from Dermatology Clinics or did not consult for itching or other symptoms in the following 4 weeks after the last dose. Other variables were: number of doses, age, sex and familiar history or cohabiting cases of scabies.

Results A total of 37 patients were included and 39 applications were made. There were 16 applications from April 2020 to December 2020 (mean of 1.78±1.79 applications/month; 95% CI 0.41 to 3.05) and 23 from January to April 2021 (mean of 4.6±2.6 applications/month; 95% CI 1.37 to 7.83). Ivermectin was effective in 87.2% (34/39) patients and in the remaining 12.8% (5/39) therapeutic failure occurred, so they required treatment for a second time. A patient was excluded because it was unclear if treatment had been ineffective or reinfestation had occurred. 56.4% (22/39) of patients received two SD separated for 7–14 days. 58.5% (24/39) of patients were women and the mean age of the sample was 31.1±19.3 years (95% CI 26.8 to 37.4). 54.0% (21/39) of the patients were aged between 11 and 30 years, and 74.4% (29/39) had a familiar history or cohabitants within their family nucleus with scabies.

Conclusion and relevance In our sample, ivermectin effectiveness was greater than 90% in scabies resistant to topical 5% permethrin and seems independent of the number of doses received. Results suggest that scabies mainly affects women and young people. Infections in cohabitants seem to have an increased frequency and may have been influenced by confinement and delays of treatments during the SARS-CoV-2 pandemic.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-178 THERAPEUTIC DRUG MONITORING OF GENTAMICIN AFTER PRE-DIALYSIS ADMINISTRATION

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Background and importance With the increase of multidrug-resistant Gram-negative bacteria, aminoglycoside therapy is frequently essential, and its management is especially problematic in dialysis patients.

Aim and objectives The aim was to calculate the mean dose of gentamicin required to optimise pharmacokinetic/pharmacodynamics (PK/PD) parameters in intermittent haemodialysis patients to determine an initial dosing protocol.

Material and methods We performed a retrospective observational study including patients treated with gentamicin from January 2009 to April 2020, who were on a 4-hour haemodialysis programme three times per week. Gentamicin was administered 1 hour pre-dialysis and monitoring was performed by drawing a trough level (pre-dose) and a peak level (30 min after the infusion ended) at each administration. Gentamicin concentration was analysed by *chemiluminescent* microparticle immunoassay (CMIA). The estimation of kinetic parameters was performed by Bayesian methods with a single-compartment population model implemented in the Abbottbase-Pharmacokinetic System. Dialysis was introduced into the model as a disposition factor that increases drug clearance only during the 4 hours of dialysis. Data were evaluated using chi-square test. Significance was designated at $p < 0.05$.

Results We identified 19 dialysis patients on gentamicin treatment. Gentamicin was used in 7 cases to treat infections caused by carbapenemase-producing *Klebsiella pneumoniae*, 8 skin-and-soft tissue infections, 5 urinary tract infections, 3 bacteraemias, 2 pneumonias and 1 endocarditis. Mean and range of age was 66 (45–80) years, weight 67.89 (44–88) kg and haematocrit 29.6% (22%–38%). The ratio of ABW/IBD was 1.04. Nine patients used the FX80 dialyser, 7 used the FX10 and 3 other dialysers, with a mean filtration rate of 2200 mL. In all patients residual diuresis was nil. Treatment duration was variable, 17 (4–47) days. Gentamicin was initiated at a mean dose (\pm SD) of 2.35 ± 0.52 mg/kg (80–240 mg). After monitoring, 76.5% of patients achieved optimal levels of both C_{max} (> 8 μ g/mL) and C_{min} (< 2 μ g/mL), compared to 26.7% at baseline ($p < 0.001$). The mean dose to maintain target values was 2.56 ± 0.53 mg/kg, being the mean kinetic parameters: $V_d = 0.33 \pm 0.1$ L/kg; inter-dialysis $CL = 0.46 \pm 0.16$ L/hour and half-life = 33.65 ± 17.29 hours.

Conclusion and relevance To optimise the PK/PD parameters of gentamicin in patients undergoing haemodialysis, an initial dose of 2.5 mg/kg 1 hour pre-dialysis is proposed, without the need for loading doses. However, due to its complex management and high pharmacokinetic variability, strict monitoring from the first dose is essential.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-179 DESCRIPTION AND FOLLOW-UP OF THE USE OF EMTRICITABIN/TENOFOVIR FOR HIV PRE-EXPOSURE PROPHYLAXIS

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Background and importance The Spanish National Health System agreed to finance emtricitabin/tenofovir (FTC/TDF) in November 2019 with an indication of pre-exposure prophylaxis (PrEP) as an HIV prevention measure. PrEP consists of taking one FTC/TDF tablet daily. The role of hospital pharmacist in the treatment of HIV-negative individuals is to follow up by monitoring adherence, interactions and reasons for discontinuation of treatment.

Aim and objectives To describe the use of FTC/TDF for PrEP in a tertiary hospital and follow-up of candidate HIV-negative individuals from the start of therapy.

Material and methods Retrospective, observational and Hospital ID Clinic study including all non-infected individuals who started treatment from December 2019 to April 2021.

Variables analysed: age, sex, risk behaviours, persistence, treatment duration, treatment withdrawal reason, adherence (adherent if $\geq 95\%$) and reasons for low adherence.

Data were obtained from the electronic medical records and outpatient dispensing module.

Results Eighty-eight HIV-negative individuals were included, 98% (86/88) were men, all of them being men practising sex with men (MSM). The mean age was 40 ± 9 years.

Persistence to treatment (mean persistence = 6 months) was 91% (80/88). The remaining 9% (8/88) abandoned the treatment. The reasons for dropping out were: 4/8 adverse reactions (AR) (3 gastrointestinal complaints and 1 renal toxicity), 1/8 absence of risky sexual practices (= stable partner), 1/8 lockdown and 2/8 unidentified due to lack of follow-up.

82% of the non-infected people were adherent to treatment, being the mean adherence to treatment 95%. The mean adherence of the individuals considered non-adherent was 76%. The reasons for poor adherence were: 3/14 gastrointestinal AR (flatulence and abdominal pain), 1/14 absence of risky sexual relations, 1/14 lockdown and 9/14 unidentified due to lack of follow-up.

Conclusion and relevance The main profile of HIV-negative individuals in treatment with PrEP is MSM.

In general, both persistence and adherence to treatment were good. However, considering the short duration of treatment, a long-term study should be performed.

Results show that the most frequent reasons for treatment withdrawal and low adherence are AR.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-182 INCREASE IN THE PRESCRIPTION OF BENZODIAZEPINES IN THE CONTEXT OF THE SARS-COV-2 PANDEMIC

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Background and importance The most frequently recorded mental health problem is anxiety disorder and in the context of the SARS-CoV-2 pandemic, where an increase in anxiety cases has been evidenced, benzodiazepine derivatives (N05BA) have been one of the most prescribed pharmacological groups in most developed countries for this problem. Although their short-term benefits have been demonstrated, increasing their consumption may have long-term risks.

Aim and objectives The main aim of this study was to find out the prescriptions of benzodiazepine derivatives from 2018 to 2021 in the context of the SARS-CoV-2 pandemic and the variation in them. A secondary objective was to learn which benzodiazepine derivatives varied more.

Material and methods Retrospective, observational and cross-sectional study. The study period included June 2018, June 2019, June 2020 and June 2021. The study population included the 710 581 inhabitants associated with the prescribing doctors of benzodiazepine derivatives from the study province.

Results Total study population N=710 581; 21.61% (153.574) with a benzodiazepine prescription, 67.33% (103 416) women, between June 2018 and June 2021.

The prescribed benzodiazepine derivatives were: alprazolam, diazepam, diazepam/pyridoxine, clonazepam, lorazepam, ketazolam, clobazam, pinazepam, clonazepam dipotassium, bromazepam, bentazepam, diazepam/sulpiride and diazepam/sulpiride/pyridoxine.

June 2018: 35 800 prescriptions, 67.30% (24 085) women; June 2019: 37 601, 67.20% (25 262) women; June 2020: 39 547, 67.30% (26 622) women; and June 2021: 40 626, 67.60% (27.477) women.

From June 2018 to June 2019 prescriptions increased 5.03% (1801), from June 2019 to June 2020 they increased 5.20% (1946); and from June 2020 to June 2021 they increased 2.73% (1079), which represented a 13.48% increase in prescriptions (4826) from June 2018 to June 2021.

The largest prescription increases were diazepam +23%, lorazepam +18%, bromazepam +12.5%, and alprazolam +12.3%.

The largest prescription decreases were clonazepam and bentazepam -100%, pinazepam -96.43% and clobazepam -22.45%.

Conclusion and relevance In the context of the SARS-CoV-2 pandemic we have seen a progressive increase in benzodiazepines of 13.48% (4826 prescriptions) from June 2018 to June 2021, with women being the users of 67.33% of prescriptions on average. These data allow us to know the current situation of the prescription of benzodiazepine derivatives to the population and to focus on mental health both in the validation of treatments and in pharmaceutical care.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-186 2020 ANTIMICROBIAL CONSUMPTION INDICATORS: ANALYSIS COMPARED WITH PREVIOUS YEARS

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Background and importance A reference panel of antimicrobial consumption indicators was published in 2019 by a committee from the Spanish Society of Hospital Pharmacy (SEFH) and the Spanish Society of Infectious Diseases and Clinical Microbiology (SEIMC).

Aim and objectives To calculate 2020 hospital antimicrobial consumption indicators and carry out a comparative analysis of these consumption indicators with those observed in the previous 2 years.

Material and methods Based on the panel, 10 antimicrobial consumption indicators were selected. The unit of measurement for the consumption was the number of defined daily doses per 100 stays (DDD/100e).

Results Antibacterials overall consumption (OC) 1.5% (86.5 to 85.2) decrease in 2019; and 4.7% increase in 2020 compared to 2019 (89.2).

Antifungals OC 3% decrease in 2019 (7.05 to 6.84); 26% increase in 2020 compared to 2019 (8.65).

Carbapenems: in 2019, consumption decreased by 4.2% (10.17 to 9.74); in 2020 it increased by 2% compared to 2019 (9.94).

Fluoroquinolones: maintained overall 37.4% decrease (13.01 in 2018, 10.83 in 2019 and 8.14 in 2020).

Fosfomycin: maintained overall increase of 27.6% (0.49 in 2018, 0.65 in 2019 and 0.62 in 2020).

Aminoglycosides: maintained overall decrease of 40.7% (3.27 in 2018, 2.32 in 2019 and 1.94 in 2020).

Colistin: 12.8% decrease in 2019 (1.09 to 0.95), and an 8.4% increase in 2020 compared to 2019 (1.03).

Anti-pseudomonal cephalosporins: maintained overall increase of 19% (2.11 in 2018, 2.47 in 2019 and 2.51 in 2020).

Amoxicillin-clavulanate/piperacillin-tazobactam ratio: maintained decrease of 47% compared to 2018 (4.34 in 2018, 3.54 in 2019 and 2.26 in 2020).

Fluconazole/equinocandins ratio: 24% rise in 2019 (4.14 to 5.45); in 2020 it decreased by 16% (4.57).

Conclusion and relevance During 2020, a change in trend has been perceived in a series of antimicrobial consumption indicators, with higher antibacterials and antifungals OC, carbapenems and colistin consumption, and a decreased fluconazole/equinocandins ratio. This change in trend could be related to the increase of multiresistant bacterial and fungal infections associated with COVID-19.

The downward trend in the consumption of fluoroquinolones and aminoglycosides and the upward trend in anti-pseudomonal cephalosporins and fosfomycin was maintained. Interventions carried out through the antimicrobial stewardship programme aimed at optimising and/or de-escalating empirical antimicrobial treatment may be behind this trend.

The amoxicillin-clavulanate/piperacillin-tazobactam ratio may have been influenced by frequent piperacillin-tazobactam stock-outs in the years studied.

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Conflict of interest No conflict of interest

4CPS-187 PHARMACIST–CLINICIAN COLLABORATIVE STUDY FOR PROSPECTIVE IDENTIFICATION OF DRUG INTERACTIONS IN HIV PATIENTS

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Background and importance As for the general population, HIV patients with antiretroviral treatment (ART) tend to be polymedicated. In this scenario it is crucial to verify the real-time prevalence of interactions and their clinical relevance.

Aim and objectives Review of ART and comedication in HIV patients by a hospital pharmacist in order to detect interactions and improve safety.

Material and methods Prospective study carried out in consecutive patients seen by a physician and a pharmacist between April and May 2021. Variables collected: age, sex, viral load (VL), ART and comedication (according to their Anatomical Therapeutic Chemical (ATC) classification).

Interactions between ART and comedications were reviewed in Lexicomp, Liverpool and Micromedex databases, and classified according to their level of interaction: no interaction and potential weak interaction (little relevance in clinical practice), potential interaction (monitoring is recommended) and contraindicated. Recommendations were developed based on the previously mentioned databases.

Results The study included 100 patients, mean age 48 years, 72% men. VL <50 copies/mL: 95%. Of those 100 patients, 68 used comedication that included 229 drugs, with a mean of 3.3 drugs per patient. Some type of interaction was found in 57 (24.9%) of the 229 drugs (39 (68.4%) potential interaction, 17 (29.8%) potential weak interaction and 1 (1.8%) contraindicated). The main ATC groups with high prevalence of interactions were: nervous system (54%), musculoskeletal system (15%) and cardiovascular system (12%). The remaining minority groups (19%) included alimentary tract, blood and haematopoietic organs, dermatological, anti-infectives and anti-neoplastic/immunosuppressants. The aforementioned 57 detected interactions affected: comedication (46), ART (9), both (1) and physiological factors (1). As a result, the following recommendations were developed: analytical control of thyroid function, separation of drug intake, drug substitution (antipsychotics, anxiolytics, analgesics), monitoring of immunosuppressant levels, control of kidney function and performance of an electrocardiogram.

Conclusion and relevance Most of the interactions were potential (68.4%), affecting mainly comedication and especially drugs for the nervous system. Even though HIV physicians are well aware of ART interactions, as polymedication increases, real-time pharmacist review is a safety need. It was gratifying to have the opportunity to intercept all these interactions in real-time with the prescriber.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-189 ASSOCIATION BETWEEN THE DEVELOPMENT OF IMMUNE-RELATED ADVERSE EVENTS AND THE EFFECTIVENESS OF IPILIMUMAB IN ADVANCED MELANOMA

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Background and importance The development of immuno-related adverse events (irAE) might be associated with better outcomes in oncological patients treated with immunotherapy.

Aim and objectives The main aim was to study the association between irAE incidence and the effectiveness of ipilimumab in monotherapy for patients diagnosed with locally advanced or metastatic melanoma. The secondary objectives were to analyse and to describe the incidence of irAE.

Material and methods Retrospective, observational and longitudinal study in a tertiary care hospital which included every patient diagnosed with advanced melanoma initiating treatment with ipilimumab in monotherapy between February 2015 and December 2020. Follow-up was carried out until March 2021 or death for every patient receiving at least two cycles. The variables studied were: sex, age, disease record, location and histology of primary tumour, staging, functional status according to the Eastern Cooperative Oncology Group (ECOG), metastasis, mutational status of BRAF gene, treatment duration, reason for treatment suspension, and irAE appearance as well as its gravity according to Common Terminology Criteria for Adverse Events (CTCAE) version 5.0. Statistical analysis was carried out with Stata version 16. Effectiveness was measured as overall survival (OS) and it was calculated by Kaplan–Meier estimation. Survival curves were compared by log-rank test.

Results 39 patients were included, most of them men (64.1%) with a median age of 61 (54–72.5) years. 97.4% had an ECOG score between 0 and 1. 59.0% of patients suffered at least one irAE during follow-up. OS median for patients without irAE was 8.7 months. In the group that suffered one irAE, it was 21.8 months and in the group with two or more 13.1 months. Hazard ratio was 0.596 (95% CI 0.296 to 1.200).

Classification of irAE was as follows: 43.5% cutaneous, 26.1% gastrointestinal, 17.4% hepatobiliary and 13% other. Median OS for patients with irAE with severity degree 1 was 5.3 months, for the group with severity degree 2 it was 27.1 months and for the group with severity degree 3 it was 13.1 months.

Conclusion and relevance In our patients, the development of irAE was associated with higher OS. More studies are needed in order to elucidate if these results are significant.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-190 TELEPHARMACY: A PILOT EXPERIENCE IN TIMES OF COVID-19 IN A TERTIARY HOSPITAL

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Background and importance The use of telepharmacy technology allows pharmacists to provide clinical pharmaceutical services to patients who need regular services during the COVID-19 pandemic while maintaining distance and minimising face-to-face meetings.

Aim and objectives To analyse the implementation of a telepharmacy system in a tertiary hospital as a pilot project during the COVID-19 pandemic.

Material and methods Prospective observational study conducted from March 2020 to May 2021 in the Outpatient Unit (OU) of the Pharmacy Service of a tertiary hospital. Telepharmacy was implemented by selecting patients who agreed to participate in this project. A circuit was established in which the pharmacist carried out pharmaceutical care to collect relevant information on the pharmacological treatment of the patients, validated the treatment and proceeded to carry out the hospital dispensing, followed by the dispatch of medication to the Pharmacy Office closest to the patient's home. Once the medication had been dispensed, the hospital pharmacist performed pharmacotherapeutic follow-up telephone consultations to check that everything was correct.

Results During this period, 5878 patients attended the OU, 2875 (48.9%) were selected to benefit from the implementation of telepharmacy because of their advanced age, mobility problems, vulnerability due to their disease, and distance due to living in a rural area. 33 515 hospital dispensations were done, 15 500 (46.2%) were dispensed through the telepharmacy system, with an average of 6 hospital dispensations per patient.

The largest number of patients served by the telepharmacy system were from Neurology (363, 14.6%) with 2136 dispenses (18.0%), followed by Rheumatology (348; 14.0%) with 1832 dispenses (15.5%), in third place was Dermatology (191; 7.7%) with 889 dispenses (7.5%) and in fourth place Pneumology (112, 4.5%) with 792 dispenses (6.0%). The average number of dispensations per month at OU was 2700, of which 1500 were face-to-face and 1200 were shipments.

Conclusion and relevance The implementation of telepharmacy has been a new challenge for the Pharmacy Service. It has proved to be a helpful tool to facilitate pharmaceutical care and hospital dispensing of medicines during the pandemic, avoiding face-to-face visits.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-192 IMPACT OF THE SARS-COV-2 PANDEMIC ON THE USE OF ANTIFUNGALS IN AN INTENSIVE CARE UNIT IN A THIRD-LEVEL HOSPITAL

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Background and importance With the arrival of SARS-CoV-2, it has been observed that the number of cases of fungal infection has increased in critically ill patients, especially invasive pulmonary aspergillosis (IPA).

Aim and objectives To analyse the use of antifungals, expressed in defined daily dose per 100 annual hospital stays (DDD/

100S), and the difference in economic impact between 2019 and 2020 in the intensive care unit (ICU) of a tertiary hospital.

Material and methods Retrospective descriptive study of the use of antifungals in the ICU unit during the period 2019–2020. The data were obtained from the STOCK-Athos-APD drug management electronic program and PRISMA electronic prescription program. For each antifungal agent, the following information was collected: annual global DDD, annual DDD/100S and economic cost of antifungal agents in both years. To calculate this expense the mean annual cost/stay was used.

Results Eight antifungals were studied (liposomal amphotericin B, anidulafungin, caspofungin, micafungin, fluconazole, voriconazole, posaconazole and isavuconazole). The registered stays for admission to the ICU were 5768 in 2019 and 5782 in 2020. The global DDD/100S of antifungals in 2019 was 37.73 while in 2020 it increased to 38.43.

The antifungals with the highest increase were isavuconazole and posaconazole, with a difference of 4.2 and 5.1 DDD/100S, respectively, despite being antifungals of restricted use in our hospital. This increase is due to the rise in IPA cases and a period of shortage of voriconazole, the first-line antifungal in our hospital for IPA in patients without renal failure and without drugs with a possible interaction. However, there was a reduction in the DDD/100S of fluconazole. This is due to a greater number of patients with complicated candidaemia, long-term in the ICU who required a broad-spectrum antifungal such as caspofungin. DDD/100S of the rest of antifungals was not modified compared to the previous year. Therefore, the cost of antifungals in the ICU had an increase of € 112 086.62 (43.8% more than in 2019).

Conclusion and relevance The global DDD/100S of many antifungals in ICU has shown a slight increase between both years. The consumption of these has changed, and this has been manifested with an increment in economic spending as they are drugs with a greater economic impact.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-193 SELECTION OF CLINICAL RULES FOR THE SCREENING OF HIGH-RISK SITUATIONS IN PAEDIATRIC MEDICINE

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Background and importance We developed a clinical decision support system (CDSS) to monitor high-risk situations related to drugs from electronic health records. It involves clinical rules (CR) that trigger alerts to clinical pharmacists based on drug prescriptions, laboratory values, vital signs, and medical problems (eg, vitamin K antagonists + international normalised ratio (INR) ≥ 4).

Aim and objectives We describe a methodology to select CR to extend our approach to the paediatric department.

Material and methods CR were identified with a literature review and scored by 14 senior physicians (expert) divided in two groups (A: general/specialised paediatrics; B: neonatology/intensive care) for two criteria: criticality (low, moderate, high, extreme—risk); relevance (no, need to be adapted to be, highly, very—relevant). The pharmacist in charge of CDSS

scored CR technical feasibility (no, hardly, easily, very easily—feasible). ‘Very relevant’ and ‘easily feasible’ CR were retained if average criticality score was ‘high’ when applicable for different specialties (assessed by numerous experts) or ‘extreme’ when applicable for a specific specialty (assessed by only one expert).

Results Fifty-six CR potentially relevant for children were selected from the literature and divided into five risk classes: drug contraindicated (34%), medication and abnormal laboratory value (27%), drug–drug interaction (19%), inadequate administration mode (11%) and prescription omission (9%). Twenty-four CR were retained after expert assessment, 8 (33.3%) concerned both groups, 14 (58.3%) were specific for group A and 2 (8.3%) for group B. The three most critical CR involved prescribing potassium and hyperkalaemia, glucose-lowering drugs and hypoglycaemia, and vancomycin not adjusted to renal function. Development in CDSS was assessed as ‘very easily’ feasible for 5 CR (21%) including 3 CR (12.5%) concerning both groups.

Conclusion and relevance We identified 24 CR in five risk classes that could be monitored using our CDSS. Assessment based on expert opinion according to risk (criticality), clinical practice (relevance) and technical consideration (feasibility) allowed CR prioritisation to be developed. One-fifth of CR would be immediately implementable with some likely to cover the entire paediatric department since they are common to both groups. A pilot study using these CR will assess the workload associated with this new practice.

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Conflict of interest No conflict of interest

4CPS-194

CLINICAL IMPACT OF A PHARMACIST-LED DISCHARGE MEDICATION REVIEW SERVICE: AN ANALYSIS OF PREVALENCE AND ACCEPTANCE OF INTERVENTIONS

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Background and importance Hospital discharge is linked to an increase in the risk of drug-related problems (DRPs). If these are not recognised and solved, they could be carried over to primary care, with the risk of insufficient follow-up resulting in potential harm to the patient.

Aim and objectives To evaluate a pharmacist-led discharge medication review service by analysing identified DRPs and the acceptance rate of suggested pharmacists’ interventions (PIs) in addition to assessing the clinical significance of these findings.

Material and methods A two-phased mixed method study: (1) retrospective descriptive analyses of the number and type of identified DRPs and recommended interventions based on a validated classification system¹; (2) independent expert panel rating (2 physicians, 1 clinical pharmacist, 1 registered nurse) of the potential clinical impact of a cross section of PIs using the validated rating system CLEO_{de}.² The overall agreement was determined by the Kendall coefficient of concordance.

Results A total of 291 identified DRPs in 205 patients were analysed: the most common included ‘drug interaction’ (34%; n = 99), ‘error in medication process’ (8.2%; n = 24) and ‘duplication’ (8.2%; n = 24). The interventions most frequently suggested were ‘optimisation of administration/route’ (19.6%; n = 57), ‘therapy stopped’ (16.2%; n = 47) and ‘dose adjustment’ (15.8%; n = 46). Physicians accepted 69% (n = 74) of the pharmacists’ recommendations. 64% (n = 38) of the interventions presented to the panel were considered to have a clinical impact. Overall agreement between raters for the clinical impact of PIs was substantial (Kendall κ 0.734; $p < 0.001$).

Conclusion and relevance The expert panel’s independent assessment showed that the pharmacist-led discharge service is clinically beneficial for patients. The prevalence of analysed DRPs and the physicians’ high acceptance rate highlight the valuable role of pharmacists in improving patient safety at the time of discharge.

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4CPS-195

MEDICATION-RELATED READMISSIONS: DOCUMENTATION AND COMMUNICATION TO THE NEXT HEALTHCARE PROVIDERS AND PATIENTS

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Background and importance Of all readmissions, 21% are medication-related readmissions (MRRs). However, it is unknown whether MRRs are recognised and communicated in the care continuum.

Aim and objectives To assess the proportion of preventable and non-preventable readmissions that contain documentation on the contribution of medication in the patient records (which are then regarded as recognised MRRs).

Material and methods In a previous study, a multidisciplinary team of physicians and pharmacists assessed the medication-relatedness and preventability of unplanned readmissions from seven departments (the gold standard). In the current cross-sectional observational study, patient records were evaluated. A MRR was regarded as documented – and therefore recognised by healthcare providers – when the causal medication(s) was mentioned in patient records (in duplo, using notes from physicians, nurses, pharmacy teams and discharge letters). A MRR was regarded as communicated when documentation was found for the next healthcare providers, patients and/or caregivers. The primary outcome was the proportion of readmissions that contained documentation on the causal medication(s). Secondary outcomes were the differences between the documentation of preventable and non-preventable MRRs and differences in the length of stay (LOS) between documented and undocumented MRRs. Lastly, the proportion of communicated MRRs was assessed. Descriptive data-analysis was used.

Results Of 181 included MRRs, 72 (40%) were deemed preventable by the multidisciplinary team. For 159 of 181 MRRs (88%), documentation on the causal medication(s) was present. The causal medication was documented more often for non-

preventable readmissions compared to preventable readmissions (95% vs 78%; $p=0.002$). The LOS was longer for readmissions where the causal medication was undocumented (median 8 days vs 5 days; $p=0.062$). Of 159 documented MRRs, 137 (86%) were communicated to the general practitioner, 4 (3%) to the community pharmacy and 93 (59%) to patients and/or caregivers.

Conclusion and relevance This study shows that for 88% of MRRs the causal medication was documented in the patient records. The causal medication was lacking more often for preventable MRRs. These results imply that MRRs are not always recognised, which could impact patients' wellness as an increased LOS was found for unrecognised MRRs. Communication of MRRs to the next healthcare providers and patients needs improvement.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-196 ABSTRACT WITHDRAWN

4CPS-197 EVALUATION OF ADHERENCE TO CYSTIC FIBROSIS TRANSMEMBRANE CONDUCTANCE PROTEIN MODULATOR DRUGS

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background and importance In patients with cystic fibrosis (CF), long-term adherence to various treatments is considered low (46%–70%). Cystic fibrosis transmembrane conductance regulator (CFTR) modulators have recently been licensed. Low adherence to these treatments may decrease efficacy.

Aim and objectives To assess adherence to CFTR modulators and determine if there are differences because of length of treatment.

Material and methods Retrospective observational study of CF patients under treatment with a CFTR modulator (tezacaftor/ivacaftor; elexacaftor/tezacaftor/ivacaftor; lumacaftor/ivacaftor) dispensed at the outpatient unit of the Children's Hospital Pharmacy Service, between January 2020 and April 2021. Demographic variables (age and sex), prescription and dispensing dates, and amount dispensed were obtained from the electronic prescription records. Adherence was calculated using the medication possession ratio (MPR). $MPR \geq 80\%$ was considered adequate adherence. Continuous variables were expressed as mean (SD) or median (Q1-Q3), and categorical variables as absolute and relative frequency. A non-parametric test of comparison of proportions was used to assess the relationship between adherence and length of treatment (less or greater than 12 months). Statistical analysis was performed with Stata version 13.

Results Eighty-two patients (36 women, 43.9%), 67 (81.7%) of whom were adults with a median of 31.2 years (Q1-Q3 = 26.1–39.0) and 15 (18.3%) were children or adolescents with a median of 11.6 years (Q1-Q3 = 7.6–15.6). Treatments dispensed were: tezacaftor/ivacaftor + ivacaftor (61 patients; 74.4%), elexacaftor/tezacaftor/ivacaftor + ivacaftor (13 patients; 15.9%) and lumacaftor/ivacaftor (8 patients; 9.8%). At the time of analysis, 55 patients (67.1%) had been in treatment for less than 12 months and 27 (32.9%) more than 12 months. The mean MPR was 102.7% (SD 11.5%). Eighty-one patients (98.7%) had adequate adherence. The mean MPR in the group lasting less than 12 months was 104.8% (SD

11.7%) and 98.3% (SD 9.7%) in those lasting more than 12 months ($p=0.327$).

Conclusion and relevance Adherence to CFTR modulators is higher than observed for other drugs in CF patients, but there is a need to study whether adherence with these drugs is maintained in the long term. Although there were no differences in adherence according to the length of treatment, the only patient considered non-adherent was on treatment greater than 12 months.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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4CPS-198 THE IMPACT OF A PHARMACIST-LED MEDICATION REVIEW ON THE MEDICINE RISK SCORE: A NON-RANDOMISED CONTROLLED STUDY

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Background and importance Multiple studies have shown that pharmacist-led medication reviews can reduce and prevent drug-related problems. Medication reviews require great economic resources and, consequently, the pharmacists need to prioritise the patients who would benefit the most from a medication review. A group of researchers have designed an algorithm called Medicine Risk Score (MERIS) to identify patients who are at increased risk of experiencing medication errors.¹ Even though the algorithm has been used regularly in the selection of patients for medication review, the impact on the patients' MERIS-scores has not yet been investigated.

Aim and objectives To investigate the impact of a pharmacist-led medication review on the MERIS-score for hospitalised patients.

Material and methods In a controlled, prospective study the MERIS-scores for patients who underwent a pharmacist-led medication review (intervention group – Hospital A) were compared with the MERIS-scores for patients who did not undergo a medication review (control group – Hospital B). Additionally, it was investigated to what extent a change in the MERIS-score was related to the drug-related problems identified. Participants: patients without a medication review in recent months and a MERIS score ≥ 14 , admitted to a medical or cardiology department at two local hospitals. Primary outcome: change in MERIS-scores calculated as the difference in MERIS-score before medication review and 1½ days after.

Results A total of 54 patients were included in the intervention group and 162 patients in the control group. By comparing the changes in the MERIS-scores, no statistically significant difference between the two groups was observed ($p=0.84$). Of the drugs included in the identified drug-related problems, slightly over 50% had a potential risk of harm or interaction, which influenced the MERIS-score. However, only 17.2% of the drugs would, if the recommendations were implemented, lead to changes in the MERIS-scores.

Conclusion and relevance A pharmacist-led medication review does not seem to have an impact on the MERIS-score for hospitalised patients. Further studies are needed to identify interventions that can reduce patient risk of medication errors.

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Conflict of interest No conflict of interest

4CPS-200 EFFECTIVENESS OF ERENUMAB AND GALCANEZUMAB IN THE PREVENTION OF MIGRAINE

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Background and importance Migraine is a disease with a high personal and socioeconomic impact. The new prophylactic treatments erenumab and galcanezumab showed benefits versus placebo with few side effects.

Aim and objectives To evaluate the effectiveness of erenumab and galcanezumab by changing the MIDAS score and reducing the number of migraine episodes 12 weeks after starting treatment.

Material and methods Retrospective descriptive study of patients who started treatment with erenumab or galcanezumab since their inclusion in the Hospital's Pharmacotherapeutic Guide (10 March 2020), complying with the funding criteria and the use criteria established by the Pharmacy and Therapeutics Commission, and who have been in treatment for at least 12 weeks (end of study 23 April 2021). The main variable is combined and includes reduction of MIDAS scale by 30% when the baseline score was > 20 or ≥ 5 points when the baseline score was 11–20 and/or reduction in the number of monthly migraines of at least 50%, both variables at 12 weeks of treatment.

Results 74 patients, 82.4% women with a median age of 47 (IQR 14) years. 66.2% with chronic migraine, with a median number of monthly migraines of 15 (IQR 15) and a median MIDAS score of 76 (IQR 67). 48 (65%) patients started treatment with galcanezumab and 26 (35%) with erenumab. The main variable was reached in 62 patients (83.8%). Eight no-responder patients continued with the treatment. At week 24, 6 of them reached effectiveness.

At week 12, 7 patients (9.5%) stopped treatment, 6 due to lack of response, although 2 of them had reached one of the variables of the main variable, and 1 patient due to a suspected allergic reaction. According to the type of migraine (chronic or episodic) and the prescribed drug, there were not statistically significant differences in the main variable. Switch of treatment was done in 13 patients (17.5%) mainly due to lack of effectiveness.

Conclusion and relevance The effectiveness of the treatments at 12 weeks is high (83.8%). Two-thirds of the patients who did not reach the main variable continued with treatment and 75% of them achieved effectiveness at 24 weeks; so it seems that some patients may need a longer time in which to reach a response.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-201 AUDIT ON THE PRESCRIPTION AND ADMINISTRATION OF PARKINSON'S DISEASE MEDICATION ON ADMISSION TO HOSPITAL

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Background and importance The National Institute for Health and Care Excellence (NICE) recommends that Parkinson's disease (PD) patients who are hospitalised take levodopa within 30 min of their individually prescribed administration time. In some cases this may require self-medication. Serious complications can develop if levodopa is not taken on time that can lead to increased care needs and increased length of stay in hospital.

Aim and objectives To evaluate whether the prescription and administration of PD medicines in an acute hospital complies with best practice recommendations.

Material and methods This baseline audit was carried out over a 12-week period in 2021. Data were collected on 50 PD admissions to the hospital. Data relating to PD medicines prescribed for the management of motor symptoms were collected. The following information was recorded:

- Unintentional discrepancies on the admission prescription following a medication reconciliation
- The number of delayed or omitted doses of PD medicines since arrival to hospital until time of data collection
- The number of patients that administered their own PD medicines.

Results Unintentional discrepancies on the admission prescription were associated with 34% (n=47) of PD medicines reviewed. The majority of patients (n=40; 80%) were affected by a delay or omission of PD medicines since admission to hospital. Over one-third (n=106; 36%) of doses of levodopa PD medicines were delayed or omitted. One-quarter of medication reconciliations were completed within 24 hours of the patient meeting the Emergency Department triage nurse. One-fifth (20%) of admissions took their own PD medicines while in hospital.

Conclusion and relevance Greater emphasis should be placed on accurately prescribing and administering PD medicines for patients on admission to hospital. Consideration should be given to introducing a self-administration policy for PD patients admitted to hospital.

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Conflict of interest No conflict of interest

4CPS-202 OPTIMISATION OF SUBCUTANEOUS BIOLOGICAL THERAPIES IN RHEUMATIC AND DERMATOLOGICAL DISEASES

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Background and importance The optimisation strategies are based on dose reduction or increasing the dosing interval. In this way, patients have fewer adverse effects, more adherence and the same benefit.

Aim and objectives To analyse the optimisation of subcutaneous biological therapies (BT) by the Rheumatology and Dermatology Services, as well as evaluating the cost avoided, in a third-level hospital.

Material and methods Retrospective observational study of patients with rheumatoid arthritis (RA), ankylosing spondylitis (AS), psoriatic arthritis (PsA) and plaque psoriasis, in treatment with biological drugs and optimisation dosage, during the year 2020. The evaluation of the cost avoided was the difference between the cost with the usual dosage and optimisation dosage. Variables: sex, previous BT, year of initiation with BT, current BT (biosimilar/reference), dosage, drug cost. Information was collected from the hospital's information systems.

Results 95 patients were included with BT optimisation: 38% with RA, 27% with AD, 22% with PsA and 13% with psoriasis. 100% of patients were on the therapeutic target for at least 6 months and the reduction of doses between 20% and 50% spacing the administration interval. 43% of the patients were women, and 57% men. 81% had not had another previous biological and 77% had the same biological drug ≥ 4 years. The optimised BT were: tumour necrosis factor alpha antagonists (anti-TNF α drugs): adalimumab (47%), etanercept (40%) and certolizumab (5%); anti-interleukin (IL) 6: tocilizumab (1%); anti-IL17A: ixekizumab (3%) and secukinumab (1%); anti-IL23: guselkumab (1%); anti-IL12–23: ustekinumab (2%). The most common intervals were: 21% adalimumab every 21 days, followed by 17% with etanercept every 21 days. The use of biosimilars versus the reference drugs of adalimumab and etanercept was: 29%/71% and 68%/32%, respectively.

The costs avoided were: Rheumatology: € 216 968.29. With the usual dose, it would have meant an annual cost of: € 405 381.08 and with optimised: € 188 412.79; Dermatology: € 18 670.02. With the usual dose it would have cost € 43 362.38 and with the optimisation: € 24 692.36.

Conclusion and relevance The optimisation of biological therapies has managed to keep our patients in therapeutic objective. Optimisation is a beneficial strategy for the patient and for our health system, since we obtain significant savings in effects adverse effects and costs of therapy.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-203 COMPARISON OF PIRFENIDONA VERSUS NINTENDANIB IN IDIOPATHIC PULMONARY FIBROSIS

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Background and importance Idiopathic pulmonary fibrosis (IPF) is a chronic and progressive disease. Its treatment with antifibrotic drugs (pirfenidone and nintedanib) is characterised by a high incidence of adverse effects (AE) that together with

the progression of the disease make therapeutic persistence difficult.

Aim and objectives The objective was to compare pirfenidone and nintedanib in terms of effectiveness, safety, and durability of treatment in a tertiary hospital.

Material and methods Retrospective observational study of patients treated with pirfenidone and/or nintedanib between November 2012 and May 2021.

Variables collected: age, sex, forced vital capacity (FVC), dose, duration of treatment, reason for suspension, AE and adherence. Effectiveness was measured as a <10% reduction in FVC at 12 and 24 months. Data sources: outpatient dispensing program and clinical history. Analysis with SPSS Statistics 21.

Results 83 patients received pirfenidone and 58 nintedanib (76% and 69% men, respectively). Mean age 73 years with pirfenidone and 72 years with nintedanib. Dose reductions were greater with nintedanib (38% vs 18% pirfenidone, $p=0.008$), and more patients switched drugs with nintedanib (26%) than with pirfenidone (17%) without statistically significant differences ($p=0.194$).

The percentage of patients who progressed was higher with pirfenidone (38% vs 23%) without statistically significant differences ($p=0.132$). The speed of progression was also higher with pirfenidone (within the first 12 months: 73% vs 38%, $p=0.028$).

The median durability by Kaplan–Meier was greater with nintedanib: 23 months (95% CI 12 to 33) versus 22 months (95% CI 11 to 33), although without statistical significance ($p=0.689$).

Reasons for suspension: with pirfenidone 23/45 death, 19/45 AE, 2/45 change of hospital and 1/45 lung transplantation; with nintedanib 9/23 death, 8/23 AE, 3/23 anticoagulant treatment and 3/23 change of hospital.

The percentage of patients with AE was practically the same: 45% (37/83) pirfenidone and 43% (25/58) nintedanib.

Adherence was similar in both groups (92% for pirfenidone and 87% for nintedanib).

Conclusion and relevance Pirfenidone and nintedanib have very similar safety and durability profiles, and it seems that with pirfenidone a greater number of patients progress and do so faster; however, larger sample size studies would be necessary to achieve statistical significance.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-204 AN EXPLORATION OF PATIENTS' PERCEPTIONS OF COLORECTAL CANCER AND ITS MANAGEMENT: A QUALITATIVE STUDY AT INITIATION OF TREATMENT WITH CHEMOTHERAPY

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Background and importance Chemotherapy remains the backbone of treatment for colorectal cancer, often administered in combination with surgery. Due to its mode of action, it may

lead to adverse effects that can affect patients' physically and psychosocially. However, there is a paucity of studies that portray the patients' perceptions of colorectal cancer and chemotherapy at initiation of treatment.

Aim and objectives The aim of the study was to explore patients' perceptions of colorectal cancer and chemotherapy at initiation of treatment.

Material and methods In-depth semi-structured interviews were conducted with 16 patients with newly diagnosed colorectal cancer on their first cycle of treatment with XELOX or FOLFOX. The study took place at the national oncology centre, between October 2018 and September 2019. Interviews were audio recorded and transcribed verbatim. Data were analysed independently by two researchers using interpretative phenomenological approach. Ethical approval was granted.

Results Three themes were identified: patients' perceptions, knowledge, and influences on patients' attitudes and knowledge about the illness and treatment. The 'shock' experienced by patients on receiving a diagnosis of cancer was worse among those patients who were initially misdiagnosed for benign gastrointestinal disease. They could not believe that colorectal cancer presented with vague symptoms such as altered bowel habit and abdominal pain. Patients felt 'devastated' on being advised that they were to receive chemotherapy as despite improvements in treatment this illness was still associated with a fatal outcome. A nurse-led general information session was provided to all patients who were about to initiate chemotherapy as a group. Despite this, a lack of knowledge about treatment-specific adverse effects was evident through the patients' expectation of experiencing severe alopecia and debilitating fatigue with their proposed treatment. At this phase of the treatment journey, patients' knowledge was heavily based on perception. Witnessing relatives and friends' cancer experiences affected patients' attitude towards chemotherapy by expecting a challenging treatment journey. However, this patients' negative perception towards treatment was outweighed by their expected treatment's curative potential.

Conclusion and relevance Being aware of patients' perceptions towards colorectal cancer and its management with chemotherapy may assist healthcare professionals in addressing misperceptions and irrational fear. Pharmacists, being experts in medicines, are well-positioned to conduct individual counselling using patient-tailored treatment-specific information prior initiation of treatment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-205 QUANTIFYING PROBLEMATIC PRESCRIBING CASCADES IN THE NETHERLANDS

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Background and importance A prescribing cascade (PC) is defined as the misinterpretation of an adverse drug event (ADE) from one medication (index medication) as a medical condition, which is subsequently treated with another medication (marker). A PC is problematic when the benefits of this

combination of medication do not outweigh the risks on the patient's health. PCs have been described previously, but unawareness remains amongst pharmacists. The average length of stay in hospitals has decreased, which results in PCs where the index medication is initiated in the hospital and the ADE is treated in primary care.

Aim and objectives For this reason, we aimed to quantify the occurrence of problematic PCs using community pharmacy records.

Material and methods A mixed-methods study was conducted to compose a list of problematic PCs relevant for the Netherlands, including a literature review and an assessment by 16 experts (pharmacists and physicians in hospitals and primary care). Next, a retrospective cohort study using the Prescription Sequence Symmetry Analysis (PSSA) method was performed to quantify PCs. Data were extracted from 656 community pharmacies from 2015 until 2020. The PSSA method evaluates the asymmetry in the distribution of the prescription of the marker medication before and after the prescription of the index medication. An adjusted sequence ratio (aSR) was calculated to adjust for prescribing trends over time. An aSR ≥ 1 indicates an increased probability of an index medication followed by a marker medication. Data were analysed using SPSS version 22.

Results Experts assessed 90 PCs from literature, and 59 were categorised as problematic PCs. These PCs mostly concerned antidepressants, antipsychotics and lipid-modifying agents as index medication. Depression, erectile dysfunction and urinary incontinence were the most frequently occurring ADEs. A significant aSR was found for 37 (63%) of 59 PCs. For 16 PCs the aSR was between 1 and 1.5 and for 21 the aSR was >1.5 . The highest aSR was 4.28 (95% CI 4.08 to 4.49) for amiodarone, followed by thyroid hormones, based on 654 incident users.

Conclusion and relevance In this study 37 (63%) of 59 problematic PC had a significant positive association when quantified. This illustrates that more awareness is needed by pharmacists to prevent PCs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest Corporate sponsored research or other substantive relationships: KNMP and Ncontrol.

4CPS-206 RIBOCICLIB AS FIRST LINE FOR METASTASIC BREAST CANCER: ANALYSIS OF USE AND SECURITY

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Background and importance Therapeutic management of luminal metastatic breast cancer (MBC) has suffered significant progresses with the approval of cyclin-dependent kinase (CDK) inhibitors such as ribociclib.

Aim and objectives To know the characteristics of patients treated with ribociclib as first-line in our centre, and efficacy, frequency and severity of adverse reactions (ARs) associated with it. To compare our results with the pivotal trial MONALEESA-2 of ribociclib as first-line treatment.

Material and methods Retrospective, observational, descriptive study of women aged ≥ 18 years that received ribociclib as first-line treatment until July 2020 in a tertiary hospital. Follow-up was carried out until March 2021. Following the PFS was cut short by the end of the study.

Variables: age, Eastern Cooperative Oncology Group (ECOG) scale, hormonal therapy in combination, length of treatment, progression-free survival (PFS), ARs, dose adjustment, treatment interruption and suspension.

ARs were classified according to National Institute Cancer: Common Terminology Criteria for Adverse Events (CTCAE) v5.0. Data were collected from patients' medical records and dispensing software. PFS was calculated by Kaplan–Meier using SPSS software.

Results Fourty patients were included, median age 62 (rank 41–81) years. ECOG before starting: 0 (n=26), 1 (n=13) and 2 (n=1). Ribociclib was used in combination with fulvestrant (n=6), letrozole (n=30), exemestane (n=3) and anastrozole (n=1). Median length of treatment 19 (2–38) cycles. Twenty-four patients continued ribociclib at the end of the study. Sixteen discontinued permanently: twelve due to disease progression, one death and three ARs (liver–kidney toxicity and neutropenia).

PFS were 26.2 months (95% CI 21.9 to 30.5), similar to the pivotal trial, MONALEESA-2 (25.3 months). Initial dose was 600 mg in 37 patients and 400 mg in three patients. Twenty required dose reduction, of which 16 required 400 mg, and four were first reduced to 400 mg and then to 200 mg. Administration was delayed for at least 1 week due to ADRs (n=24).

Twenty presented grade $\frac{3}{4}$ ADRs: neutropenia (n=9), impaired liver profile (n=6), skin toxicity (n=4), anaemia (n=2); vomiting/diarrhoea, oedema, renal toxicity and asthenia (n=1).

Conclusion and relevance In our centre, ribociclib was used in accordance with indications. Likewise, the pattern of ARs was similar, highlighting neutropenia as dose limiting. As hospital pharmacists is necessary to manage AEs and dose reductions; and improve adherence to obtain the best therapeutic outcomes.

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Conflict of interest No conflict of interest

4CPS-207 IMPROVING THE SAFETY OF PHARMACOTHERAPY IN PAEDIATRIC HAEMATO-ONCOLOGY BY CLINICAL PHARMACY SERVICES

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Background and importance Prevention of drug-related problems (DRP) beneficially affects patient outcomes. Children who are treated for haemato-oncological diseases or who are receiving a haematopoietic stem cell transplantation (HSCT) are highly susceptible to DRP. Paediatric clinical pharmacy services (CPS) showed a positive impact on several outcome measures including reduction of DRP.

Aim and objectives This evaluation aimed to assess the impact of CPS in a paediatric tertiary care centre specialising in haemato-oncology by quantifying DRP and pharmaceutical interventions (PI), determining their acceptance rate, rating their clinical significance and estimating economic benefit.

Material and methods From June until December 2020, a clinical pharmacist (CP) provided CPS, which included medication reviews and subsequent ward round participations (A: haemato-oncology, 11 beds; B: HSCT unit, 10 beds). The CP and an independent expert panel consisting of two clinical pharmacists and two paediatric haemato-oncologists assessed the PI for clinical significance.¹ Economic benefit was estimated retrospectively by drug therapy cost reductions and avoided follow-up costs based on prevention and management of adverse drug reactions (ADR).²

Results During 32 ward rounds, 230 DRP were addressed in 36 children (median age 7 (0.4–17) years). The acceptance rate for PI was 73.5%. The most common DRP concerned need for drug monitoring, need for information/therapy discussion and drug–drug interactions; the most common PI were drug-monitoring, drug-information and dose adjustments. The CP assessed 66% of PI as very significant or significant and correlation with the expert rating was significant ($p \leq 0.0001$). Costs of CPS were € 7200. PI led to estimated drug therapy cost reductions of € 5500. Prevention of 11 and identification of 24 ADR led to estimated avoided follow-up costs of € 14 300–€ 27 500 and € 31 200, respectively.

Conclusion and relevance This evaluation showed that CPS for a tertiary care centre specialising in paediatric haemato-oncology is capable of identifying and preventing DRP by clinically significant PI. The estimated economic benefit of CPS was at least six-fold higher than its costs. Based on the results, CPS were expanded in our hospital.

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Conflict of interest No conflict of interest

4CPS-209

BENEFIT OF MEDICATION REVIEWS BY A RENAL PHARMACIST IN THE SETTING OF A COMPUTERISED PHYSICIAN ORDER ENTRY SYSTEM

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Background and importance A 'renal pharmacist consultant service' (RPCS) reviewing patients with renal impairment (RI) for drug-related problems (DRP) can foster patient safety.¹ However, the benefit of this service in the new setting of a computerised physician order entry (CPOE) system with a clinical decision support system (CDSS) is unknown.

Aim and objectives The aim of the study was to evaluate a RPCS on wards with CPOE-CDSS, its need in general and its effectiveness on prescription changes and thereby on patient safety.

Material and methods Over a period of 3 months (February–April 2021), patients with $eGFR_{\text{absolute}}/KreaCl < 60$ mL/min of one surgical and one orthopedic ward at a German University Hospital received a medication review for DRP by a renal pharmacist for all medication presented in the CPOE-CDSS Meona during weekdays. Written consultations explaining DRP

and recommending interventions to solve them (eg, dose or drug adaptation) were presented to physicians directly in the drug chart tab of the CPOE-system. The prescription changes were retrospectively evaluated. Ethical approval was obtained from the ethics committee at LMU Munich (registration number 21–0743).

Results During 53 working days, 712 (30.5%) of 2331 screened patients were included with an $eGFR_{\text{absolute}}/KreaCl < 60$ mL/min and a pharmacist-led medication review was performed for all medication presented in the CPOE-system (Meona). In 79/712 (11.1%) patients one or more DRP were detected (median 1 DRP (1–3) per patient) and written recommendations were shared via Meona. In total, 104 DRP were identified, mostly caused by 'dosage too high' ($n=55$; 52.9%), 'dosage regime wrong' ($n=13$; 12.5%) and 'contraindication' ($n=9$; 8.7%). Acceptance rate of recommendations was 74.0% ($n=77/104$). In 9 cases (8.7%) the recommendation was consciously retained after discussion because of lack of alternatives, in 11 (10.6%) the prescription remained unchanged for unknown reasons and in 7 (6.7%) the result was unknown due to discharge.

Conclusion and relevance The pharmacist-led medication reviews identified DRP in patients with RI even in the setting of prescribing in a CPOE-CDSS. A RPCS in this setting successfully increased appropriate prescribing by physicians and thus improved patient safety.

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Conflict of interest No conflict of interest

4CPS-210

IMPACT OF THE ANTIBIOTIC THERAPY USED DURING THE SARS-COV-2 PANDEMIC ON THE INCIDENCE OF CLOSTRIDIODES DIFFICILE INFECTION

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Background and importance Suspicion of bacterial coinfection in patients with SARS-CoV-2 pneumonia has led to an increased consumption of antibiotics used in the treatment of community-acquired pneumonia (CAP). One of the best-known risk factors for *Clostridioides difficile* infection (CDI) development is antibiotic treatment but there are inconsistent findings regarding which groups of antibiotics are most strongly associated.

Aim and objectives We aimed to compare the risk of developing CDI during hospitalisation in the internal medicine division to changes in antibiotics consumption in the pre-pandemic and COVID-19 pandemic period.

Material and methods Single centre retrospective cohort study was conducted in a secondary hospital (900 beds). Hospitalised patients in the 2019 and 2020 periods who presented hospital-acquired diarrhoea with simultaneous *C. difficile* toxin determination were included. We selected patients admitted to internal medicine units to compare the incidence of CDI with

the change in the antibiotic consumption profile between both periods.

Microbiological diagnosis consisted of simultaneous detection of glutamate dehydrogenase and toxins and enzyme immunoassay test. Positive results were confirmed by PCR.

Statistical treatment: to compare the CDI incidence between the two periods the rate ratio was calculated. Antibiotic consumption comparison was performed using independent samples Z-test.

Results

Parameter	2019 (pre-pandemic period)	2020 (pandemic period)	P value
Total/mean (patient-days)	74.012/10.16	72.742/9.2	
Age (years) gender (male%)	8146.5%	7948.5%	
Incidence CDI/10 000 patient-days	6.35	2.47	RR= 0.39, p<0.001
Antibiotic consumption DDD/100 patient-days			
Ceftriaxone	11.68	21.75	p<0.01
Amoxicillin/clavulanic	14.96	10.44	p<0.01
Quinolones	13.67	9.07	p<0.01
Carbapenems	4.39	4.48	p=0.4
Piperacilin/tazobactam	5.13	4.71	p<0.01

Conclusion and relevance Changes in antimicrobial use related to the outbreak suggest that clinicians overprescribed first-line CAP-focused antibiotics.

CDI incidence reduction was related to a marked decreased use of quinolones and amoxicillin/clavulanic despite the fact that consumption of third-generation cephalosporins has doubled.

Another implemented protocol such as more comprehensive cleaning and hand-washing hygiene could have contributed to the marked CDI decrease.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-211 REDUCTION OF FLUSHING VOLUME AND INCOMPATIBILITIES BY A CLINICAL PHARMACIST IN A PAEDIATRIC INTENSIVE CARE UNIT

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Background and importance Incompatibilities of drugs administered via the same Y-site can have serious consequences. Therefore, incompatible drugs should be administered through different infusion lines. If separate administration is not possible, flushing should be performed between drug administrations. However, children in critical care units have a high risk for fluid overload which is associated with a higher morbidity. Consequently, unnecessary fluids should be avoided [1].

Aim and objectives The aim of our study was to evaluate the intervention to reduce flushing volume without increasing incompatibilities in a paediatric intensive care unit (PICU).

Material and methods We performed an intervention study in our 13-bed PICU in Kassel to determine the flushing volume (S1P0 January–July 2020; S1P1: October 2020–August 2021). Patients with ≥ 2 IV drugs, stay >24 hours, and age 0–18 years were included. As part of this study two 4-week bedside observations were conducted to survey compatibility of co-administered drugs (S2P0 July 2020; S2P1 October 2020). As an intervention, patient-specific compatibility and flushing charts were created by a clinical pharmacist. The Mann-Whitney U test was used for quantitative variables and the χ^2 test for categorical variables. The analyses were performed using R version 4.1.1.

Results 170 patients (85 patients per period) were included in the intervention study. 23 (S2P0) and 24 (S2P1) patients with 504 (S2P0) and 523 (S2P1) drug combinations were part of the bedside observation. The median of the flushing volume was significantly reduced from 0.68 mL/kg/day (Q25/Q75 0.31/1.33) to 0.35 mL/kg/day (Q25/Q75 0.08/0.74); $p<0.001$. Also, the number of daily flushing processes decreased (S1P0 median (Q25/Q75) 2.60 (1.33/3.40), S1P1 median (Q25/Q75) 1.44 (0.67/2.33); $p<0.001$). Furthermore, the observational study demonstrated a 51% reduction in the number of administered incompatible combinations (S2P0: 8.93%, S2P1: 4.39%, $\chi^2=7.46$; $p=0.002$). Combinations without literature data were administered in both periods, and again the number could be reduced (S2P0: 8.13%, S2P1: 3.82%, $\chi^2=8.96$, $p=0.003$).

Conclusion and relevance Our results show that incompatibilities are very common in PICU and that relevant compatibility data, especially for children, are still lacking. A pharmaceutical intervention can not only help to reduce flushing volume but can also reduce incompatibilities.

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4CPS-213 A COMPARATIVE RISK ANALYSIS COMPARING THE CONVENTIONAL AND FULLY AUTOMATED MANAGEMENT OF CLINICAL TRIALS IN AN ONCOLOGY PHARMACY

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Background and importance A software module (APOTECA-trial) was introduced in clinical practice to manage clinical trials and investigational drugs, thereby minimising manual activities and ensuring maximum traceability (1). APOTECA-trial was developed in accordance with the Good Clinical Practice (GCP) guidelines, in particular with regard to subject safety, outcome reliability, characteristics of electronic systems/data, and quality management with a risk-based approach.

Aim and objectives The objective of this study was to assess the risk associated with the pharmacy-based management of

clinical trials before and after the implementation of the software module APOTECAtrial.

Material and methods The conventional manual process and the improvements introduced after the implementation of APOTECAtrial were assessed through a comparative risk analysis. First, the process was divided into seven phases (delivery to the pharmacy, preparation/dispensing, returns management, disposal, storage, data management, monitoring). The activities related to each phase and the corresponding potential failures were identified. The risk was assessed by rating the severity (S), frequency (F) and detectability (D) of the potential effect of the failures. The risk index ($S \times F \times D$) was calculated for each activity (RI) and for the entire process (RI_{total}). The index of improvement (IR before implementation divided by IR after implementation) was calculated for each area (IM) and for the entire process (IM_{total}).

Results Overall, 37 activities were assessed. The RI_{total} decreased by 53%, from 449 (before implementation) to 207 (after implementation). The IM_{total} amounted to 2.2. The highest IR reduction was found in the preparation/dispensing phase (from 152 to 42) with an IM equal to 3.6. IM values ranged between 1.7 and 4.5. Most of the improvements introduced (79%) referred to traceability and data integrity, while 21% impacted on the quality of the drug dispensed.

Conclusion and relevance The risk analysis revealed that fully-automated management of clinical trials represents an important improvement of the clinical pharmacy practice in terms of safety. Since the potential risks are significantly reduced, the automated process guarantees high-quality standards and GCP-compliance. Several manual and repetitive activities were simplified, thereby allowing pharmacists to spend more time on clinical and patient-oriented tasks.

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Conflict of interest No conflict of interest

4CPS-214 EXPERIENCE OF USE OF CANNABIDIOL IN PAEDIATRIC PATIENTS

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Background and importance Cannabidiol (CBD) is an orphan medicine recently approved in Europe for the treatment of Dravet (DS) and Lennox–Gastaut syndromes (LGS) in combination with clobazam, and for tuberous sclerosis. However, there is growing evidence that other types of refractory epilepsy could be treated with this drug.

Aim and objectives To evaluate the use of CBD in a paediatric hospital, as well as its effectiveness and safety.

Material and methods Observational, retrospective study carried out between January 2017 and September 2021, including all patients treated with CBD in our hospital.

Variables included Age, sex, weight, concomitant antiepileptic drugs (AEDs), length of treatment, initial and maintenance dose, reasons for discontinuation and adverse events (AEs) related to CBD. Efficacy was assessed following two

criteria: reduction in number of seizures and opinion of caregivers.

Data were collected from electronic medical records and the pharmacy dispensing program.

Results Thirty-one patients were included: male 61.3% (n=19); median age 10 (2–16) years. Median weight 28 (14–80) kg median initial dose: 3 mg/kg/day (1–12). CBD was prescribed for LGS 61.3% (n=19), refractory epilepsy 13% (n=4), DS 6.5% (n=2), epileptic encephalopathy 6.5% (n=2), West syndrome 6.5% (n=2), Rett syndrome 3.1% (n=1) and tuberous sclerosis 3.1% (n=1). Median of concomitant AEDs was 3 (0–4). Twenty (64.5%) patients received CBD in combination with clobazam.

Two patients (6.5%) discontinued CBD in the first 2 weeks of treatment. Both presented a significant increase in number of seizures. Twenty-nine (93.5%) patients reached a maintenance dose of 15 mg/kg/day (5–44); the median length of treatment was 7 (3–69) months. Treatment was discontinued in 8 cases (25.8%) because the number of seizures was not reduced, and one also presented rash (3.4%). To date, 21 (67.7%) patients continue on CBD: in 14 (45.2%) cases, number of seizures was significantly reduced and caregiver's appreciation of effectiveness was good; and 7 (22.5%) responded partially.

Most frequent AEs were: irritability 24.4% (n=7), diarrhoea 13.79% (n=4) and anorexia 10.34% (n=3). Other AEs described were: drooling 6.9% (n=2), somnolence (n=2); rash 3.4% (n=1), hepatobiliary disorders (n=1) and asthenia (n=1).

Conclusion and relevance CBD was prescribed in numerous indications due to the lack of therapeutic alternatives in some seizures-refractory patients. It has been an effective option in most of our patients and its security profile is consistent with clinical trials.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-218 EVALUATION OF THE IMPACT OF INCORPORATING A PHARMACIST INTO A HOSPITAL EMERGENCY DEPARTMENT

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Background and importance Attending a hospital emergency department (HED) is considered a high-risk situation regarding medicines appropriate reconciliation and medication errors. Thus, patients may well benefit from incorporating a pharmacist into the healthcare team who helps with medication management review.

Aim and objectives This study aimed to analyse the interventions proposed by the pharmacy team to the medical team in our HED setting and to evaluate the positive impact this may have on patients' management.

Material and methods Patients' prescriptions were assessed and pharmacotherapy changes, if needed, were registered in their clinical history. At the end of the work day, we reviewed if proposals had been accepted or rejected. This prospective study was conducted in a tertiary hospital over 1 month.

Results 200 patients (54% males and 46% females) admitted to HED were evaluated by the pharmacy team. Mean age was 75 (31–99) years.

66 interventions were proposed in 54 patients (27%). 55% were accepted and 22% rejected. The remaining 23% could not be appraised as patients had been discharged prior to the medical team evaluation of the suggestions.

Drug-related problems found were: 45% related to reconciliation (overdosing, underdosing, posology disparities, absence or no longer taking medicine prescription); 13% overdosing according to renal function or indication; 10% excessive anticholinergic burden that may have contributed to the current clinical problem; 9% underdosing for the indication; 8% lack of indication; 6% lack of prescription of a highly likely needed drug; 4% duplicities; 3% not optimal drug for the indication and 2% allergy-related problems.

Proposed actions were: dosing adjustments (50%), prescription (20%), discontinuation (20%), posology modification (7%) and alternative drug selection (3%).

Affected drug families were: antibiotics (22%), antidepressants, antipsychotics and anxiolytics (15%), antithrombotics (14%), blood pressure lowering agents (9%), vitamin and electrolytes supplements (9%), antiepileptics (7%), immunosuppressors (4%) and others below 3% of incidence (painkillers, statins, antiretrovirals, antiarrhythmics, anti-gouts, thyroid hormones and eye-drops).

Conclusion and relevance Multidisciplinary teams are beneficial to patients' care. Incorporating a pharmacist in a HED reduces the incidence of medication errors and can positively contribute to the management of patients. Medicines reconciliation, dosing and indication checking and pharmacotherapy optimisation are actions in which the pharmacy team is capable of actively contributing for patients' best outcomes.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-221 POTENTIALLY INAPPROPRIATE MEDICINES IN OLDER PATIENTS

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Background and importance Chronic diseases, physiological changes associated with aging, and altered drug pharmacodynamics and pharmacokinetics as consequences of aging place elderly patients at high risk of prescribing potentially inappropriate medication (PIMs). Screening Tool of the Older Person's potentially inappropriate Prescriptions (STOPP) criteria refers to drugs classified according to the systems of the organs in which they operate.

Aim and objectives To determine the prevalence rate of PIMs in older patients (≥ 65 years) by using STOPP criteria on admission to the university hospital.

Material and methods A cross-sectional study including 250 patients ≥ 65 years, who had two or more drugs prescribed. Data collection lasted for 2 months and was conducted by a pharmacist. Approval for the study was granted by the ethics

committee of the hospital. Informed consent was obtained from all participants.

The inadequacy of prescribed drugs was assessed on the basis of STOPP criteria, using a shortened version with 30 indicators. Statistical analysis was performed using the software PASW Statistics (PASW Inc., Chicago, IL, USA) version 22 and Microsoft Excel 2010.

Results The mean age in the group was 74.23 ± 6.92 years. The majority were male patients (62.1%). 218 (87.90%) patients had hypertension. Mean of prescribed drugs was 5.25 ± 2.70 . We identified a total of 62 PIMs prescribed for 57 (22.98%) patients. Pantoprazole (46.77%) was the most prescribed, followed by diazepam (16.13%) and omeprazole (14.52%). The higher prevalence of PIMs related to proton pump inhibitors (PPIs) (42 of a total of 62 PIMs or 67.74%). Only 4 (13.33%) criteria were shown to be relevant for identifying PIMs (long-term use of PPIs, long-acting benzodiazepines, presence of therapeutic duplications, and use of thiazide diuretics in patients with gout). Correlation between the number of drug prescribed and the number of PIMs was significant ($\rho=0.297$; $p<0.01$).

Conclusion and relevance The STOPP criteria should be used when prescribing drugs to older patients with multimorbidity and polypharmacy in order to avoid the prescribing of inappropriate ones.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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Conflict of interest No conflict of interest

4CPS-222 ADHERENCE IN POLYMEDICATED ELDERLY PATIENTS ADMITTED TO A TRAUMA WARD

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Background and importance Polymedication is one of the most important problems facing healthcare professionals in Europe today.

Aim and objectives To analyse adherence in polymedicated elderly patients and its relationship with the number of drugs prescribed.

Material and methods Cross-sectional observational study, carried out between February and May 2021 in the Traumatology area of a tertiary hospital. Patients >75 years old, multipathological (≥ 2 chronic pathologies) and polymedicated (≥ 5 chronic medications) were included. We excluded those with whom we were unable to communicate, due to their physical/mental condition and absence of a companion.

The clinical history was reviewed, collecting anthropometric variables, pathologies and home medication, confirmed by a personal interview.

Adherence to treatment was measured using the Morisky–Green questionnaire, which consists of four dichotomous yes/no questions to obtain information on patient compliance. Adherence was related to the number of drugs prescribed.

The Shapiro–Wilk normality test and the non-parametric Mann–Whitney U test were used for statistical analysis. Results with p values <0.05 were considered significant.

Results 48 patients were selected, 76.2% female; mean age was 83.8 ± 5.4 years.

The mean number of pathologies/patient was 6 ± 2.6 . 61.9% of patients had five or more diseases. The most frequent health problems were hypertension (66.7%), hypercholesterolaemia (42.8%), diabetes mellitus (33.3%) and depression (33.3%). The mean number of medications/patient was 9 ± 3.4 . 35.7% of patients were highly polymedicated (≥ 10 medications).

The Morisky–Green test showed that 82.5% were adherent to treatment. 22.5% of patients were not taking ≥ 2 prescribed and necessary medications. In addition, 36.6% were found to self-medicate.

No statistically significant relationship was found between the number of medications and adherence ($p=0.8$).

Conclusion and relevance Contrary to other recently published studies, adherence was good in our sample and was not related to the number of medications. The first finding may be related to the fact that many patients had caregivers who took care of their medication.

This study shows that a significant proportion of the population is self-medicating. This calls for closer monitoring by community pharmacists, with patient education and collaboration with hospital pharmacists, whose easy access to medical records can help to conduct studies on the prevalence of polymedicated patients and the appropriateness of their prescriptions.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-223 ADHERENCE TO ABIRATERONE AND CORTICOID IN PATIENTS WITH PROSTATE CANCER

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Background and importance The concomitant administration of abiraterone with corticoids is necessary to manage adverse events related to mineralocorticoid effect. A proper adherence to both therapies is needed to reach effectiveness in metastatic prostate cancer (mPC).

Aim and objectives To measure and compare adherence to abiraterone and concomitant corticoids in patients with mPC.

Material and methods Retrospective observational study, which included patients under treatment with abiraterone, and corticosteroid (prednisone/dexamethasone) that attended the Outpatient Pharmaceutical Care Unit (OPCU) between March 2020 and February 2021. Abiraterone is dispensed in the hospital pharmacy and concomitant treatment with corticoid is dispensed in the community pharmacy.

Full treatment adherence was measured by combining two indirect methods: dispensing registration and the Morisky–Green (MG) test. Patients with a dispensing record greater than 95% and a score in the MG questionnaire of 4 were considered adherent.

To obtain data, the Ambulatory Information System (AIS) was used, which includes electronic prescriptions, and reports

of dispensations in the community pharmacy as well as the dispensing registration system of the hospital pharmacy.

Statistical analysis: qualitative variables were expressed percentage-wise and compared using the Chi-square test.

Results Thirty patients were included, with an average age of 74 (SD 10.8) years. Of them 50% were aged over 80 years. The average number of drugs per patient was 9.9 (SD 3.7) so 85% were polymedicated patients (drugs >6). Of the 30 patients treated with abiraterone, 2 died and 2 abandoned the treatment.

Of those aged over 80 years, 69.2% were abiraterone adherents whereas under 80 the figure was 84.6% ($p<0.352$). In those over 80, 46.2% were corticoid adherents

Polymedicated patients were 72% abiraterone-adherent, while non-polymedicated patients were 100% adherent ($p<0.234$). Polymedicated patients were 40.9% corticoid-adherent.

By dispensation recounts 84% abiraterone and 46% corticosteroid were adherent patients; while according to the MG test, 85% abiraterone and 81% corticosteroid were adherent patients.

Combining both methods, adherence data were observed to be higher in patients treated with abiraterone compared with corticoids (77% vs 42%), with no significant statistically difference ($p=0.147$)

Conclusion and relevance Abiraterone combined adherence is higher than corticoid adherence, but not statically significant in this small study group. Good adherence must be concomitant in both drugs in order to avoid side effects. This assessment helps identify patients with adherence problems and prioritise pharmaceutical care actions.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-224 IMPACT OF PROACTIVE MEDICATION RECONCILIATION PRIOR TO PRE-ANAESTHESIC CONSULTATION

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Background and importance Continuity of medication management in hospitals is a major issue today, and the clinical pharmacist has a key role to play in it. Surgical departments are particularly at risk, with a higher rate of unintended medication discrepancies (UMDs) found during medication reconciliation (MR) than in medical departments. An MR process prior to the pre-anaesthetic consultation (PAC) has been set up to improve the continuity of care for patients hospitalised in our vascular surgery department.

Aim and objectives The aim of our study was to assess the impact of carrying out proactive MR by a clinical pharmacist prior to the PAC versus retroactive MR.

Material and methods Proactive MRs were performed by a pharmacy intern and a pharmacy student, approximately 1 week before PACs. A telephone interview with the patient was carried out and then the retail pharmacy and/or primary care physician were contacted to collect the patient's prescriptions. The best possible medication history (BPMH) form was given

to the anaesthetist and registered into the patient's medical record. Retroactive MRs were carried out, using the same sources, after the patient's entry and after the first prescriptions.

Results Over a 6-month period, 200 MRs were performed in the vascular surgery department. 100 were proactive MRs and 100 were retroactive MRs. Concerning the populations, the average age was 66 years for proactive MRs versus 69 years for retroactive MRs, with 56% and 69% of men, respectively. The average number of home treatments was 7.4 (1–14) for proactive MRs and 8 (2–18) for retroactive MRs. As regards the UMDs found, there were 26 for the proactive MRs (ie, 0.26 UMD/patient). For retroactive MRs, there were 150 UMDs (ie, 1.55 UMD/patient).

Conclusion and relevance There are more than 5.5 times fewer UMDs when MRs are carried out proactively before the patient's entry. Carrying out MRs for PACs enables the prescription to be anticipated and the anaesthetist to obtain an exhaustive list of the patient's treatments, which also avoids forgetting to stop some of them, particularly anticoagulants. The development of prescription assistance software with a pre-prescription module would be a step forward and an added value for the reduction of medication errors.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-225 INTEGRATION OF A CLINICAL PHARMACIST IN A THERAPEUTIC EDUCATION TEAM FOR DIABETIC PATIENTS: AN INITIATIVE THAT IS WORTH GOLD!

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Background and importance Since 10 September 2020, the new instruction relating to the gradation of ambulatory care allowed multidisciplinary day hospitalisations (MDH) to be carried out with three or four healthcare workers enabling the integration of a clinical Pharmacist (CP). Therefore, it permits incorporation of therapeutic patient education (TPE) in these MDHs for the patient's benefit, who meets all the healthcare workers at the same time.

Aim and objectives The aim of this study was to assess the patient benefit and the economic gain of integrating a CP into a diabetology TPE team.

Material and methods In January 2021, implementation of the MDH in our hospital by a multidisciplinary diabetology TPE team composed of a diabetologist, a nurse, a dietitian and a CP. Realisation of a patient satisfaction survey and an economic evaluation of the MDH model of TPE over 9 months. The overall gain of three and four healthcare workers in MDH represents €326 and €584, respectively, for healthcare workers repaid at the base rate used by the French Social Security system. The CP examined the global medication management of the patient via an interactive game in order to ensure a good compliance and the acquisition of safety skills.

Results This survey has shown that 98% of patients (n=41) were satisfied by the establishment of a pharmaceutical time

in these MDHs and by the meeting of all the TPE team on the same day. In these MDHs the fourth healthcare worker is a CP. Therefore a MDH with four healthcare workers brings an additional profit of €258 per MDH. From January to September 2021, 41 MDH of TPE with a CP were realised for an overall gain of €23 944 and 82 MDH without a CP for an overall gain of €26 732. This MDH model with four healthcare workers including a CP made it possible to obtain an additional profit of €10 578 for 41 MDHs.

Conclusion and relevance The CP has their own place in this activity. This MDH TPE model provides a significant financial gain that can be used for the implementation of other projects. These MDHs enhance clinical pharmacy activities and can be extended to other chronic pathologies.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-226 THE ROLE OF THE CLINICAL PHARMACIST IN THE SCREENING OF CANDIDATES FOR ONCO-HAEMATOLOGICAL CLINICAL TRIALS

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Background and importance Over the last decade the number of clinical trials (CTs) has increased exponentially worldwide as well as their complexity.

The identification of possible interactions of the concomitant medication with the investigational drug is a key point to avoid bias in the study result, and to ensure patient safety.

The pharmacist, as a member of the investigational team, may also be involved in screening/randomisation of the subjects.

Aim and objectives To review the concomitant medication of patients who are candidates to start a CT in order to detect possible interactions.

Material and methods Descriptive study carried out in a tertiary university hospital over a 1-year period (September 2020–August 2021). All patients who were candidates to participate in an onco-haematology clinical trial that included an oral investigational drug were included. Information on pharmacological treatment was obtained through a clinical interview conducted in the pharmaceutical care consultation or by telephone. The inclusion/exclusion criteria relating to concomitant prohibited/authorised medication described in the protocol of each trial were applied.

We retrospectively collected: sex, diagnosis, concomitant medication, pharmaceutical interventions, type of intervention, how many of these were taking alternative medicine products, and number of screening failures.

Results A total of 410 patients (53.90% women) were interviewed. According to the diagnosis, 17.32% of the patients had lung cancer, 16.83% genitourinary, 16.10% neuroendocrine tumours, 14.88% breast cancer, 8.78% haematological tumours and 26.09% others. A total of 2262 drugs were reconciled, the median of which they took per patient (range) was 5 (0–16). Interventions were performed in 155/410 (37.80%) patients. Most of these (69.03%) were for suspension of treatment not authorised by protocol. 26.10% of the

patients were taking alternative therapy at the time of screening. Finally, 20.49% were screening failures.

Conclusion and relevance The results of our study show that approximately 4 in 10 patients require at least one change in their usual treatment.

The involvement of the pharmacist in the assessment of interactions may play a central role in the research process, which can directly influence the inclusion of a patient in a clinical trial.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-227 FEEDBACK FROM A REGION ON THE USE OF E-THERAPEUTIC PATIENT EDUCATION DURING THE HEALTH CRISIS: HIGH-SPEED INTERVIEWS!

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Background and importance The coronavirus disease-19 (COVID-19) pandemic has strongly impacted organisation of care. Some patients with chronic diseases did not get their regular follow-ups. New digital health care techniques, such as e-therapeutic patient education (e-TPE), allowed maintenance of the continuity of these patients' care.

Aim and objectives Objectives of this study were to assess in a French region how TPE programmes have adapted during the lockdown due to the COVID-19 pandemic and to evaluate the establishment of e-TPE.

Material and methods A survey was conducted in February 2021 based on an online questionnaire containing 21 questions submitted to 180 TPE programme coordinators in a region. This questionnaire was composed by three parts: the first one is about TPE programmes that have been achieved, the second one concerns the adaptation of the sessions during the first lockdown, and the last one refers to the implementation of e-TPE.

Results A total of 62 questionnaires were collected corresponding to 80 TPE programmes in the region. The majority of health professionals (79%, n = 49) completely stopped their programmes during the first lockdown and 21% (n = 13) kept it either with reduced activity or with continued TPE sessions. Among the second group, the majority of their programmes have been adapted to the context: development of teleconsultation and e-TPE sessions. The e-TPE sessions were set up by 13 coordinators using different tools: internet platforms such as 'app'e-sante' or 'Mydiabby' and videoconferences. The advantages stated by healthcare professionals were: easy access to sessions and limited travel (n = 7), maintenance of the link with the patient (n = 5) and adaptability to the patient's organisational issues (n = 4). Drawbacks were also highlighted, in particular the lack of interaction between healthcare professionals and the patient (n = 8) but also some internet connection issues in certain residential areas (n = 5).

Conclusion and relevance The development of e-TPE allowed the decompartmentalisation of the ambulatory patients' care. The patients and healthcare professionals who

participated in the digital sessions declared themselves to be fully satisfied. The e-TPE is a digital tool at the service of the clinical pharmacist to achieve their mission of health promotion.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-229 IMPLEMENTATION OF AN INTERPROFESSIONAL PREOPERATIVE MEDICATION MANAGEMENT PROGRAMME IN CARDIAC SURGERY: A PRE-POST QUALITY IMPROVEMENT STUDY

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Background and importance In order to ensure the efficacy and safety of a prescribed drug regimen during cardiac surgery, a standardised preoperative management strategy is needed in routine care. However, data are lacking on how many drugs need preoperative management and which strategies are effective in routine care.

Aim and objectives To investigate the overall need of preoperative medication management in cardiac surgery patients and to determine the efficacy of an interprofessional preoperative medication management bundle in routine care.

Material and methods An interprofessional cooperation of cardiac surgeons and hospital pharmacists developed an evidence-based preoperative medication management standard for the most common drugs (eg, oral anticoagulants, antidiabetics, etc.) which was subsequently implemented in clinical routine. Briefly, the standard was included in the admission letter for the primary care physician, sent to the referring hospitals, distributed as a pocket card to the physicians, and an interprofessional hotline for inquiries was made available. Before and after implementation, the timepoints of the last preoperative drug intake were assessed by pharmacists and cardiac surgeons according to the determined standard in two samples of consecutively admitted patients (except emergencies). The study was approved by the local ethics committee.

Results Before implementation, 222 of 273 included patients (78.7%) were admitted to surgery with at least one drug that needed active preoperative management according to the defined standard. Management was deemed correct for 30.0% of direct oral anticoagulants (DOAC) (n=52), 28.2% of metformin (n=39), 15.5% of sodium-glucose transporter II (SLGT-2) inhibitors (n=19) and 78.9% of prophylactic platelet inhibitors (n=142). Six months after implementation, 249 of 290 patients (85.9%) had at least one drug that needed to be perioperatively addressed. The number of correctly managed drugs increased for DOAC to 68.4% (n=57) and to 96.4% for platelet inhibitors in prophylaxis (n=167), but only slightly for metformin (n= 36) to 44.4% and to 24.0% for SLGT-2 inhibitors (n= 25).

Conclusion and relevance The standardised preoperative management bundle effectively improved perioperative drug therapy; however, the results indicate that there is potential for

further improvement, especially in patients referred from other hospitals.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-231 ARE WE SUSTAINABLE? A BASELINE QUESTIONNAIRE REGARDING THE ENVIRONMENTAL IMPACT OF PHARMACY PRACTICE ACROSS THE COUNTRY

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Background and importance We are on course for a global temperature rise which will see millions of people displaced, injured or dying through rising sea levels, starvation and disease by the end of this century. The health costs are projected to be extraordinary. The use of medicines and medicinal products create waste and pollution. The COVID pandemic and the relentless consumption of personal protective equipment (PPE) has escalated this issue. We must strive towards reducing waste, and ultimately pollution, in order to increase sustainability both for our patients, and for global health.

Aim and objectives To determine the awareness of qualified pharmacists across the UK with regard to the health risks of a climate crisis, as well as the impact of pharmacy on the environment.

Material and methods In July 2021, we invited all of our members (n=4788) to complete a short survey to gauge their understanding of the role of pharmacy in the promotion of a sustainable approach to healthcare via an emailed link to a 10-item survey in Webropol. The results were analysed using descriptive statistics and thematic analysis. No completion incentives were offered. Ethical approval was not required for this study.

Results One hundred and seven pharmacists responded to the survey (2.23% response rate). Ninety-four percent of respondents believed that there were aspects of pharmacy practice. Themes to improve sustainability included; sustainable prescribing and deprescribing, raising awareness and penalties for poor practice. Sixty-five percent of respondents provided suggestions on how the proposed changes could be measured, such as measuring the carbon footprint of your organisation, creating energy and waste logs as well as encouraging working from home. Ninety-four percent of respondents believed that aspects of practice were wasteful, and only 37% felt empowered to make change in their organisation. Ninety percent of respondents believed that an increased focus on climate change was required at an organisational level and that leadership was required at all levels of practice.

Conclusion and relevance Survey respondents believe that aspects of pharmacy practice are not sustainable; however, most do not feel empowered to make change. There is a need for national guidance to support changes in practice, and for local champions and leadership at all levels.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-232 PHARMACIST-LED MEDICATION REVIEW UNVEILED MORE MEDICATION-RELATED PROBLEMS IN POSSIBLY MEDICATION-RELATED HOSPITALISATIONS THAN IN UNLIKELY MEDICATION-RELATED HOSPITALISATIONS IN ELDERLY PATIENTS

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Background and importance Elderly patients are prone to unsafe and/or ineffective pharmacotherapy. Medication-related admissions are common in older people and over half of these hospitalisations are preventable.

Aim and objectives The aim of this study was to identify medication-related problems associated with medication-related admissions in hospital in older people.

Material and methods We performed a retrospective study by analysing the folders of patients over 75 years old, undergoing pharmacist-led medication review as part of the multidisciplinary geriatric mobile team, between March and October 2021. We performed the assessment tool for identifying hospital admissions related to medicine (AT-HARM10) to assess hospital admissions as being either possibly or unlikely medication-related (MRH). First, we compared demographic- and therapeutic-related variables between possibly and unlikely MRH. Therapeutic-related variables were number of treatments upon admission, potentially inappropriate medication as measured by both START/STOPP and PIMcheck, number of drug interactions, drug burden index (DBI), and number of medication errors during medication reconciliation at admission. Secondly, we performed univariate logistic regression by calculating odds ratios with 95% confidence intervals to identify medication-related problems associated with MRH.

Results We included 67 patients, 32 possibly MRH and 35 unlikely MRH. Most demographics were comparable between the two groups except a higher proportion of women (81.3% vs 54.3%; p<0.05) and less under nutrition (16.7% vs 54.5%; p<0.05) in possibly MRH. In possibly MRH, we found higher numbers of (i) START/STOPP items (4.8±2.7 vs 2.3±2.0; p<0.05), (ii) PIMcheck overuses (2.0±1.7 vs 1.3±1.4; p<0.05), (iii) drug interactions (8.7±8.9 vs 4.6±4.9; p<0.05) and a higher DBI score (0.9±0.8 vs 0.3±0.5; p<0.05). Interestingly, we unveiled more medication errors during medication reconciliation at admission in possibly MRH (4.3±3.3 vs 2.7±2.3; p<0.05).

START/STOPP items (OR 1.54; 95% CI 1.21 to 1.96), PIMcheck overuses (OR 1.5; 95% CI 1.05 to 2.13), drug interactions (OR 1.13; 95% CI 1.02 to 1.24) were identified as medication-related problems associated with MRH. DBI (OR 5.8; 95% CI 2.05 to 16.42) was also significantly associated with MRH.

Conclusion and relevance Our results illustrate a balanced proportion of MRA in patients treated by the multidisciplinary geriatric mobile team. We unveiled more medication-related problems in patients possibly MRH than in unlikely MRH, suggesting that AT-HARM10 may be used to identify patients requiring priority on pharmacist-led medication review.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-233 THERAPEUTIC SWITCH OF ANTIRETROVIRAL TREATMENTS: EFFICACY, TOLERABILITY AND REASON FOR CHANGE

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Background and importance The introduction of bithersy has been a great advance in antiretroviral treatment. This has made it possible to obtain the same results in terms of efficacy with a smaller number of active ingredients (API), simplification of dosage, reduction of adverse effects (AE) and decrease in interactions.

Aim and objectives Describe the patient's profile, description of current bithersy and previous treatment

The second objective was to study the efficacy, safety and interactions of bithersy, as well as the reason for switching.

Material and methods A retrospective descriptive study conducted in a tertiary hospital. Patients treated with dolutegravir + lamivudine/dolutegravir + rilpivirine bithersy during the period 2016–2021 were included.

Variables were collected through the electronic medical record: demographics (sex, age), comorbidities, viral load (CV) and CD4 prior to change of therapy and 12 months post-switch, previous treatment and reason for change.

Results A total of 104 patients on treatment with 105 bithersies based on dolutegravir/lamivudine (68/105) and dolutegravir/rilpivirine (37/105) were included. 70.2% were men with a median age of 51 (24–84) years.

The main pretreatment for dolutegravir/lamivudine was dolutegravir/lamivudine/abacavir (79.4%), while for dolutegravir/rilpivirine it was dolutegravir/rilpivirine/tenofovir-alafenamide (78.4%).

In 85.7% of patients it involved a reduction in the number of APIs (pre: 3 vs post: 2) and in 14.3% a simplification of the regimen to a single tablet/day.

Prior to the switch, 97.1% of patients had undetectable CV (<50 copies/mL) and CD4 levels of 750 (300–2720) cells/ μ L. After 1 year post-switch, 95.2% were CV-negative with CD4 levels 800 (354–1580) cells/ μ L. One episode of nervousness was collected as an AE. No interactions were detected.

The main reason for therapeutic switch was simplification (62.9%) followed by comorbidities, mainly cardiovascular (31.4%), AE (2.9%), interactions (1.9%) and loss of efficacy (0.9%).

Conclusion and relevance Treatment with dolutegravir-based bithersies has proven to be an effective, safe therapy with no relevant interactions.

The principal reason for switching to bithersy is simplification, achieving a reduction in both the number of tablets and the number of APIs versus previous therapies.

The role of the pharmacist was fundamental for pharmaceutical care and clinical follow-up, detection of interactions, as well as the monitoring of adverse effects.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-234 IMPACT OF AN INTENSIVE MONITORING PROGRAMME ON METHOTREXATE ELIMINATION

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Background and importance High-dose methotrexate (hDMTX) can cause significant toxicities, especially renal ones. Adequate patient management is essential to prevent them and reduce hospital stay.

Aim and objectives To determine if the implementation of an intensive monitoring programme (IMP) of MTX concentrations ([MTX]) and supporting measures improved the methotrexate clearance in comparison with a standard monitoring programme (SMP) in patients with haematological malignancies.

Material and methods Retrospective observational study was performed including patients admitted to a haematology ward between January 2020 and September 2021, all treated at hDMTX (≥ 500 mg/m²).

SMP consisted of (A) daily pH monitoring and (B) pharmacokinetic monitoring 48 hours after starting infusion and every 24 hours until [MTX]<0.2 μ M.

IMP consisted of (A) 6-hourly pH monitoring and (B) pharmacokinetic monitoring at 12, 23, 36 and 42 hours after starting infusion. Then, individualised monitoring based on a Bayesian estimation of MTX clearance and volume of distribution until [MTX]<0.2 μ M.

Demographic and treatment variables were collected from hospital health electronic records. Participants were divided into two groups: IMP and SMP. The principal variable was defined as time (days) to [MTX]<0.2 μ M from start of infusion.

Statistical analysis was conducted with STATA version 17.1. Mann–Whitney test was performed to compare medians of the principal variable. Other variables were analysed with descriptive statistics.

Results Demographic and treatment variables are summarised below:

Variable \pm SD	SMP	IMP
Sex (count)	12 female, 7 male	8 female, 14 male
Age (years)	50.89 \pm 13.28	63.45 \pm 6.79
Body surface area (m ²)	1.67 \pm 0.16	1.72 \pm 0.13
Diagnosis* (count)	7 ALLB, 9 NHL, 3 ALLT	2 ALLB, 16 NHL, 4 PCL
Total dose (mg)	3130.7 \pm 2063	2043.4 \pm 2247.3
Basal serum creatinine (mg/dL)	1.01 \pm 0.78	0.77 \pm 0.19
Final serum creatinine (mg/dL)	0.8 \pm 0.35	0.78 \pm 0.24

*B-cell acute lymphoblastic leukemia (ALLB), T-cell acute lymphoblastic leukemia (ALLT), non-Hodgkin lymphoma (NHL), primary cerebral lymphoma (PCL).

41 treatment courses with MTX were included (19 SMP/22 IMP). Median time to [MTX]<0.2 μ M in SMP group was 3 (range 2–12) days and for IMP group was 3 (range 2–4) days (p=0.2382). 4 patients in the SMP group needed 5–12 days to obtain [MTX]<0.2 μ M.

Conclusion and relevance Although no statistically relevant signification was determined comparing both groups, a narrower range in the median of MTX clearance was observed in the IMP group. Thus, early MTX monitoring could possibly result in faster MTX elimination and lower length of hospital stay.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-240 DEVELOPMENT OF A 25% BENZYL BENZOATE LOTION FOR A CASE OF RESISTANT NORWEGIAN SCABIES

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Background and importance Norwegian scabies is a severe type of scabies affecting immunocompromised patients caused by *Sarcoptes scabiei* var. *hominis*, a highly contagious variant unresponsive to the first-line scabies drugs, permethrin and ivermectine.

Aim and objectives The aim of this study was to formulate a 25% benzyl benzoate lotion for the treatment of Norwegian scabies in an oncology patient who had previously received first-line treatments without result, and to evaluate its efficacy and tolerability.

Material and methods A search of the available literature on the use of benzyl benzoate in Norwegian scabies and its physicochemical characteristics was performed. A Standard Operating Procedure was created following the guidelines of the Good Manufacturing Practice Guide.

The patient's evolution in terms of the lesions was monitored.

Results We found literature supporting the efficacy of benzyl benzoate in Norwegian scabies. However, there is no commercially available lotion containing this active ingredient at the required concentration.

Benzyl benzoate is a lipophilic liquid, insoluble in water and miscible in fatty oils, which makes it necessary to formulate it in oily vehicles; in our case we used the ones we had available in the laboratory to make other formulations.

The formula designed was: benzyl benzoate 25 g, coconut oil 37.5 g and liquid petroleum jelly 37.5 g.

Modus operandi: weigh the components separately in a beaker. Mix the coconut oil, previously tempered in a water bath at 25°C, with the liquid petroleum jelly. Gradually add the above mixture to the benzyl benzoate and homogenise. Package in a polypropylene bottle.

A shelf life of 30 days at room temperature was assigned according to the 'Spanish Guide to Good Practice in the Preparation of Medicines in Hospital Pharmacy Services'.

It was administered alternately with permethrin and after 2 weeks of treatment the patient's lesions improved and the itching disappeared.

Conclusion and relevance The preparation was effective, safe and well tolerated. However, a comparison between patients treated with this formulation and a control group with the oily vehicles alone would be necessary to ascertain whether the efficacy is due to the benzoate or to the occlusive effect of the oils on the *S. scabiei*. Similarly, patients treated with permethrin monotherapy should be compared with those treated with permethrin alternating with benzoate.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-241 EFFECTIVENESS, DURABILITY AND SAFETY OF DOLUTEGRAVIR AND LAMIVUDINE VERSUS TENOFOVIR ALAFENAMIDE, EMTRICITABINE AND BICTEGRAVIR IN A REAL-LIFE COHORT OF HIV-INFECTED ADULTS

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Background and importance Real-world studies on the effectiveness, durability and safety of two-drug regimens (2-DR) compared to three-drug regimens (3-DR) are needed to confirm clinical trial results and support their use in clinical practice.

Aim and objectives To assess the virological effectiveness of a 2-DR with dolutegravir/lamivudine (DTG/3TC) versus a 3-DR with tenofovir alafenamide/emtricitabine/bictegravir (TAF/FTC/BIC) and to compare the durability and safety of both regimens in an intention-to-treat analysis at 24 weeks in a real-life cohort of HIV-1 treatment-naïve (TN) and treatment-experienced (TE) patients.

Material and methods This was an observational, ambispective study that included all TN and TE patients who started 2-DR or 3-DR between 1 July 2018, and 30 September 2021. The primary endpoint was the percentage of patients with viral load (VL) ≥ 50 , at 24 weeks, of 2-DR versus 3-DR in TN and VL < 50 copies/mL in TE. Rate of patients that continued with treatment and number of adverse events (AE) were also measured. Statistical analyses were performed with Stata 15.0.

Results 239 patients were included (27 TN and 212 TE). In TN group, 74% were on 2-DR and 55% were on 3-DR in TE group. In TN, logVL at study treatment initiation was 4.6 (4.1–5.1) in 2-DR and 5.4 (3.9–6) in 3-DR. Percentage of TE with VL < 50 copies/mL at study treatment initiation was 84.6% in 2-DR and 73.7% in 3-DR. Five (20%) TN on 2-DR had VL ≥ 50 copies/mL at week 24 versus two (29%) patients in 3-DR group, (difference: -8.8%; 95% CI -57.3 to 39.8%, $p=0.71$). In TE patients on 2-DR, 85.5% achieved VL < 50 copies/mL at week 24 versus 87.5% in 3-DR group (difference: -2%; 95% CI -13.5 to 9.5%, $p=0.74$). At week 24, 95% of 2-DR patients continued with treatment versus 85.7% in 3-DR. In TE, 93.8% of 2-DR were on treatment versus 91.2% 3-DR patients. Eight TN in the 2-DR group (40%) reported any AE and two (28.6%) in the 3-DR group ($p=0.68$). In the TE group, 23 patients (19.7%) on 2-DR had an AE compared to 25 patients (26.3%) in 3-DR group ($p=0.25$).

Conclusion and relevance This study shows a similar effectiveness profile of DTG/3TC compared to TAF/FTC/BIC at 24 weeks. Additionally, durability and safety of 2-DR were confirmed to be similar to 3-DR.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-243 INFLUENCE OF VENOVENOUS EXTRACORPOREAL MEMBRANE OXYGENATION ON THE PHARMACOKINETICS OF VANCOMYCIN IN ADULTS: CAN AN OPTIMAL PHARMACODYNAMIC TARGET BE ACHIEVED?

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Background and importance Patients undergoing extracorporeal membrane oxygenation (ECMO) may present significant changes in antibiotics pharmacokinetics (PK).

Aim and objectives To describe the PK of vancomycin in ECMO patients and the achievement of a therapeutic pharmacokinetics/pharmacodynamics (PK/PD) target.

Material and methods Retrospective PK study in adult critically ill patients treated with vancomycin with therapeutic drug monitoring (TDM) and undergoing venovenous ECMO in a university hospital from July 2017 to October 2021.

TDM samples (steady state): before dose and 2 hours after the intravenous infusion (intermittent infusion) or at any time (continuous infusion). PK parameters and area under the curve in plasma (AUC_{24h}) estimated by Bayesian software.

Data collected: demographics, clinical, microbiological and PK/PD parameters: AUC_{24h}, minimum inhibitory concentration (MIC), clearance (Cl), elimination half-life (t_{1/2}), volume of distribution (V_d) and dosage recommendation. Infratherapeutic, therapeutic or supratherapeutic PK/PD target defined: AUC/MIC <400, 400–600 and >600, respectively.

Results Ten episodes of treatment from 7 patients: median (range): 58.5(35–68) years, 6 (85.7%) men. Infection type: respiratory 8 (80%) and bacteraemia 2 (20%); directed treatment in 6 (60%); most frequent pathogens: *Staphylococcus epidermidis* 3 (50.0%) (MIC: 1, 2 and 2 mg/L), methicillin-resistant *S.aureus* (MSSA) 2 (33.3%) (MIC: 0.5 and 0.5 mg/dL) and *S. haemolyticus* 1 (16.7%) (MIC: 1 mg/L).

Conclusion and relevance A high interindividual variability in vancomycin PK and need for dose adjustments was observed in critically ill patients with ECMO, which highlights the need for close therapeutic monitoring.

ECMO and CRRT patients were more likely to have supratherapeutic plasma concentrations requiring dose reductions.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-244 CARDIOVASCULAR, RENAL AND BONE EVALUATION OF A HIV POPULATION OVER 60 YEARS OLD

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Background and importance Advances in antiretroviral treatment (ART) have resulted in an increase in life expectancy in HIV patients. For this reason, a rise in comorbidities related to chronic diseases and long-term toxicities of ART have been observed, becoming the main causes of morbidity and mortality among patients with HIV.

Aim and objectives To evaluate the presence of cardiovascular, bone and kidney alterations in a cohort of HIV patients aged ≥60 years.

Material and methods Observational, descriptive and retrospective study (using medical history and prescription records) of patients with HIV aged ≥60 years with ART in February 2021 that were under treatment since a previous cross-sectional study carried out in 2012 were selected.

Demographic (age and sex), clinical (time since HIV diagnosis, diagnosis of hypertension and diabetes mellitus (DM), cardiovascular risk scale REGICOR, cardiovascular and renal events and diagnoses of osteopenia/osteoporosis and CD4 lymphocyte and viral load (VL)) and pharmacological (chronic medication not related to ART, ART change number and reasons for change) were collected in 2012 and 2021.

Results 51 HIV patients with mean±SD age of 66.4±6.2 years were analysed. 60.8% were men with a mean age of 22.3 ±8.1 years since diagnosis.

In 2012 and 2021, patients diagnosed with hypertension were 15.7% and 35.3%, respectively, DM was 11.8% and 25.5%, respectively, and REGICOR was 5% and 7%, respectively.

During the considered period, 17.6% had a cardiovascular event, 13.7% were diagnosed with kidney disease and 49.0% with osteopenia/osteoporosis. 7.8% had some bone event.

In 2012 and 2021, mean CD4 lymphocytes were 601.7 (±312.7) and 722.7 (±310.6) cells/mm³, respectively, and 90.2% had undetectable VL in both years.

In 2012, 15.7% of the patients were receiving lipid-lowering therapy, 5.9% antiplatelet/anticoagulant and 11.8% oral

Abstract 4CPS-243 Table 1 PKPD data

	BW (kg)	eGFR (mL/min)	Dose (mg/kg/day)	Cmin/Cmax or C _{ss} (mg/L)	AUC _{0–24h} (mg*h/L)	AUC/MIC	t _{1/2} (h)	V _d (L/kg)	Cl(L/h)	Dose action
1	83	106	24.1 mg/kg/24h	12.1	291	145.5	7.2	0.7	6.6	Increase
2	60	101	16.6 mg/kg/8h	12.8/25.9	500	500	6.7	0.7	5.6	Maintain
3	50	133	30.0 mg/kg/24h	18.4	441	882	7.2	0.7	4.0	Increase**
4	50	121	20.0 mg/kg/12h	13.9/44.5	640	1280	7.9	0.6	3.0	Reduce
5	80.5	95	43.5 mg/kg/24h	17.8	672	672	6.4	0.6	5.6	Reduce
6	80.5	104	37.3 mg/kg/24h	22.6	542	271	8.5	0.7	4.6	Increase
7	85	132	35.3 mg/kg/24h	25.9	620	620	8.6	0.7	5.3	Reduce
8	83	34*	24.1 mg/kg/24h	29	696	696	21	0.8	2.4	Reduce
9	123	25*	16.3 mg/kg/24h	28.8	691	691	27.5	0.6	2.1	Discontinue
10	123	50*	10.2mg/kg/24h	27.6	660	660	48.2	1.1	2.0	Reduce

*Continuous renal replacement therapy (CRRT).

antidiabetic drugs/insulin. In 2021, the equivalent figures were 47.1%, 15.7% and 25.5%, respectively.

19.6% started treatment with calcium, cholecalciferol and/or bisphosphonate during the period.

In total, 113 treatment changes were made: musculoskeletal disorders (23%), simplification (21.2%), metabolism disorders (11.5%), virological failure (8.8%), resistance and kidney disorders (8.0%), interactions (7.1%) and others (12.6%).

Conclusion and relevance Cardiovascular, kidney and bone alterations are frequent in HIV patients aged ≥ 60 years. Treatment changes are conditioned by patients' comorbidities and are focused on avoiding long-term toxicities.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-246 MEDICATION-RELATED ADMISSION WAS MORE FREQUENT IN ELDERLY PATIENTS HOSPITALISED IN AN ORTHOPEDIC UNIT THAN IN AN EMERGENCY DEPARTMENT IN TWO FRENCH HOSPITALS

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Background and importance Medication-related admissions (MRAs) are common in the elderly and are preventable in almost half of cases. Pharmaceutical care aims to promote medication safety and reduce potentially inappropriate prescriptions. In our hospitals, clinical pharmacists perform medication reviews in both the emergency department (ED) and orthopedic units. As part of an ongoing process of quality improvement, we conducted a study to identify MRAs in patients over 75 years old hospitalised in these two clinical settings.

Aim and objectives The aim of this study was to compare MRAs prevalence in elderly patients hospitalised in the ED and orthopedic units in order to reassess the management of clinical pharmacists' interventions during hospitalisations.

Material and methods This prospective observational multi-centre study was conducted between May 2019 and March 2020, and included patients aged over 75 years admitted to the ED and orthopedic surgery departments of two French hospitals. We used the AT-HARM10 tool to distinguish possibly versus unlikely MRAs in elderly patients.

Results We included 266 patients. 166 patients were included in the ED (mean age 86.0 ± 5.7 years; sex ratio 0.6; mean number of prescribed drugs 7.7 ± 3.8). 100 patients were included in the orthopedic surgery departments (mean age 85.2 ± 6.1 years; sex ratio 0.3; mean number of prescribed drugs 6.4 ± 3.6). We identified 91 (55%) MRAs in ED and 75 (75%) MRAs in orthopedic units ($p < 0.05$). Among MRAs, the most represented question of the AT-HARM10 was P5 in both groups (Might side effects of the medications the patient was taking prior to hospitalisation have caused the admission?) and the most involved drugs were those acting on the nervous system (ATC-N).

Conclusion and relevance We found MRAs rates comparable to results reported in previous studies about elderly patients in ED. MRAs were more frequent in elderly patients admitted in orthopedic surgery. These results led us to prioritise more

medication reviews by clinical pharmacists for older patients in surgery departments, to guarantee a continuity of patient's care and potentially avoid re-hospitalisations.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-247 EVALUATION OF THE CLINICAL IMPACT OF MEDICATION RECONCILIATION ON ADMISSION USING THE CLEO TOOL

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Background and importance Medication reconciliation is a clinical pharmacy process to prevent medication errors at transitions of care. We integrated this activity into the management of elderly patients in our hospital a year ago. CLEO is a comprehensive tool that assesses especially clinical impact of pharmacists' interventions (PIs) developed by experts of the French Society of Clinical Pharmacy (SFPC). We used it to evaluate the potential clinical impact of medication reconciliation on the patient.

Aim and objectives The aim of this study was to assess unintentional medication discrepancies (UD) in admission orders with potential for patient harm (moderate or major clinical impact) with the CLEO tool.

Material and methods We conducted a prospective observational monocentric study between September 2020 and August 2021 on internal medicine patients aged over 65 years in a French hospital. They all benefitted from medication reconciliation upon admission and we used the CLEO tool to rank the clinical impact (Negative/Null/Minor/Moderate/Major/Avoids Fatality) of UD. UD were scored by two experienced clinicians.

Results 318 patients were included (mean age 82.3 ± 8.0 years; sex ratio 0.4; mean number of prescribed drugs 8.0 ± 4.0 ; mean length of stay 8.2 ± 6.7 days). 176 patients had at least 1 UD (55%) and we found 2.1 UD per patient. 63% of UD were associated with a "moderate" clinical impact ("The PI can prevent harm that requires further monitoring/treatment, but does not lead to or does not extend a hospital stay") and 2% were "major" ("The PI can prevent harm which causes or lengthens a hospital stay OR causes permanent disability or handicap").

Conclusion and relevance The identification of UD with moderate and major clinical impact underline the significance of the sustainability of medication reconciliation in routine clinical practice. Furthermore, according to the Multi-Center Medication Reconciliation Quality Improvement Studies (MARQUIS), the cost of harmful medication error to hospitals in the USA is about \$4655. If we expanded to 241 UD with a moderate or major clinical impact, we could easily calculate significant annual savings to hospitals as a result of avoided harmful medication errors, providing useful input to convince hospital boards about medication reconciliation return on investment, in addition to the benefit expected for patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-249 ELTROMBOPAG FOR TREATMENT OF AUTOIMMUNE THROMBOCYTOPENIA ASSOCIATED WITH COVID-19 VACCINE: A CASE REPORT

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Background and importance Cases of thrombocytopenia, including immune thrombocytopenia (ITP), have been reported after receiving Vaxzevria, typically within the first 4 weeks after vaccination.

Very rarely, these events presented with very low platelet levels ($<20 \times 10^9/L$) and/or were associated with bleeding.

Intravenous immunoglobulins and dexamethasone (high doses) are used to treat IPT secondary to COVID-19 vaccine.

Aim and objectives To describe a case of severe ITP secondary to COVID-19 vaccine successfully treated with eltrombopag.

Material and methods A 60-year-old male, with a clinical history of hypertension, consulted to the emergency department for spontaneous appearance of ecchymosis and petechiae of 10–12 days of evolution.

To highlight, he had received a first dose of Vaxzevria on 27 May 2021.

Physical examination revealed diffuse haematomas on the chest and arms. No haematuria, gingivorrhagia or active digestive bleeding were observed.

As the platelet count was $6 \times 10^9/L$ and no other relevant alterations were observed, it was oriented as an acute ITP possibly related to Vaxzevria.

Corticosteroid treatment was started with methylprednisolone 1 mg/kg/day. The serological study and immune profile were negative. A thoracoabdominal computed tomography scan ruled out a neoproliferative process.

Although the patient remained stable, he required a bolus of dexamethasone 40 mg/day for 4 days in the absence of a platelet response to methylprednisolone. Despite this, plaquetopenia persisted, so a bone marrow aspirate was performed. The study confirmed the presence of megakaryocytes, which indicated the existence of peripheral plaquetopenia. Therefore, treatment with eltrombopag was started.

Results Treatment with eltrombopag 50 mg/day was started on 22 July 2021, with a platelet count of $5 \times 10^9/L$. After 1 week the platelet count was $4 \times 10^9/L$ so the dose was raised to 75 mg/day. Five days after increasing the dose, the platelet count rose to $21 \times 10^9/L$. Two days after it was $41 \times 10^9/L$ so the patient was discharged with outpatient monitoring. On 14 October 2021 the platelet count was $101 \times 10^9/L$.

Conclusion and relevance Mild and transient thrombocytopenia is a common adverse event described for Vaxzevria. Cases presented with very low platelet levels are very rare. Nevertheless, the benefit of vaccination continues to outweigh the risks.

We describe a severe case of ITP secondary to COVID-19 vaccine successfully treated with eltrombopag after failure of systemic corticosteroids.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-250 HOME DELIVERY FOR OUTPATIENTS WITH IMMUNE-MEDIATED DISEASES: EXPERIENCE AND PATIENT SATISFACTION

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Background and importance Patients with immune-mediated diseases (IMIDs) frequently need therapies from the hospital pharmacy. Due to the COVID-19 pandemic, a home delivery service (HDS) with telepharmacy follow-up was started to avoid unnecessary visits to hospital.

Aim and objectives To describe the population that accepted the HDS and evaluate their satisfaction about it.

Material and methods Descriptive retrospective observational study in a cohort of patients with IMIDs who had received HDS from February to August 2021. Data collected were age, sex, pathology, distance to hospital, number of shipments and satisfaction survey score. Surveys were made by telephone and scored the Pharmacy Service, the transport company and global satisfaction by means of seven questions (each with scores ranging from 1 to 5).

Results 130 patients received HDS (7.23% of IMIDs outpatients), 116 of them were contacted for the survey. 81.9% were female. Median age was 74 (IQR 65.50–80.00) years. Pathologies distribution: 63 (54.31%) rheumatoid arthritis; 18 (15.52%) spondyloarthropathies; 14 (12.07%) multiple sclerosis; 7 (6.03%) inflammatory bowel disease; 5 (4.31%) psoriasis; 5 (4.31%) connective tissue diseases and 4 (3.45%) other IMIDs (hydradenitis or vasculitis). 22.41% patients lived outside of the city centre where the hospital is located. Patients received an average of 2.17 (SD 1.12) shipments during these months.

84.48% patients were offered HDS from the hospital pharmacy; 15.52% asked for the service themselves. Main reason chosen by patients to accepted HDS was the COVID-19 pandemic situation or self-insolation due to contact or infection (75.86%), followed by mobility difficulties (31.90%), distance to hospital (6.90%) and work schedule (0.86%).

Average survey score for Pharmacy Service: 4.93 (SD 0.29) about pharmacist follow-up, 5.00 (SD 0) about correct medication and 4.98 (SD 0.13) about shipping material. In relation to the transport company, the scores were 5.00 (SD 0) about carrier treatment, 4.86 (SD 0.58) about schedule compliance and 5.00 (SD 0) about proper packaging conditions. Average score for global satisfaction was 4.99 (SD 0.10).

Conclusion and relevance The pandemic situation increased HDS necessity (75.86% of patients requested it) but its continuity is justified specially due to mobility difficulties (31.90%) in older or incapacitated people, a frequent situation in IMIDs outpatients.

Home delivery is a service that is highly valued by patients. Even so, telepharmacy follow-up and trying to adapt the shipping schedule could be areas to improve the service.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-251 INFLUENCE OF POLYPHARMACY AND COMORBIDITIES IN THE QUALITY OF LIFE OF PATIENTS WHO SUFFER HIP FRACTURE

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Background and importance Hip fracture is an increasing disease as the population get older. It has direct consequences in health systems in terms of quality of life and economic investment. Furthermore, these patients usually have comorbidities and take multiple medications.

Aim and objectives To analyse the impact of polypharmacy and comorbidity on the quality of life (QoL) of patients with hip fracture.

Material and methods Prospective and observational study with consecutive sampling of patients aged over 65 years admitted for hip fracture surgery during the study period. Functional ability (CUPAX test), nutritional risk (NRS), frailty (Fried *et al*), Charlson Comorbidity index, number of drugs and QoL variables were collected. QoL was assessed using the EuroQol-5D-3L questionnaire at the time of admission which referred to their baseline condition before the hip fracture.

A stepwise multiple regression was performed to study independent variables associated with QoL. The significance level for the different analyses was established as $p < 0.05$. The data analysis was performed using SPSS.

Results The study included 33 patients, mean age 79 years (SD \pm 7), 73% women. Charlson Comorbidity Index was 5 (IC 4.2–5.5). The mean number of medications taken was 7.5 (IC 5.8–9.1). In the multiple regression analysis (adjusted $R^2=0.293$, $p=0.001$) the comorbidity index was associated with a lower EQ-5D index, while the number of drugs had no relation to the EQ-5D. None of the clinical variables of performance status, physical function and nutritional status showed statistical significance in the multivariable model.

Conclusion and relevance Charlson Comorbidity index but not the number of drugs had an impact on the QoL of admitted patients with hip fracture.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-252 ORAL AND INTRAVENOUS IRON IN THE TREATMENT OF PERIOPERATIVE ANAEMIA

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Background and importance Anaemia is common in the perioperative period and is associated with worse patient outcomes. Carboxymaltose intravenous iron (CII) administration contributes to its correction, at the expense of greater cost. Oral

iron might be a more efficient alternative, so an assessment of effectiveness is needed.

Aim and objectives Assessment of effectiveness of oral iron and CII as combined therapy in the treatment of perioperative anaemia in surgical patients.

Material and methods This was an observational, retrospective, single centre study. Data were obtained from medical prescription covering a 2-year period (January 2017–December 2018). Surgical patients who received CII and oral iron in combination during the perioperative period were included.

The following variables were collected: sex, age, type of surgery, haemoglobin (Hb) before and after treatment with CII and oral iron, and duration of treatment.

Median and range was calculated for quantitative variables. Percentage was selected as the descriptive measure for discrete variables.

The primary variable considered to assess the effectiveness of the treatments was an increase of Hb >1 g/dL in the preoperative and postoperative periods in comparison with basal Hb in both stages.

Results A total of 37 patients who received CII and oral iron together during the perioperative period were included (18 in preoperative period and 34 in postoperative). Median age was 47 (40–59) years. 85.3% ($n=29$) of the patients were women. Most common types of surgery were gynaecological (67%) and digestive (14%).

In the preoperative period, 18 patients who received oral iron had a basal Hb of 10.2 (9.0–10.6) g/dL. After 76.5 (28.5–137) days of treatment, no increase of Hb was observed (10.2 g/dL, 8.4–11.2). Only 11.1% ($n=2$) of patients obtained increases of Hb >1 g/dL. After posterior administration of CII, Hb values reached 11.0 (9.5–11.7) g/dL. An increase of Hb >1 g/dL was found in 27.8% ($n=5$) of patients.

In the postoperative period, 34 patients who received oral iron had a basal Hb of 10.6 (9.5–11.5) g/dL, reaching a value of Hb of 12.6 (11.0–13.0) g/dL after 56 (48.3–90) days of treatment. 52.9% ($n=18$) of patients obtained increases of Hb >1 g/dL.

Conclusion and relevance CII treatment was more effective than oral iron in the perioperative period.

Oral iron treatment was more effective in the postoperative period in comparison with the preoperative period.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-258 ACTIVATION, ADHERENCE AND HEALTH OUTCOMES IN PATIENTS WITH MODERATE TO SEVERE PSORIASIS TREATED WITH BIOLOGICAL DRUGS

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Background and importance Searching for novel methods that could increase the effectiveness of treatment with biological drugs we wanted to carry out a study to evaluate the measurement of patient activation.

Aim and objectives To evaluate activation according to the Patient Activation Measure-13 (PAM-13) questionnaire and to analyse the relationship between adherence and health outcomes in patients with moderate to severe psoriasis treated with biological drugs.

Material and methods *Design:* prospective observational study. *Inclusion criteria:* patients with moderate to severe psoriasis treated with biological drugs for more than 6 months, who attended dermatology consultations from 1 June 2020 to 1 July 2020. *Variables:* demographic (sex and age), related to treatment (time under treatment with biological drugs and study drug) and related to effectiveness (Psoriasis Area Severity Index (PASI): non-responders PASI \geq 5).

The patient's ability to play an active role in health care was measured using the PAM-13 questionnaire: not active \leq 55.1 and active \geq 55.2.

Adherence to treatment was assessed by combining the Simplified Medication Adherence Questionnaire (SMAQ) and the rate of possession of the medication at 6–12 months (TPM; adherents TPM \geq 80%). Non-adherent patients were those classified as non-adherent according to either of the two methods.

Results 31 patients (45% women) were included, with a mean of 48 years (95% CI 44 to 52), in treatment with biologics for 3.6 years (IQR 3.5); in active treatment with: adalimumab (32%; 10/31), secukinumab (29%; 9/31), ixekizumab (19%; 6/31) or others (19%; 6/31).

Two patients were considered to be non-responders (6%; 2/31). The PAM-13 classified 19% (6/31) of the patients as not activated. 29% (9/31) were considered non-adherent.

When associating activation with adherence, no differences were observed ($\chi^2=1.6$; $p=0.208$) with 50% (3/6) of non-activated patients considered non-adherent.

When relating activation to effectiveness, statistically significant differences were observed ($\chi^2=8.9$; $p=0.003$). The two non-responders were considered unactivated, while 86% (25/29) of the responding patients were considered activated.

Conclusion and relevance The higher proportion of responding patients found among activated patients indicates a positive relationship between activation and health outcomes, so promoting patient activation could contribute to improving the effectiveness of biological drugs in patients with moderate to severe psoriasis.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-260 PERSISTENCE AND SAFETY OF CALCITONIN GENE-RELATED PEPTIDE INHIBITORS IN CHRONIC MIGRAINE

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Background and importance Monoclonal antibodies against calcitonin gene-related peptide or its receptor (mAb-CGRP) offer improvements over available drugs in migraine prophylaxis. Safety and persistence are essential to achieve disease management goals.

Aim and objectives To assess the persistence and safety of mAb-CGRP in patients with chronic migraine in clinical practice.

Material and methods In this observational retrospective single-centre study, all patients with chronic migraine treated for at least 1 month with mAb-CGRP between December 2019 and September 2021 were included.

The primary outcome was first- and second-line persistence (patients treated less than 3 months were excluded), which was analysed using Kaplan–Meier survival curves and the log-rank test for comparison. Secondary outcomes were adverse effect rate and reasons for discontinuation.

Variables collected were age, sex, number of migraines/month, previous treatments, mAb-CGRP type, start and discontinuation date, reasons for discontinuation, mAb-CGRP switching and adverse effects (AEs).

Results Ninety-four patients with median migraines/month of 14 (IQR 10–20) were included; median age: 50 years (IQR 44–58); 84.04% women. All patients received at least three previous preventive treatments: botulinum toxin (100%), tricyclic antidepressants (90.43%), neuromodulators (88.30%), calcium-channel blockers (64.89%), beta-blockers (59.57%) and others (21.28%).

The main reason for discontinuation was ineffectiveness (80.77%). Other reasons were treatment ending, pregnancy, loss of follow-up and patient's decision.

Median overall persistence for first- and second-line treatment was 13.6 months (95% CI 11.01 to 16.19) and 9.0 months (95% CI 4.61 to 13.39), respectively. Median persistence in first line for erenumab was 13.4 months (95% CI 10.94 to 15.86), for galcanezumab 15.3 months (95% CI 11.81 to 18.79) and fremanezumab was not reached ($p>0.05$). The 12-month overall persistence rates for first and second line were 67.04% and 52.10%, respectively ($p>0.05$).

AEs appeared in 21 patients: constipation (8.51%), injection-related headache (5.32%), fatigue/arthritis (4.26%),

Abstract 4CPS-260 Table 1

	Treatment line					
	First		Second		Third	
mAb-CGRP	Patients	Discontinuation	Patients	Discontinuation	Patients	Discontinuation
All	94 (100%)	38 (40.43%)	29 (34.52%)	11 (37.93%)	8 (8.51%)	3 (37.50%)
Erenumab	42 (44.68%)	17 (40.48%)	16 (55.17%)	7 (43.75%)	0	
Galcanezumab	40 (42.55%)	19 (45.23%)	12 (41.38%)	4 (33.33%)	0	
Fremanezumab	12 (12.77%)	2 (16.68%)	1 (3.45%)	0	8 (100%)	3 (37.50%)

injection-site reaction (4.26%), vertigo (2.13%) and menstrual disorders (2.13%). Other AEs were weight loss, insomnia and alopecia. One patient discontinued due to hypersensitivity.

Conclusion and relevance First- and second-line treatment with mAb-CGRP showed similar levels of persistence. First-line erenumab and galcanezumab also demonstrated the same results. The frequency of AEs is lower than reported in clinical trials, so we can conclude that mAb-CGRPs are safe drugs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-261 ABSTRACT WITHDRAWN

4CPS-262 EVALUATION OF DRY EYE SEVERITY AND THERAPEUTIC ADHERENCE OF PATIENTS ON AUTOLOGOUS SERUM EYE DROPS

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Background and importance Autologous serum eye drops (ASC) are used as a last resort in the most severe forms of dry eyes. Their manufacture and outpatient dispensing take place in few hospitals, which implies important logistical constraints for patients (blood sampling before preparation, frozen storage, monthly or bimonthly dispensing).

Aim and objectives The objective was to characterise patients treated with ASC, their dry eye severity (DES) and their adherence to treatment despite the constraints.

Material and methods This study was multicentric (4 hospitals), prospective and non-interventional conducted since Summer 2020. Treatment with ASC was the only inclusion criteria. Symptoms of ocular irritation in DES and how they affect functioning related to vision was assessed by the validated Ocular Surface Disease Index (OSDI) form. Therapeutic adherence was assessed using a Girerd validated form adapted to eye drops. One form combining both measures was given to each outpatient coming to collect his/her ASC at each participating hospital pharmacy. Forms could be filled on site or at home. Answers were collected and analysed using Excel software.

Results Sixty-seven forms recovered from the 231 patients treated with ASC. The average age was 55 (3–88) years (1 no response (NR)). 67% of respondents were women. The most common indication was graft-versus-host disease (28%). Patients had been treated for an average of 31 (0.75–120) months. According to the OSDI score (1 NR), the DES was ‘normal’ in 18%, ‘mild’ in 28%, ‘moderate’ in 31% and ‘severe’ in 21% of patients. Regarding the Girerd score, 60 patients never had an ASC deficiency since their last hospital visit and only 5 forgot to take their drug in the morning before completing the form; also 22% of our patients had ‘good compliance’, 57% ‘minimal compliance problems’ and 21% ‘poor compliance’.

Conclusion and relevance This study showed that more than half of the patients on ASC suffered from moderate to severe dry eye, and that adherence to treatment was satisfactory, even for treatments administered for more than 7 years. This work leads us to study the possibility of assessing more generally the impact of ASC treatment on patients' quality of life.

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Conflict of interest No conflict of interest

4CPS-263 EVALUATION OF THE EFFECTIVENESS AND SAFETY OF SWITCHING FROM INTRAVENOUS TO SUBCUTANEOUS TOCILIZUMAB

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Background and importance In the context of the COVID-19 pandemic, one of the strategies implemented to minimise patient visits to health centres was switching the administration of tocilizumab (TCZ) from intravenous (IV) to subcutaneous (SC).

Aim and objectives To evaluate the effectiveness and safety of switching from IV to SC TCZ.

Material and methods Retrospective observational study conducted in a tertiary hospital including patients receiving active treatment of IV TCZ during the period March–April 2020.

Data were collected on the following variables: age, sex, pathology, switching to SC TCZ, switching back to IV administration, physician assessment or patient self-assessment, as well as adverse reactions. The follow-up period was 1 year.

Results A total of 45 patients were included, with a median age of 54 (40–62) years. Women represented 85%.

Patients included were diagnosed with rheumatoid arthritis (49%), juvenile idiopathic arthritis (18%), Graves disease (13%), lupus (2%), spondylarthritis (2%) and other diagnoses (16%). The prescribing physicians were rheumatologists (62%), internists (24%) and paediatricians (13%).

Of 45 patients, 71% (n=32) switched to SC TCZ during the study period. 86% of rheumatology, 83% of paediatrics and 27% of internal medicine patients changed to SC TCZ.

Aggravation after switching to SC TCZ was reported in 7/32 (22%) cases (5 with rheumatoid arthritis and 2 with juvenile idiopathic arthritis). All of these switched back to IV administration, plus 4 additional patients for undetermined reasons. Of those who switched back to IV administration due to clinical worsening, 4 reported improvement afterwards.

Regarding safety, only 2 patients suffered adverse reactions after switching to SC (injection site reaction, palpitations, tremor and oedema). Neither of them switched back to IV administration.

Conclusion and relevance One-fifth of the patients reported loss of effectiveness when changing from IV to SC form, and one-third switched back to IV administration. Regarding safety, the toxicity profile of both forms was similar to other studies.

The effectiveness results observed are in contrast with the MUSASHI study, which did not report loss of efficacy after

switching from IV to SC. However, effectiveness was not measured using the internationally validated ordinary objective scales (DAS28, CDAI), but physician subjective assessments or patient self-assessments, which represents a significant limitation for our study.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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4CPS-266 DETECTION AND FOLLOW-UP OF DRUG-RELATED PROBLEMS FOR PATIENTS WITH CARDIOVASCULAR DISEASE: A STUDY OF THE MEDICINE START SERVICE IN HOSPITAL PHARMACIES

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Background and importance Medication treatment of cardiovascular disease (CVD) commonly consists of multiple drugs in long-term use, which efficiently reduces mortality and morbidity. Optimal treatment is often not achieved due to poor adherence and drug-related problems (DRPs). DRPs are defined as “an event or circumstance involving drug therapy that actually or potentially interferes with desired health outcomes”. Medicine Start Service (MSS) is a government-funded pharmacy service, free of charge for all patients with a new CVD medication, that aims to improve patient safety. Patients are offered two consultations with a pharmacist, focusing on DRPs and beliefs and concerns about their new medication. Whether MSS is efficient to detect DRPs is unknown.

Aim and objectives To assess the number and nature of DRPs detected during MSS consultations, and to map out how pharmacists followed up those DRPs.

Material and methods A prospective, uncontrolled, multicentre, intervention study was conducted from September 2019 to February 2021 in three pharmacies based in different hospitals. Adult patients filling a first-time prescription for one or more CVD medications were offered a consultation with a pharmacist 1–2 and 3–5 weeks after initiating treatment. The consultation was conducted in the pharmacy or by telephone and followed the national MSS semi-structured interview guide. DRPs were registered and classified into seven different categories according to a modification of the system developed by Ruths *et al.*[1]

Results A total of 67 patients completed consultation 1 and 2. Pharmacists detected 83 and 67 DRPs in consultation 1 and 2, respectively. DRPs related to adverse drug reactions (ADR) were most frequent (41.3%), followed by lack of knowledge about medication and disease (21.3%) and medicine use (12.0%). The pharmacists followed up 90.1% of the DRPs independently, most frequently by giving advice and counselling (60.1%), and conferred or referred to a doctor in 9.9% of cases.

Conclusion and relevance Pharmacists detected relevant DRPs in a majority of patients with newly started CVD medicines, including ADRs and problems related to medicine use. Early detection of such problems may be of importance for patient safety in the critical phase of transition from hospital to community.

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Conflict of interest No conflict of interest

4CPS-267 DESIGN, IMPLEMENTATION AND EVALUATION OF A MEDICATION COUNSELLING SERVICE BY PHARMACISTS USING TEACH-BACK AT HOSPITAL DISCHARGE

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Background and importance Pharmacists can utilise teach-back as a method to enhance patients' understanding of medication counselling at hospital discharge. However, the evidence regarding its impact on patient outcomes is inconsistent, and there is no standardised approach in the literature to implement pharmacist-led discharge medication counselling, with limited descriptions of pharmacist training reported.

Aim and objectives To develop and implement a standardised discharge medication counselling service utilising the teach-back method, and to evaluate feedback from patients and pharmacists regarding the service.

Material and methods A standardised procedure and checklist were developed for the discharge medication counselling process. Participating pharmacists were trained on teach-back by undertaking an online education module and watching a video created by the research team which demonstrated teach-back. Pharmacists provided discharge medication counselling to patients using teach-back and provided a patient-friendly list of medication changes to take home. To attain feedback on the intervention, patients were surveyed via telephone within 7 days of discharge and intervention pharmacists completed an anonymous online survey.

Results Thirty-two patients participated in the study, with a mean age of 57 (19–91) years and mean Charlson Comorbidity Index score of 3 (0–8). Two-thirds of patients received medication counselling on antithrombotics. The mean counselling time was 24 min/patient (SD 12 min, range 7–60 min). All patients responded to the survey, whereby 94% had increased confidence regarding medication knowledge and 91% understood what potential side effects to be mindful of at home. Overall, 94% of patients were satisfied with the discharge medication counselling experience and with the information provided. Eight of the nine intervention pharmacists (89%) agreed they were given adequate training and that teach-back was feasible to apply in practice.

Conclusion and relevance This is the first study to evaluate patients' perspectives on teach-back medication counselling by pharmacists. Despite the small sample size, the included patients were diverse in terms of age and comorbidities, and most patients experienced positive outcomes from the discharge medication counselling. With the standardised approach and a comprehensive description of the training, this study can be used to guide the development of discharge medication counselling services using teach-back in future.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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Conflict of interest No conflict of interest

4CPS-269 ANALYSIS OF RECURRENCES AND RISK FACTORS IN INFECTION BY *CLOSTRIDIUM DIFFICILE*

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Background and importance Recurrences in *Clostridium difficile* infection (CDI) involve increased morbidity and high costs for the healthcare system.

Aim and objectives Analysing the risk of recurrence in patients with CDI according to the prediction scale proposed in the 2020 clinical practice guideline of the Spanish Society of Chemotherapy, Internal Medicine and Anaesthesia and Reanimation. To check whether the calculated risk corresponds to the recurrences presented and to establish the main risk factors observed.

Material and methods Hospitalised patients with CDI were selected from 1 February 2019 to 30 April 2020. The collected data were: sex, age, antibiotics in the previous 3 months and concomitantly with vancomycin or fidaxomicin, immunosuppression, severity (leukocytes >15 000/mm³ or creatinine >1.5 mg/dL), duration of diarrhoea, inflammatory bowel disease (IBD), liver cirrhosis and neoplasia. Recurrence was defined as a new episode of CDI 2–8 weeks after the first episode. The risk of recurrence was calculated using the scale: 1 point for >65 years, immunosuppression, severity, concomitant antibiotics and diarrhoea >5 days; 2 points if episode during previous year, neoplasia, IBD and liver cirrhosis; 3 points if recurrence. A score ≥3 is considered high risk of recurrence.

Results 69 patients with CDI were identified (54% women and 46% men); the median age was 65 years. 88% of patients received antibiotics during the previous 3 months: 39% quinolones, 34% third-generation cephalosporins, 26% amoxicillin-clavulanic acid, 26% piperacillin-tazobactam and 20% carbapenems. Of the 69 patients identified, 20 recurrences were observed, 9 of them with a score ≥3, which represents a degree of coincidence between the scale and the patients studied of 45%. Of the total sample, 36 patients had a score ≥3, and 9 of them had a recurrence (25%). Of the patients with recurrences, the following risk factors were identified: 50% presented immunosuppression, 40% neoplasia, 30% concomitant antibiotics; and 40% of the subjects had neoplasia and immunosuppression.

Conclusion and relevance The calculated risk of recurrence does not correspond to the results obtained in the analysed sample. The choice of treatment should be guided by the patient's individual risk factors.

Immunosuppression and neoplasia are the main risk factors for recurrence, increasing the risk when both situations coexist.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-270 INVESTIGATING THE USE OF PATIENT FRAILTY TO GUIDE PHARMACIST-LED MEDICATION REVIEW

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Background and importance As the worldwide population ages, chronologically ‘old’ patients are becoming a diverse group with different healthcare needs. Frailty has been suggested as an alternative to chronological age for identifying patients at risk of poorer health outcomes. It is proposed that patient frailty could help to prioritise patients who can benefit most from pharmacist-led medication review.

Aim and objectives To examine a relationship between patient frailty and (1) specific high-risk medication use criteria and (2) potentially inappropriate prescribing using the Medication Appropriateness Index (MAI).

Material and methods A convenience sample of 58 patients was obtained from patients reviewed by a Geriatric Emergency Medicine Service. Data including medication lists, medical history, age, sex and Clinical Frailty Scale score was gathered. These data were used to assess how many high-risk medication criteria each patient met. A subgroup of 40 patients had the Medication Appropriateness Index (MAI) tool applied. A correlation coefficient was calculated using Excel (Microsoft Office 2019) to investigate the relationships between CFS and high-risk medication criteria, and CFS and MAI.

Results The correlation coefficient between CFS and high-risk medication use criteria was calculated as 0.13. A higher correlation coefficient of 0.4 was found for the relationship between CFS and MAI. Patients’ CFS score ranged from 3 to 8. In the 58 patient sample 45% of patients had a CFS score = 6 (moderately frail), 96% of patients had at least one high-risk criteria present, polypharmacy was present in 85% of patients and 48% of participants were taking at least one ‘high-risk’ drug. All 40 patients who had the MAI tool applied scored ≥ 1 , the range was 1–29 per patient. 31% (103/331) of drugs examined were deemed inappropriate by meeting one or more of the criteria outlined in the MAI tool.

Conclusion and relevance This study failed to identify a specific level of frailty at which pharmacist intervention may be of most benefit. However, the group of patients included in this study are at high risk of adverse drug effects and are a population that should be prioritised for pharmacist review.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Thanks to Aisling Kerr, Deirdre Lynch and colleagues in the pharmacy department and GEMS, CUH.

Conflict of interest No conflict of interest

4CPS-271 ADHERENCE TO MEPOLIZUMAB AND BENRALIZUMAB IN REAL CLINICAL PRACTICE

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Background and importance Mepolizumab and benralizumab are two biological drugs used in severe uncontrolled asthma

(SUA) patients. There is a lack of data in actual clinical practice regarding the relationship of effectiveness and adherence.

Aim and objectives The aim of this study was to describe the treatment adherence of mepolizumab and benralizumab in SUA patients and to assess the relationship between this adherence and effectiveness.

Material and methods Retrospective observational study developed in the Outpatient Pharmaceutical Care Unit of a tertiary university hospital. All patients diagnosed with SUA who were under treatment with mepolizumab and benralizumab were included during the period January 2017–March 2021.

Data collected: demographic; pharmacological: drug (mepolizumab/benralizumab), duration of treatment (DOT), concomitant administration of oral corticosteroids (OC); phenotype (eosinophilic/allergic/other).

Non-adherence was evaluated by reviewing all scheduled drug dispensing visits in the computerised application. This fact was considered every time that a patient collected medication later than scheduled according to frequency of administration (28 days for mepolizumab and 56 days for benralizumab), by which dispensation missed (DM) was defined.

The number of DM was identified for mepolizumab (DM-mepolizumab) and benralizumab (DM-benralizumab).

Effectiveness was defined by evaluating at baseline/3/6/12 months: the *Asthma Control Test* (ACT) parameter, forced expiratory volume in the first second (FEV₁) and need for OC.

Results are presented as median (standard deviation) for quantitative variables and number (percentage) for qualitative variables.

Results Thirty-four patients were included: age 59 (12) years, women 21 (55.3%), obese 10 (26.3%), Caucasian 31 (81.6%).

Results were: mepolizumab 22 (57.9%) and benralizumab 16 (42.1%), both drugs were used sequentially in 4 patients (11.8%). Naïve 22 (57.9%), DOT 20.0 (11.7) months, concomitant OC 15 (39.5%); eosinophilic phenotype 26 (68.4%), allergic 5 (14.7%), others 7 (18.4%).

A total of 622 dispensations were identified: mepolizumab 505 (76.5%) and benralizumab 155 (23.5%).

DM 30 (4.8%) were distributed as DM-mepolizumab 27/30 (90%) versus DM-benralizumab 3/30 (76.5%).

Effectiveness (baseline/3/6/12 months) was shown to be: ACT 12/20/17/17, the FEV₁ of 58%/76%/72%/83% and the number of patients with OC of 15/17/16/9.

Conclusion and relevance Mepolizumab or benralizumab were collected later than expected in less than 5% of scheduled dispensations. Thus a high grade of adherence to these drugs could be considered.

More adherence to the biological drug was related to higher effectiveness according to the values of ACT, FEV₁ and use of OC for the first year of treatment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-273 IMPACT OF A SPECIALIST PHARMACIST ON HEPATO-PANCREATICO-BILIARY (HPB) SURGICAL WARD ROUNDS AT A LARGE TERTIARY LIVER CENTRE

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Background and importance Surgical patients are at risk of medication-related adverse events, with some of these patients having comorbidities requiring long-term medications prior to surgery. Published data suggest pharmacist interventions can reduce adverse drug reactions (ADRs) and medication errors and reduce hospital length of stay.

The effect of implementing a pharmacist into the HpB surgical ward round (WR) was unknown; this would also support ongoing service development projects in liver pharmacy on patient pathways.

Aim and objectives To establish the range and clinical impact of interventions made by the specialist pharmacist when attending HpB post-surgical WR as part of ongoing pharmacy engagement and service development.

1. To measure the number of interventions being made by the specialist pharmacist on WR.
2. To determine the common themes of pharmacist interventions.
3. To determine the proportion of 'on the spot' pharmaceutical advice given to healthcare professionals and patients as part of this process.

Material and methods A prospective study of 1 month, with attendance at two WR per week. Review of all postsurgical HpB on an inpatient ward. All interventions were collated and categorised based on commonality.

Results Over the course of data collection, the pharmacist reviewed 140 patients and made 477 interventions as part of the WR. This included 45 history medications restarted, identification of 32 ADRs to current treatment, 16 instances of vancomycin dose adjustments, confirmation of anticoagulation for 17 patients and addition of 101 antibiotic stop dates contributing to better antimicrobial stewardship. There were also 70 instances of a nurse/doctor/patient requiring additional information on medication treatments.

Conclusion and relevance This study has highlighted the scale of interventions a pharmacist can make on a WR, emphasising not only adjustment of medications but also the need for medication-related information by healthcare professionals and patients alike.

Moving forward a pharmacist will attend at least two WR per week, with potential scope for support in pre-assessment and postoperative clinics to review weaning of analgesia and long-term management of pancreatic replacement, for example.

With the recent announcement regarding new standards for the initial education and training of pharmacists in the UK, it would be valuable to assess the impact of a prescribing pharmacist on these WR.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-274 EVALUATION OF PHARMACEUTICAL INTERVENTIONS DOCUMENTED BY A PHARMACY TECHNICIAN: WHERE DO PHARMACY TECHNICIANS HAVE THE BIGGEST IMPACT TO AVOID DRUG-RELATED PROBLEMS?

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Background and importance In the field of clinical pharmacy services there are activities that are suitable for pharmacy technicians under the supervision of a pharmacist. At the university hospital in Dresden one full-time pharmacist and one half-time pharmacy technician (4 hours/day) are looking after 80 beds in the department of urology. The main tasks of the pharmacy technician are medication reconciliation as well as clinical prioritisation by using guidelines to identify patients who are at high risk of drug-related problems.

Aim and objectives The aim of this study was to identify the clinical pharmacy services where the integration of pharmacy technicians has the biggest impact on avoiding drug-related problems.

Material and methods Since 2019 the pharmacy technician has recorded their interventions in a categorical Excel worksheet, and there are two documentation weeks per quarter. The categories are drug name, short description of the drug-related problem, intervention, classification (dose-related problems, consultation of general practitioner, consultation of patient, electronic prescription, other drug-related problems after discussion with the pharmacist, drug substitution).

Results During 22 documentation weeks from January 2019 to September 2020 the pharmacy technician documented 468 interventions. The main interventions were drug substitution on admission considering local guidelines (n=181; 39%), consultation with the general practitioner because of identified discrepancies on the medicine lists (n=138; 29%) and consultation with patients because of identified discrepancies (n=78; 17%). Dose-related interventions and other drug-related problems were detected by the pharmacy technician and discussed with doctors under the supervision of the pharmacist (n=49; 10%).

Conclusion and relevance Especially in the field of medication reconciliation, trained pharmacy technicians can be suitable to prevent medication errors. Consultations with general practitioners and patients because of identified discrepancies on the medication lists are time-intensive and probably would not happen in the same way without integration of the pharmacy technician. Drug substitution in consideration of local guidelines and the preparation of the electronic prescription led to fewer queries from nurses or doctors.

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Conflict of interest No conflict of interest

Section 5: Patient safety and quality assurance

5PSQ-003 DEVELOPMENT AND APPLICABILITY OF THE MEDHIPPRO-Q: A QUESTIONNAIRE ASSESSING MEDICAL DOCTORS' EXPERIENCE WITH MEDICATION MANAGEMENT IN THE HIP FRACTURE PATIENT PATHWAY

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Background and importance Hip fracture patients are characterised by polypharmacy and multiple care transitions within and between home, hospital, and rehabilitation institution/nursing home (ie, the patient pathway). Each care transition increases the risk of medication discrepancies. Thus, there is need to achieve a correct medication list, optimised for each patient, and ensure a seamless patient handover. Before implementing a clinical pharmacist intervention to address these issues, an evaluation of medical doctors' perceptions of the current situation was needed. However, no appropriate questionnaire was identified.

Aim and objectives To develop a valid and feasible questionnaire to assess medical doctors' experience with medication management of hip fracture patients in all care settings, and present an example of its applicability.

Material and methods The study took place in a region in South-Eastern Norway (approximate population: 250 000) from September 2017 to August 2018. The emerging questionnaire (MedHipPro-Q) was developed qualitatively through semi-structured interviews with stakeholders, cognitive interviews with future respondents, and a feasibility test. The novel MedHipPro-Q was thereafter distributed to hospital doctors.

Results Three questionnaire dimensions were identified: (1) Medication reconciliation and review, (2) Communication of key information and (3) Profession and setting. The MedHipPro-Q showed face and content validity through its representativeness of how stakeholders experienced medication management in all settings, and good feasibility. Almost half of the doctors in the emergency care unit responded ($n = 9/20$). They described medication lists missing at admission ($n = 7/9$), and using median 6–10 (range 3–20) min writing the medication part of the admission journal. In the orthopaedic department, 15/31 responded, and expressed that patients needed more medication reviews ($n = 12/15$), but wished for someone else to perform it ($n = 13/15$). A third of the doctors in the orthopaedic department ($n = 5/15$) always write the mandatory medication list at discharge.

Conclusion and relevance The MedHipPro-Q showed emerging validity and appeared feasible. It was able to identify problem areas that could be addressed by the planned clinical pharmacist intervention.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-006 DOSING LOW MOLECULAR WEIGHT HEPARINS IN RENAL IMPAIRMENT: A NATIONWIDE SURVEY

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Background and importance International guidelines vary in their advice whether or not to reduce the therapeutic dose of low molecular weight heparins (LMWHs) in renal impairment. The use of anti-Xa monitoring as a basis of dose adjustments is also a matter of debate.

Aim and objectives To study the nationwide treatment policies of therapeutically dosed LMWHs in renal impairment in hospitals.

Material and methods An 11-item survey was distributed to clinical pharmacists nationwide between June 2020 and March 2021. Primary outcome was the hospital dosing regimen for therapeutically dosed LMWHs in renally impaired patients. Secondary outcomes were the proportion of hospitals that used anti-Xa monitoring and the anti-Xa target range used. Descriptive statistics were used to analyse the data.

Results The survey was completed by 56 of the 69 (81%) hospital organisations nationwide. Of the included hospitals, 91% applied a fixed-dose reduction at the start of the LMWH treatment in renally impaired patients (71% reduced if estimated glomerular filtration rate (eGFR) <50 mL/min and 20% if eGFR <30 mL/min). The majority (64%) of hospitals applied a dose reduction of 25% if eGFR is 30–50 mL/min and of 50% if eGFR is <30 mL/min. Anti-Xa levels were not routinely monitored in renally impaired patients in 43% of hospitals, while 20% of hospitals monitored anti-Xa if eGFR <50 mL/min, 25% if eGFR <30 mL/min and 12% with other eGFR cut-off values. Target ranges of 1.0–2.0 IU/mL (once-daily dosing) and 0.5/0.6–1.0 IU/mL (twice-daily dosing) were used in 69% of hospitals that monitored anti-Xa.

The most commonly applied treatment regimen was dose reduction if eGFR <50 mL/min without anti-Xa monitoring, regardless of the type of LMWH.

Conclusion and relevance This study demonstrates substantial nationwide diversity in the treatment policies of therapeutically dosed LMWHs in renally impaired patients in hospitals. The most commonly used treatment regimen in hospitals is to apply a fixed dose reduction if eGFR is <50 mL/min, without anti-Xa monitoring. This treatment regimen is not yet described in LMWH treatment guidelines in renally impaired patients and should be explored in future research.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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5PSQ-008 ASSESSMENT OF PATIENT-CONTROLLED ANALGESIA (PCA) PRACTICES IN A PUBLIC HOSPITAL

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Background and importance PCA pumps help patients manage their pain by guaranteeing them autonomy, while lightening nursing workload. In this context, the prescriptions must contain the information necessary for secure programming (background dose, bolus, inter-dose, etc.) leaving no possibility for interpretation. This project was founded in response to repeated adverse event reports concerning patient-controlled analgesia (PCA) (8 reports between 2017 and 2020 with a majority of overdoses requiring care).

Aim and objectives An assessment of the prescription and monitoring of PCA is carried out with the aim of having a database in order to standardise the method of prescription using a multidisciplinary working group.

Material and methods Information is collected through an interview of the health executive of each department using a

seven-item questionnaire: prescription, monitoring, pump use, clarity of prescription, nurse skills and presence of a pain-referent (specialised nurse). The information was collected in the care unit using PCA between June and September 2021.

Results Seven department health executives were interviewed. Concerning the prescription: five departments use a computerised prescription, none include dilution information, and programming details are added by the prescriber because there is no prepared protocol. Two services use a paper prescription that is also the follow-up paper: they contain dilution information but not the background dose. Five services carry out the follow-up with a paper follow-up sheet, which differs according to the service, and two services use written computer transmissions. Concerning the other items: there is a lack of training sessions about the PCA pump use, only one service had a recent course by the company.

Conclusion and relevance The assessment showed a disparity in the method of prescription and monitoring. It appears that essential data are missing, data which are necessary to have a complete prescription. It would be interesting to work on a computer protocol making it possible to simplify the prescription (basic dose, bolus, inter-dose, etc.), as well as to propose a single paper prescription for non-computerised services. A working group comprising representatives of the pharmacy department, prescribers from the care units concerned, health executives and pain-adviser nurses has been set up to work on this issue with the objective of improving patient care.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-009 PATIENT SAFETY AND MEDICATION SAFETY CULTURE IN A HOSPITAL PHARMACY DEPARTMENT: A MIXED-METHODS STUDY

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Background and importance Pharmacists play an essential role in patient safety culture and medication safety, coordinating and implementing patient safety initiatives and preventing medication errors; however, there is limited literature on safety culture in pharmacy departments specifically. While patient safety culture surveys are a widely accepted measurement tool to measure patient safety culture, there is no widely used tool to measure attitudes towards medication safety. Measuring patient and medication safety culture could identify important areas for improvement.

Aim and objectives To assess the perceptions, opinions and attitudes of pharmacy staff to the patient and medication safety culture in a hospital pharmacy department.

Material and methods A mixed-methods cross-sectional survey study was conducted in a hospital pharmacy department over a 2-week period in June 2021. The quantitative phase involved a patient safety culture assessment, using an adapted version of the Safety Attitudes Questionnaire (SAQ) and a medication safety culture assessment with 12 Likert-scaled questions developed by the research team. Statistical analysis was performed on the quantitative data. Qualitative data from two open-ended questions on recommendations to improve

patient and medication safety were subjected to thematic analysis.

Results Forty-four staff members completed the questionnaire (30 pharmacists and 14 pharmacy technicians) resulting in a 75.9% response rate. The pharmacy department scored below the SAQ international benchmark in four domains, with particularly low scores in the 'Perception of Management' and 'Working Conditions' domains. Medication safety culture scores were positive with a mean score of 61.8. Seven themes emerged from the qualitative data: (1) Communication, (2) Staffing Issues, (3) Training and Education, (4) Digital and Technological Advances, (5) Environment, (6) Collaboration and (7) Medication Safety Initiatives.

Conclusion and relevance Survey respondents identified many barriers to improving safety in the hospital including staffing issues, communication, lack of training and education and work environment. Pharmacy staff recommended the use of more technological advances, collaboration with multidisciplinary teams and more medication safety initiatives. These are important recommendations which should be discussed with hospital management and introduced to improve the safety culture in the hospital.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-010 IDENTIFICATION OF INCORRECT DOSING OF DIRECT ORAL ANTICOAGULANTS: AN IMPORTANT INTERVENTION TO IMPROVE PATIENT SAFETY

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Background and importance Incorrect dosing of direct oral anticoagulants (DOACs) potentially increases the risk of bleeding or thromboembolic events. For guideline-conforming dosing [1] multiple factors such as indication, age, body weight, renal function, drug interactions and risk of bleeding have to be considered. Therefore, correct dosing of DOACs represents a challenge in clinical practice.

Aim and objectives This study aimed to quantify DOAC dosing errors, identify barriers of correct dosing, assess potential reasons for errors and to investigate the acceptance rate of pharmaceutical interventions addressing dosing errors.

Material and methods During a 6-month study period (April–September 2021) all DOAC prescriptions of clinical pharmacist (CP)-reviewed patients in a 1740 bed tertiary care hospital were prospectively collected. Prescriptions were assessed for dosing errors and, if necessary, corrections were recommended to prescribers. Doses according to Summary of Product Characteristics (SPC) criteria were considered correct. A total of 813 beds on 44 different wards (including surgical and internal medicine patients) were covered by 17 CPs.

Results Dosing checks were performed in 811 patients (44.5% women, median age 78 years, median estimated glomerular filtration rate (eGFR) Modification of Diet in Renal Disease (MDRD) 60 mL/min/1.73 m²). A total of 194 incorrect doses (23.9%) were identified. The most common DOAC indication was atrial fibrillation (76.2%). The most frequently evaluated DOAC was edoxaban (31.1%). A significant relation was found between apixaban 2×2.5 mg ($X^2(1, N = 123) = 18.1$,

$p < 0.001$) as well as dabigatran 2×150 mg ($X^2(1, N = 40) = 5.95, p = 0.015$) and incorrect dosing. A risk factor significantly related with incorrect dosing was age above 80 years ($X^2(1, N = 351) = 7.0, p = 0.008$). 45.9% of dosing errors were corrected following a pharmaceutical intervention. A common reason given for incorrect dosing was 'unstable renal function'.

Conclusion and relevance This study showed that DOAC dosing errors are frequent and pharmaceutical interventions can contribute to a reduction of these errors. Special caution is needed in elderly patients. Measures to increase acceptance rate need to be further investigated.

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Conflict of interest No conflict of interest

5PSQ-011 INTRAVENOUS POTASSIUM CHLORIDE: HOSPITAL-WIDE EVALUATION AND BENEFITS OF A VIDEO COURSE

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Background and importance Never-events are a main point in the making secure the medication circuit. As they are preventable events we wanted to set up a support that fitted with the knowledge of our health professionals (HP). We decided to focus on one of them, namely intravenous potassium chloride (KCl).

Aim and objectives We aimed to assess the knowledge of HP about intravenous KCl to produce a relevant and suitable support.

Material and methods Two pharmacy residents created a Google Forms survey on various aspects of intravenous KCl: prescription, storage, preparation, adverse effects, recognition, and administration. For each topic there were four or five items which were true or false. All HP of our hospital could answer online or on a paper form. An item was 'known' if the rate of correct answers was $\geq 80\%$.

We then made a video according to the lack of knowledge found through the survey.

Finally a new Google Forms survey was created to assess the video content and the satisfaction of HP.

Results We registered 144 answers. 78 were from nurses and caregivers (60%). The rate of correct answers varied from 67% for midwives to 83% for pharmacists (mean 75%). The units of prescription for children (44%), the warning labelling (42%) and the adverse effects (22%) were the lesser known items.

The video lasted about 4 min and covered all the topics from the first survey. It was available on the hospital's document management system.

The second survey registered 34 answers. Nearly 27% were from pharmacy technicians. The average rating of the content of the video was 9.5/10. The mean score for knowledge improvement was 8.4/10. HP declared an improvement in their knowledge about adverse effects (50%) and prescription (42%).

Conclusion and relevance The first evaluation showed an overall good knowledge about intravenous KCl. The video format was well received and will be complemented with a poster for care units. The improvement in prescription and adverse effects knowledge fits with the results of the first survey. It will be a useful tool for further courses for HP. The positive feedback will encourage us to develop the same approach for the other never-events.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-012 ARE 12 MONTHS OF TREATMENT WITH MONOCLONAL ANTIBODIES SUFFICIENT FOR MIGRAINE ATTACK PREVENTION?

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Background and importance Monoclonal antibodies (MAB) galcanezumab, erenumab and fremanezumab have been recently incorporated into the treatments for migraine attack prevention. All have proven to be safe and effective at reducing the number of migraine days (MD) versus placebo in short-duration clinical trials. However, some uncertainties remain unsolved, such as the optimal therapy duration. Clinical practice guidelines recommend treatment maintenance for 12 months.

Aim and objectives To analyse patients' clinical situation after the year of treatment.

Material and methods Prospective and observational study conducted in a tertiary hospital between December 2019 and August 2021.

After 12 months, neurologists decide whether the patient should continue with chronic treatment or, as recommended, stop and ask for re-evaluation if migraine worsens. All patients are reviewed 3 months after discontinuation.

Pharmacists' tasks range from validating and dispensing all treatments to medication counselling and follow-up.

Results 97 patients completed the first 12-month treatment course. 15.5% (15) were maintained chronically (8 as they had a strong likelihood of worsening if discontinued; 3 because MD diminished although they still had >15 days monthly; 2 since an effect was demonstrated during the last 3 months of treatment and 2 due to previous failure of dose reduction attempts).

32% (31) of patients required treatment reintroduction: 8 in less than 3 months (mean 1.57 (0–2) months) and 24 in ≥ 3 months (mean 4.08 (3–6) months). 21 of them have reached the second course 3 months' evaluation and all continue with effectiveness.

6.2% (6) changed to another preventative therapy (*botulinum toxin*, mainly) when their condition worsened and 2.1% (2) to another MAB. 8.2% (8) switched directly to another MAB due to poor response to the first one. 36% (35) remain in a clinically stable condition without a preventative therapy (20 after ≥ 3 months and 15 in the first 3 months).

Conclusion and relevance Effect of treatment remains for at least 3 months after discontinuation in 45% (44) of patients.

24% (23) of patients are either maintained chronically or need an early re-start.

64% (62) of patients still need preventive therapy for migraine attacks after 12 months of therapy.

Further studies with larger samples are required to establish the optimal duration for MAB as patients tend to worsen with time. Will they end up being chronic medications?

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-013 ANTINEOPLASTIC DRUGS AND THROMBOSIS: ANALYSIS OF A COHORT OF PATIENTS WITH CANCER-ASSOCIATED THROMBOSIS

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Background and importance Venous thromboembolic disease occurs in 10%–20% of cancer patients and results in high morbimortality. Cancer is associated with various factors that increase thrombotic risk; in addition, the incidence of cancer-associated thrombosis (CAT) is related to the type of tumour, staging and antineoplastic treatment.

Aim and objectives To analyse the prevalence of antineoplastic drugs associated with thrombosis and to identify the thrombotic risk in a cohort of patients with a CAT.

Material and methods A retrospective observational study, which included oncological patients admitted to a third-level hospital during 2019 with a diagnosis of CAT. Biodemographical, clinical and antineoplastic treatment-related variables were recorded.

Different sources associate some antineoplastic drugs to CAT (5-fluorouracil, cisplatin, doxorubicin, paclitaxel, among others). Besides, according to the American Society of Clinical Oncology (ASCO) Guidelines, stomach and pancreas (very high) and lung, lymphoma, gynaecological, bladder, testicles and kidneys (high) are the most related tumours to CAT.

The thrombotic risk prior to the initiation of chemotherapy was determined according to the Khorana Risk Score (KRS), where 3: high; 1–2: intermediate; 0: low, which considers: tumour location, body mass index (BMI) >35, haemoglobin <10 g/dL, leukocytes >11 000/μL and platelets >350 000/μL.

Results We included 50 (48% men) oncological patients, with a median age of 68 (54–75) years.

When CAT occurred, 42 (84%) patients were receiving antineoplastic treatment, 23 (55%) of them were associated with CAT: paclitaxel (30.7%), 5-fluorouracil (30.7%), cisplatin (15.4%), bevacizumab (7.7%), cetuximab (7.7%), doxorubicin (7.7%), others (15.4%). 6 patients received 2 CAT-associated drugs.

46% of patients had a tumour location associated with a very high (10% stomach, 10% pancreas) or high incidence (14% lung, 6% gynaecological, 4% kidney, 2% testicle) of CAT.

Patients were classified as low (36%), intermediate (50%) and high (14%) thrombotic risk according to the KRS. Of these, 55%, 61% and 20%, respectively, were receiving oncological treatment associated with CAT. 50% of low-risk patients (n=5) were receiving 2 CAT-related drugs.

Conclusion and relevance A high number of patients (55%) received oncological treatment associated with CAT.

According to KRS, a significant number of patients (64%) presented intermediate or high risk.

The majority of patients who were receiving oncological drugs associated with CAT presented low or intermediate risk of thrombosis according to KRS.

Although the analysed group is small, these results could be used to analyse the need to initiate thromboembolic prophylaxis in certain groups, beyond those of high risk.

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Conflict of interest No conflict of interest

5PSQ-014 SAFETY AND TOLERANCE PROFILE OF NIVOLUMAB AND PEMBROLIZUMAB

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Background and importance Anti-PD1 immunotherapies such as nivolumab and pembrolizumab represent a revolution for their efficacy in the care of oncology pathology.

Aim and objectives Shown to be safe and well tolerated in clinical trials, our objective was to define and compare the tolerance of these two treatments in a real-life setting.

Material and methods We performed a retrospective study including all the patients treated with nivolumab or pembrolizumab from January 2015 to February 2021.

For each patient, data on undesirable effects (UE) were collected from the reports of the oncology 1-day hospitalisation, gathered in the patient's computerised record.

A Fisher test was conducted for the statistical analysis.

Results The study cohort included 148 patients on nivolumab and 131 patients on pembrolizumab.

During the study period, 192 UE occurred with pembrolizumab and 331 UE with nivolumab, respectively; 28% and 15% of patients did not exhibit an UE (significant difference; $p=0.007$).

The most frequent UE with pembrolizumab were arthralgia (18%), dyspnea (18%), alteration of the general state (15%), anaemia and neutropenia (15%) and immune or infectious pneumopathy (15%).

The most frequent UE with nivolumab were pain (29%), severe asthenia (27%), alteration of the general state (21%), immune or infectious pneumopathy (18%), anorexia (15%), dermal toxicity (13%) and immune-mediated diarrhoea (10%).

A statistical difference was observed for haematologic toxicity ($p=0.0066$) with more UE for pembrolizumab. Conversely, nivolumab appeared to cause more asthenia ($p=0.001$), coughing spells ($p=0.01$) and anorexia ($p<10^{-4}$) than pembrolizumab.

The grade 4 adverse effects (mostly pulmonary or alteration of the general state) led to cessation of treatment for 33 patients on pembrolizumab and 44 on nivolumab (non-significant difference; $p=0.2$).

Conclusion and relevance Anti-PD1 has proved to be a huge benefit in term of efficacy and tolerance compared to conventional chemotherapies. However, as shown in our real-life study, adverse effects which can be major still occurred. Their harmfulness seems to be underestimated and requires

awareness to be promoted among prescribers to improve patient care.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-015 ANTIBIOTIC DESENSITISATION IN PATIENTS WHO WERE PREVIOUSLY TREATED WITH POTENTIALLY ALLERGY-TRIGGERING MOLECULES

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Background and importance Patients with antibiotic allergy label (AAL) are frequent in hospitals. AAL may lead to the use of more expensive and less effective or safe alternative options.

Desensitisation is a strategy to manage AAL patients by inducing drug tolerance. Several patients receive antibiotics that are similar molecules to the one that will be desensitised later, for example, from the beta-lactam family.

Aim and objectives To analyse the percentage of patients undergoing desensitisation that were previously exposed to potentially allergy-triggering molecules.

Material and methods Retrospective study in a 400-bed university hospital from 2015 to 2021. All patients undergoing antibiotic desensitisation during this period were included.

Demographic, clinical and microbiological data were collected. Quantitative variables are presented by median and interquartile range (IQR) and univariate analysis was by Chi-square test.

Results 17 desensitisations in 14 patients: 10 women, age 74 (58–83) years, *Charlson Comorbidity Index* 6 (3–12), *QuickSOFA* score for sepsis 0.5 (0–2).

Infection focus: 4 endovascular, 4 pulmonary, 2 intra-abdominal, 2 skin and soft tissue. Ten community-acquired infections, 10 bacteraemia.

Microbiology: 6 Enterobacterales, 3 *Staphylococcus* spp, 2 *Pseudomonas aeruginosa*, 2 *Streptococcus* spp. Seven were polymicrobial.

Carbapenem was desensitised in 6 episodes, 5 cephalosporins, 3 penicillins. Desensitisations were completed in 15 cases. Median duration of antibiotic treatment after desensitisation was 9 (0–50) days.

Six patients were previously exposed to a similar molecule to the one that was later desensitised.

Abstract 5PSQ-015 Table 1

Patient	Previous antibiotic	Desensitised antibiotic
2	Imipenem	Ceftolozane/tazobactam
4	Meropenem	Ceftaroline
7	Ceftazidime	Cloxacillin
11	Penicillin G	Ceftriaxone
12	Imipenem	Ceftaroline
13	Cefotaxime	Ampicillin

We compared both groups ('exposed' vs 'not-exposed'). We found significant differences with bacteraemia ($p=0.026$) and the exposed group had bacteraemia more frequently.

We did not find significant differences, but tendencies with infection focus ($p=0.053$), endovascular focus was exposed more frequently to similar previous antibiotic; *Staphylococcus* ($p=0.068$), all patients that had staphylococcal infection were exposed to similar molecule; duration of antibiotic treatment ($p=0.053$), exposed group had the longest duration.

Conclusion and relevance Despite the fact that desensitisation strategy is not frequently used, many of the patients have been previously treated with antibiotics that could have triggered an allergy with clinical consequences.

Beta-lactam desensitisation in patients with bacteraemia is especially interesting due to the severity of this pathology and the high activity of this antibiotic family.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-018 ANALYSIS OF THE USE OF FONDAPARINUX IN SUSPECTED HEPARIN-INDUCED THROMBOCYTOPENIA

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Background and importance Heparin-induced thrombocytopenia (HIT) is a rare but serious complication caused by antibodies to the heparin/platelet factor 4 complex. It produces sudden thrombocytopenia (decrease of more than 50% of the platelet count) during the first days of treatment with thrombosis. Once the diagnosis is suspected/confirmed by antigenic methods, heparin should be discontinued and replaced with alternative anticoagulants. Fondaparinux is frequently used as 'off label'.

Aim and objectives To analyse the relationship between fondaparinux and platelet recovery when it is used in suspected HIT, as well as the correct diagnosis of this pathology coinciding with the COVID-19 pandemic, a disease that also frequently produces thrombocytopenia, in a tertiary hospital.

Material and methods Cross-sectional descriptive observational study. All patients who started treatment with fondaparinux during 4 months were collected, coinciding with a high number of admissions due to COVID-19. The variables collected were: sex, age, platelet count at the start of heparin or derivatives, at the beginning and end of treatment with fondaparinux, days of treatment with heparin and fondaparinux, request for antigenic tests to confirm HIT, and diagnosis of COVID-19.

Results 40 patients (31 men, 77.5%) were included. The mean age was 71.5 (32–98) years. The mean platelet count at baseline was $136 \times 10^3/\mu\text{L}$, when heparin was discontinued and fondaparinux was initiated it was $87 \times 10^3/\mu\text{L}$ and when fondaparinux was discontinued $151 \times 10^3/\mu\text{L}$. The median number of days with heparin was 6 (0–58), with fondaparinux 6.5 (1–41). 57.5% ($n=23$) of the patients were diagnosed with COVID-19. Tests for diagnosis of HIT were requested in only 10% of cases ($n=4$), being confirmed in 1 patient.

Conclusion and relevance In our case series, there was a high number of suspected HIT. Although after treatment with fondaparinux, the platelet count recovers, this is probably due in

most cases to other reasons, such as COVID-19 infection, coinciding with the recovery of the problem that causes it rather than to treatment with fondaparinux. Following the low proportion of requests for antigenic tests to confirm HIT, we consider it vitally important to promote these tests, which would avoid overdiagnosis in most patients and stop the use of such a common and useful drug, heparin, when thrombocytopenia is not in fact due to this cause.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-019 ASSESSMENT OF THE LEVEL OF KNOWLEDGE AND MOTIVATION IN HOSPITAL CENTRE STAFF FOR GETTING VACCINATED AGAINST SARS-COV-2

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Background and importance When there were still some doubts in the population about the efficacy and safety of the approved vaccines for SARS-CoV-2, healthcare professionals were among the first to be vaccinated in our country.

Aim and objectives To analyse the level of knowledge and motivation in hospital staff for getting vaccinated against SARS-CoV-2 with the administered COVID-19 mRNA vaccine. **Material and methods** Descriptive, observational and retrospective study. All hospital staff vaccinated with COVID-19 mRNA vaccine and who had signed the informed consent for data collection were included. Through telephone interview, sociodemographic data (sex, age) were collected and also questions about: (1) motivation for getting vaccinated; (2) previous knowledge about the possible AEFI (Adverse Event Following Immunisation); (3) technical information (TI) about the vaccine prior to first dose, to second dose and after the second one; (4) anxiety/fear/worry about being vaccinated; (5) probability of being vaccinated again, if necessary and (6) if medication was taken to alleviate symptoms. The level of agreement or disagreement with the question made was considered using a Likert scale. Related qualitative variables were analysed using the Chi-square technique. $p < 0.05$ was established as statistically significant.

Results About 108 (88.5%) hospital staff were vaccinated. About 66 (61.1%) workers (81.8% women) with a mean ages of 42.7 ± 10.7 years completed the interview and were included in the study. About 65 (98.5%) belonged to the 18–65 years age group.

About 40 (60.6%) workers took medication for alleviate symptoms. Correlations were significant between (1) level of knowledge about AEFI and level of motivation for getting vaccinated, (2) level of TI and taking medication to alleviate symptoms and (3) level of motivation and probability of being vaccinated again if necessary. It seems that (1) more knowledge about AEFI means to be more motivated to be vaccinated ($p = 0.037$) and (2) more level of TI means to have more desire to get vaccinated again, if necessary ($p = 0.001$) and also less use of drugs to relieve symptoms ($p = 0.027$).

Conclusion and relevance Nearly 90% of our hospital staff were vaccinated against SARS-CoV-2. Knowledge about the AEFI determined the motivation for getting vaccinated. Besides, the level of the staff's motivation determined less

consumption of medication to alleviate symptoms, as well as a greater trend to receive a new vaccine dose, if necessary.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-021 PATIENT'S AND PHYSICIAN'S ACCEPTANCE OF A PHARMACIST-LED INTERVENTION TO REDUCE ANTICHOLINERGIC BURDEN

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Background and importance The anticholinergic burden has been repeatedly associated with adverse events in elderly patients.

Aim and objectives We aimed to determine the acceptance of a pharmacist-led intervention to reduce the anticholinergic burden.

Material and methods Design: interventional prospective study carried out from January to May 2021.

Population: institutionalised patients from a Spanish nursing home.

Variables collected: sex, age, prescribed drugs, prescribed anticholinergic drugs (ADs) according to Drug Burden Index (<https://www.anticholinergicscales.es/>), Charlson Comorbidity index, Barthel index, intervention proposals and intervention acceptance.

Pharmacists led the design of the treatment interventions: every patient was interviewed and their treatment reviewed; the pharmacist then proposed treatment modifications of ADs on deprescription (withdrawal, dose reduction or switch), these modifications were evaluated by physicians and later offered to patients.

The study was carried out according to national ethical standards, and patients' written consents were collected.

Statistical analyses were carried out with Pearson's Chi-square test.

Results Overall, of 157 patients who resided in the nursing home, 99 (63.1%) received anticholinergics and were assessed for intervention. 59.6% men, mean age 72.5 ± 7.9 years, median Charlson Comorbidity index: 2 (0–9), mean Barthel index: 88.0 ± 15.2 . Median prescribed drugs: 10 (1–19), median prescribed ADs: 2 (1–5).

Treatment modifications were proposed for 37 patients who received a total of 85 ADs. Overall, 97 treatment modification proposals were designed.

39 interventions were finally accepted. No statistically significant differences in acceptance were found according to intervention design ($p > 0.05$).

The ADs most frequently proposed for intervention were: tramadol (15), pregabalin (9), lorazepam (8), alprazolam (8) and tamsulosin (7).

Interventions over anxiolytics and sedatives were rejected significantly more often by patients when compared to other drugs ($p < 0.005$).

Conclusion and relevance A significant percentage of physicians and patients rejected the proposed interventions. The success of the intervention was limited by the patient's rejection,

Abstract 5PSQ-021 Table 1

Interventions	Intervention proposals	Accepted by physicians	Accepted by patients
Withdrawal	47 (48.4%)	28 (59.6%)	22 (46.8%)
Dose reduction	41 (42.3%)	22 (53.7%)	12 (29.3%)
Switch	9 (9.3%)	5 (55.6%)	4 (44.4%)
Total	97	56	39

particularly in treatment modifications of anxiolytics and sedatives.

This study suggests that pharmacists may find it difficult to achieve anticholinergic burden reductions by suggesting AD changes to physicians and patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-022 DESENSITISATION PROTOCOL FOR ADALIMUMAB IN ARTHROPATHIC PSORIASIS: A CASE REPORT

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Background and importance Desensitisation protocols allow the induction of tolerance to a drug causing hypersensitivity, achieving adequate administration of the treatment and avoiding the loss of a therapeutic alternative.

Aim and objectives To describe a desensitisation protocol for subcutaneous adalimumab.

Material and methods A 51-year-old woman diagnosed with arthropathic psoriasis (AP) failed multiple different lines of treatment (apremilast, secukinumab, adalimumab, etanercept, tofacitinib) due to allergic reactions. Given the limited therapeutic alternatives, adalimumab was restarted, presenting again a hypersensitivity episode represented as a maculopapular eczematous reaction. The allergologist proposed a desensitisation regimen to adalimumab to induce tolerance to the drug.

Results A desensitisation protocol (DP) was designed to progressively reach the therapeutic dose of 40 mg. The protocol consisted of six doses of increasing concentration administered one every 15 days. Doses were prepared from a 40 mg/0.8 mL vial of adalimumab. Dilutions were made with sterile water to prepare five solutions of increasing concentration: 0.5 mg/mL, 1.25 mg/mL, 5 mg/mL, 10 mg/mL and 20 mg/mL. The first three solutions (0.5 mg/mL, 1.25 mg/mL, 5 mg/mL) were obtained by taking 0.5 mL from the vial and diluting with sterile water to a dilution of 5 mg/mL. From this concentration the required doses were obtained. The fourth and fifth solutions (10 mg/mL, 20 mg/mL) were obtained by taking 0.8 mL from the vial and diluting with sterile water to the final concentration. For the sixth dose (40 mg/0.8 mL) the entire vial was used and no dilution was required.

The DP was administered by the allergologist at the hospital. Premedication consisted of antihistamines and corticoids administered on the same day as the PD. After each administration, the observation time for adverse reactions was at least 1 hour. During the administration cycles the patient had no adverse reactions. After the six doses of DP, the patient

continued with the usual dose of adalimumab 40 mg/0.8 mL for 6 months, administered at home. No adverse reactions were observed. She showed clinical and analytical improvement, with the prospect of continuing the treatment.

Conclusion and relevance DP for adalimumab was successful. The use of DP allowed an adequate and safe administration of adalimumab, avoiding the loss of a therapeutic line in a patient diagnosed with AP with very few treatment options.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-023 NEUTROPENIA AS AN INDICATOR OF TRIFLURIDINE-TIPIRACIL EFFICACY IN METASTATIC COLORECTAL CANCER

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Background and importance Trifluridine-tipiracil (TAS102) is indicated in third- and/or fourth-line metastatic colorectal cancer (mCRC) after progression with standard treatments based on overall survival benefit shown in the RECURSE and J003 studies. Longer survival is shown in patients who develop neutropenia as a toxicity.

Aim and objectives Analysis of correlation between efficacy of TAS102 and neutropenia.

Material and methods 43 patients with mCRC treated with this drug between January 2018 and September 2021 at Juan Ramón Jiménez Hospital (Huelva). Variables described: age, sex, KRAS mutation, performance status (PS), line of treatment and toxicities. Relationship between overall survival (OS) and progression-free survival (PFS) and the grade of neutropenia analysed by means of a Cox regression analysis, obtaining a hazard ratio. Survival medians presented using Kaplan–Meier curves.

Results Median age, 66 years. 58.3% were men. Only 6 patients with PS >2. 97.5% had neutropenia (51.3% grade 1, 41% grade 2 and 7.7% grade 3). All patients progressed, 79.1% have died to date.

The regression analysis was statistically significant ($p=0.05$); the variables grade of neutropenia and G3 neutropenia (neutrophils $<1000-500/\text{mm}^3$ according to CTCAE) were significant for overall survival ($p=0.009$; HR 2.83; CI 1.35 to 5.9, $p=0.028$; HR 5.36; CI 1.199 to 23.985, respectively). There was also a correlation between PFS and neutropenia ($p=0.004$) but not with degrees of neutropenia.

The median OS in patients with neutropenia G2 was 1.8 months (CI 0.67 to 3.61) and 5.3 months for G3 neutropenia (CI 8.6 to 25.27). Median PFS for patients with neutropenia G2 was 2.6 months (CI 1.09 to 4.66) and 4.6 months for G3 neutropenia (CI 2.59 to 6.58).

Conclusion and relevance Neutropenia is a common adverse effect and the main dose-limiting toxicity. Data published in a Japanese series (Yohei Nose *et al*; Katsuya Makihara *et al* and T. Yoshino *et al*) have suggested a correlation between severity of neutropenia and survival. Similar outcomes were obtained in our study, with more favourable data mainly in OS in patients with grade 3 neutropenia. We understand neutropenia to be a possible efficacy predictor for TAS-102. More studies with a larger number of patients are necessary.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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Conflict of interest No conflict of interest

5PSQ-026 **CLINICAL IMPORTANCE OF GENETIC VARIANTS IN CAPECITABINE BIOACTIVATION PATHWAY FOR THE PREDICTION OF RESPONSE IN COLORECTAL CANCER PATIENTS**

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Background and importance Colorectal cancer (CRC) is one of the most prevalent neoplasms worldwide. Capecitabine (Xeloda), an oral prodrug of 5-fluorouracil, is one of the standard treatments for patients with advanced CRC (stages III-IV). In clinical practice, capecitabine response shows high interindividual variability. This variability may be due to the presence of polymorphisms in genes related to the bioactivation of capecitabine to fluorouracil (*CES1*, *CES2*, *CDA*, *TYMP*) that may alter drug bioavailability.

Aim and objectives To assess treatment response and evaluate the influence of genetic polymorphisms in *CES1* (rs171647871, rs71647871), *CES1P1* (rs rs187684, rs11861118), *CES2* (rs11075646), *CDA* (rs532545, rs602950, rs2072671), *TYMP* (rs11479) as predictive biomarkers in CRC patients treated with capecitabine.

Material and methods A prospective cohort study was carried out in CRC patients under adjuvant capecitabine treatment. DNA was extracted from buccal swabs. Genetic polymorphisms were determined by real-time polymerase chain reaction (PCR) with TaqMan probes. Treatment response was assessed using the RECIST criteria v1.1 for complete response (CR), partial response (PR), stable disease (SD) and progressive disease (PD). Patients were grouped into response (CR+PR) and no response (SD+PD).

Results 53 CRC patients were included; 43.4% (23/53) were woman; mean age was 63±11 years; 54.72% (29/53) had family history of cancer; 84.62% (44/52) had adenocarcinoma, major cancer stage was IIIB 57.69% (30/52), the principal primary tumour location was rectum 37.74 (20/53) and main histological grade was G2 54.72% (29/53). Main treatment regimens were XELOX 58.49% (31/53) and capecitabine monotherapy 37.74% (20/53). 88.68% used capecitabine-based regimens as first line of treatment. Response could be evaluated in 50 patients. RECIST response was 76% CR (38/50), 4% SD (2/50) and 20% PD (10/50). Overall, 78% (39/50) patients responded to treatment. An association between tumour grade and response was observed ($p=0.03$), OR 2.71; 95% CI 1.82 to 189.39 for G1 vs G3 and OR 2.17; 95% CI 1.35 to 78.39 for G2 vs G3. No significant association was found between treatment response and the analysed polymorphisms ($p>0.05$).

Conclusion and relevance CRC patients with lower histological grades are associated with capecitabine-positive response. No

significant association was found between response and genetic variants in *CES1*, *CES2*, *CDA* and *TYMP*.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-027 **MISUSE ASSESSMENT AND RISKS OF NSAIDS PRESCRIPTIONS FOR ELDERLY PATIENTS IN SURGICAL UNITS**

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Background and importance Non-steroidal anti-inflammatory drugs (NSAIDs) should be used with caution for elderly patients due to the high risk of gastrointestinal and renal adverse effects (AE). However, this drug class is widely used in the perioperative period for their analgesic properties, to spare using opioids. Due to serious AE imputed by pharmacovigilance in Orthopedic Surgery Departments (OSD), a study of NSAIDs prescriptions was conducted in this care unit. Clinical pharmacy development in OSD highlighted dysfunctions in prescribing NSAIDs for patients aged over 75 years who are at high risk of AE.

Aim and objectives To quantify how commonly postoperative prescription of NSAIDs are used and to assess the risks associated for patients aged over 75 years in OSD.

Material and methods We performed a retrospective, observational study between January and October 2021 on all NSAIDs prescriptions for patients aged over 75 years in OSD. Treatments which may cause renal failure in elderly patients (angiotensin-converting enzyme inhibitors (ACE inhibitors), angiotensin receptor blockers (ARB), diuretics) were noted. Specific attention was given to patients having presented a serious AE including a declaration to pharmacovigilance.

Results In total, 584 patients received NSAIDs in the OSD. 80 patients were aged over 75 years (13.7%), of which 21 patients were taking ACE inhibitors (26%) at the same time, 17 patients an ARB (21%) and 13 patients diuretics (16%). A combination of three nephrotoxic drugs was found for 2 patients and a combination of two for 20 patients. The median creatinine before surgery was 69 µM (40–141 µM) and median renal clearance was 78 mL/min. Serious renal AE were identified in 5 patients (6.25%) leading to prolonged hospitalisation and haemodialysis for one patient. AE were present within 48 hours of taking NSAIDs. No other AE were detected.

Conclusion and relevance The inappropriate prescriptions of NSAIDs observed in elderly patient and their association with other potentially nephrotoxic drugs increases the risk of renal AE. The actions implemented initially were setting analgesic protocols adapted to the patient's age according to the latest recommendations. Secondly, both pharmaceutical and medical prescriptions were being monitored daily. Since surgery involves several prescribers (anaesthesiologists, surgeons, doctors), harmonising prescription practices is currently being considered.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-028 ASSESSMENT OF SUSPICION OF ALLERGY TO CORONAVIRUS DISEASE 2019 VACCINE BY SKIN TESTING: RESULTS FROM A MONOCENTRIC COHORT

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Background and importance National recommendations mention vaccinating against COVID-19 patients at risk of allergy after referring them to an allergologist. Included patients had suspected allergy to one of the vaccine's components (polyethylene glycols (PEG) and polysorbates) or with a history of immediate reaction to a first injection of an mRNA vaccine. Patients at risk were referred to the allergology unit for investigation.

Aim and objectives The purpose of this monocentric retrospective study was to assess positive skin tests (ST), and anaphylaxis reaction during vaccination after allergological work-up.

Material and methods For any tested patient, pharmacy extemporaneously prepared: PEG 400 and 4000 (100 mg/mL), prick 1:1 and intradermal tests (IDT) 1:100 000, 1:10 000, 1:1000, 1:100, 1:10; polysorbate 80 (PS80) (0.4 mg/mL), prick 1:1, IDT 1:1000, 1:100, 1:10; and Comirnaty vaccine (30 µg/0.3 mL), prick 1:1 and IDT 1:10. ST readings were done after 20 minutes.

Patients' characteristics, test results and indications of allergological work-up were collected. Vaccination was authorised if negative ST. Patients were systematically recalled after vaccination to assess side effects including anaphylaxis.

Results Between 1 February and 31 August 2021, 49 patients, age (mean±SD) 54.5±17.8 years and female 81.6%, performed ST: 20 were tested after a reaction to the Comirnaty (19 after the first dose and 1 after the second dose) and 29 for a suspected allergy to an excipient. Among them, 3 had positive ST (one patient to PS80 prick test and vaccine IDT 1:10, and two patients to vaccine IDT 1:10 without positive ST to PS80 and PEG). Vaccination with Comirnaty was contraindicated for these 3 patients. Four patients had delayed positive ST to the vaccine. They were not considered allergic and vaccination was authorised. Of the 46 patients with negative ST, 39 (85%) were vaccinated (one with VaxZveria) without any anaphylaxis reaction (7 did not answer the pharmacist's call).

Conclusion and relevance Positive ST to the vaccine are rare (6%). No patients had simultaneously positive ST to the vaccine and PEG. These results may suggest that the exact predictive positive value remain uncertain and that IDT to the vaccine might be irritating.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-029 EVALUATION OF THE EFFICACY AND SAFETY OF ERENUMAB IN THE PROPHYLAXIS OF CHRONIC AND EPISODIC MIGRAINE

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Background and importance The use of monoclonal antibodies against the CGRP receptor in the treatment of migraine was approved by the Commission of Pharmacy within the programme of drugs capable of evaluating health outcomes (MERS). An evaluation should be carried out in 3 months with a reduction of at least 50% in the number of episodes.

Aim and objectives The purpose was to evaluate the efficacy and safety of erenumab in the treatment of chronic and episodic migraine

Material and methods This was a retrospective observational study. Patients with chronic or episodic migraine and treated with erenumab (between November 2019 and January 2021) were included.

Demographic and clinical data were collected with the following variables: classification of migraine, number of episodes/month before treatment, days of migraine per month during the treatment and adverse events.

For the collection of the number of migraines and rescues a registration calendar was designed that was delivered to the patient at each visit.

Results 30 patients were included, median age 50.5 years, 78.4% women, 66.7% suffered chronic migraine and 33.3% episodic migraine. 100% of the patients had tried at least three previous treatments.

In the patients with chronic migraine the mean of days of migraine previous to the treatment were 24.52±4.18 and in the patients with episodic migraine this was 12.5±1.69. After 3 months of treatment 10 (50%) chronic migraine patients and 7 (70%) episodic migraine patients responded to the treatment (at least a 50% reduction compared to the previous number of basal migraines).

The percentage of reduction of the number of migraines/month in responder patients was greater at 6 months (71% of mean reduction for both chronic and episodic migraines) than 3 months after the start (57% of mean reduction for chronic and 63% for episodic migraines).

In relation to the safety of erenumab, 15 patients showed possible adverse effects, the most common being constipation (9 patients, 30%) and skin reactions (4 patients, 15.3%), detecting two cases of serious adverse reactions which forced treatment to be stopped.

Conclusion and relevance The ratio of response to the treatment in both chronic and episodic migraines were greater than 50% which contrasts with the results in the pivotal trials. This can be explained because of the different inclusion criteria. Moreover according to our results we can observe a tendency towards a greater response as the persistence of the treatment is increased. We can conclude that erenumab is an effective and safe drug in the treatment of migraine.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-030 USE OF CEFIDEROCOL FOR MULTIDRUG-RESISTANT ACINETOBACTER BAUMANNII IN PATIENTS WITH SARS-COV-2: TWO CASE REPORTS

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Background and importance Cefiderocol is a new siderophore cephalosporin for the treatment of multidrug-resistant Gram-negative pathogens such as *Acinetobacter baumannii* (AB).

Aim and objectives To describe our clinical experience with cefiderocol use in two SARS-CoV-2 patients with ventilator-associated pneumonia (VAP) due to multidrug-resistant AB (MRAB).

Material and methods A descriptive retrospective study on cefiderocol therapy in two patients with MRAB was conducted until 31 August 2021. The electronic medical record was used to collect data: comorbidities, baseline clinical context, treatment, and clinical evolution of patients.

Results A 49-year-old man with hypertension, obesity and chronic renal insufficiency was diagnosed with SARS-CoV-2. He required orotracheal intubation (OI) and mechanical ventilation (MV). The patient presented VAP after 4 weeks in the intensive care unit (ICU). Panresistant AB was isolated from bronchoalveolar lavage (BAL) and was treated with cefepime, imipenem, tigecycline and nebulised colistin. Given his poor clinical improvement, cefiderocol 2 g/8 hours (14 days) was initiated. No renal dose adjustment was performed for cefiderocol. Clinical evolution was favourable. The patient remained afebrile and acute phase reactants (APR) decreased. Unfavourable evolution and increased APR were observed on the third day after treatment with cefiderocol, with presence of AB in BAL. The patient died of multiorgan dysfunction syndrome 8 days later.

A 65-year-old man with hypertension, dyslipidaemia and diabetes was diagnosed with SARS-CoV-2. He required OI and MV. After 4 weeks in ICU, the patient presented VAP due to MRAB and coinfection with *Mycoplasma pneumoniae*. Tigecycline, nebulised colistin and ceftazidime/avibactam were used. A clinical worsening was observed and cefiderocol 2 g/8 hours (14 days) and amikacin (5 days) were started. The patient remained afebrile and APR slightly decreased after initiation of cefiderocol and amikacin treatments. BAL culture was negative, although AB colonisation persisted in pharynx. Tigecycline, piperacillin/tazobactam and nebulised colistin were administered. After 71 days in ICU, the patient was transferred to a hospital ward, where he remained for 98 days before discharge.

Conclusion and relevance The use of cefiderocol led to a slight improvement in two patients with VAP caused by MRAB. One patient died due to multiorgan dysfunction syndrome after cefiderocol therapy, and the other case required subsequent antibiotherapy due to persistence of MRAB.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-031 EVALUATION OF THE SAFETY AND TOLERANCE OF THE COMMERCIAL PRESENTATION OF CYCLOSPORINE 0.1% COLLYRIUM

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Background and importance Cyclosporine collyrium is used in the treatment of severe keratitis in adult patients with xerophthalmia who do not improve despite treatment with eye drops. The current commercial presentation has a concentration of 0.1% although there is also a 0.05% formulation.

Aim and objectives The purpose was to evaluate the safety of 0.1% cyclosporine collyrium and assess the rate of patients who do not tolerate this presentation and its causes.

Material and methods This was a retrospective observational study. It was carried out in a model hospital in this area. All patients treated with cyclosporine collyrium between January and September 2021 were included.

Demographic (sex and age) data were collected from the computerised clinical history.

A questionnaire was produced for the clinic interview of the external patients who had adverse reactions after treatment with 0.1% cyclosporine collyrium such that they had to switch to the 0.05% formulation. In this questionnaire the reason for the switch, the type of adverse reaction, severity and time of appearance (immediate/late) were included.

Results 137 patients who picked up 0.1% cyclosporine collyrium from the Pharmacy External Patients Unit were included, 84.67% were women and the mean age was 64 years.

11.67% of the patients suffered some adverse reaction which forced them to switch from the 0.1% cyclosporine presentation to the 0.05% cyclosporine compound made by the Pharmacy Unit.

Within the described adverse reactions, 100% of patients exhibited stinging, 31.25% irritation, 25.00% pain, 12.50% blurry vision, 31.25% reddening, 12.5% swelling, 31.25% photosensitivity and 18.75% dry eyes.

100% of the adverse reactions occurred immediately following application of the collyrium. The adverse reactions were classified as severe (68.75%), moderate (25%) and mild (6.25%) by the patients.

The adverse reactions were reversible and autolimited.

The switch to our compounding was well tolerated in 100% of cases.

Conclusion and relevance The 0.1% cyclosporine presentation is safe and it was well tolerated by most of our patients; only 11.67% experienced an adverse reaction.

Moreover, these patients did not suffer any adverse reaction with our preservative-free 0.05% cyclosporine Pharmacy Unit compound, thus we do not know if the adverse reactions were due to the higher cyclosporine concentration or some of its excipients. Further research is needed.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-032 COMPLIANCE ANALYSIS OF PAEDIATRIC ANTICANCER DRUG DOSING

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Background and importance The optimal dose of anticancer drugs is the one that produces the maximum antitumour effect associated with an acceptable level of toxicity. Low doses will be ineffective against cancer, while high doses will produce intolerable toxicity, especially in children.

Aim and objectives The purpose of this study was to evaluate and analyse the compliance of dosages related to children anticancer drugs underdose or overdose.

Material and methods It was a retrospective study based on the recalculation of doses of 270 prescriptions of cytotoxic drugs in the paediatric hemato-oncology department of Rabat.

Results The anticancer drugs most often used are vincristine (21.5%), cyclophosphamide (14.4%), mercaptopurine (10%), methotrexate (7.8%), etoposide (6.7%), other drugs (39.6%).

Of 270 recalculated doses of anticancer drugs, 67.8% were compliant, 27.4% were underdosed and 4.8% were overdosed.

45.1% of deviation cases were not justified, 33.3% of the doses were rounded off, 9.6% represented the maximum that can be administered, 8.6% were calculated according to weight and not by body surface area, and 3.2% were for children in denutrition.

Concerning the recorded underdoses, the maximum deviation noted was 47.3% with an average of 14.7% compared to the therapeutic dose. For the overdoses, the maximum deviation was 41.6% with an average of 4% compared to the therapeutic dose.

Based on the number of drugs with anomalies, the most underdosed drugs were cyclophosphamide (17.5%) followed by vincristine (16.2%) then etoposide (13.5%). Conversely, the most overdosed drugs were mercaptopurine (23%) followed by methotrexate (15.3%).

Based on the average deviation between prescribed and therapeutic doses, the most underdosed drugs were high-dose methotrexate (35%), mercaptopurine (28%) and adriamycin (26%), whereas the most overdosed drugs were vincristine (42%), mercaptopurine (9%) and high-dose methotrexate (6%).

The interventions made by pharmacists in cases of dose deviations were to recalculate the prescribed doses and inform the prescribing physician either to detect a possible error of overdosing in order to correct it or to look for the reason for underdosing if this is not mentioned on the chemotherapy preparation sheet.

Conclusion and relevance According to the results, almost half of the anomalies are unjustified, hence the importance of pharmaceutical validation of chemotherapy orders and dose compliance verification by the hospital pharmacist to better manage anticancer drugs risks.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-033 POSITIVE IMPACT OF AN IMPLEMENTED WARD PHARMACIST IN A MULTIPROFESSIONAL CANCER CARE TEAM IN GERMANY

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Background and importance There is an increasing demand for better management of patients due to high numbers of newly diagnosed cancer patients and increasing complexity of

chemotherapeutics. Pharmacists are able to ensure patient's safety and quality of life.¹

Aim and objectives The objective of this intervention study was to evaluate the benefit of a pharmacist embedded in a multiprofessional cancer care team on an oncology ward of a maximum care hospital with >1000 beds in Germany.

Material and methods The present study, conducted from 2020 to 2021, was a single-centre, controlled, retrospective and prospective intervention study consisting of three different phases P₀, P₁ and P₂ with a duration of 3 months each. P₀ represented the retrospective control phase as there was no pharmacist on ward. In the prospective phases P₁ and P₂, the ward pharmacist determined, documented, and solved medication errors (MEs) as part of their daily work. ME was defined as any unintentional mistake in prescription of drugs. MEs can result in avoidable adverse drug events. In P₂, newly developed medical standards exist to allow the pharmacist to work in a more structured environment. Throughout all phases, two clinical pharmacists independently identified all MEs which they detected from archived medical files (P₀) or electronic patient records (P₁ and P₂). The classification as clinically relevant ME was set after confirmation by an oncologist to ensure clinical relevance.

Results The three phases with 52, 46 and 50 patients, respectively, were comparable regarding the baseline characteristics. For better comparability the MEs refer to the number of medication lines (ML) which comply with one drug per day. The statistical analysis showed a significant reduction of clinically relevant MEs (P₀: 34 MEs/100 ML vs P₁: 8 MEs/100 ML vs P₂: 2 MEs/100 ML; p<0.001) for all phases.

Conclusion and relevance The implementation of a ward pharmacist had a significant impact on the reduction of MEs and consequently increased the patient's medication safety. Although these results cannot be easily transferred to other disciplines, the present study clearly shows the benefit of a ward pharmacist in oncology together with oncology-related services (eg, preparation of cytostatics) offered by the hospital pharmacy.

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5PSQ-034 HOMOGENEITY OF OPINION EXPERT ON CLEO SCALE WHEN APPLIED TO 50 MODELLED PHARMACEUTICAL INTERVENTIONS

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Background and importance The CLEO Scale is a three-dimensional tool to assess the clinical, economic and organisational impact of pharmacists' interventions (PI) which would resolve drug-related problems in prescriptions.

AVICENNE is an advanced real-time pharmaceutical decision support system based on the patient's data, pharmaceutical algorithms and PharmaClass (Keenturtle) which enhances the PI relevance.

Aim and objectives This study aimed to analyse the reliability of the CLEO scale.

Material and methods From the 171 modelled clinical situations in PharmaClass, the 50 most frequent were chosen. For each situation a PI was retrospectively and randomly selected between November 2019 and November 2020 in the AVICENNE database. It contained 1263 PI transmitted after of PharmaClass alerts' analysis in two 1700 beds health facilities.

A multiprofessional panel of 11 clinicians have rated independently the PIs using the CLEO scale. CLEO evaluates the clinical, economical and organisational impact of PI. The panel re-rated the PIs after a 1-month washout period.

Intra-class correlation coefficients in absolute agreement on single unit ($ICC_{A,1}$) are calculated using the 'Psych' package on Rstudio to measure inter- and intra-rater reliabilities of the panel.

Results The PIs were rated as having a minor, medium, major or vital clinical impact in, respectively, 10%, 70%, 16% and 4% of situations.

Direct drug management costs were reduced by the PI in 24%, unchanged in 62% and increased in 14% of the situations. The care process did not change in 78% of the situations, 20% of PIs improved it and 2% of PIs altered it. On average less than 3 min are needed per evaluation.

Inter-rater reliability ($ICC_{A,1}$) was poor for clinical ($ICC_{A,1} = 0.297$) and organiaational ($ICC_{A,1} = 0.338$) dimensions and moderate for economic dimensions ($ICC_{A,1} = 0.665$). Intra-rater reliability was moderate for clinical ($ICC_{A,1} = 0.611$) and organisational ($ICC_{A,1} = 0.726$) dimensions and excellent for economic dimensions ($ICC_{A,1} = 0.914$).

Conclusion and relevance Almost all of AVICENNE PIs prevent a temporary or permanent damage or the need of care to reduce their gravity. The CLEO tool offers a limited validity when used by untrained clinicians. Symbolic artificial intelligence reinforces the therapeutic safety of patients and the relevance of care.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-035 INTENSIFICATING THERAPY WITH USTEKINUMAB IN NON-FIRST-LINE CROHN'S DISEASE: CLINICAL EXPERIENCE, SAFETY AND EFFECTIVENESS IN THE 'REAL WORLD'

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Background and importance Ustekinumab is a real option for treating Crohn's disease (CD) refractory to anti-tumour necrosis factor (anti-TNF) drugs. After a first intravenous dose, it is administered as a subcutaneous maintainance dose every 8–12 weeks.

Some observational studies display that a dosage interval shortening (DIS) may improve clinical results in patients with partial response or early exhaustion of response between different doses.

Aim and objectives Quantifying proportion of patients treated with ustekinumab who require DIS.

Assessing effectiveness and safety of DIS with ustekinumab in refractory CD.

Material and methods We conducted an observational and retrospective research study in adult patients with CD refractory to anti-TNF drugs. Patients started treatment with ustekinumab, firstly intravenous 6 mg/kg, and then subcutaneous 90 mg every 8 weeks. Included in the study were patients with DIS in June 2019–February 2021, with later follow-up of at least 6 months.

Effectiveness: assessed with clinical remission (CRem), defined as obtaining a Harvey–Bradshaw Index (HBI) <4, and clinical response (CResp), defined as a reduction of >3 points in HBI with respect to baseline. Both endpoints were evaluated at 3 and 6 months.

Tolerance/safety: determined at 3 and 6 months. Every discontinuation or adverse event will be notified.

Results Data of 41 patients (21 men) treated with ustekinumab for at least 1 year were obtained. Population had a median of 1.6 previous biological treatments. 15 patients have maintained the initial regimen with ustekinumab. However, 26 patients (63.4%) needed DIS, for partial response (17/26; 65.4%) or early exhaustion of response (9/26; 34.6%). 16 of these had data after DIS of at least 6 months: 7 patients had a dose every 6 weeks, and 7 had a dose every 4 weeks.

CRem was obtained in 10 patients (62.5%) at 3 and 6 months. CResp was reached in 5 patients (31.2%) at 3 months and in 7 patients (43.7%) at 6 months. 2 patients stopped the treatment for ineffectiveness. There were no adverse events or discontinuations for safety reasons associated with DIS.

Conclusion and relevance A high number of patients have required DIS with ustekinumab. DIS of ustekinumab has shown high safety and ability for rescuing a substantial percentage of patients with partial response or early exhaustion of response. Effectiveness results are similar at 3 and 6 months after intensification, which might be important for making decisions about treatment earlier.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-036 IMPROVEMENT IN POSTOPERATIVE PAIN CONTROL BY THE INTRODUCTION OF ELASTOMERIC LOCAL ANAESTHETIC LEVOPIVACAINE PUMPS IN PATIENTS UNDERGOING ARTHROPLASTY

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Background and importance In order to improve pain control in patients undergoing arthroplasty, in March 2021 the Pain Management Unit introduced a new protocol that included the use of elastomeric levobupivacaine pumps administered in the adductor canal.

Aim and objectives To evaluate the reduction of postoperative pain and the need for rescue analgesia after the introduction of elastomeric levobupivacaine pumps.

Material and methods Study design: retrospective and quasi-experimental in a 254-bed regional hospital.

Sample: all patients who underwent arthroplasty. Two study groups were established: PRE group (August 2020–February 2021) and POST group (March–September 2021).

Variables: demographic data, anaesthetic risk according to American Society of Anesthesiologists (ASA) visual analogue scale (VAS) pain score at rest on the intervention day (day 0), VAS on day 1 at rest and on movement, and VAS on day 2 (discharge day) at rest and on movement, and need for rescue medication.

Data were obtained from the paper nursing register and the patient's electronic medical records. The statistical analysis was carried out with SPSS v19 and χ^2 or Student's test were applied according to the type of variable. A p value <0.05 was considered statistically significant.

Results Ninety-three patients, 36 (38.7%) men; age 72 (7) years. Anaesthetic risk: 1 (1.1%) patient ASA I, 74 (80.4%) ASA II and 17 (18.5%) ASA III. PRE group, 39 (41.9%) and POST group 54 (58.1%). No statistically significant differences were observed among groups.

PRE vs POST group: VAS at rest on day 0, 3.7 (2.9) vs 1.9 (1.8) ($p < 0.001$), VAS at rest on day 1, 3.3 (1.6) vs 2.3 (1.1) and 6.4 (1.4) and 3.8 (1.6) on movement ($p < 0.001$) and VAS at rest on day 2, 2.7 (1.6) vs 2.0 (1.3) and 5.2 (1.3) vs 3.7 (1.5) on movement ($p < 0.025$).

Use of rescue medication: day 0, 9 (23.1%) patients in PRE group and 9 (16.7%) in POST group; day 1, 7 (17.9%) in PRE and 6 (11.1%) in POST and day 2, 2 (5.13%) in PRE and 3 (5.56%) in POST ($p > 0.05$).

Conclusion and relevance Better pain control can be appreciated with the introduction of levobupivacaine pumps; however, no statistically significant differences in the use of rescue analgesic medication between groups have been observed.

It is unknown whether the functional recovery of these patients would be affected, an interesting topic for future studies.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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5PSQ-040 PHARMACEUTICALS IN HOSPITAL WASTEWATER: A REVIEW

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Background and importance Concern about potential deleterious effects of pharmaceuticals in the environment is rapidly growing worldwide, particularly in Europe, which is considered as the front-runner in the field of 'eco-pharmacovigilance'. The recently approved European 'Green Deal' has turned attention on pharmaceuticals as environmental pollutants. The European Commission's 'Strategic Approach to Pharmaceuticals in the Environment' reflects on the importance of effluents from potential hotspots like hospitals and potential additional treatment to this wastewater. In the same vein, the European Association of Hospital Pharmacists (EAHP) published a statement, highlighting the "need for measures to better address pharmaceutical contamination" and "the development of

interdisciplinary education, and training programs for healthcare professionals with urgency". However, we believe that to date, this issue has not been sufficiently considered by healthcare professionals in general and hospital pharmacists in particular.

Aim and objectives We aimed to review published data about the presence of pharmaceuticals in hospital wastewater worldwide, in order to raise awareness among hospital pharmacists about the matter.

Material and methods To this end, we used the Pharmaceutical Database published by the German Environment Agency – Umweltbundesamt, which collects all published information about the presence of pharmaceuticals, including wastewater from hospitals. The database was downloaded on 13 September 2021. 'Sewage hospital (untreated)' & 'Sewage hospital (treated)' matrices were considered. Metabolites were excluded.

Results A total of 67 publications were found reporting positive detection of 221 different parent drugs in hospital wastewater. These studies were carried out in 27 different countries of which 15 were European, with Portugal, Italy, Switzerland and Norway being the ones with the most published data.

An additional treatment to hospital wastewater was reported in 11 different countries, six of which were European.

The three most frequently detected drugs were ciprofloxacin, sulfamethoxazole and ibuprofen.

Conclusion and relevance A considerable amount of research about the presence of pharmaceuticals in hospital wastewater has been performed, mainly in European countries. We hope our research helps in raising concern in hospital pharmacists about this issue.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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5PSQ-041 SAFETY AND EFFICACY OF HIGH DOSES OF IRINOTECAN IN PATIENTS WITH METASTATIC COLORECTAL CANCER TREATED WITH FOLFIRI SCHEME BASED ON UGT1A1 GENOTYPE: A SYSTEMATIC REVIEW

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Background and importance Irinotecan's antineoplastic activity, as well as its safety, depends on the action of its active metabolite, SN-38, which is inactivated by UDP-glucuronosyltransferase (UGT), an enzyme encoded by the *UGT1A1* gene. The presence of the *28 allele decreases the elimination of SN-38. Some studies have shown the possibility of using doses of irinotecan higher than 180 mg/m² in patients with the *UGT1A1**1/*1 and *1/*28 genotypes.

Aim and objectives To analyse published data about the use of a higher dose than 180 mg/m² of irinotecan and its relationship with the efficacy and safety in metastatic colorectal

cancer (mCRC) patients with the *UGT1A1**1/*1 and *1/*28 genotypes treated with the FOLFIRI scheme.

Material and methods A systematic review was carried out in Medline. The quest was done for articles published up to November 2020. MeSH terms used were: irinotecan and *UGT1A1*. Methods used were based on those recommended according to Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA). We searched for randomised clinical trials (RCTs) and observational studies. Four reviewers independently assessed the eligibility of each study. To assess the methodological quality of the RCT and the observational studies included, the Jadad and the Newcastle-Ottawa (NOS) scales were used, respectively.

Results Search strategy reported 595 references, of which 13 were selected for analysis, 7 (53.8%) evaluating both efficacy and safety and 6 (46.2%) only safety. In relation to the studies that evaluated efficacy and safety, 6 (85.7%) were in favour of increasing the dose in terms of objective response rate (ORR) and progression-free survival (PFS), and even in one of them, in overall survival (OS). Studies evaluating safety suggested that doses of irinotecan greater than 180 mg/m² are tolerated by most *UGT1A1**1/*1 and *1/*28 patients. Of all the studies analysed, only one of them showed greater toxicity (grade ≥ 3) in the group with increased doses of irinotecan compared to the control group.

Conclusion and relevance The present systematic review shows the convenience of assessing the irinotecan dose adjustment within the FOLFIRI scheme based on *UGT1A1* polymorphisms, with a potential increase in the probabilities of an adequate clinical response.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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5PSQ-042 TOXICITY OF REMDESIVIR AS TREATMENT OF NON-CRITICALLY ILL COVID-19 PATIENTS

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Background and importance Remdesivir is currently included in clinical guidelines for COVID-19 treatment. Although safety data were published in ACTT-1, the toxicity of this drug in regular clinical practice is still unknown.

Aim and objectives In this study we aimed to describe remdesivir's toxicity in patients only requiring supplemental low-flow oxygen (no high-flow oxygen requirements or other non-invasive ventilation at start of treatment).

Material and methods Retrospective cohort including patients treated with remdesivir following Spanish Medicines and Health Products Agency criteria (non-critical patients requiring low-flow oxygen) between August and October 2020 in a tertiary-level hospital. Exclusion criteria were being under 18 years of age and participation in clinical trials with remdesivir. The percentage of adverse reactions occurring in the 14 days following on from the beginning of treatment was the primary outcome. Secondly, the number of treatment discontinuations were assessed. Categorical variables were expressed as

proportions while continuous values were formulated as median and interquartile range (IQR).

Results 264 patients were included (59.2% men, mean age 66 years; IQR 54–82). In the 14 days following on from the beginning of treatment, an adverse reaction (AR) was reported in 146 (55.3%) patients. In 91 (34.5%) of them it was grade ≥ 2 AR, in 31 (11.7%) grade ≥ 3 and in 8 (3.0%) of them grade ≥ 4 . Median of days until toxicity began was 3.5 days (IQR 1.2–9.0). The most common AR was an increase in transaminases, which happened in 114 (43.2%) patients, 29.1% of them being grade ≥ 3 and 3.9% grade ≥ 4 . Regarding renal toxicity, an increase in serum creatinine occurred in 51 (19.8%) patients, 27.5% of them being grade ≥ 3 and 9.8% grade ≥ 4 . One patient suffered a grade 3 anaphylactic reaction during infusion and another one developed hepatitis during the follow-up period. Two more patients suffered gastrointestinal toxicity (grade 1–2 nausea and diarrhoea). During the study period, 31 (12.1%) patients discontinued remdesivir treatment, 12.5% of them due to AR or toxicity related to the drug.

Conclusion and relevance Increased transaminases was the most common AR in this population, matching remdesivir's European Public Assessment Report (EPAR) specifications, followed by an increase in the serum creatinine levels (frequency not detailed on the EPAR). However, only 12.5% of treatment discontinuations were due to adverse reactions or toxicity linked to remdesivir. Further investigation is needed to unravel the degree of involvement of the drug in this toxicity.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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5PSQ-043 BENZODIAZEPINES AND HYPNOTIC ANTIPSYCHOTICS IN A PSYCHIATRIC HOSPITAL

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Background and importance Benzodiazepines are the most prescribed psychotropic drugs as anxiolytics (with excessive sedation as the main adverse effect), which leads to their possible abuse and dependence, and constitutes a major problem especially among patients who are under regular psychopharmacological treatment.

Aim and objectives To analyse the prevalence of prescription benzodiazepines (BZD) prescribed in a psychiatric hospital, as well as their association with other hypnotic drugs.

Material and methods Descriptive cross-sectional study of the prescriptions of admitted patients. A database was created with the information: history, sex, age, diagnosis, prescribed BZD and concomitant sedative antipsychotics. Statistical analysis was performed with the SPSS program and degree of significance $p \leq 0.05$.

Results 150 patients, 87 (58.0%) men and 63 (42.0%) women, with a mean age of 44.2 ± 12.8 years.

Mean BZD/patient of 1.9 ± 0.8 . Total number of prescriptions with BZD was 138 (92.0%), of which 2 (2.3%) corresponded to BZD of short duration, 78 (56.5%) to BZD of intermediate duration and 102 (73.9%) at least one long-acting BZD.

43.3% (n=65) received monotherapy, and a combination of hypnotic BZD plus anxiolytic 49.3% (n=74) ($\chi^2=24.1$; $p<0.01$).

Prevalence of each BZD: use as hypnotics (flurazepam, lorazepam and ketazolam) 98 (65.3%) and as anxiolytics (clorazepate, diazepam and lorazepam) 115 (76.7%). 63.9% of prescriptions were conditional on whether the patient needed them.

The significantly ($p<0.05$) hypnotic antipsychotic most used in conjunction with BZD was clonazepam 35 (23.3%), followed by levomepromazine 9 (6.0%), quetiapine 5 (3.3%), olanzapine 3 (2.0%) and haloperidol 2 (1.3%).

Conclusion and relevance High percentage of long-acting BZD prescriptions (73.9%). The most frequent side effects when using BZD with their long-half life are when the duration of the treatment is prolonged and if they are combined with other psychoactive substances such as alcohol or toxic substances.

BZDs are significantly more associated with clonazepam than other antipsychotics with a sedative profile such as levomepromazine, quetiapine or olanzapine.

The available scientific evidence indicates that BZDs are effective in the short-term treatment of anxiety and insomnia, and their prolonged use is considered, in general, inappropriate as it is not exempt from risks: mental and physical dependence, tolerance and withdrawal syndrome, traffic accidents, falls, hip fractures and cognitive impairment.

Possible interventions aimed at suspending BDZs include: substitution with other drugs, psychological support, oral recommendations, written review of medication guidelines, educational interventions, and dose reduction.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-044 CONCILIATION AND PHARMACEUTICAL CARE ON DISCHARGE IN THE PSYCHIATRIC PATIENT

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Background and importance During the pharmacotherapeutic process of patients, various drug-related problems (DRPs) may appear, some inherent to the drug itself and others derived from healthcare. 25% of medication errors in hospitalised patients are due to an incorrect reconciliation of medication at admission¹.

Aim and objectives Guarantee that patients receive the necessary chronic and hospital medications, avoiding duplications and interactions between them.

Promote adherence to treatment through oral and written pharmacotherapeutic information (FTI) upon discharge.

Material and methods Comprehensive pharmaceutical care was divided into two actions:

1 Reconciliation of medication at hospital admission: avoid DRPs that occur in the transmission of FTI between the different levels of care through the process called medication reconciliation.

2 Reconciliation and FTI, oral and written, at hospital discharge: the medication prescribed at discharge is compared with that registered during admission and FTI is provided at discharge, oral and written, to the patient and/or caregiver.

Main sources of information: clinical history, reports from medium/long stay centres, electronic prescription and personal interview with patients/relatives.

Results The average stay in the short-stay unit was 14 days. The most prevalent pathologies were: schizophrenia, followed by schizoaffective and personality disorders.

Over 6 months, all the patients admitted to the psychiatric hospital were registered, a total of 246 patients with a mean age of 45.4 (range 17–86) years and an average number of medications/patient of 7.

Primary and specialised care medication was reconciled for all of them, resulting in 170 interventions/discrepancies, and of 96 prescriptions 97.6% (166) were accepted.

During the indicated period, 24 patients (19.6%) met the FTI requirements at discharge.

Conclusion and relevance Coordination and direct and active communication between the different healthcare professionals involved in patient care increases the quality of their healthcare.

The integration of the liaison pharmacist in the hospitalisation units allows safe and efficient use of medicines. Likewise, it brings the work of the pharmacist closer to hospitalised patients, facilitating and expanding pharmaceutical care in the hospital and during care transitions.

Added value of improving adherence to treatment: the patient is provided with knowledge of their treatment through oral and written information at the time of discharge.

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5PSQ-045 ANALYSIS OF ANTIPSYCHOTIC POLYTHERAPY IN A PSYCHIATRIC HOSPITAL

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Background and importance An increasingly widespread practice in psychiatry is the use of antipsychotic combination therapy, not supported in the first line by any evidence-based clinical practice guideline. In this practice, the use of daily doses higher than those recommended in the technical data sheet is usually appreciated.

Aim and objectives To describe the use of antipsychotics (APs) in a psychiatric hospital, as well as to analyse whether the doses used exceed the maximum recommended daily doses.

Material and methods Descriptive cross-sectional study of all the prescriptions of hospitalised patients.

Information collected: sex, age, diagnosis, prescribed APs and its dose percentage (sum of the percentage of total daily dose of one or more APs with respect to the maximum dose of the card technique for the age of the patient and indication treated). The 'if needed' doses of APs were also taken into account. SPSS program ($p\leq0.05$).

Results 150 patients, 101 (67.3%) men and 49 (32.7%) women; mean age of 42.7 (range 64–17) years.

10 patients (6.7%) had been prescribed first generation APs, 119 (79.3%) second generation APs and 31 (20.7%) had a combination of first and second generation APs.

30.7% (n=46) received antipsychotic monotherapy, and 70.7% (n=106) a combination of more than one AP ($\chi^2=12.9$; $p<0.01$).

Number of prescriptions with doses of APs within the technical sheet ($\leq 100\%$) was 62 (41.3%), and outside ($>100\%$) was 89 (59.3%), of which even 29 (19.3%) prescriptions presented doses of APs $\geq 200\%$. Of the APs $>100\%$, 95.3% corresponded to the sum of different APs and only 4.7% to a single APs.

Percentage of patients who have exceeded 100% of the dose is significantly higher among those who have been prescribed >1 APs ($\chi^2=39.4$; $p<0.05$).

Percentage mean APs dose per patient: 127.7% (range 28–379).

Conclusion and relevance More than half (59.3%) of the APs prescriptions exceed the sum of 100% doses; of these, $>90\%$ are due to the sum of the percentage doses of the different APs. Although it may reflect the complexity and resistance of the pathologies treated, it does not agree with the recommendations of the national and international guidelines regarding the management of APs.

Current electronic prescription systems do not alert when the maximum dose is exceeded due to the sum of the combination of APs, which opens a possible way of improvement.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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5PSQ-046 IMPACT OF THE COVID-19 PANDEMIC ON A NOTIFICATION AND LEARNING SYSTEM FOR PATIENT SAFETY IN A PSYCHIATRIC HOSPITAL

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Background and importance The incident notification system is a tool that complements others for promoting a patient safety culture and defining the risk profile of a health organisation.

Aim and objectives This study was carried out to find out how the COVID-19 pandemic has influenced the number of notifications of incidents related to patient safety through the evolution of a notification and learning system for patient safety (SiNASP) since its implementation.

Material and methods The classification of reported incidents was done with the matrix of the 'Severity Assessment Code' (SAC); SAC=1 extreme risk, SAC=2 high risk, SAC=3, medium risk, SAC=4, low risk, No-SAC=does not reach the patient.

Descriptive study of the results obtained from the analysis of the notifications received from its implementation 2011–2020.

SPSS program ($p\leq 0.05$).

Results 295 incidents related to the safety of patients at the psychiatric hospital or one of its resources were reported.

%SAC=2 was 11.9%, %SAC=3 of 24.1%, %SAC=4 of 24.8% and without-SAC 39.3% of the incidents.

94.6% (n=199) of notifications occurred in hospitalisation, with nursing being the professional group that made the most notifications (53.2%).

27.5% were situations with the capacity to cause an incident, 11.9% incidents that did not reach the patient and 60.7% (179) reached the patient; of the latter, 39.3% (116) did not cause damage, 21.0% (62) caused temporary damage and required intervention or prolonged hospitalisation, and 0.3% (1) compromised the patient's life.

Most frequently recorded incident is related to medication (17.8%), followed by infrastructure problems (13.4%) and altered/aggressive behaviour (12.6%).

By year, a statistically significant decrease ($p<0.05$) is observed in the number of notifications in 2020 (13) and the increasing annual average of the previous years (34.3).

Average number of reports disseminated/case presentation sessions was 7.1 until 2019 and only 2 in 2020.

Conclusion and relevance Nursing is the group that reports the most, and the notification of incidents should be promoted to the rest of the healthcare personnel.

During the pandemic, a significant reduction in the reporting of incidents was observed, possibly due to the increased workload and attention to other priority activities of healthcare professionals associated with COVID.

The development of newsletters to disseminate the results of the SiNASP among healthcare providers and the holding of training sessions for new staff have also been negatively affected by the pandemic, having previously proven to be a useful tool for promoting a culture of safety among sanitary professionals.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-048 ANALYSIS OF THE UNIT DOSE SYSTEM OF MEDICATION DISTRIBUTION IN MENTAL HEALTH PHARMACY

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Background and importance The unit dose system of medication distribution (UDDS) is a pharmacy-coordinated method of dispensing and controlling medications in healthcare settings. In our hospital, medications contained in single-unit packages are delivered for each patient by doses (sorted by administration time) for a 24-hour period.

Aim and objectives To detect and analyse errors in the cart-fill process in a UDSS by doses.

Material and methods A prospective observational study was conducted during the month of April 2021. The errors found in the cart-fill process in a UDSS by doses were assessed. Medication was daily prepared by doses for each patient for a 24-hour period, according to physicians' prescriptions. Patients were randomly selected and their medication, prepared and double-checked by the pharmacy staff, was reviewed by a pharmacist.

The following variables were collected: number of patients, prescription lines, units of medicines and detected errors. Errors were classified into four possible categories: incorrect dose (over or under), incorrect unit of medicine (excess, default or absence), medicine not prescribed, and incorrect administration time.

Results Medication of 500 patients was reviewed. A total of 4232 prescription lines and 6000 units of medicines were

assessed. Only 5 errors were detected, which represents an error rate of 0.083%.

The errors detected were the following: 1 of incorrect dose by overdose (0.016%), 1 of incorrect unit of medicine by excess (0.016%), 1 of incorrect unit of medicine by default (0.016%) and 2 of incorrect administration time (0.033%).

Conclusion and relevance The review of the medication carts before their arrival at the Clinical Units allows the detection of potential medication errors in their preparation that may affect the safety of the patient. The percentage of error obtained indicates the degree of quality related to the medication dispensing system. In this case, the error rate is low, although it could be lower in the case of automation of the process instead of manual preparation.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-049 STARTING POINT TO PROMOTE A POTENTIALLY INAPPROPRIATE PRESCRIPTION ASSESSMENT PROJECT

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Background and importance Potentially inappropriate prescriptions (PIPs) in polymedicated elderly patients are related to adverse drug reactions, hospitalisation, increased hospital stay and higher healthcare costs. In our environment a system or a department to detect and analyse these PIPs is not available.

Aim and objectives To evaluate the prevalence and type of PIPs at hospital admission to assess whether the implementation of pharmaceutical intervention strategies in this population is useful and which ones would be the most efficient.

Material and methods Cross-sectional descriptive observational study. Patients over 65 years of age treated with ≥ 6 chronic drugs admitted to a tertiary hospital from 10–16 May 2021 were included. Demographic and clinical variables were recorded: age, sex, admission department, background, history of falls, pharmacological ambulatory treatment, number and type of PIPs detected, and anticholinergic burden (AB). Current ambulatory treatment was obtained by reviewing the medical records. To identify PIPs, the Screening Tool of Older Persons Prescriptions (STOPP) criteria (2014 edition Spanish version) was selected. Due to the lack of e-tools, 121 criteria could not be manually analysed in every patient, so a bibliographic search was carried out to select the 20 STOPP criteria most frequently reported in the literature. The anticholinergic burden was calculated with the Drug Burden Index (DBI) using the Anticholinergic Burden Calculator. Descriptive statistical analysis was performed with the Stata version 12.1 program.

Results 102 patients (53% women) were included. Age: 80.4 \pm 7.8 years. Pathologies/patient: 7.7 \pm 2.7. Drugs/patient: 10.2 \pm 2.9 (39% excessive polypharmacy with ≥ 10 drugs). Had falls: 68%. 1018 drugs were analysed. 208 PIPs (2.04 \pm 1.7 PIPs/patient) were detected. The most frequently observed PIPs were: 15% benzodiazepines ≥ 4 weeks, 14% drugs without

indication based on clinical evidence, 9% medications with a longer duration than indicated, 8% loop diuretics in hypertension/incontinence and 8% medications that cause constipation in patients with chronic constipation. AB: 0.7 \pm 0.6. High-risk AB: 32%.

Conclusion and relevance PIPs are quite prevalent in our environment. Having tools for the systematic detection of PIPs would be very useful. These data suggest that developing a multidisciplinary pilot project, led by a pharmacist, to intervene in patients at highest risk and therefore contribute to improving the quality and safety of drug prescription would be beneficial.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-051 COST-EFFECTIVENESS OF A PRESURGICAL PHARMACEUTICAL CARE CONSULTATION

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Background and importance 4.7% of Spanish hospital patients suffer a preventable adverse event (AE) due to medication errors. In surgical specialties, errors may result in important negative consequences, so hospital pharmacists have implemented new programmes to prevent them.

We created a Presurgical Pharmaceutical Care Consultation in 2016 to avoid errors prior to surgery with managing a patient's chronic medication.

Aim and objectives The aim was to analyse the economic impact of implementing this consultation based on the presurgical medication errors avoided with pharmaceutical interventions.

Material and methods We analysed all the interventions performed by pharmacists in the Presurgical Pharmaceutical Care Consultation between 2016 and 2020 in Traumatology, General, Cardiac and Thoracic Surgery Services of a third-level hospital.

Two clinical pharmacists and two anaesthesiologists composed a multidisciplinary team for intervention analysis and classification. Each prevented error was classified according to its probability of causing an AE, based on literature and clinical judgement. Assigned probability could be 0, 0.01, 0.1, 0.4 or 0.6 (1 was not considered due to a conservative approach). We calculated the cost of each prevented error as: 'AE probability * € 6924', € 6924 being the cost of an AE according to the Spanish literature, adjusted by the 2020 Consumer Price Index. A sensitivity analysis was performed using an AE cost 20% higher or lower. The total cost of hiring pharmacists (one full-time pharmacist in the consultation during 5 years) was € 227 470 (€ 45 494 per year).

Results Between 2016 and 2020, 3101 patients were assisted in our Consultation (51.30% male, mean age 66.4 years), on whom 1179 interventions were performed to prevent medication errors. Classification according to probability of causing an AE was as follows: 0: 6 (0.5%), 0.01: 224 (19.0%), 0.1: 346 (29.3%), 0.4: 497 (42.2%) and 0.6: 106 (9.0%), meaning that 299 AE could be avoided in total. Cost avoidance was estimated at € 2 076 785 (sensitivity analysis € 1 657 490–€

2 486 385). Cost-benefit ratio of the Presurgical Pharmacist Consultation was € 9.1 in savings for each invested euro (sensitivity analysis € 5.4–€ 10.9).

Conclusion and relevance The implementation of our Presurgical Pharmaceutical Care Consultation was cost-effective, preventing more than 200 medication errors per year. It could be extrapolated to other hospitals in order to improve surgical patient safety in a cost-effective way.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-053 INFLUENCE OF AUGMENTED RENAL CLEARANCE IN THE LOWER INCIDENCE OF LINEZOLID-RELATED HAEMATOLOGICAL TOXICITY

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Background and importance Linezolid-related haematological toxicity has been described to be a major cause of treatment withdrawal and transfusion requirements, especially in renal injured patients (<60 mL/min/1.73 m²).

Aim and objectives To evaluate the influence of augmented renal clearance (ARC) in the incidence of haematological toxicity as part of the antimicrobial stewardship programme in which our Pharmacy Department participates.

Material and methods A retrospective, observational study was conducted. Hospitalised patients aged >18 years treated with oral or intravenous linezolid for ≥5 days during the period 2014–2019 in a university hospital were included. Two groups were compared: ARC patients with a filtration rate of ≥130 mL/min/1.73 m² (≥120 mL/min/1.73 m² for women) versus reference patients (60–90 mL/min/1.73 m²) according to the CKD-EPI formula. Exclusion criteria: critically ill, ≤100×10³/mm³ platelets or <10 mg/dL haemoglobin as baseline.

Data were picked by electronic system. Demographic (gender, age) and clinical characteristics (duration of treatment, site of infection, haematological parameters (platelets, haemoglobin and neutrophils) at duration of therapy, concomitant immunosuppressant therapies and chemotherapy <6 months) were registered.

Haematological toxicity was defined as a decrease of 25% in platelets, 25% in haemoglobin and/or 50% in neutrophils from baseline.

Fisher's exact test was performed by XLSTAT program. Level of significance p<0.05.

Results 92 patients were studied: 46 ARC patients (54% male) median age 39 (18–74) years and 46 reference patients (71% male), median age 57 (21–79) years. Median duration of treatment was 7 (5–28) days and 9 (5–25) days, respectively. Site of infection: 58.7% respiratory tract infections (RTIs), 21.7% soft tissues and 13% bacteraemia in the first group and 48.3% soft tissues, 26% RTIs and 21.7% bacteremia in the second group.

In the ARC population, 8.7% were under immunosuppressant treatment and 8.7% had received chemotherapy <6 months vs 17.4% and 8.7% in the reference population.

Haematological toxicity was observed in 6.5% ARC patients vs 28.3% (p=0.006). Thrombocytopenia 4.4% vs 19.6% (p=0.024), anaemia 2.2% vs 13% (p=0.049) and neutropenia

2.2% vs 13% (p=0.049). 8.7% patients in the reference group required transfusion and none of ARC patients.

Conclusion and relevance Our findings suggest an association between ARC and a lower incidence of linezolid-related haematological toxicity.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-055 LONG-TERM EFFECTIVENESS OF ADALIMUMAB IN SECOND-LINE OF BIOLOGICAL THERAPY IN ULCERATIVE COLITIS AND INFLUENCE OF THE FIRST-LINE TREATMENT

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Background and importance Ulcerative colitis (UC) presents high levels of tumour necrosis factor alpha (TNFα) in colonic mucosa. Poor response to retreatment with a second TNF antagonist agent (anti-TNF) has been suggested in patients refractory to first line treatment with an anti-TNF.

Aim and objectives To evaluate long-term effectiveness of adalimumab as second anti-TNF and influence of the first anti-TNF treatment in UC.

Material and methods A descriptive retrospective study was conducted in patients with UC treated with adalimumab as second anti-TNF (January 2013–July 2021). Variables recorded were: age, sex, previous anti-TNF, response to anti-TNF treatment, duration of therapy and Mayo clinic score (MCS). Effectiveness was evaluated by MCS at 6, 36 and 72 months. Clinical remission (R) was defined as MCS ≤2 points. Clinical response (CR) was a decrease of ≥3 points in MCS with respect to baseline. Lack of response (LOR) was defined as none of the above. Patients with LOR and treatment suspension in a certain week were assumed as LOR in subsequent weeks. Influence of effect of first anti-TNF was estimated using association between types of response to first and second anti-TNF. Primary non-response (PNR) to anti-TNF therapy was considered as LOR in induction period (before week 10 for infliximab and before week 4 for adalimumab). Secondary non-response (SNR) to anti-TNF treatment was defined as LOR after induction period.

Results Thirty-one patients were included (54.8% women). Median age was 43 (86–21) years. All patients received infliximab as first anti-TNF. Median adalimumab treatment duration was 18 (1–91) months. MCS at 6 months: 32.26% R, 19.36% CR and 48.38% LOR. MCS at 36 months: 25.80% R, 3.23% CR and 70.97% LOR. MCS at 72 months: 6.45% R, 3.23% CR and 90.32% LOR. Two patients with PNR to adalimumab (2/10, 20%) had PNR to first anti-TNF and 8 with PNR to adalimumab (8/10, 80%) presented SNR to first anti-TNF. All patients with SNR to adalimumab demonstrated SNR to first anti-TNF.

Conclusion and relevance Adalimumab as a second anti-TNF maintained more than a quarter of patients with UC in R at 36 months, but almost all patients lost effectiveness at 72 months. Adalimumab's PNR was less frequent in patients with PNR to a first anti-TNF therapy than in those with SNR.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-056 **LOT QUALITY ASSURANCE SAMPLING (LQAS) OF A TELEPHARMACY PROGRAMME FROM THE HOSPITAL PHARMACY TO THE OUTPATIENT THROUGH THE COMMUNITY PHARMACY**

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Background and importance The clinical tasks of telepharmacy practice must adhere to a standardised procedure and revolve around the patient's clinical record. Single clinical acts must be favoured. A pre-delivery validation procedure must be established before drugs reach the patients' home. It is also essential to ensure no discrimination, confidentiality, security and traceability of the whole process (Spanish Society of Hospital Pharmacy Statement on Telepharmacy).

Indicators monitoring is necessary to assess whether we are at pre-established levels of quality and to detect the existence of problematic situations.

We started a new programme by which 'Hospital-Use Medication' is provided to outpatients through the community pharmacy, using an app to request medication by the patient and telephone communication for follow-up by the hospital pharmacist.

Aim and objectives To monitor the quality of an informed drug delivery telepharmacy programme (CPDDTP) from the hospital pharmacy to the patient, through the community pharmacy.

Material and methods Design: quality monitoring study using the LQAS method and a satisfaction survey.

Scope: dispensations made through CPDDTP are monitored by means of a random sample from January–August 2021.

Criteria evaluated: C1: validation by the pharmacist based on the clinical sheet; C2: correct dose, frequency and administration route; C3: hospital pharmacist–patient communication; C4: adherence; C5: dispensing according to protocol, single clinical act if possible; C6: time to get the medicine from request; S1: assessment of patient satisfaction by telephone survey.

Starting from a 95% compliance standard, assuming a minimum threshold of 80%, an alpha error = 5% and a beta error = 20%, a sample size of 27 cases and the minimum number of protocol compliance of 23 were calculated (85%).

Results A random sampling of 14 092 dispensations was made. 25 of 27 cases of protocol compliance were obtained (92.59%). The survey of the selected patients showed 97.4% global satisfaction. Areas to improve: a mobile app to contact patients, and diffusion of the hospital pharmacy contact e-mail and usefulness.

Conclusion and relevance The results show the absence of a quality problem in the initial procedure studied and the patient satisfaction. The LQAS method gives us a quick way to decide if we are in a quality problem situation using a small sample. In future follow-ups, pharmaceutical care interventions should be evaluated.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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5PSQ-057 **ACTIVE PHARMACOVIGILANCE OF PATIROMER IN A CENTRAL HOSPITAL PHARMACEUTICAL CONSULTATION SETTING**

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Background and importance Hyperkalaemia is an electrolyte disorder, common among patients with chronic kidney disease, diabetes mellitus or heart failure (HF). Its occurrence is associated with an increase in mortality risk. Patiromer was recently approved by the European Medicines Agency (EMA) for the treatment of hyperkalaemia, and is under additional monitoring, allowing quick identification of possible new safety information.

Aim and objectives To assess the adverse events (AE) of patiromer in HF patients with chronic hyperkalaemia.

Material and methods Prospective observational study that included HF patients treated with patiromer to optimise kaleemia and renin angiotensin aldosterone system inhibitor (RAASi) medication, followed in a pharmaceutical consultation between November 2020 and September 2021. A questionnaire evaluating the occurrence of adverse events was applied to all patients on days 1, 3, 7 and 30 after starting therapy and thereafter monthly, or whenever a clinical change was considered relevant. The clinically significant AE were reported to our National Pharmacovigilance System (NPS).

Results During the study period, 19 patients were included, 15 males (78.9%) with a mean age of 69.1±10.2 years. A total of 13 AE occurred in 11 patients. Expected AE such as gastrointestinal disorders (diarrhoea (n=4), flatulence (n=1)), hypomagnesemia (n=3) and cases of unexpected anaemia (n=1), CKD worsening (n=1) and metabolic acidosis (n=3) were reported. Causality has already been confirmed by the NPS in 4 reported AE: 2 metabolic acidosis were considered possible, 1 diarrhoea and 1 flatulence were considered probable. Patiromer was discontinued in 7 patients due to AE, 2 of which resulted in hospitalisation (metabolic acidosis).

Conclusion and relevance As of June 2021, the World Health Organization (WHO) has received 10 reports of metabolic acidosis associated with patiromer, including the 2 reported in this study. Despite this AE being unexpected, these reports raise concerns and can lead to safety signal and new recommendations for patiromer's use. These preliminary results prove that establishing pharmacovigilance networks, particularly for new drugs, prescribed to patients who are often comorbid, is indispensable to assure safe healthcare in the real world.

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5PSQ-058 EFFICACY AND MARGINAL COST OF TREATMENT WITH TOCILIZUMAB IN COVID-19 PATIENTS

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Background and importance Pharmacological treatment of SARS-CoV-2 infection focuses primarily on antiviral and immunomodulatory agents. Tocilizumab is a humanised monoclonal antibody that binds to the IL-6 receptor (IL6-R) that has been used to combat the disease. Effectiveness results in controlled trials are controversial and therefore it is necessary to evaluate the evolution of patients in real clinical practice, as well as the cost of treatment.

Aim and objectives The aim of this study was to evaluate overall survival of patients treated with tocilizumab and the factors that influence survival. In addition, the marginal cost of treatment with tocilizumab is analysed.

Material and methods Retrospective observational study in a cohort of COVID-19 patients (n=508) treated with tocilizumab. The time period of the selected patients was 1 year. Patients were stratified according to hospitalisation unit (intensive care unit (ICU) or non-ICU) at the time of administration of the first dose of tocilizumab. Survival was assessed by Cox regression. The costs assumed were the acquisition costs and were evaluated using the cost-effectiveness ratio. Costs were analysed by bootstrapping in each subgroup. The efficacy measure was calculated as the restricted median survival (RMST). The cost-effectiveness ratio was calculated as the ratio cost (€)/RMST (years). SPSS software was used for analysis.

Results Age and ICU hospitalisation negatively affect the survival of patients treated with tocilizumab. Patients older than 71.5 years have a worse survival rate than younger patients (58.8% vs 88.7%, $p=0.000$). Survival rate of ICU patients vs non-ICU patients was 67.7% vs 79.1% ($p=0.037$). The mean cost of treatment in our cohort was € 534.07/year (€ 697.84/year in patients older than 71.5 years vs € 466.82/year in younger patients).

Conclusion and relevance Treatment with tocilizumab in patients with COVID-19 is more effective in patients admitted to the non-ICU versus ICU. In addition, survival is higher in younger patients aged 71.5 years. The mean cost of treatment with tocilizumab was € 534.07/year. The cost-effectiveness ratio is important from the healthcare payer's point of view because it is indicative of the cost of treatment per unit of efficacy measured in survival years in each subgroup. There is a bias in treatment efficacy due to the different severity of ICU and non-ICU patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-059 CHARACTERISATION OF MEDICATION ERRORS IN A PUBLIC HOSPITAL

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Background and importance Health care is associated with risk management in which we include medication errors. These

remain a major cause of morbidity and mortality. In 2017, the World Health Organization launched the Global Patient Safety Challenge: Medication Without Harm, the goal of which is to globally reduce the level of severe, avoidable harm related to medications by 50% over 5 years.

Aim and objectives Characterisation of medication errors according to the National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) Index.

Material and methods An observational, descriptive and retrospective study was conducted over 2 years.

This study included all prescriptions with at least one pharmaceutical intervention conducted on inpatients admitted from 1 January 2019 to 31 December 2020 and it was based on pharmaceutical records and clinical files. The identified medication errors were categorised according to the NCCMERP Index (Category A: no error; Category B, C, D: error, no harm; Category E, F, G, H: error, harm and Category I: error, death). The medication errors that could not be categorised according to the NCCMERP Index due to omission of information were excluded.

Results From a total of 8076 pharmaceutical interventions, it was possible to categorise 1831 medication errors.

According to the NCCMERP categories the following distribution was found: 57.67% (1056/1831) Category A; 15.78% (289/1831) Category B; 19.93% (365/1831) Category C; 3.77% (69/1831) Category D; 2.51% (46/1831) Category E; 0.16% (3/1831) Category F; 0% Category G; 0.05% (1/1831) Category H; and 0.11% (2/1831) Category I. These results include 57.67% with no error, 39.48% with error and no harm, 2.72% with error and harm and 0.11% with error and death.

The medication errors from Categories E to I involved 16 medications. Acenocoumarol and enoxaparin were the drugs involved in the errors that led to death.

Conclusion and relevance Characterising medication errors is essential to identify system failures and their severity. Evidence suggests that knowledge can improve perception of safety culture and potentially reduce patient harm.

The pharmacist is a core element in the health care system, improving patient safety and care quality, by raising awareness of medication management among other healthcare providers.

The overall challenge is to identify the weaknesses at each stage of the medication process and find strategies to avoid them and/or minimise their frequency and impact.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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Conflict of interest No conflict of interest

5PSQ-060 LONG-TERM EFFECTIVENESS OF OMALIZUMAB FOR CHRONIC IDIOPATHIC URTICARIA IN CLINICAL PRACTICE

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Background and importance Omalizumab is a monoclonal antibody directed against immunoglobulin-E and used in patients with antihistaminic refractory chronic idiopathic urticaria

(CIU). Real-life data on the long-term effectiveness of omalizumab could provide relevant information for healthcare professionals.

Aim and objectives To evaluate the long-term effectiveness of omalizumab in CIU in clinical practice.

Material and methods Descriptive retrospective study was developed. All patients on treatment with omalizumab between October 2020 and June 2021 were included. Digital clinical history and Farmatools application were used to collect the following variables: gender, age, previous therapy, duration of treatment, regimen with omalizumab and baseline Urticaria Activity Score during a 7-day period (UAS7). Effectiveness endpoint was measured using UAS7 at 6, 30 and 60 months. No response to treatment (NR) was defined by UAS7 >15. Mild disease (MD) was defined as UAS7 = 7–15. Adequate disease control (DC) presented UAS7 ≤6. Total response (TR) was considered as UAS7 = 0. Patients with NR and omalizumab therapy suspension in a certain month were considered as NR in the following months.

Results Forty-seven patients were included in the study: 23.4% of patients were male and 76.6% were female. Median age was 45 (11–76) years. All patients had previously received H1 antihistamines and 72.3% were treated with corticosteroids. Median duration of treatment with omalizumab was 18 (11–56) months. Omalizumab regimens were as follows: 19.1% of patients were treated with 150 mg/28 days, 78.7% received 300 mg/28 days and 2.2% were treated with 450 mg/28 days. All patients presented NR at baseline, with UAS7 >15. Effectiveness data for UAS7 at 6 months were: 5.7% of patients presented NR, 14.3% MD, 5.7% DC and 74.3% TR. Effectiveness evaluations of UAS7 at 30 months: 6.7% of patients had NR, 6.7% MD, 40% DC and 46.6% TR. Effectiveness assessments of UAS7 at 60 months were: 28.6% of patients had NR, no patients presented MD, 28.6% DC and 42.8% TR.

Conclusion and relevance Omalizumab showed long-term effectiveness in CIU patients, maintaining almost half of the patients with TR and almost one-third of patients with DC at 60 months.

REFERENCES AND/OR ACKNOWLEDGEMENTS

None

Conflict of interest No conflict of interest

5PSQ-062 REAL CLINICAL PRACTICE RESULTS OF INTERLEUKIN-23 BLOCKERS IN REFRACTORY PSORIASIS

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Background and importance Risankizumab and guselkumab are anti-interleukin-23 monoclonal antibodies used for moderate to severe psoriasis (msPs).

Aim and objectives To evaluate the effectiveness and safety of interleukin-23 blockers in patients with msPs refractory to other biological agents in clinical practice.

Material and methods A descriptive retrospective study conducted from November 2017 to September 2021. All patients with msPs receiving risankizumab or guselkumab and previously treated with other biological agents were included.

Electronic medical history and Farmatools application were used to record the following variables: age, sex, previous biological treatments, anti-interleukin-23 monoclonal antibodies used, therapy duration and baseline Psoriasis Area and Severity Index (PASI). Guselkumab regimen was 100 mg by subcutaneous administration at weeks 0 and 4, followed by a maintenance dose of 100 mg every 8 weeks. Risankizumab scheme was 150 mg by subcutaneous injection at weeks 0 and 4, followed by a maintenance dose of 150 mg every 12 weeks. Effectiveness endpoint was PASI90 (≥90% reduction from baseline PASI) at 16 and 52 weeks. Safety was assessed by adverse events (AE) and treatment withdrawals associated with AE.

Results Thirty-six patients were included: 40% of patients were female and 60% were male. Median age was 48 (28–82) years. The most frequent previous biologic treatments were: 94.3% patients with adalimumab, 88.6% etanercept and 77.1% ustekinumab. Median number of previous biological agents was 4 (1–6) therapies. Guselkumab was used in 65.7% of patients and risankizumab in 34.3%. Median duration of interleukin-23 blocker treatment was 12 (1–31) months. Median of baseline PASI values was 13 (7–21). PASI90 was reached by 44% of patients at week 16 and 70.6% at week 52. According to the safety profile of therapies, 17.1% of patients presented some AE. A total of 14 AE were collected: 5 hypercholesterolaemia, 3 hypertriglyceridaemia, 2 hypertransaminasemia, 2 hyperglycaemia, 1 albuminuria and 1 non-alcoholic fatty liver. No treatment withdrawals associated with AE were observed.

Conclusion and relevance The effectiveness of anti-interleukin-23 antibodies increased over time in our patients with msPs refractory to other biological agents. Almost three-quarters of patients reached PASI90 at week 52. Safety was acceptable, without treatment withdrawals.

REFERENCES AND/OR ACKNOWLEDGEMENTS

None

Conflict of interest No conflict of interest

5PSQ-063 PERSISTENCE OF TYROSINE KINASE INHIBITORS IN ADVANCED RENAL CELL CARCINOMA

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Background and importance Tyrosine kinase inhibitors (TKI) are increasingly used as oral targeted therapies in oncology, where advanced renal cell carcinoma (RCC) is one the main indications.

Aim and objectives To assess the persistence of treatment with TKI in patients with RCC.

Material and methods Retrospective observational study of patients with RCC in treatment with TKI from January 2019 to December 2020. Patients who were in clinical trials were excluded.

Variables collected were age; gender; TKI: sunitinib, pazopanib, axitinib, cabozantinib or tivozanib; line treatment, start and discontinuation date and causes of suspension TKI treatment. Persistence was defined as time (months) from the start of treatment until its discontinuation due to toxicity or inefficiency. Persistence was calculated with Kaplan–Meier survival

curves (log rank test). The data were obtained from the history clinical electronic program (DIRAYA) and from the prescription program (ATHOS). The statistics program used was SPSS 20.0.

Results 46 patients were included, 71.7% men and 28.3% women. Median age was 66.5 (IQR 61–73) years.

TKI treatment chosen was: sunitinib (41.4%), pazopanib (30.4%), axitinib (15.2%), cabozantinib (8.7%) and tivozanib (4.3%). The indication was in first line in 58.7% (27) of cases and 28.3% as second line.

Median persistence was 13 months (95% CI 5.4 to 20.6). At the end of the follow-up period, 39.1% (18) of patients continued with the initial TKI treatment and 60.9% (28) had to discontinue. The causes for suspension were: toxicity (46.4%), progression (35.7%) and progression and toxicity (7.1%). 1 patient ended the treatment due to stability and 2 patients continued their follow-up in another hospital.

Conclusion and relevance A priori there are no differences in persistence between the drugs. The main cause of discontinuation in our cohort was toxicity.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-065 IMMUNOTHERAPY: RECOGNISING AND TREATING ADVERSE EFFECTS

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Background and importance Immunotherapy has changed the landscape of cancer treatment in recent years. Among them, immune checkpoint inhibitors are increasingly used for certain cancers; however, this has resulted in increased reports of immune-related adverse events (irAEs).

Aim and objectives Identify the irAEs, their gravity, management and appearance time, according to treatment and pathology.

Material and methods Retrospective, descriptive study of patients treated with methylprednisolone, mycophenolate mofetil and infliximab in the last 5 years (2017–2021) after presenting irAEs. The variables collected were: sex, age, weight, pathology, immunotherapy, grade, type, management and appearance time of toxicity, continuation or suspension of treatment.

Results The total number of patients who presented irAEs was 52 (52% men) of a total of 612 patients treated with it in the study period. Medium age was 61(39–88) years, weight 67±10 kg. Seventy-five percent of patients suffered from non-small-cell lung cancer, 21% melanoma, 2% bladder and 2% kidney cancer. 69% received pembrolizumab, 11% nivolumab, 8% atezolizumab, 6% ipilimumab, 4% nivolumab/ipilimumab and 2% durvalumab.

Fifty-two percent presented irAEs grade 2; 31% grade 3; 9% grade 4, the rest being unknown. 25% showed nephrotoxicity as an adverse effect; 23% hepatitis, 23% diarrhoea, 9% pneumonitis, 8% colitis, 4% thyroiditis, 4% pancreatitis, 2% pericardial effusion and 2% oesophagitis. 75% of patients received a decreased regimen of oral methylprednisolone for 15 days, 15% unique intravenous dose of infliximab 5 mg/kg and 10% mycophenolate mofetil for 60±15 days.

In about 71% of patients, irAEs were found during the first line treatment, 27% in the second and 2% in the sixth. Median days until appearance was 58 (16–644) days.

Sixty percent continued their immunotherapy and in 40% this was stopped.

Conclusion and relevance Immunotherapy drugs can occasionally cause some adverse effects. In our study the most common one was nephrotoxicity due to pembrolizumab. Despite this, most patients continued treatment once the adverse event was resolved. As reported in some guides, the majority of irAEs were solved using methylprednisolone. More studies are needed based on obtaining more specific conclusions.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-066 PATIENT OUTCOMES AFTER THE IMPLEMENTATION OF A HUMANISED ENHANCED RECOVERY AFTER KNEE JOINT REPLACEMENT SURGERY PROGRAMME

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Background and importance Surgery complications, hospital stay length and patient satisfaction are hospital quality indicators. The implementation of an Enhanced Recovery after Surgery (ERAS) programme is an ideal strategy to improve those indicators and humanise clinical activities in hospitals.

Aim and objectives To evaluate the impact of an ERAS programme and a preoperative consultation on health outcomes and patient-reported outcomes (PROs).

Material and methods In March 2021, an ERAS programme for knee joint replacement was implemented by a multidisciplinary team of orthopaedics, nurses and pharmacists. The group developed new standardised perioperative protocols and a preoperative multidisciplinary consultation ('school of patients'), where chronic medication is reconciled by the pharmacist and it is explained to patients what knee joint replacement surgery is.

An observational and prospective study was conducted in all patients operated for knee joint replacement from March to June 2021. Main health outcomes were hospital stay length, readmissions after 30 days and surgery cancellations due to incorrect drug management. Concerning PROs, patients were asked about their satisfaction about the school and pain management, and their quality of life before and after surgery (EuroQol 5D (EQ-5D)).

Results A total of 61 patients were attended; 60.66% of them were female and mean age was 82 (ICR 71.9–86.9) years. The median number of chronic drugs was 6 (ICR 3–9). The median hospital stay length was 4 days (ICR 3–6), whereas it was 7 days in 2019 (ICR 2–52).

No surgery cancellations or hospital readmissions within 30 days after surgery took place.

Patient satisfaction with pain management was 8.30/10. Mean pain visual analogue scale (VAS) score 24 hours after surgery was 2.63. Patients referred to a mean improvement in their mobility and in their knee pain after the surgery of 0.55 (p=0.02) and 0.73 points (p=0.02), respectively.

Self-reported health rating was 62.42 before the surgery and 77.27 afterwards ($p < 0.05$).

The school earned an overall satisfaction rating of 9.8/10.

Conclusion and relevance The implementation of an ERAS programme has proven highly successful in accomplishing faster recovery, which has led to a reduction in hospital stay length and surgery cancellations. In addition, the programme achieved good PROs (high patient satisfaction and an optimal pain management).

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-067 ARE POLY (ADP-RIBOSE) POLYMERASE INHIBITORS WELL TOLERATED BY OUR PATIENTS? A SAFETY STUDY IN REAL-WORD PRACTICE

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Background and importance Poly (ADP-ribose) polymerase inhibitors (PARPi) are used for maintenance therapy in ovarian cancer after a platinum-sensitive relapse. Treatment individualisation is crucial due to the frequency of adverse events (AEs).

Aim and objectives To assess the safety of PARPi for maintenance treatment in ovarian cancer. To compare the obtained results with reference trials.

Material and methods Retrospective observational study from March 2020 to March 2021. All ovarian cancer patients that received PARPi for maintenance after platinum-based chemotherapy were included. Collected data: age, prescribed PARPi and dose, previous chemotherapy lines, BRCA mutational status, AEs and grade according to Common Terminology Criteria for Adverse Events (CTCAE), time until grade 3 or greater AEs and management. Data were collected from digital clinical history. Reference trials: olaparib: SOLO2/ENGOT-Ov21; niraparib: NOVA/ENGOT-Ov21. Rucaparib comparison was excluded due to a shortage of patients.

Results 40 patients included: olaparib (20), niraparib (18), rucaparib (2). All patients started PARPi therapy with standard dose. Mean age: 55 (range: 37–74) years. Mean chemotherapy regimens received: 3. Patients that did not presented BRCA mutation started treatment with niraparib. 86% patients suffered AEs, of which 62.5% were classified as grade 3. Olaparib: 93% patients presented AEs, grade 3: 50%. Niraparib: 75% presented AEs, grade 3: 66%. Rucaparib: 100% presented grade 3 AEs. Of the total grade 3 AEs reported: 50% were haematological toxicity (olaparib: 14%, niraparib: 83%, rucaparib: 50%), 25% were gastrointestinal toxicity (olaparib 43%, rucaparib 50%) and the remaining 25% were other toxicity (olaparib 43%, niraparib 17%). Mean time until first appearance of grade 3 toxicity: 5.4 months and 4-month median. 65% patients required a dose reduction due to AEs (olaparib: 36%, niraparib: 41%, rucaparib: 100%) of which 6 patients discontinued PARPi due to a second major haematological AE: niraparib (5), rucaparib (1). Both trials SOLO2/ENGOT-Ov21 and NOVA/ENGOT-Ov21 showed an overall less AE incidence.

Conclusion and relevance AEs related to PARPi therapy are common, and more than the half of the patients required a dose reduction. These findings are in line with both trials.

However, in contrast with the revised trials, we report an overall higher AEs incidence, haematological AEs being the main concern specially with niraparib. More studies are needed to improve the PARPi tolerance without compromising efficacy.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-068 INCIDENCE OF POST-ARTESUNATE-INDUCED HAEMOLYSIS AFTER SEVERE MALARIA

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Background and importance Intravenous artesunate is the main therapy for severe malaria. Overall it is a well-tolerated treatment but, in some cases, could lead to a post-artesunate-induced haemolysis (PAIH), which could be a serious late complication that courses with acute anaemia.

Aim and objectives To assess the frequency of PAIH in patients treated with artesunate for severe malaria.

Material and methods Retrospective observational study from September 2015 to September 2021. All patients that were diagnosed with severe malaria and treated with intravenous artesunate were included. Data collected: demographic, mean parasitaemia: before/after artesunate, mean dose of artesunate administered, biochemical parameters represented as mean with standard deviation (\pm SD): lactate dehydrogenase (LDH), haemoglobin (Hb), total bilirubin (TB). Biochemical parameters were collected at the moment of hospitalisation, prior to discharge, 2 weeks and 1 month after discharge. Anaemia severity: mild (10–12 mg/dL), moderate (8–10 mg/dL), severe (< 8 mg/dL). Data were collected from the digital clinical history. A significative Hb drop from the baseline compatible with hemolysis started after discharge, and with no other clinical explanation was considered to be PAIH.

Results 47 patients included, 95% men, mean age: 38 years, range: 21–59 years, parasitaemia before artesunate: 6%, after artesunate: 0.5%. Mean artesunate dose 480 mg. Biochemical parameters at the moment of hospitalisation: LDH: 372 ± 115 U/L, Hb: 13 ± 2 g/dL, TB: 2.82 ± 3.78 mg/dL. Prior to discharge: LDH: 326 ± 113 U/L, Hb: 11.5 ± 1.5 g/dL, TB: 1.03 ± 1.05 mg/dL. Two weeks after discharge: LDH: 302 ± 90.5 U/L Hb: 12 ± 1.3 g/dL, TB: 1.2 ± 1.8 mg/dL. A month after discharge: LDH: 240 ± 80 U/L, Hb: 13 ± 3 g/dL, TB: 0.8 ± 0.6 mg/dL. 24 (51%) patients had anaemia in the moment of discharge. 19 (40%) still had anaemia 2 weeks after discharge and 10 (21%) a month after discharge. 11 (23%) patients experimented a Hb drop compatible with PAIH, of which 8 (17%) were detected 2 weeks after discharge, though none of them were severe. Anaemia was mild in every case.

Conclusion and relevance PAIH is a relatively common event that in most cases is asymptomatic and does not require medical intervention, and this may lead to it being an underdiagnosed event. Most PAIH cases are detected in the first month after hospitalisation. Hb should be monitored after discharge in every patient that receives artesunate in order to prevent a possible severe PAIH event.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-070 USEFULNESS OF PHARMACEUTICAL VALIDATION IN CHEMOTHERAPY PRESCRIPTIONS

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Background and importance One of the most frequent complications of antineoplastic treatment is the drugs' toxicity, which can lead to temporary or definitive treatment interruptions, dose reduction, prescription of support drugs and even visits to the doctor and hospital admissions. Pharmaceutical validation aims to optimise chemotherapy treatment in order to obtain the best results for patients' health.

Aim and objectives To describe the pharmaceutical interventions made in the oncohaematology area during the validation of intravenous cytostatic preparations that led to a change in prescribing.

Material and methods Observational, descriptive and retrospective study in which the pharmaceutical interventions carried out in intravenous chemotherapy prescriptions in oncohaematological day hospital recorded between November 2020 to September 2021, were analysed. The programme used for prescribing and recording was OncoFarm.

Interventions were classified into 9 groups: (1) upper/lower dose <10%; (2) upper/lower dose >10%; (3) inappropriate cycle frequency; (4) relevant interaction or adverse effect; (5) dose adjustment (renal and hepatic impairment, toxicity); (6) incorrect protocol; (7) missing drug; (8) excess drug; (9) others.

Results During the study period, 1554 outpatients (67% oncological and 33% haematological) received chemotherapy treatment. 124 chemotherapy prescriptions of 101 patients were changed due to medication errors detected during pharmaceutical validation. According to the classification: in 23% of prescriptions (29/124) a reduction of the dose was made, this dose difference being greater than 10% in 90% of cases, avoiding mostly a patient overdose; 10% (13/124) changes were due to inadequate chemotherapy cycle frequency; 27% (34/124) changes were temporary suspension of treatment, change of dose and/or administration of supportive medication due to drug toxicity or dose adjustment due to renal or hepatic impairment; in 12% (15/124) changes were due to an inadequate frequency of chemotherapy cycle; in 14% (17/124) there was a lack or surplus of medication and in the remaining 14% (17/124) the prescription changes were for other reasons.

Conclusion and relevance Despite the number of pharmaceutical interventions not representing a large volume in the total number of patients treated, they led to a probable reduction in adverse drug events, toxicities and patients' overdose. This gives us an idea of the benefit of having a pharmacist as part of the multidisciplinary team in oncohaematology and the importance of pharmaceutical validation in chemotherapy treatment optimisation and patient safety.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-074 COVID-19 VACCINES: ADVERSE EVENTS AFTER A SECOND DOSE OF PFIZER OR ASTRAZENECA VACCINES IN HEALTHCARE WORKERS WHO RECEIVED A FIRST DOSE OF ASTRAZENECA VACCINE

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Background and importance The COVID-19 vaccines have shown excellent safety and efficacy profiles. Healthcare workers (HCW), a priority group for vaccination in Portugal, were probably the first to receive mixed vaccines for COVID-19. A previous study reported more adverse events (AE) after using two different COVID-19 vaccines in adults aged 50 years and older. To our knowledge, there are no data for younger individuals.

Aim and objectives To identify and compare self-reported AE after a second dose of Pfizer or AstraZeneca vaccines in HCW who received a first dose of AstraZeneca vaccine.

Material and methods Prospective, cohort study, including hospital HCW who received a first dose of AstraZeneca vaccine, and a second dose of AstraZeneca (group A) or Pfizer (group B) and completed a pharmacovigilance monitoring plan. Specific local reactions and systemic events were assessed until 10 days after each dose of the vaccine by means of a questionnaire. The data were processed using SPSS 26.0.

Results The study included 247 HCW, mean age 41.7±10.8 years, with 75% being female. Of them, 127 were included in group A and 120 in group B. In group A, 76.4% reported at least 1 AE, with a total of 423 AE and a median of 3 (0–15). In group B, 87.5% reported at least 1 AE, with a total of 594 AE and a median of 5 (0–17). The systemic AE with higher incidence were fatigue, malaise and headache in both groups, and chills for group A and somnolence for group B. We found a statistically significant difference in the occurrence of AE ($p<0.05$; OR 0.462 (0.234;0.910)) and in the number of AE in both groups ($p<0.05$).

Conclusion and relevance The reported AE frequency in this study is in agreement with that described by other authors. In this study, HCW receiving a second dose of Pfizer were more likely to have an AE and higher number of AE. There are some limitations, namely, post-vaccination symptom data were self-reported and not verified. Active surveillance should continue to check the vaccines' risk/benefit ratio over time. This safety profile knowledge in younger individuals may contribute to boosting trust in vaccines.

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5PSQ-076 EVALUATION AND MONITORING OF BIOCHEMICAL PARAMETERS IN PATIENTS ON PARENTERAL NUTRITION

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Background and importance Nutritional support by the parenteral route aims to prevent and recover nutritional deficits whenever enteral nutrition is insufficient or contraindicated. Caloric requirements must be calculated according to the degree of metabolic stress, percentage of ideal weight and extent of intestinal failure. During parenteral nutrition (PN) complications such as hydroelectrolyte and metabolic imbalance may occur (eg, refeeding syndrome), which increase morbidity and mortality among patients.

Aim and objectives Monitoring the effectiveness of the protocol established in 2006 that provides for the PN onset within 72 hours with caloric restriction (in the first 24 hours starts with 50% of caloric needs, in 48 hours with 75%, and in 72 hours and following with 100%), as well as evaluating compliance with the recommendations of the American Society for Parenteral and Enteral Nutrition/European Society for Clinical Nutrition and Metabolism (ASPEN/ESPEN) PN guidelines.

Material and methods Retrospective analysis of biochemical parameters (albumin, total protein, C-reactive protein (CRP), serum creatinine (Cr), potassium, phosphate and magnesium) in patients with PN. Data were collected through the patient's clinical records and the calculation of nutritional needs was carried out using the Harris–Benedict formula.

Results Forty patients (14 women and 26 men) were analysed in the period April–August 2021 (age 72 ± 12 years). The majority of patients were in Surgery Ward (78% patients). PN bags administered: 82% 1600 kcal, 13% 2200 kcal and 5% 1400 kcal. Gastric neoplasms and peritonitis were the main diagnoses associated with NP. The average onset of NP administration was 9 ± 7 days. All patients showed high CRP (>5 mg/dL), low total protein (<6.6 g/dL) and 85% of patients showed hypoalbuminaemia at onset of PN. Although, daily analyses of the recommended electrolytes were not performed, it was observed that 20% developed hypokalaemia, 18% hypophosphataemia and 8% hypomagnesaemia. No refeeding syndrome was diagnosed in the studied sample.

Conclusion and relevance The start of 72-hour PN protocol with caloric restriction allowed avoidance of the refeeding syndrome, which usually appears within the first 7 days after the onset of PN. The compliance of ESPEN/ASPEN guidelines for daily monitoring of electrolytes was not observed for all patients. So, it will be proposed to reinforce pharmaceutical interventions, as well as developing together with the clinical team a monitoring protocol for patients under PN.

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Conflict of interest No conflict of interest

5PSQ-077 BEVACIZUMAB VERSUS BIOSIMILAR: USE IN OPHTHALMOLOGY

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Background and importance Bevacizumab is an anti-vascular endothelial growth factor (anti-VEGF) antibody currently used in ophthalmology as an off-label treatment for age-related macular degeneration, diabetic macular oedema, and oedema

secondary to retinal vein occlusion. Despite its off-label use, various studies have shown similar results between bevacizumab and other anti-VEGF treatments. With the availability of a biosimilar with the same presentation and excipients, a switch programme was implemented.

Aim and objectives Compare the effectiveness of bevacizumab Avastin versus biosimilar MVASI in the ophthalmology service.

Material and methods A retrospective observational study analysed 122 patients (65 male, 57 female) who underwent the first intravitreal administration (IVI) between January 2020 and March 2021. Data from best corrected visual acuity (BCVA) and central subfield thickness (CST) were collected. Exclusion criteria were the absence of registration of optical coherence tomography (OCT) and BCVA or failure to comply to three loading dose injectins. The patients were divided into three groups: group 1, 63 patients (3IVI of Avastin), group 2, 30 patients (3 IVI of biosimilar) and group 3, 29 patients (3 IVI, transitioning from Avastin to the biosimilar, either with 1 or 2 Avastin administrations). Manova test was used to determine statistically significant differences among the groups, taking into account the values of BCVA and CST, patients' age, and the number of days between the last registration prior to the first IVI and the first posterior to the third IVI, without any corrections for differences between groups. T-tests were used to obtain graphic representations of the results.

Results The sample analysed had a mean age of 71.56 years. After three IVI, in group 1, there was 82% of improvement for CST; in group 2 there was 92% and for group 3 there was 84%. MANOVA test was performed showing no statistical significance in BCVA and OCT central thickness difference between the three groups (Willk's lambda ($p=0.238$)) neither between MVASI group with the Avastin group (Hotelling's T-squared test ($p=0.114$, equal covariance)).

Conclusion and relevance We found no difference, for the analysed sample, in outcomes and adverse effects between Avastin and biosimilar MVASI, which proves the possibility of replacing Avastin with the biosimilar MVASI already in use in oncological patients, ensuring a significant cost reduction.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-078 THROMBOEMBOLIC PROPHYLAXIS IN PATIENTS TREATED WITH ORAL IMMUNOMODULATORS IN MULTIPLE MYELOMA

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Background and importance Venous thromboembolic disease is a frequent and important complication in haematologic patients and is associated with a worse prognosis. Thromboembolism prophylaxis (TP) is recommended in patients with multiple myeloma (MM) and treated with immunomodulators.

Aim and objectives To assess the adequacy of TP in patients with MM at treatment onset with thalidomide and lenalidomide according to thromboembolic risk.

Material and methods Descriptive retrospective study was conducted (January 2016–January 2021) including patients with MM in treatment with thalidomide or lenalidomide.

Farmatools application and electronic medical history were used to record: sex, age, MM treatment and duration, risk factors at MM treatment onset, thromboprophylactic drug and prophylactic doses.

Khorana scale was used as a predictive model to assess thromboembolic risk. This scale uses the variables: location of involvement, platelet and leukocyte levels, treatment with erythropoiesis stimulants or low haemoglobin and body mass index. Depending on the value obtained, the patient is classified as: low risk (LR, score=0), intermediate (IR, 1–2) and high risk (HR, ≥ 3). The recommended TP for scores ≤ 1 is low-dose acetylsalicylic acid (ASA) or low molecular weight heparin (LMWH) at prophylactic doses, and for scores ≥ 2 it is LMWH as prophylactic.

Results Forty patients (68% female) with a median age of 73 (range 52–87) years were included. The median duration of MM treatment was 8.1 (0.7–40) months. Two patients (5%) presented LR, both with lenalidomide and received appropriated TP with LMWH.

Thirty-three patients (83%) presented IR: 14 (35%) in treatment with lenalidomide, 6 (15%) thalidomide and 13 (33%) with both treatments. TP treatment was low-dose ASA in 2 (5%) patients and LMWH in 29 (73%). Three patients (7%) with IR received LMWH doses higher than prophylactic and two patients (5%) did not receive TP.

Two patients (5%) presented HR, both with lenalidomide and received appropriated TP with LMWH.

No data were found in 3 patients (7%).

Conclusion and relevance TP was in accordance with recommendations in most of the patients with MM treated with oral immunomodulators. A few patients did not receive adequate TP. Almost all the patients presented intermediate thromboembolic risk at MM treatment onset.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-080 ERTAPENEM-INDUCED NEUROTOXICITY: ROLE OF PLASMA CONCENTRATION MONITORING

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Background and importance Carbapenems, such as ertapenem, are beta-lactam-type antibiotics used to treat a wide variety of infections. Neurological disorders have been observed in patients during ertapenem treatment, although the factors that contribute to this toxicity are not well defined and ertapenem plasma levels have not been taken into account.

Aim and objectives The aim of the study was to evaluate the relationship between ertapenem plasma concentrations and ertapenem-induced neurological toxicity.

Material and methods Retrospective cohort study conducted at a tertiary care medical centre, from October 2019 to February 2021.

Adult patients treated with ertapenem for a minimum period of 72 hours having at least one determination of ertapenem concentration were included, favouring those with old age and comorbidities. Critical patients were excluded.

The modified Karch–Lasagna algorithm was used to establish and categorise the relationship between ertapenem use

and the appearance of any clinical signs or symptoms that might indicate neurotoxicity, considering neurotoxicity when a score ≥ 6 was obtained.

To analyse ertapenem blood samples we use a high-resolution liquid chromatography system with an UV/visible detector. Non-parametric tests were performed to search for any difference between groups.

Results 102 patients were included, 53% males, with a median age of 72 years.

Ertapenem plasma concentration was analysed at a mean of 6.4 (± 4.1) days since starting antibiotic administration. 13/102 patients (12.7%) presented neurological disorders during ertapenem treatment, mainly confusional state and drowsiness. We also noted 3 cases of hallucinations as well as 1 patient who presented epileptic seizure and finally died.

Mean ertapenem blood concentration in patients who experienced neurotoxicity was 32.16 $\mu\text{g/mL}$ (95% CI 8 to 56.3) vs 14.63 $\mu\text{g/mL}$ (95% CI 11.4 to 17.8) for those who did not present. A statistically significant difference was observed in the median ertapenem blood concentration between the two groups (18.66 $\mu\text{g/mL}$ neurotoxicity group vs 9.7 $\mu\text{g/mL}$ control group; $p = 0.014$).

Conclusion and relevance We can conclude that the group of patients who presented neurological disorders had higher concentrations of ertapenem. Therapeutic drug monitoring can help identify those patients with high risk for neurotoxicity.

However, more studies are needed to define which patients could obtain the greatest benefit from a close control of ertapenem blood concentration in order to prevent this neurotoxicity.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-081 IMPACT OF PHARMACY INTERVENTION ON REDUCTION OF MEDICATION-RELATED PROBLEMS IN ELDERLY PATIENTS IN A NURSING HOME

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Background and importance Medication-related problems (MRPs) are events or situations involving drug therapy that potentially interfere with the desired outcome for a patient. Elderly patients are especially vulnerable to these problems because of their comorbidity and polypharmacy.

Aim and objectives To estimate the prevalence of MRPs in a nursing home, identify the most frequently involved therapeutic groups and evaluate the degree of pharmaceutical interventions (PI) acceptance by the physician.

Material and methods A cross-sectional observational study was conducted (April 2021) in patients aged over 65 years in a nursing home. Electronic prescription program and clinical history were used to collect the following data: sex, age, drugs prescribed and therapeutic group, frailty index (FI), number and type of MRPs, PIs and degree of acceptance. FI was determined according to a frailty scale based on comprehensive geriatric assessment in nursing homes.[1] Patients' PIs were performed according to their FI, geriatric assessment scales and explicit criteria for inappropriate medication in

geriatrics (Beers and STOPP-START) and were assessed by the physician.

Results Thirty-one patients (58.1% women) with mean age of 79 (62–96) years were evaluated. Seventeen patients (54.8%) were over 80 years old. Mean number of drugs prescribed was 8.1 (SD 3.2) and mean FI was 0.4 (SD 0.2) (moderate frailty). One-hundred and twenty-three MRPs were recorded, with a mean of 4 (SD 1.2) MRPs/patient. Most frequent MRPs were: probability of adverse effects (30%), low therapeutic utility (21%), inadequate duration (18%), inadequate dose (13%), untreated indication (10%), therapeutic duplicity (4%) and pathology–drug interaction (4%). Main therapeutic groups involved in MRPs were: antidepressants (19%), antipsychotics (12%), anti-inflammatories (5%), vitamin D derivatives (5%) and diuretics (5%). One-hundred and fourteen PIs were performed, with a mean of 3.7 PI/patient (SD 1.2). Most frequent PIs were: treatment discontinuation (48%), drug substitution (24%), dose adjustment (18%), treatment initiation (7%) and recommended administration (3%). Ninety PIs (79%) were accepted and 24 (21%) were not accepted.

Conclusion and relevance Our study showed a high prevalence of MRPs. Main therapeutic groups involved were psychotropic drugs (antidepressants and antipsychotics). High acceptance of PIs supports integration of pharmacist into multidisciplinary team of nursing homes, as it improves the safety and quality of patient care.

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Conflict of interest No conflict of interest

5PSQ-082 EFFECTIVENESS IN REAL LIFE OF BIOLOGICAL DRUGS USED IN MIGRAINE PROPHYLAXIS

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Background and importance The effectiveness that the new migraine drugs have demonstrated is as much less as compared to placebo, so it is important to know the effectiveness in real life.

Aim and objectives Determine the efficacy of anti-migraine monoclonal antibody treatments in our Health Area.

Material and methods Retrospective observational study in which all patients undergoing treatment with any biological drug for migraine prophylaxis were included and their demographic data were recorded. It was classified as chronic migraine when the patient suffered more than 15 days of migraine per month (MMD) and episodic when they had more than 8 MMD. DMMS were recorded at the start of treatment and efficacy was reassessed after at least 3 months of continuous treatment.

Results A total of 38 patients, with an average age of 41.3 years, and 80% women, began treatment with anti-migraine biologics in our centre: 14 did so with galacanezumab, 13 with erenumab and 8 with fremanezumab, according to efficiency criteria in every moment. 29% had chronic migraine. The mean baseline MMD was 11.4 and the mean MMD at

re-evaluation was 3.5 days, registering an overall reduction of 7.9 MMD. 7.8% of the patients (2 with 10 baseline MMD and 1 with 8 MMD) were able to reduce the MMD to 0.

Conclusion and relevance In our sample, a global reduction in monthly migraine days of 7.9 compared to baseline was observed and 8% of patients went on to not having any migraine days.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-083 USE OF ISAVUCONAZOLE IN PATIENTS WITH COVID-19 IN AN INTENSIVE CARE UNIT

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Background and importance Isavuconazole is a new antifungal triazole authorised for invasive aspergillosis and mucormycosis. It is a therapeutic alternative to voriconazole and liposomal amphotericin B for invasive aspergillosis, and to liposomal amphotericin B in mucormycosis.

Aim and objectives To analyse prescription characteristics of isavuconazole in patients with COVID-19 in an intensive care unit (ICU) as well as its effectiveness and safety.

Material and methods A cross-sectional, observational study was conducted (June 2020–April 2021). Patients with COVID-19 in an ICU on treatment with isavuconazole were included. Electronic prescription program and clinical history were used to collect the following data: sex, age, comorbidities, coinfection with other pathogens in addition to SARS-CoV-2, type of therapy (empirical/targeted), duration and previous azole treatment (yes/no). Effectiveness was evaluated by symptoms resolution, reasons for treatment suspension and status (alive/death) 30 days after completion of treatment. Safety was assessed according to adverse events (AE).

Results Thirty-three patients (54.5% men) with mean age of 61 (35–77) years were evaluated. Twenty-nine patients (87.9%) had comorbidities, the most frequent were: hypertension (19.1%), dyslipidaemia (12.8%), obesity (11.7%) and diabetes (8.5%). Thirty-two (96.9%) had coinfections, with a mean of 1.8 (SD 1.2) infections/patient. The most implicated pathogens were: *Acinetobacter baumannii* (18.8%), *Candida albicans* (11.6%) and *Aspergillus fumigatus* (8.7%). Twenty-three patients (69.7%) received isavuconazole as empirical therapy and 10 (30.3%) as targeted. Mean duration of treatment was 12.3 (SD 7.5) days. Twenty-five (75.6%) patients had not previously received azole treatment, 7 (21.3%) had received voriconazole and 1 (3%) fluconazole. Symptoms resolution was observed in 12 (36.4%) cases. Seven patients (21.2%) discontinued treatment due to negative culture, 12 (36.4%) due to symptoms resolution and 14 (42.4%) due to death. At 30 days completion of treatment, 15 patients (45.5%) remained alive and 18 (54.5%) had died. AE were recorded in 6 cases (18.2%): liver disorders (n=4) and electrolytic alterations (n=2).

Conclusion and relevance Most patients presented comorbidities and coinfections in addition to COVID-19. Effectiveness of isavuconazole was adequate in approximately one-third of patients, despite the high severity and clinical complexity.

Approximately half the patients remained alive at 30 days following completion of treatment. Isavuconazol was well tolerated in most cases.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-084 HOME DELIVERY AND TELEPHARMACY PROGRAMME: SATISFACTION OF PATIENTS

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Background and importance The SARS-CoV-2 pandemic has generated new needs in outpatient care of the hospital pharmacy. Despite the current improvement in the pandemic situation, many of the implemented progress have been maintained. Telepharmacy and home delivery programmes avoid hospital visits for vulnerable patients (elderly, pluripathology, mobility problems).

Aim and objectives To analyse the degree of satisfaction of patients included in a telepharmacy and home delivery programme.

Material and methods Descriptive retrospective study of patients included in a telepharmacy and home delivery programme between November 2020 and September 2021 was conducted. Electronic clinical history and prescription software Farmatools were used to record data: sex, age, pathology, locality, transport conditions of the medication and number of shipments per patient. A telephone survey was conducted, consisting of four questions about: satisfaction with telepharmacy programme (yes/no), adequate pharmaceutical telephone support (yes/no), medication delivery conditions (correct/incorrect) and global assessment (ranged 1–10). Comments and suggestions were also requested.

Results Fifty-six patients were included, 35 (63%) were women and 21 (37%) men. Mean age was 65 (37–90) years. The pathologies involved were: 11 (20%) infectious diseases, 10 (18%) respiratory, 9 (16%) rheumatic, 8 (14%) neurological, 7 (12%) renal, 5 (9%) haematological, 3 (5%) ophthalmological, 2 (4%) digestive and 1 (2%) allergic. A total of 456 medication shipments were delivered during the study period, with a mean of 8 (2–24) per patient. The shipments were distributed among 31 different localities in the same health area. The medication for 27 (48%) patients required refrigerated transport, and 29 (52%) required ambient temperature. All (100%) patients were satisfied with telepharmacy programme and reported an adequate pharmaceutical telephone support. Medication delivery conditions were considered correct to 54 (96%) patients and incorrect to 2 (4%). Mean global assessment score was 9.6 (8–10). Four (7%) patients suggested an improvement in delivery conditions.

Conclusion and relevance The survey results indicated a high degree of satisfaction of the patients included in the telepharmacy and home delivery programme. Although this system of pharmaceutical care and distribution of medicines was implemented because of the pandemic, its subsequent maintenance has allowed vulnerable patients to benefit. Further measures could be implemented to improve delivery conditions.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-085 REAL-WORLD SAFETY AND TOLERABILITY OF PALBOCICLIB AS FIRST-LINE THERAPY IN PATIENTS WITH LOCALLY ADVANCED OR METASTATIC BREAST CANCER

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Background and importance Palbociclib is a selective cyclin-dependent kinase inhibitor approved for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer (LA/MBC) in combination with an aromatase inhibitor as first-line treatment, or with fulvestrant in previously treated patients. Real-world data regarding its safety and tolerability when prescribed as first-line treatment are still scarce.

Aim and objectives To determine the long-term safety profile of palbociclib when prescribed as first-line treatment for HR-positive, HER2-negative LA/MBC.

Material and methods An observational, retrospective, descriptive study was performed at a tertiary hospital. All patients who started palbociclib as first-line treatment for HR-positive, HER2-negative LA/MBC between January 2018 and August 2019 were included. Adverse events (AE) were graded according to CTCAE v5.0 criteria. Frequency and causes of dose delays, reductions or permanent treatment discontinuations were collected. Clinical and analytical data were obtained from electronic clinical records, and treatment data from the dispensing electronic program. External reference data were used from the PALOMA-2 trial to compare the real-world data.

Results A total of 49 women were studied, median follow-up 33 (1–44) months. All patients had an AE of any grade and 39 (79.6%) presented grade 3 or 4 AE. Grade 3 or 4 AE included neutropenia (69.4%), leukopenia (34.7%) and thrombocytopenia (6.1%). Toxicity led to a dose delay in 39 (79.6%) patients; neutropenia (82.1%), thrombocytopenia (7.7%) and fatigue (7.7%) were the AE most frequently involved. A first dose reduction was necessary in 31 (63.3%) of the patients, while 13 (26.5%) required further reductions. Neutropenia (70.4%) was the main cause of dose reduction. Permanent treatment interruption was mandatory in 6 (12.8%) patients, because of neutropenia (50.0%), pneumonitis (16.6%), asthenia (16.6%) and blurred vision and dizziness (16.6%). Two (4.3%) deaths occurred due to pneumonitis and progressive multifocal leukoencephalopathy. More cycle delays, dose reductions and dose interruptions were reported in comparison with the PALOMA-2 trial (79.6% vs 67.0%, 63.3% vs 36.0% and 12.8% vs 9.7%, respectively).

Conclusion and relevance The real clinical practice toxicity profile of palbociclib as first-line treatment for HR-positive, HER2-negative LA/MBC is similar to that previously reported in PALOMA-2, although more treatment modifications were necessary.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-086 EVALUATION OF THE EFFECTIVENESS OF BEZLOTOXUMAB ON PREVENTION OF RECURRENT CLOSTRIDIUM DIFFICILE INFECTION

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Background and importance *Clostridium difficile* is the most common cause of infectious diarrhoea in hospitalised patients. Immunocompromised patients usually present recurrences after antibiotic therapy. Bezlotoxumab is a human monoclonal antibody that binds *C. difficile* toxin B, approved for prevention of recurrent *C. difficile* infection (CDI) in high-risk patients (older than 65 years, history of recurrences in the last 6 months, infection with a hypervirulent strain).

Aim and objectives The aim of this study was to assess the effectiveness of bezlotoxumab in patients from a third-level hospital with CDI.

Material and methods Observational retrospective study from October 2018 to April 2021 was developed. Patients with CDI that were treated with bezlotoxumab were selected. Farmatools application, Farmis-Oncofarm and digital clinical history were used to record variables: age, gender, previous episodes of recurrence in the last 6 months and treatments, immune status, *C. difficile* strain, initial and sustained cure rate.

Results In the study period, 37 patients with median age 70 (16–85) years were included, 22 of them were older than 65 (59.5%) years: 16 women (43%) and 21 men (57%). Twelve (32.4%) patients had at least one previous episode of CDI and 26 (70.3%) were immunocompromised and 1 patient was diagnosed with having a hypervirulent *C. difficile* strain. Twenty-nine (78%) patients received previous treatment with oral vancomycin and/or metronidazole. The rates of initial and sustained clinical cure were 54% (n=20) and 81% (n=30), respectively. Five patients died before the sustained cure rate could be measured.

Conclusion and relevance The effectiveness obtained measured with the initial clinical cure was lower than the results described by the pivotal trial (54% vs 80%) and the sustained clinical cure was higher (81% vs 64%). These results showed that bezlotoxumab appears to be an effective alternative to patients at high risk of recurrent CDI, although further studies including more patients would give more information about the use of this new drug.

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<https://www.nejm.org/doi/full/10.1056/NEJMoa1602615>

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5PSQ-087 LONG-TERM DUAL ANTIPLATELET THERAPY: CONTROVERSY CONTINUES

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Background and importance Long-term dual antiplatelet therapy (DAPT) is one of the most researched therapies that involves the combination of acetylsalicylic acid (ASA) and platelet adenosine diphosphate receptor inhibitor (P2Y₁₂).

The main indication for DAPT is prevention of coronary events after an acute coronary syndrome (ACS) or after a percutaneous coronary intervention (PCI) but in practice, there is confusion. Recommendations indicate that DAPT can be maintained over a year depending on the ischaemic and haemorrhagic risk of each patient.

Aim and objectives The aim of this study was to investigate DAPT indications and risk factors related to extending this therapy for over a year despite the fact that suspension of one antiplatelet drug was indicated (medication discrepancies).

Material and methods Of a total number of 221 patients with DAPT from January 2009–2020, this observational and retrospective study was based on a simple random sampling including 33% of the total of patients. Data were obtained by review of electronic medical records.

Variables collected demographic, clinical services, DAPT indication, drugs used, durability, risk factors of extending DAPT and medication discrepancies.

Results Final analyses included 70 patients. Median age 69 (IQR 63–78) years, 88.6% men. The median of years with DAPT was 6.5 (IQR 3–11). The prescribing clinical services were cardiology (84.3%), vascular surgery (5.7%) and others (10%).

Patients treated with ASA+clopidogrel were 87.1%, 10% with ASA+ticagrelor and 2.9% others. Of the 70 patients studied, 91.4% had indications for use of DAPT therapy and 8.6% did not. According to therapeutic indication, 61.4% had ACS and PCI and 30% had stable coronary artery disease and PCI. Among patients without indication, 4.3% were treated for conservative management of ACS and 4.3% for stroke prevention.

Risk factors that may justify long-term therapy were: 40% previous acute myocardial infarction, 34.3% multivessel coronary artery disease, 10% recurrent ischemic events and others. 8.6% of patients had medication discrepancies.

Conclusion and relevance Many patients had indication for DAPT at the beginning of treatment and had risk factors that would justify long-term DAPT but duration was not evaluated.

It is necessary for a multidisciplinary team to manage this therapy, considering the risk–benefit to each patient.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-088 ANTI SARS-COV-2 MONOCLONAL ANTIBODIES: FROM CLINICAL TRIAL TO REAL-WORLD EVIDENCE

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Background and importance Monoclonal antibodies (mAbs) against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) were recently shown to be promising in preventing hospitalisation and death among patients with mild to moderate COVID-19 symptoms in randomised controlled trials. These medicines are subject to additional monitoring and, in our country, this occurs through the Italian Medicine Agency (AIFA). They have been authorised in subjects >12 years, positive for SARS-CoV-2, not hospitalised for COVID-19, not on oxygen therapy, with mild to moderate symptoms of recent onset at high risk of progression into severe disease. In the absence of solid safety and efficacy data, regulatory bodies recommend infusion in a hospital/protected setting. To our knowledge, limited data are available on real-life use of mAbs.

Aim and objectives The aim of the work was to evaluate the risk of a hospitalisation or death in patients using these medications and the occurrence of side effects.

Material and methods Clinical data of SARS-Cov-2 patients that initiated mAb infusions supplied by our SC Pharmacy, Eastern Piedmont Storage Hub Centres (serving over 1 million inhabitants), were retrospectively collected during the March–August 2021 period. The primary endpoint was a composite of COVID-19-related hospitalisation or death at day 28.

Results The population included 85 patients; median age 68 years (80% male); 18 positive due to nosocomial infection; main comorbidities were cardiovascular and onco-haematological diseases (33%–16%). The proportion of patients with COVID-19-related hospitalisation at 28 days was 16% (14 events). There were a total of 9 deaths. The mean time between mAb therapy and *reverse transcription-polymerase chain reaction* (RT-PCR) negative nasopharyngeal swab test was 19 days. AEs were observed in only 3 patients (hypotension, dyspnoea, chills, fever).

Conclusion and relevance Our results were consistent with recent results showing a reduced risk of hospitalisation or death in outpatients with mild-to-moderate COVID-19. Multi-disciplinary dialogue between the pharmacist, virologist and general practitioner showed the need to define homogenous methodologies for collection of clinical data in the real-world context (ie, nasopharyngeal swab test execution data). Further real-world studies are needed to validate these findings.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-090 USE OF MONOCLONAL ANTIBODIES AGAINST THE CALCITONIN GENE-RELATED PEPTIDE PATHWAY IN CHRONIC MIGRAINE IN CLINICAL PRACTICE

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Background and importance Migraine is a neurological disorder with a high prevalence. Monoclonal antibodies against the calcitonin gene-related peptide pathway (CGRP-mAbs) are indicated for the prevention of chronic migraine (CM).

Aim and objectives The aim of this study was to assess effectiveness and safety of CGRP-mAbs in CM in clinical practice.

Material and methods Descriptive retrospective study was conducted in patients with CM receiving CGRP-mAbs between May 2018 and September 2021. Electronic clinical history and prescription software Farmatools were used to record data: gender, age, previous preventive treatment, CGRP-mAb prescribed, dosage, duration of therapy and monthly migraine days. Effectiveness was measured by the reduction in pain intensity (any subjective clinical improvement) and the reduction $\geq 50\%$ of monthly migraine days from baseline. Failure to meet both criteria was considered as non-response. Effectiveness endpoints were measured at 3 and 9 months. Safety was evaluated according to adverse events (AE) and discontinuations of treatment.

Results Thirty-nine patients were included, 33 (85%) were women and 6 (15%) men. Mean age was 48 (23–74) years. Mean of prior preventive drugs was 6 (3–14), including: botulinum toxin A (n=39), topiramate (n=30), flunarizine (n=28), amitriptyline (n=27), zonisamide (n=26) and propranolol (n=24). Nineteen (49%) patients received galcanezumab 120 mg monthly (with 240 mg induction dose), 13 (33%) erenumab 70 mg monthly and 7 (18%) fremanezumab 225 mg monthly. Mean duration of therapy was 11 (4–22) months. Baseline monthly migraine days were ≥ 8 in all patients. At 3 months: 66% of patients presented both reduction in pain intensity and reduction $\geq 50\%$ of monthly migraine days, 5% presented only reduction in pain intensity and 29% no response. At 9 months: 48% patients presented both reduction in pain intensity and reduction $\geq 50\%$ of monthly migraine days, 10% presented only reduction in pain intensity and 42% no response. According to the safety profile, 8% patients presented injection site reactions as AE. No discontinuations of treatment were reported.

Conclusion and relevance CGRP-mAbs presented an adequate effectiveness in more than half of the patients at 3 months, although this effectiveness was slightly reduced at 9 months. CGRP-mAbs were well tolerated, with few AEs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-091 DALBAVANCIN ADMINISTRATION IN OUTPATIENTS TO REDUCE HOSPITAL STAY IN SELECTED PATIENTS

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Background and importance Dalbavancin is a semisynthetic glycopeptide active against Gram-positive bacteria, approved in acute bacterial skin and skin structure infections (ABSSSI). Its use has been extended, in selected patients, to other complicated infections to avoid prolonging the hospital stay, such as: endocarditis, bacteraemia with difficulty controlling focus, and osteoarticular infections. The usual treatment regimen is a loading dose of 1500 mg followed by 1000 mg after 15 days. **Aim and objectives** The objective of the study was to evaluate the days of hospital stay avoided with the use of dalbavancin in these patients.

Material and methods Observational, transversal, unicentre study in patients hospitalised between August 2020 and October 2021 in a third-level hospital who had received at least one dose of dalbavancin after discharge. The days of stay avoided were calculated according to the doses of dalbavancin administered. Information sources: electronic prescription programme ATHOS-Prisma and computerised medical record Diraya.

Results Thirty patients were included, the mean age was 63 ±17 years, 17 (56.7%) were men and 13 (43.3%) women. 43.3% suffered from endocarditis, 26.7% osteoarticular infections; 13.3% bacteraemia with difficulty controlling focus; 10.0%, ABSSSI; and 6.7%, other types of infections. The most frequently isolated microorganisms were: *Staphylococcus spp* 54.8% of the cases and *Enterococcus spp* 22.6%. The median hospital stays according to pathology were: endocarditis, 20±13 days; ABSSSI, 7±3 days and bacteraemia with difficulty controlling focus, 21±5 days. In osteoarticular infections, differences were found between spondylodiscitis, whose median of hospital stay was 31±6 days, and septic prosthetic infections, 12±3 days. In ABSSSI, the media was reduced by half, and in osteoarticular infections an average of 30 days per patient was avoided. In patients with endocarditis, in 61.5% (8/13) of the cases, 30 days of hospital stay were avoided; in 23.1% (3/13), 15 days; and, in the rest of patients, 15.4% (2/13), the hospital days avoided were not estimated because the treatment with dalbavancin was prolonged due to patient comorbidities.

Conclusion and relevance The use of dalbavancin in selected patients, in infections that require a prolonged hospital stay due to the patient receiving intravenous treatment, has been shown to be useful in shortening the length of hospital stay.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-092 TREATMENT OF METASTATIC HER2+ BREAST CANCER: USE OF TRASTUZUMAB BIOSIMILARS IN COMBINATION WITH PERTUZUMAB

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Background and importance Pertuzumab is indicated for use in combination with trastuzumab and docetaxel in adult patients with HER2-positive metastatic or locally recurrent unresectable breast cancer, who have not received previous anti-HER2 therapy or chemotherapy for their metastatic disease. The first biosimilars of trastuzumab were marketed in 2018. Biosimilar medicines are safe and effective, provide a lower cost treatment option for the national health service, and therefore allow increased access to high-cost therapies.

Aim and objectives Cost-effectiveness comparison of pertuzumab+trastuzumab originator versus pertuzumab+trastuzumab biosimilar. Evaluation of the efficacy and safety of treatment with biosimilar trastuzumab and economic impact.

Material and methods Retrospective observational study. Data of the number of patients, treatment cycles and association prescribed were extrapolated from the consultation of prescriptions entered on the drug regulatory agency's monitoring register platform. Monitoring registers platform is an IT system that allows access to treatment in a homogeneous manner throughout the country.

These are instruments that allow the control of the prescriptive appropriateness and are an administrative control modality.

Results In our hospital since 2014, 30 patients have been treated. There are 11 active treatments; 3 patients have started treatment directly with biosimilar trastuzumab. Of the 19 closed treatments more than 84% ended before the switch to biosimilar trastuzumab took place. For the 11 currently active treatments, the average number of cycles per patient is 80. The number of treatments performed to date with trastuzumab biosimilar-pertuzumab combination has been 464. Each cycle of biosimilar trastuzumab has an average cost of €315. Each cycle of originator trastuzumab had an average cost of €1011. The switch to biosimilar trastuzumab has resulted in a saving of about €323 000.

Conclusion and relevance In clinical practice, treatment in combination with biosimilar trastuzumab has demonstrated efficacy and safety, with no increase in end-of-treatment for progression/toxicity/causes dependent on the biosimilar drug. The reduction in economic impact was significant.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-093 PERSISTENCE OF TREATMENT WITH INTERLEUKIN -17 INHIBITORS IN SKIN DISORDERS

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Background and importance Ixekizumab and secukinumab are two monoclonal antibodies indicated in psoriasis (Ps), psoriatic arthritis (PsA) and ankylosing spondylitis in patients with inadequate response to conventional treatments by selective neutralisation of interleukin-17 (IL-17).

Aim and objectives Evaluating the persistence of IL-17 inhibitors in patients diagnosed with psoriasis and psoriatic arthritis in a reference hospital of the area.

Material and methods We made a retrospective study (May 2017 to August 2021) in which we included all patients who

initiated treatment with IL-17 inhibitors. Data of sex, age, diagnostic, previous biological treatment, start date and last dispensation date were collected.

IL-17's persistence was calculated in months using the Kaplan–Meier method and log-rank test to compare the survival along diagnostic, drug and line of treatment using SPSS Statistics, considering a p value <0.05 .

Results A total of 80 patients were included (33 with ixekizumab (60% Ps, 40% PsA) and 47 with secukinumab (49% Ps, 51% PsA). 36% were men, median age 54 (IQR 42–60) years. 31.25% were treated as first line, 13.75% as second line and 55% at third line or more with a median of two previous biological drugs.

46.25% discontinued treatment during the study (60% ixekizumab, 50% secukinumab). 55% of patients had been treated for more than a year with IL-17 (35% of them for more than 2 years) and the rest 45% interrupted treatment before completing a year (58% for less than 6 months).

IL-17's persistence was 24.1 months (95% CI 17.9 to 30.2) vs 30.9 months (95% CI 24.3 to 37.4) for ixekizumab and secukinumab, respectively, and did not show a significant difference ($p=0.774$).

Comparing between groups, there were no differences in ixekizumab's persistence in Ps vs PsA (24.5 vs 14.2 months, $p=0.97$), secukinumab's persistence in Ps vs PsA (32.5 vs 24.3 months, $p=0.6$), Ps' persistence of ixekizumab vs secukinumab ($p=0.79$) and PsA's persistence of ixekizumab vs secukinumab ($p=0.83$). Regarding the persistence of the treatment line this was similar in each group, and did not show any statistical differences.

Conclusion and relevance Both IL-17 inhibitors show a similar and considerable persistence of nearby 30 months globally. No significant differences were found either between between the drugs, diagnostics nor line of treatment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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Conflict of interest No conflict of interest

5PSQ-094 REASONS FOR DISCONTINUATION OF SELECTIVE IMMUNOSUPPRESSIVE BIOLOGICAL TREATMENTS AGAINST PSORIASIS

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Background and importance Psoriasis is a chronic inflammatory skin disease. Pharmacological therapy in moderate-severe psoriasis requires systemic hospital-dispensed treatments (SHDT) whose objective is to improve quality of life.

Aim and objectives The primary endpoint of the study was to determine the cause for discontinuity (CD) of SHDT against psoriasis. The secondary objective was to analyse the CD by drug.

Material and methods An observational, descriptive and retrospective study was carried out on the population diagnosed with psoriasis and SHDT between 2016 and 2020 under follow-up by dermatology at our hospital. Data were obtained

from the medical records and prescription medications program.

The CDs were grouped into seven items: lack/loss of efficacy, lack of adherence, patient decision, unacceptable toxicity, loss to follow-up, death, and others.

The drugs included were: adalimumab, apremilast, brodalumab, certolizumab pegol, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab.

Results 205 SHDTs for psoriasis were reviewed: 70 ustekinumab, 37 adalimumab, 28 secukinumab, 24 apremilast, 15 etanercept, 15 ixekizumab, 9 guselkumab, 4 brodalumab, 2 infliximab and 1 tildrakizumab. 86 treatment discontinuations were described: 53.5% lack/loss of effectiveness, 20.9% lack of adherence, 10.5% loss of follow-up, 7% other reasons, 4.7% unacceptable toxicity, 4.7% death and 3.5% patient decision.

51.2% of the incidents were with ustekinumab. 17.4% of discontinuations occurred in the adalimumab group, 9.3% apremilast, 9.3% etanercept, 9.3% secukinumab, 2.3% infliximab and 1.2% guselkumab.

100% of the infliximab discontinued treatments were due to lack of adherence, 100% of the treatment discontinuities due to unacceptable toxicity were associated with apremilast, and 100% of the losses to follow-up were detected in ustekinumab.

Conclusion and relevance The main CD in SHDT for psoriasis in our centre is due to lack/loss of response. Ustekinumab has been the drug that has registered the most discontinuations and losses to follow-up; this is explained by it being the treatment with the highest prevalence in the study. Visiting the hospital for infliximab administration has been shown to reduce adherence and interrupt treatment in patients who receive it.

The increment in SHDT that appeared in recent years to treat psoriasis increases the therapeutic options. Knowing the main CD of the different drugs and the characteristics of the patients helps to individualise the treatment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-095 COMPARISON BETWEEN THE MAXIMUM RECOMMENDED DOSE OF AZATHIOPRINE ACCORDING TO THE ENZYMIC ACTIVITY OF THIOPURINE METHYLTRANSFERASE AND 6-THIOGUANINE LEVELS WITH THE MAXIMUM TOLERATED DOSE

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Background and importance Azathioprine (AZA) is an analogue of purines used in inflammatory bowel disease (IBD) treatment. AZA is transformed by thiopurine methyltransferase (TPMT) into its metabolites, including 6-methylmercaptopurine (6-MMP) and 6-thioguanine (6-TGN).

Aim and objectives (1) Compare the maximum recommended dose of AZA according to TPMT activity and the maximum

tolerated dose (MTD), (2) evaluate the MTD and 6-TGN levels and (3) analyse the prevalence of each activity of TPMT.

Material and methods Retrospective observational study in patients with IBD treated with AZA and determination of TPMT activity between February 2017 and May 2021. Demographic, clinical data, metabolites (6-TGN (target 300–550 pmol/0.2 mL) and 6-MMP) and phenotype (activity of TPMT (IU/mL), determined by HPLC) were collected. AZA dosage was adjusted according to TPMT activity: treatment not recommended (poor; TPMT <5.0 IU/mL), 0.5 mg/kg (low; TPMT 5.1–13.7 IU/mL), 5 mg/kg (intermediate; TPMT 13.8–18 IU/mL), 2.5 mg/kg (moderate; TPMT 18.1–26.0 IU/mL) and 3.0 mg/kg (high activity; TPMT 26.1–40.0 IU/mL).

Results 131 patients were included, 61 (46.6%) women, mean age 34.7(SD 17.4) years. TPMT phenotype: low activity in 19 (14.5%) patients, intermediate activity 54 (41.2%) and moderate activity 58 (44.3%).

When analysing the dosage, in 30 (22.9%) patients the dosage according MTD was higher than according to the activity of TPMT, in 43 (32.8%) it was lower and in 58 (44.3%) it was within the range.

6-TGN levels in the patients receiving the MTD were higher than recommended in 35 (26.7%) patients, lower in 24 (18.3%) and within range in 72 (54.9%). Median 6-MMP/6-TGN ratio was 1.57 (SD1.7) in patients with 6-TGN levels <300 pmol/0.2 mL and only 3 (2.3%) had a ratio >4.

Mean serum creatinine was 0.70 (SD 0.35) mg/dL. Patients' renal function did not interfere in the elimination of AZA metabolites.

AZA posology was decreased in 31 (23.7%) patients and withdrawn in 22 (16.8%) due to adverse events. Most frequent adverse events detected were: digestive intolerance in 10 (7.6%) patients, leukopenia 7 (5.3%), lymphopenia 5 (3.8%), hypertransaminasaemia 4 (3.1%) and nausea 3 (2.3%).

Conclusion and relevance The phenotypes of intermediate and moderate activity of TPMT were the most prevalent. 6-TGN levels were high in almost a quarter of patients, increasing the risk of toxicity. In half the patients, the recommended dose based on TPMT activity was not coincident with MTD, suggesting the need to analyse other genetic factors that might influence AZA metabolism.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-097 USE AND PERSISTENCE OF FIRST-LINE BIOLOGICAL TREATMENTS FOR PSORIASIS

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Background and importance Psoriasis is a chronic, relapsing, immunologically mediated inflammatory dermatosis. Disease control is key to the physical, emotional and psychological well-being of patients.

Aim and objectives The main objective of the study was to identify the biological drugs chosen by the dermatologists at our centre as the first-line to treat psoriasis. The secondary objective was to determine the persistence of the drugs used in the first-line treatments.

Material and methods An observational, descriptive and retrospective study was carried out on patients diagnosed with psoriasis who were treated with selective immunosuppressive biological medication in our centre between 2016 and 2020. Data were collected from the medical history and the medication prescription program.

Results A total of 160 patients who started biological treatment for psoriasis were included; 38.8% were women. The mean age of the patients was 52±14.5 years. The treatments used in first-line therapy of psoriasis were: ustekinumab 42.5%, adalimumab 21.3%, apremilast 12.5%, secukinumab 10%, etanercept 8.8% and ixekizumab 3.1%. Only 3 patients started with brodalumab, guselkumab or infliximab, and none with certolizumab-pegol, risankizumab or tildrakizumab as first choice treatment. Those therapies with only one patient on treatment were excluded from the secondary endpoint analysis.

The treatments with the longest persistence were: etanercept (1296±418 days), ustekinumab (1090±739 days), secukinumab (813±368 days), adalimumab (803±664 days), ixekizumab (715±343 days) and apremilast (713±336 days).

Only 43.13% of the initiations were anti-TNF-α drugs.

Conclusion and relevance The result of the study shows the preference of ustekinumab as the first option by the dermatologist at our centre in the treatment of psoriasis, over others that are included in the regional guides. The study results show the preference of ustekinumab as the first option by the dermatologists in our centre in the treatment of psoriasis, compared to other drugs that are included in the regional opinion.

The drug with the longest persistence was etanercept, followed by ustekinumab, probably because they were the first commercialised molecules. The treatment durations show great interindividual variability.

With the arrival of new biological drugs indicated in this pathology, it is the job of the specialist pharmacist to promote the rational and protocolised use of the drug within the hospital's pharmacotherapeutic commissions.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-098 EXPERIENCE IN THE TREATMENT OF *CLOSTRIDIUM DIFFICILE* INFECTION

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Background and importance *Clostridium difficile* infection (CDI) can cause acute diarrhoea. One of the complications of CDI is recurrences. There are risk factors for multiple recurrences of the disease. Vancomycin and oral metronidazole are considered the treatment of choice. Other drugs, such as fidaxomicin and bezlotuxumab, may help in the control of recurrences.

Aim and objectives To analyse the use of fidaxomicin and bezlotuxumab in our hospital.

To analyse recurrences after treatment with fidaxomicin and early bezlotuxumab administration.

Material and methods Retrospective study including all patients treated with fidaxomicin from January 2014 to April 2021. Variables collected: age, gender, previous treatment

(vancomycin/metronidazol), days and regimen of treatment, recurrence or death at 8 weeks. Risk factors evaluated: age >65 years, use of antibiotics in the previous 3 months, ICD in the last 6 months, severe disease (oncological patient, immunosuppressed, renal failure). Tapered dosage of fidaxomicin oral was defined as 200 mg/12 hours (5 days) and 200 mg/48 hours (D7–D25).

Data were obtained from the pharmacy dispensation program and the patients' digital clinical records.

Results Forty-one patients were included, 25 women (61%), mean age 69 (21–99) years, 73.2% (n=30) were older than 65 years. 95.1% (n=39) had received antibiotics in the previous 3 months, 51.2% (n=21) had suffered CDI in the last 6 months, 60.9% (n=26) had severe baseline disease and 21.9% (n=9) were immunosuppressed. As first line, 41.4% (n=17) received vancomycin and metronidazole, 44% (n=18) received vancomycin and 14.6% (n=6) received fidaxomicin. 63.4% (n=26) received fidaxomicin 200 mg/12 hours (10 days), in 14.6% (n=9) the extended regimen was used and 22% (n=6) received 200 mg/12 hours for longer. 82.9% (n=34) of fidaxomicin-treated patients had no CDI recurrence at 8 weeks. 22% (n=9) of the patients died. Nine fidaxomicin-treated patients were administered bezlotuxumab and none subsequently developed CDI. All were older than 65 years and 66.6% (n=6) were oncology patients.

Conclusion and relevance The CDI treatment was mostly adjusted to the recommendations in the therapeutic guidelines, with vancomycin/metronidazole as first-line and fidaxomicin in recurrences. The use of bezlotuxumab was adapted to the considerations of the Therapeutic Positioning Index and was used in patients with a higher risk of recurrence.

Although in the pivotal studies the recurrence rate with bezlotuxumab was 16.5%, in our study there were no recurrences. In the case of fidaxomicin, the recurrence rate was 17.1%, which was higher than the published studies.

Limitations: small sample size and the impact of the joint use of bezlotuxumab and fidaxomicin has not been measured.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-103

DEVELOPMENT AND TESTING OF A SMARTPHONE-BASED SOLID ORAL DOSAGE FORM IMAGE RECOGNITION SYSTEM BY MACHINE LEARNING TO SUPPORT THE IDENTIFICATION OF DISPENSING ERRORS

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Background and importance Misidentification of oral dosage forms contribute to medication errors and compromise patient safety. Especially in manual dose dispensing, identification and verification of medicinal products at point-of-care can be a challenge for healthcare professionals. Machine learning is a powerful tool for object detection and image classification. As mobile technology and smartphones have developed exponentially in terms of computing power and

camera systems, handheld devices could serve as a convenient and cost-effective solution for real-time point-of-care tools for supporting the identification and verification of dispensed oral dosage forms for pharmacists, physicians and nurses in hospital settings.

Aim and objectives We aimed to develop and test the real-world point-of-care applicability of a smartphone-based pill recognition system using machine learning.

Material and methods Formularies and number of dispensed oral dosage forms of three hospitals were evaluated to select the 10 most commonly prescribed medications. A total of 8960 images were taken with a Sony IMX363 camera sensor with resolution of 12 megapixels under various conditions (lighting, distance, angle, dose container) and were used without augmentation to train the model. Microsoft Azure Custom Vision platform was utilised to develop our object detection and image classification model. An application was built using Android Developer Studio, and the model was exported in TensorFlow lite format and integrated in the application. A validation dataset of 200 test images were captured by two pharmacists at the Central Clinical Pharmacy, and precision, recall, mean average precision (mAP) and F1 score evaluation metrics were calculated.

Results Our model reached 98.1% precision, 87.4% recall and 96.4% mAP after training, with probability and overlap thresholds set to 50% and 30%, respectively, under the reference condition. Confusion matrix of 200 real-world test images showed a lower overall mAP (73.04%), recall (72.35%) and F1 score (70.6%). Per-class (medication) precision and recall ranges were between 50% and 100% and 20% and 100% respectively.

Conclusion and relevance Our model's performance indicates promising potential for application of smartphone-based identification and verification of dispensed medications at point-of-care. Eventually, the robustness of the model must be improved by adding more images and extending the dataset with additional commonly used medications before such a system can be utilised in a healthcare setting.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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5PSQ-104

VOLUNTARY ELECTRONIC REPORTING OF MEDICATION ERRORS AND ADVERSE DRUGS EVENTS DURING THE FIRST YEAR OF THE COVID-19 PANDEMIC

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Background and importance Evidence regarding the rate of medication errors (ME) and adverse drugs events (ADE) during the COVID-19 pandemic is limited. In that period the risk of ME and unsafe medication practices was potentially higher than average. Thus, voluntary hospital reporting systems are valuable sources of information on ME and ADE.

Aim and objectives To describe the ME and ADE registered in the voluntary electronic notification system of our centre (TPSC Cloud) during the first year of the COVID-19

pandemic and compare them with the same period in the previous year.

Material and methods A retrospective observational study of ME and AE notifications in the TPSC Cloud from March 2020 to February 2021 compared to notifications recorded from March 2019 to February 2020.

Five types of incidents were differentiated: situations with the capacity to cause ME, ME that do not reach the patient, ME that reach the patient without ADE, ME with ADE, and ADE without ME. The drugs involved in those incidents and the professional notifier also were identified.

Results 249 incidents were reported from March 2020 to February 2021, which was 31.02% less than in the previous period (n=361) from March 2019 to February 2020. The most common ME was prescription error in both periods (70.4% vs 67.3%). The incident profile by typology was similar in both periods. The most frequent was ME that did not reach the patient (40.24% vs 43.47%), followed by ME that reached the patient without ADE (23.42% vs 28.53%). Systemic anti-infectives drugs were the most involved in both periods (n=57; 22.89% vs n=73; 20.22%).

84 ADE without ME were reported from March 2020 to February 2021, representing an increase of 500% compared with March 2019 to February 2020 (n=14). Emphasising the notification of 35 ADE of lopinavir/ritonavir and 4 of hydroxychloroquine used in the initial treatment of COVID-19.

The main notifier in both periods was the pharmacist (80.48% vs 65.60%).

Conclusion and relevance During the first COVID-19 pandemic year, notifications of ME decreased, due to care load pressure, but incident profile was similar. Otherwise, ADE notifications increased notably, due to active pharmacovigilance carried out by pharmacists on off-label drugs used to treat COVID-19.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-106 IMPLEMENTATION OF ADVANCED THERAPY MEDICINAL PRODUCTS (ATMP) RECONSTITUTION IN A UNIVERSITY TEACHING HOSPITAL IN FRANCE: PROPOSAL OF A DECISION-MAKING ALGORITHM

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Background and importance ATMP (genetically modified organisms (GMO) ones or not) use is rising in oncology, and requires the establishment of a specific organisation to ensure a safety circuit.

Aim and objectives To implement ATMP reconstitution in our institution we built a decisional algorithm for risk and feasibility assessment for each ATMP.

Material and methods A team of seven oncology pharmacists was constituted to take into account the complexity of the organisations in our institution and associate several pharmaceutical competencies. They first identified a flow diagram

based on critical steps. For each step, according to regulations, professional guidelines and expertise field of each pharmacist, three brainstorming sessions were organised to identify main subprocesses and key points which must be evaluated for each ATMPs. Critical points were retained and a decision-making algorithm for ATMP risks and feasibility assessment, based on a yes/no dichotomy progression, was built and validated with circuit of ATMP in clinical trials (CT) ever conducted in our institution.

Results The decision-making algorithm we built consists of six steps (ATMP nature, storage conditions, thawing conditions, preparation of a not-GMO ATMP, preparation of a GMO-ATMP, waste disposal). Each step consisted of several questions (34). If a step fails, ATMP can not be used. Critical points such as security storage back-up or qualification of waste inactivation process are yet to be implemented into the algorithm. Moreover, as some facilities might routinely be unavailable yet in hospital pharmacies (storage in vapor phase nitrogen), the algorithm takes into account availability of these facilities outside of the pharmacy through subcontracting with a warranty of ATMP quality. After retrospective scrutiny of our algorithm with ATMP circuits ever conducted in CTs (talimogene laherparepvec, axicabtagene ciloleucel), it appeared to meet all our needs.

Conclusion and relevance This tool was used prospectively to implement tisagenlecleucel, onasemnogene abeparvovec and soon betibeglogene autotemcel in our centre. Furthermore, the French Regional Health Agency identified it as a key point to make our ATMP circuit secure.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-107 SECURISING OF TISAGENLECLEUCEL THAWING AND DELIVERING

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Background and importance Tisagenlecleucel is available in 50 mL and 250 mL frozen bags (containing 10–30 mL and 30–50 mL cell suspension, respectively). Tisagenlecleucel should be thawed at 37° C then infused within 30 min to maintain cell viability. Thawing time according to volumes is a critical point which is not known.

Aim and objectives We evaluated in this work the thawing times of tisagenlecleucel according to volumes.

Material and methods Ethylene vinyl acetate empty infusion bags were provided by Novartis. Freezing tisagenlecleucel matrix was reconstituted. Empty bags (50 mL and 250 mL) were respectively filled with 10 and 20 mL and 30, 40 and 50 mL of reconstituted matrix, then frozen at –150°C. To mimic real conditions, they were placed into a second sterile bag and thawed in a water bath at +37°C. To evaluate thawing duration, volume of remaining icicles was calculated by multiplying surface (GeoToolsoftware) by thickness (measured with a caliper). Furthermore, the time to deliver the bags was measured by two different operators in triplicate.

Results 124±5 s and 191±30 s were necessary to achieve complete thawing of 50 mL bags filled at 10 and 20 mL,

respectively. 155 ± 16 s, 221 ± 12 s and 240 ± 6 s were needed to achieve complete thawing of 250 mL bags filled at 30, 40 and 50 mL, respectively. For a type of bag, decreasing volumes thawed faster, but 50 mL bags filled at 20 mL took longer to thaw than 250 mL bags filled at 30 mL (different spatial conformation and specific surfaces). Delivery of thawed bags from the pharmacy to the transplant unit was done in 4.5 ± 0.21 min.

Conclusion and relevance Thawing duration may vary by twice a function of volume. Mean lengths provide an optimal organisation in a circuit where every minute must be taken into account. A total thawing-addressing time rate of between 6.5 and 8.5 min means that the nursing team has almost 20 min to administer tisagenlecleucel.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-108 SECURISING OF TISAGENLECLEUCEL (KYMRIAH) STORAGE

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Background and importance Tisagenlecleucel is available in frozen bags stored and shipped under -120°C . The Summary of Product Characteristics (SPC) allowed storage in a cryogenic freezer (vapour phase of nitrogen (LN2) is cited only as an example). As the pharmacy does not have LN2 storage facilities, tisagenlecleucel bags are stored in a freezer set at -150°C . With only one freezer available, another freezer located in the biological haematology laboratory was chosen as a back-up freezer in case of failure.

Aim and objectives The aim of this work was to validate the thermal performance of the container transfer system between our facility and our back-up ones.

Material and methods Freezer and rooms were equipped with Cobalt2 sensor, with Thermoserver software allowing monitoring, temperature recording, and triggering of the alarm in case of temperature excursion. A Cryoexpress polystyrene transport container was preloaded with 10×100 mL sodium chloride bags and one aluminium cassette used for tisagenlecleucel bag storage in order to mimic real-life conditions. The transport container was equipped with an Emerald sensor, with Oceaview software allowing real-time monitoring of the temperature inside the container. The transport container was placed inside the freezer, the cover was opened, and the temperature was set on -140°C in order to mimic a temperature excursion. After temperature stabilisation, the freezer was opened, the container was hermetically closed and the temperature inside it was measured every 30 s until an overrun of -120°C . Two situations were tested: the container left at room temperature ($+20^{\circ}\text{C}$), and, in order to mimic the worst case scenario, left in a room maintained at $+30^{\circ}\text{C}$. Each measurement was done in duplicate. Measurement of transfer time from the pharmacy to the back-up freezer was done by two different operators in triplicate.

Results Whatever the external temperature, conditions needed by the SPC is maintained for more than 25 min (28 min and

33.5 min for an external temperature of $+20^{\circ}\text{C}$ and $+30^{\circ}\text{C}$, respectively). The transfer time from the pharmacy to the biological haematology laboratory was 3.25 ± 0.25 min.

Conclusion and relevance Transfer duration to the back-up installation is far lower than the time for which an optimum storage temperature for tisagenlecleucel is maintained with our transport system.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-110 OMEPRAZOLE DEPRESCRIPTION PROJECT IN A SOCIAL HEALTH CENTRE WITH A DEPOSIT OF MEDICINES ASSOCIATED WITH A HOSPITAL PHARMACY SERVICE

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Background and importance The use of omeprazole has become very frequent in recent years, not being indicated on many occasions, so deprescription is necessary to reduce the possible associated adverse effects.

Aim and objectives Analyse the adequacy of omeprazole treatment in institutionalised elderly patients in a social health centre.

Recommend deprescription or dose reduction in susceptible patients.

Material and methods Review of all patients treated with omeprazole in the social health centre. The data were obtained from the electronic prescription and the medical history. Data collected: age, sex, dose, duration of treatment, indication, concomitant medication and interactions. Risk factors for bleeding were also analysed in patients older than 65 years: potentially gastrolesive drugs: anticoagulants, anti-aggregants, non-steroidal anti-inflammatory drugs (NSAIDs), corticosteroids and selective serotonin reuptake inhibitors (SSRIs) and a history of peptic ulcer.

The deprescription criteria were: no indication for use, duration of treatment exceeds the technical data sheet, and absence of gastrolesive drugs that justify the association of omeprazole.

The pharmacist's recommendations were carried out in the electronic prescription program and the analysis of acceptance/rejection of the interventions took place 1 month afterwards.

Results 38 patients were being treated with omeprazole. Mean age was 84 years and 74.4% were women.

45% (17 patients) did not meet the criteria for the use of omeprazole; 16 patients were proposed for deprescription and 1 for minimum dose.

Of the 17 patients, 5 (29.4%) took omeprazole for an indicated use but all exceeded the duration recommended.

Regarding the use of potentially gastrolesive medication: 7 patients (41.2%) were being treated with NSAIDs, 5 (29.4%) with SSRIs and 2 (11.7%) with acenocoumarol, but none of them were being treated with acetylsalicylic acid or with associations of high risk of bleeding, so the use of omeprazole was not justified.

One month later, 35.3% (6/17) of the interventions have been accepted, suppressing omeprazole from treatment in 5 cases and reducing to a minimum dose in 1 case.

Conclusion and relevance Omeprazole is a well-tolerated drug, but when used for prolonged treatment it can cause serious problems, so its evaluation is decisive to correct a possible misuse of the drug. This analysis reveals that 45% of the centre's patients do not meet the appropriate criteria for the use of omeprazole.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-112 HIDDEN HARM? ASSESSING MAGNITUDE AND COSTS OF INTRAVENOUS THERAPY ADMINISTRATION ERRORS VIA SMART PUMP REPORTS

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Background and importance Most reviews of intravenous therapy administration error have been undertaken in critical care. In our study wireless pumps gave access to smart pump therapy library log data from lower acuity areas of care such as oncology infusion centres, labour and delivery, and medical-surgical wards. Analysis of the magnitude and costs of errors in these areas has previously been lacking.

Aim and objectives To establish likely incidence of moderate and catastrophic intravenous therapy administration error via 'good catch' data in areas outside of critical care, to identify and classify the medications involved and to estimate likely costs of these errors.

Material and methods A review of 3 025 414 dose error reduction system protected infusions from adult units outside of critical care across the Middle East for the volume of averted dose/duration errors was undertaken, and a recognised grading of 'moderate' and 'catastrophic'¹ was applied. Projected savings from errors prevented was assessed against current intensive care unit (ICU) bed and medical ward costs in the Gulf region² and an average length of stay extension identified from the current literature.¹

Results Catastrophic errors averted would cost, conservatively, US\$114 503 per 10 000 infusions delivered. The average 1000 bed hospital delivery ≈750 000 infusions per annum.

Conclusion and relevance The study identified an incidence rate above those in many published studies; this may be because we 'cast the net wider' and because in the areas studied there was limited clinician experience of administration of some of the medications. Competency is difficult to maintain with limited exposure to a task. The presence of insulin, potassium preparations, and cytotoxics in our results is in line with other studies. The cost savings indicate the potential value of smart intravenous technology being deployed in every part of the hospital

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5PSQ-116 MEDICATION-RELATED FOLLOW-UP OF OLDER PATIENTS AFTER HOSPITAL DISCHARGE: A MULTICENTRE RETROSPECTIVE CHART REVIEW

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Background and importance The discharge of older hospitalised patients is critical in terms of patient safety, and is partly related to transfer of information about medications from hospitals to the next healthcare provider in primary care. There are to our knowledge no previous studies evaluating information transfer and follow-up, at patient discharge, in a setting where a shared electronic health record (EHR) is used.

Aim and objectives To evaluate the prevalence of patients for whom hospitals sent adequate requests for medication-related follow-up at hospital discharge, the proportion of patients revisiting hospital because of inadequate information and follow-up requests, and the possibility of an association between medication reviews performed during hospitalisation and inadequate follow-up requests.

Material and methods We conducted a retrospective chart review. The study population was randomly selected from a cluster-randomised crossover trial which included patients 65 years or older admitted to four hospitals during 2017–2018. Our study was conducted in regions using a shared electronic health record between hospital and primary care. Each patient was assessed with respect to the adequacy of the request for follow-up. For patients with inadequate requests, data about unplanned hospital revisits were collected, and an assessment made whether the inadequate requests had contributed to the revisits. The association between medication reviews and inadequate requests was analysed with a Chi-square test.

Results A total of 699 patients were included. The patients' mean age was 80 years; an average of 10 medications were prescribed on hospital admission. The hospitals sent adequate requests for 418 (60%) patients. Thirty-eight patients (14%) had a hospital revisit within 6 months of discharge related to

Abstract 5PSQ-112 Table 1

Therapy Type	Moderate Totals n. (% vs. DERS Infusions)	Catastrophic Totals n. Magnitude: Times Maximum Rate/Dose				All Catastrophic Totals n. (% vs. DERS Infusions)
	Magnitude: Times Maximum Rate/Dose	10-99999	100	1000		
IV Fluids	35,572 (1.1758)	23	259	4	9	295 (0.009)
Simple Analgesia	10,844 (0.3584)	62	641	4	53	760 (0.0251)
Antivirals, General Antibiotics and Antifungals	20,277 (0.6702)	84	950	33	67	1,134 (0.0375)
Blood Products	35,830 (1.1843)	325	20	0	4	349 (0.0115)
Chemotherapy and Cytotoxic	11,422 (0.3775)	37	166	4	31	238 (0.0079)
Anticoagulants	2,688 (0.0888)	12	305	24	60	401 (0.0133)
Insulin	313 (0.0103)	31	77	6	37	151 (0.0050)
Electrolytes (K ⁺ and Mg ²⁺)	179 18 (0.5922)	114	725	0	18	857 (0.0283)
GI System	5,688 (0.1880)	153	1,187	5	11	1,356 (0.0448)
Labor and Delivery Meds	111 (0.0037)	6	33	0	5	44 (0.0015)
Aminoglycosides	2,288 (0.0756)	13	179	0	5	197 (0.0065)
Diuretics	549 (0.0181)	34	63	4	38	139 (0.0046)
Steroids	24 (0.0008)	0	0	2	0	2 (0.0001)
Total/All Adult	143,522 (4.7439)	894	4,605	86	338	5,923 (0.0195)

an inadequate request. The proportion of inadequate requests did not differ between patients who had received a medication review during hospitalisation and those who had not ($p=0.83$).

Conclusion and relevance The prevalence of patients for whom the hospitals sent adequate follow-up requests on discharge was low. More than 10% who had an inadequate follow-up request revisited the hospital within 6 months of discharge for reasons related to the request. Medication reviews conducted during hospitalisation did not affect the proportion of inadequate requests sent. The implementation of a shared EHR did not solve this problematic communication gap.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-117 DETERMINATION OF GENETIC POLYMORPHISMS IN THE DIHYDROPYRIMIDINE DEHYDROGENASE GENE IN A PATIENT WITH GASTRIC ADENOCARCINOMA TREATED WITH FLUOROPYRIMIDINES: A CASE REPORT

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Background and importance Fluoropyrimidines are a foundational component of chemotherapy for solid tumour malignancies. The best-known cause of intolerance to fluoropyrimidines is dihydropyrimidine dehydrogenase enzyme (DPD) deficiency, which can result from deleterious polymorphisms in the gene encoding DPD (DPYD). Partial or total deficiency of this enzyme is related to severe toxicity and in some cases it can cause the death of the patient.

Aim and objectives To determine polymorphisms in the DPYD gene in a patient with gastric adenocarcinoma treated with fluoropyrimidines in order to avoid overexposure and toxicity associated with these drugs.

Material and methods A 66-year-old man was diagnosed with stage III gastric tubular adenocarcinoma. The treatment plan consisted of four cycles of neoadjuvant chemotherapy with the FLOT protocol: docetaxel 50 mg + calcium folinate 200 mg + oxaliplatin 85 mg + 5-fluorouracil (fluoropyrimidine) 2600 mg as a 24-hour intravenous infusion, every 14 days; followed by surgical intervention. Before starting the chemotherapy regimen, determination of DPD deficiency was requested.

Results The results showed mutation c.1236 G/A (HapB3) for the DPYD gene, which indicated overexposure to fluoropyrimidines and increased toxicity like diarrhoea, mucositis, neutropenia and neurotoxicity. Due to the polymorphism detected in DPYD gene, a 5-fluorouracil dose adjustment was required. The patient received four cycles of chemotherapy from April to June 2021 according to the dose recommendations of the oncology pharmacist. Treatment was started with a 50% dose reduction of 5-fluorouracil. After the first infusion, it was well tolerated with few reported adverse side effects such as low-grade fever, xerostomia and neutropenia. Neutropenia was successfully treated with granulocyte colony stimulating factors and the patient was able to continue the treatment, increasing the 5-fluorouracil dose by 25% in the last two cycles. Despite excellent tolerance to chemotherapy, the patient died after gastrectomy due to postsurgical complications.

Conclusion and relevance Genetic analysis for the determination of polymorphisms in the DPYD gene allows us to predict

the potentially serious toxicity of fluoropyrimidines, encouraging the individualised use of these drugs. In our case, the patient was at risk of developing severe toxicity so a dose adjustment of 5-fluorouracil was required.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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5PSQ-118 LITHIUM THERAPY ON HOSPITAL ADMISSION

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Background and importance The narrow therapeutic window of lithium (serum concentration between 0.6 and 0.8 mmol/L) makes it essential to monitor its plasma concentrations and to watch for possible interactions that may lead to changes in its pharmacokinetics. Many drugs can interact with lithium, and some are used by a high percentage of the population.

Aim and objectives The aim of this study was to assess possible interactions of lithium with angiotensin-converting enzyme inhibitors (ACEi), angiotensin receptor antagonists (ARA-II) or diuretics. To intervene when necessary, and to analyse the acceptance of such interventions by the physician on hospital admission.

Material and methods A prospective analytical study was performed in a second-level hospital for a period of 8 months (1 November–30 June 2021). Every patient admitted and on treatment with lithium was included.

Concomitant treatments were analysed to detect possible interactions and whether such treatments were initiated ambulatory or during the hospital stay. When interactions were detected, the pharmacist intervened by informing the physician via ATHOS-Prisma messaging and recommending a blood test for lithium levels, in order to reduce or increase the lithium doses if necessary.

Results A total of 35 patients were included in the study; median age 47 ± 15 and 20 are women, 28 had lithium prescribed at home.

Possible interactions were detected in 8 patients. Of these, 6 patients had both drugs interacting prescribed ambulatory and 2 had at least one of the interacting drugs prescribed by the specialist at admission.

Only the interventions in those 2 patients were accepted by the physician. Both interactions were between lithium and a drug that altered renal function (ACEi/ARA-II), increasing lithium levels above their therapeutic window.

Conclusion and relevance Pharmacists' interventions were only accepted when the drug was prescribed by the specialist contacted. When the drugs were prescribed ambulatory by another physician, interventions were not effective.

The fact that the patient had been taking the interacting drugs before admission does not make it less important, and in light of the results, the pharmacist should try another path to intervene, such as contacting the specialist responsible or his usual doctor at discharge.

In short, pharmacists are essential for detecting potential risks of toxicity due to high serum levels, and avoiding low doses, which could lead to a loss of efficacy.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-121 IMPORTANCE OF CONCILIATION IN IMMUNOSUPPRESSANT TREATMENT

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Background and importance The risk associated with contraindicated administration or omission of doses of a treatment is increased in the case of immunosuppressive drugs due to their narrow therapeutic margin, with small differences between therapeutic and toxic doses.

Aim and objectives The aim of this study was to investigate whether the immunosuppressive drugs prescribed to hospital inpatients is correct, and to emphasise the role of the pharmacist in medication conciliation.

Material and methods A prospective analytical study was performed in a second-level hospital for a period of 4 months. Every patient admitted who was being treated with immunosuppressive drugs was included.

Patients with immunosuppressant treatment were analysed and their medication was reconciled with the help of the Diraya digital history software and, in the case of discordance between their home medication and the prescribed medication, the prescribing physician was contacted. The variables collected were: demographic data, immunosuppressive treatment, hospital service, error type, intervention by the pharmacist and whether this was accepted by the physician.

Results A total of 34 patients were included in the study, with a mean age of 59 ± 13 years (53% men). Of all the patients, 41% (14 patients) had errors in their immunosuppressive treatment regimen, and the pharmacist intervened in all of them. However, in 2 patients the intervention was not assessable since they were discharged on the same day of admission.

All errors occurred with the different types of tacrolimus and mycophenolate.

The emergency department was the worst at prescribing immunosuppressive drugs, with 8 patients (57%). The remaining patients were: 2 in vascular surgery, 2 in nephrology, 1 in pneumology and 1 in psychiatry.

In 9 patients (75%), the dose was incorrectly prescribed. In 2 other patients there were treatment omissions, and in another there was an error in prescribing the form of treatment release.

Most of the interventions performed by the pharmacy service were accepted by the physician (75%), modifying the immunosuppressive regimen.

Conclusion and relevance The conciliation process is aimed at detecting and correcting possible medication errors that may have gone unnoticed.

The importance of this process on the part of the pharmacist is enhanced with vitally important drugs such as immunosuppressive drugs, and in hospital services where the workload is heavy such as the emergency department.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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5PSQ-122 EXPERIENCE OF BARICITINIB-REMDESIVIR USE IN PATIENTS WITH SARS-COV-2 INFECTION

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Background and importance The rapid emergence of SARS-CoV-2 has led to the development of numerous treatments in a short period of time. The need for clinical expertise is vital for better care and follow-up of the hospitalized patient. Baricitinib and remdesivir are two treatments that can be used in combination and have been studied in some clinical trials.

Aim and objectives The aim of this study was to describe the clinical experience of the baricitinib-remdesivir combination in a tertiary hospital, as well as to analyse the adverse event (AE) profile.

Material and methods Observational, descriptive, retrospective and multidisciplinary study of all patients treated with baricitinib-remdesivir from January 2020 to September 2021. The variables collected from the clinical history and the inpatient module (Farmatools) were: age, sex, comorbidities, days of hospital stay, deaths, compliance with treatment criteria and AEs.

Results From the 50 patients studied with the baricitinib-remdesivir combination, 68% (n=34) were men, with an average age of 66 (range 22–94) years. The median days of hospitalisation was 10 (range 4–142).

80% (n=40) of patients presented comorbidities mainly: cardiovascular problems (61%), obesity (15%), obstructive pulmonary disease (14%) and toxic habits (10%).

The number of deaths was 14 (28%), 71% (n=10) were during the hospital stay.

In terms of satisfying the hospital's criteria for the initiation of treatment, 32% (n=16) of patients were not candidates.

AEs observed were 22% (n=11) infections, 8% (n=4) cardiotoxicity, 8% (n=4) hepatotoxicity and 4% (n=2) vascular events. Treatment was suspended in 4 episodes, due to a positive Quantiferon test (n=3) and due to a thromboembolic phenomenon (n=1). Of the 16 patients who did not fulfil treatment criteria, 6 presented an AE (37.5%).

Conclusion and relevance 32% of the patients were not candidates for treatment, according to the hospital pharmacotherapeutic protocol. This may lead to an increase in the number of AEs. However, more studies with larger sample sizes are needed to obtain more evidence and consistent data.

Treatment should be promoted and monitored only in patients who meet the inclusion criteria, which would lead to a much more efficient and safer pharmacotherapy.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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5PSQ-124 THE ROLE OF THE CLINICAL PHARMACIST IN AVOIDING MEDICATION ERRORS IN A CLINICAL RESEARCH ONCO-HAEMATOLOGIC UNIT

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Background and importance The complexity in the design and execution of clinical trials has created the need to coordinate a multidisciplinary team in which the pharmacist has a fundamental role to avoid medication errors (ME).

ME are especially important in clinical trials since any minimal deviation in the protocol can lead to the patient leaving the study.

Aim and objectives To analyse the medication errors detected in the clinical trials area of the Clinical Research Onco-Hematologic Pharmacy Unit, in order to identify the points of greatest risk and establish improvement measures.

Material and methods A prospective analysis of medication errors detected during 6 months (January 2021–June 2021) was conducted by pharmacists in the Clinical Research Onco-Hematologic Pharmacy Unit in the course of their activity. At the same time, the errors detected during the validation of the medical prescriptions and during the quality control of the intravenous preparations were analysed.

Results A total of 250 errors were recorded. Most of the errors detected ($n=135$; 54%) originated in the prescription process, of which the most frequent were: error in the patient's weight (31.11%), the prescription of an incorrect dose (26.67%), prescribing the wrong chemotherapy regimen (17.78%), errors in the confirmation of treatment (8.15%), and others (16.29%). In 8 (5.93%) cases, the error reached the patient. None of these caused serious consequences.

Regarding the preparation process, 115 (46%) errors were detected. 63.47% were due to errors in the conservation specifications: 57.39% storage temperature specifications and 6.08% related to photoprotection. 21.90% confusions that required a repeat of the preparation and 20% that referred to infusion systems.

Conclusion and relevance Most of the ME that occurred in the Clinical Clinical Research Onco-Hematologic Pharmacy Unit are intercepted before they reach the patient. Most of them were generated in the prescription process, mainly due to an error in the patient's weight.

The information obtained in this analysis reinforces the role of the clinical pharmacist in avoiding errors and improving measures to increase patients' safety.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-125 THE IDENTIFICATION OF HEALTH CONSEQUENCES ASSOCIATED WITH COUNTERFEIT MEDICINE AND ILLEGAL HEALTH PRODUCT APPLICATION USING PHARMACOVIGILANCE DATA

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Background and importance Information on the health damage caused by counterfeit medicines and healthcare products is not, or is only rarely found, in the scientific literature. As a result it is difficult to determine or describe in clinical practice the extent and probability of drug-related problems originating from these products and how to identify these harms in a hospital setting.

Aim and objectives Our aim was to assess the active pharmaceutical ingredients affected, the extent and characteristics of

health consequences related to counterfeit medications based on the accessible product alerts and pharmacovigilance data.

Material and methods In addition to doing a literature search, we reviewed the World Health Organization (WHO) Medical Products Alert publications in the last 20 years and collected adverse drug reactions indicating a counterfeit medicine in the WHO VigiAccess database. Furthermore, we analysed the counterfeit medicine-related adverse drug reactions in the US Food and Drug Administration (FDA) Adverse Events Reporting System (FAERS) database.

Results The top 12 most commonly involved active substances internationally were alprazolam, amoxicillin/clavulanic acid, bevacizumab, diazepam, phenobarbital, flunitrazepam, glibenclamide, heparin, insulin, levonorgestrel, sildenafil and tadalafil. Between 2003 and 2020 in the FAERS database, we identified 3868 falsified drug-related adverse drug reactions, and in the last 5 years an average of 300–500 cases, which represents 0.018% of all reported adverse drug reactions. Based on the FAERS cases we have identified less predictable adverse drug reactions as well, with PDE-5 inhibitors causing vision loss and eye bleeding, and alprazolam causing foaming mouth and suicide attempt.

Conclusion and relevance Our study showed that pharmacovigilance and toxicovigilance data are suitable for the identification and detection of health damage caused by counterfeit drugs. With the national adaptation and the development of a specific prospective data collection methodology in the clinical setting, it may also be possible to identify cases in Hungary, which will be a great step towards the prevention of patients' health damage and death related to these products. We believe that clinical pharmacists should play a more definite role in adverse drug reaction identification and toxicovigilance.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-127 THE IMPACT OF COMEDICATION ON POTENTIAL LIVER TOXICITY OF REMDESIVIR: A DESCRIPTIVE, RETROSPECTIVE ANALYSIS OF HOSPITALISED COVID-19 PATIENTS

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Background and importance Although the safety of remdesivir has been shown previously, liver toxicity is an ongoing concern. Additionally, case reports were published suggesting a possible interaction between remdesivir and Cyp3A4 and/or P-glycoprotein (P-gp) inhibitors, resulting in liver toxicity. COVID-19 infection itself may cause liver toxicity through various mechanisms.

Aim and objectives The aim of this analysis was to evaluate the impact of concomitant medication of COVID-19 patients on liver toxicity of remdesivir.

Material and methods This descriptive, retrospective analysis included hospitalised COVID-19 patients treated in regular wards from February to April 2021. Remdesivir was prescribed according to the hospital's standard operating procedure (SOP). Treatment with remdesivir was only initiated in patients with evidence of COVID-19 pneumonia and symptom onset to hospital admission ≤ 7 days. Patients with pneumonia and high risk of bacterial infection received ceftriaxone as

part of the SOPs. Data were obtained from medical charts and included demographic characteristics, concomitant medication and laboratory results of liver function (at admission and after about 5 and 10 days of hospitalisation).

Results 30 patients received remdesivir during the observation period, and in addition 11 patients without remdesivir were included as controls. Median time from symptom onset to hospitalisation was 4 days for the remdesivir group and 10 days for patients not treated with remdesivir. Remdesivir was prescribed in 17/30 patients (56%) without any other pharmacologically relevant medication. 13 patients (43%) received remdesivir together with ceftriaxone. There was no evidence of liver dysfunction, defined as alanine transaminase (ALT) values above 2.5 times the upper limit of normal, in patients with remdesivir with or without concomitant ceftriaxone. 3 patients (50% total) who received ceftriaxone without remdesivir had evidence of liver enzyme dysfunction. Only 1 patient received a P-gp inhibitor (carvedilol, 25 mg) together with remdesivir; however, no effect on ALT levels was observed.

Conclusion and relevance In this small sample retrospective study there was no evidence of clinically relevant liver toxicity with remdesivir, with or without other drugs that would impact liver enzyme function, such as ceftriaxone. Interactions with potent Cyp3A4 or P-gp inhibitors appear to be rare in a real-life clinical environment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

Conflict of interest No conflict of interest

5PSQ-128 CLINICAL INTERVENTIONS IN THE AREA OF INPATIENT PRESCRIPTIONS PERFORMED BY A HOSPITAL PHARMACY RESIDENT

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Background and importance Pharmaceutical validation of inpatient treatments is a fundamental activity in the clinical practice of the hospital pharmacist. Thanks to this, many prescription errors are detected, promoting patient safety.

Aim and objectives To describe the interventions performed by a hospital pharmacy resident in the area of pharmaceutical validation, supervised by consultant pharmacists, and to evaluate their degree of acceptance.

Material and methods Prospective interventional study conducted during September 2021. Adult inpatients, whose hospital treatment was reviewed, were included. Demographic (sex and age), clinical (clinical judgement (CJ) and inpatient clinical service) and pharmacotherapeutic (number of chronic medicines and polymedication (≥ 6 drugs)) variables were collected. Interventions were reported to the clinician via electronic prescribing software. They were classified as: Activity (reconciliation on admission/information to the clinician), Adequacy (detection of prescribing error/therapy reconciliation error), Change (therapeutic exchange), Initiation (usual treatment not prescribed/need for additional treatment), Modification Dosage Form (DF) or Posology, Suspension (duplication/unnecessary medication/allergy). Patient lists and data were collected through medical records and electronic prescribing software, and processed using Excel 2020.

Results Interventions were performed in 56 patients. 63.2% male; median age 73 years (IQR 61–80). The most frequent CJ were: heart failure (10.7%), COVID-19 (7.1%), liver dysfunction (7.1%). Services with most interventions: Internal Medicine (25.8%), General/Vascular Surgery (19.4%), Digestive (11.3%). Median number of chronic medicines: 8 (IQR 5–12). Polymedication in 71.4%. 62 interventions were performed (12.9% were 'not evaluable', reasons: discharge/death). Of the evaluable interventions, 77.8% were accepted. The percentages were: duplicity (30.9%), modification DF/posology (23.8%), usual treatment not prescribed (7.1%), therapeutic exchange (7.1%), discontinuation medication due to allergy (7.1%), therapy reconciliation error (4.8%), reconciliation on admission (4.8%), information (4.8%), additional treatment (4.8%), prescribing error (2.4%), unnecessary medication (2.4%). Of the accepted interventions, 11.9% were related to high-risk medicines according to the Institute for the Safe Use of Medicines¹⁻² (nonsteroidal anti-inflammatory drugs (NSAIDs), beta-blockers, heparin, immunosuppressants). Of the not-accepted interventions, 50.0% corresponded to errors in home treatment reconciliation.

Conclusion and relevance The data obtained demonstrate that clinical interventions performed by the hospital pharmacy resident have a high degree of acceptance, increasing the quality and safety of healthcare and avoiding medication errors.

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Conflict of interest No conflict of interest

5PSQ-130 DOSE BANDING OF INTRAVENOUS 5-FLUOROURACIL, OXALIPLATIN, PACLITAXEL AND GEMCITABIN: EVALUATION OF EFFICIENCY AND SAFETY SUBSEQUENT TO AN IMPLEMENTATION PROGRAMME

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Background and importance Dose banding (DB) is a strategy used to optimise the individualisation of antineoplastic treatments in order to reduce dose errors and achieve the highest efficiency.

Aim and objectives The aim of this work was to implement a DB system and analyse its impact on the efficiency and safety of patients treated with 5-fluorouracil (5-FU) elastomeric pumps and oxaliplatin, paclitaxel and gemcitabine solutions.

Material and methods Retrospective 5-month study, including 147 patients treated with antineoplastic agents (44 with 5-FU, 28 oxaliplatin, 36 paclitaxel and 39 gemcitabine). 5-FU was prepared in an elastomeric pump (Autofuser UFSC-2); the remaining drugs were prepared for infusion with NaCl 0.9% in a Freeflex plastic container.

Patients were divided into two groups for each drug, depending on the theoretical calculated doses adjusted to their body surface area (BSA): P1 higher-doses, P2 lower-doses. Dose-range was established with a $\pm 5\%$ variability.

In order to measure the efficiency, the number of elaborations, expired preparations and percentage of saved vials were noted.

Safety was determined comparing leucocyte (5-FU) and neutrophil levels (oxaliplatin, paclitaxel and gemcitabine) the day before the treatment and preceding the next dose.

Statistical association was investigated by applying Student's t-test, and Wilcoxon and Shapiro–Wilks tests. Non-statistical significance was considered a favourable outcome.

Results Six 5-FU, oxaliplatin and paclitaxel doses were standardised covering 93.6%, 100% and 72% of patients, respectively, and seven gemcitabine doses covering 97.5%.

A total of 1527 preparations were elaborated (412 5-FU, 312 oxaliplatin, 431 paclitaxel and 372 gemcitabine) and the percentages of expired preparations were 6.3%, 15.6%, 4.4% and 11.8%, respectively. The efficient use of vials allowed a significant saving: 23.4% for 5-FU vials, 32.2% for oxaliplatin, 52.6% paclitaxel and 22.2% gemcitabine.

There were no statistical differences between leucocyte/neutrophil levels measured before and after the treatment in either group (5-FU: $p=0.99/p=0.57$; oxaliplatin: $p=0.71/p=0.57$; paclitaxel: $p=0.90/p=0.26$; gemcitabine: $p=0.32/p=1$).

Conclusion and relevance The implementation of the project turned out to be simple and satisfactory. The process proved to be efficient after the stock adjustment (oxaliplatin and gemcitabine). The DB did not compromise safety of patients in terms of haematological toxicity. Thus, DB represents a cost-effective technique that might be taken into account.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-131 PARENTERAL NUTRITION IN ACUTE PANCREATITIS: A REVIEW OF APPROPRIATENESS

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Background and importance According to nutritional recommendations in patients with pancreatitis, adequate nutrition from the beginning has a high impact on the pathology, since these are patients at risk of malnutrition.

Aim and objectives To review the adequacy of individualised total parenteral nutrition (TPN) in patients admitted with a diagnosis of acute (AP) or exacerbated (rPAP) pancreatitis.

Material and methods Retrospective observational study including patients admitted from January 2020 to September 2021, all diagnosed with AP or rPAP.

The following variables were collected from the HCIS clinical history and Kabisoft TPN prescription program: age, sex, height, weight, diagnosis, initial TPN composition (lipids, carbohydrates, proteins), days from admission to initiation of TPN and reason for initiation.

Results A sample of 53 patients was obtained, 33 men, of whom 42 were diagnosed with BP (79.25%) and 10 with rPAP (18.87%) on admission.

The mean number of days to initiation of TPN was 3.30 (± 1.90) days. The majority of patients, 48 of the total, started TPN due to contraindications to an oral diet.

Only 10 had a lipid intake ≥ 0.8 g/kg/day; the rest had less, with a mean of 0.6 (± 0.23) g/kg/day. Protein intake was 1.1 (± 0.23) and carbohydrates 2.8 (± 0.55) g/kg/day.

Lipids accounted on average for 26.2% (± 7.31) of the average caloric intake (ACT), protein 21.4% (± 3.25) and carbohydrates 52.4% (± 5.82). Twenty-eight of the TPNs had an ACT lower than the calculated requirements. The average non-protein kcal/g nitrogen (kcalNP/gN) was 94.8 (± 19.20) and non-protein kcal/kg on average was 16.8 (± 3.84).

Conclusion and relevance In line with the European Society for Clinical Nutrition and Metabolism (ESPEN) guidelines, protein, carbohydrate and lipid intake, and non-protein kcal/kg, were lower than recommended. Total TPN kilocalories were also lower than the calculated requirements of the patients. This may be due to the fact that energy needs change according to AP severity and stage. Also, there is risk of malnutrition and, consequently, refeeding syndrome.

However, the kcalNP/gN ratio was adequate, ensuring that protein was used for tissue formation. The caloric intake of carbohydrates with respect to ACT was adequate, being between the recommended 50%–70%.

More clinical nutrition interventions will be necessary, always integrated by a multidisciplinary team.

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Conflict of interest No conflict of interest

5PSQ-135 NEW SECURITY WARNINGS FOR TOFACITINIB: ANALYSIS OF PATIENTS AT RISK

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Background and importance In July 2021, the European Medicines Agency (EMA) and the Spanish Agency for Medicines and Medical Products (AEMPS) notified healthcare professionals of a drug safety warning for tofacitinib that showed new recommendations for its use in relation to an increased risk of major adverse cardiovascular events and malignancies with use of tofacitinib relative to tumour necrosis factor alpha (TNF α) inhibitors: “Tofacitinib should not be used in patients older than 65 years of age, people who are current or past smokers, or individuals with other cardiovascular (such as diabetes or coronary artery disease) or malignancy risk factors unless there are no suitable treatment alternatives”.

Aim and objectives The objective of this study was to identify patients at increased risk of major adverse cardiovascular events and malignancies who are being treated with tofacitinib in order to communicate this fact to healthcare professionals.

Material and methods Retrospective study of patients under treatment with tofacitinib from January to September 2021. The following factors were considered as risk factors: aged 65 years or more, cardiovascular risk factors, and current malignancies. Data were recollected from the patients' clinical history and local prescription program. We prepared a personalised report that included a summary of the drug safety warning and the patients under treatment that were

considered to be at risk to each healthcare professional, offering them other treatment options based on efficacy, safety and cost.

Results We reviewed 36 patients under treatment with tofacitinib, 28 females (73%), average age 51.6 years. 32 patients had rheumatoid arthritis and 4 patients had ulcerative colitis. We identified 13 (36%) patients with an increased risk of major adverse cardiovascular events and malignancies, and all of them had rheumatoid arthritis: 7 patients were aged 65+ years, 5 patients had cardiovascular risk factors, and 2 patients had a malignancy process. We sent 11 personalised reports to healthcare professionals.

Conclusion and relevance One in three patients being treated with tofacitinib were affected by the security alert, and were considered to be a population at increased risk of major adverse cardiovascular events and malignancies. This study allowed us to find these patients and communicate this information to healthcare professionals, providing them with an alternative treatment option based on efficacy, safety and cost.

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Conflict of interest No conflict of interest

5PSQ-137 MEDICATION ERRORS RELATING TO ISOAPPEARANCES IN THE EMERGENCY ROOM

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Background and importance Medication errors (ME) are a common cause of harm to patients, especially in an emergency setting. The International Organization for Standardization (ISO) includes among the main objectives safety in the administration of medicines, sharing best practices and minimising the possibility of ME due to confusion of denominations and the external appearance of the products. This has the potential to significantly improve patient safety and the quality of healthcare. The World Health Organization (WHO) estimates that the annual cost of medication errors amounts to \$42 billion, all potentially avoidable.

Aim and objectives The aim of this study was to determine the prevalence of ME related to isoappearances in the emergency room (ER), and to give visibility and enhance the importance of the recently created Isoappearance Group in the Emergency Department to achieve ISO's objectives.

Material and methods A retrospective observational study was performed. ME that occurred in the ER in our hospital during the years 2019, 2020 and the first half of 2021 were analysed through our hospital's corporative electronic platform SNAPS (Patient Safety Notification and Learning System), developed by the Spanish Ministry, and available to all hospital professionals. In addition, the bibliography at the Institute for Safe Medication Practices (ISMP) website about 'sound-alike' and 'look-alike' errors was reviewed.

Results In the study period, 237 incidents were reported in the ER, and 44 of them were related to medication (18.5%). Specifically 22 of them (9.2%) corresponded to isoappearances (7 'sound-alike' and 15 'look-alike'). Six (27%) of the

registered isoappearances reached the patient and could have been avoided. Although they could have harmed the patients, all the incidents were resolved.

Conclusion and relevance 'Sound-alike' and 'look-alike' errors have a high frequency, and it is a priority to work specifically on them. To work on this objective, a multidisciplinary isoappearances group formed by a clinical pharmacist, a nurse, and two physicians has been set up on site in the ER to optimise stocks by reducing the available concentrations, changing the providers so that the medications' appearance was different, and promoting safety culture.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-138 IMPACT OF HIGH TEMPERATURE, SHAKING AND LIGHT ON QUALITY OF THE THERAPEUTIC PEPTIDE TEDUGLUTIDE (REVESTIVE) EVALUATED BY LC/MS/MS (ORBITRAP) PEPTIDE MAPPING ANALYSIS AND STRESS

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Background and importance Teduglutide (Revestive) is a recombinant human GLP-2 analogue indicated in the treatment of short bowel syndrome, a serious and highly disabling condition which results from either loss of portions of intestine or loss of critical intestinal function. A proteinaceous-based medicine, teduglutide is indicated to have low stability, thus the study of the effect of possible in-use mishandling and in-stress conditions are welcome to gain knowledge of its stability and degradation.

Aim and objectives To evaluate the impact on teduglutide's chemical structure when subjected to in-use mishandling and when it is degraded by the characterisation of its post-translational modifications (PTMs) obtained by liquid chromatography with tandem mass spectrometry (LC/MS/MS) (Orbitrap) peptide mapping analysis after submitting teduglutide samples to 40°C and 60°C, to smooth shaking and to accelerated light exposition.

Material and methods Samples of reconstituted teduglutide (Revestive) were submitted to 40°C and 60°C (3 hours), to smooth shaking (3 hours) and to accelerated light exposition (24 hours). Tryptic digestion was performed on these samples and the resulted fragments were separated and quantified by LC/MS/MS. BiopharmaFinder 3.1 software (Thermo Scientific) was used for PTMs identification.

Results Different PTMs related to the quality of the medicine were monitored in the primary structure of teduglutide (ie, deamidations, isomerisations and oxidations) [1]. No changes in the PTMs profiles were found in samples subjected to temperature and agitation in comparison to the PTMs profiles of fresh teduglutide. High percentages of oxidations were detected in the samples submitted to light exposition.

Conclusion and relevance The exposition to light modified the PTMs profile of teduglutide inducing oxidations in the primary structure (methionine and tryptophan residues). These

might affect teduglutide's security, efficacy and quality. Therefore, it is highly recommended to protect the drug from light during in-use manipulation. For temperature exposition (40°C and 60°C) and agitation, the PTMs profile was not modified, thus no specific recommendations need be noted in this regard.

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Raquel Pérez-Robles is currently granted a postdoctoral position from the Junta de Andalucía, Spain.

Conflict of interest No conflict of interest

5PSQ-139 ANTICHOLINERGIC RISK EVALUATION IN HOSPITALISED PATIENTS

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Background and importance The combination of drugs with anticholinergic action can cause side effects in people with morbidity. This risk increases with age and frailty. There are different scales to estimate the anticholinergic risk (AR) but there is substantial variability between them. The Anticholinergic Burden Calculator (ABC) tool allows the calculation of the Drug Burden Index (DBI), which takes into account the prescribed dose and includes sedative drugs.

Aim and objectives To determine the AR of patients admitted to a second-level hospital.

To analyse their comorbidities and to relate them to possible anticholinergic side effects.

Material and methods Cross-sectional study carried out with patients admitted to the hospital ward. Patients older than 65 years and with more than five prescribed drugs were included in the study. The variables collected from the electronic medical history were: age, gender, morbidity, hospital service, drugs and dose. To obtain the AR, the ABC tool was used, expressing the values in DBI. According to AR, the patients were classified into three groups: without risk (0), medium risk (<1) and high risk (≥ 1).

The comorbidities of each patient were analysed. Those that were related to anticholinergic effects were selected and classified into two groups: (a) somatic symptoms (dry mucosa, constipation, urinary retention) and (b) neuropsychiatric symptoms (cognitive and functional dysfunction, agitation, falls).

Results A total of 183 patients were included: 60.1% women with median age 84.3 (SD 8.9) years. According to the DBI, patients were classified into three groups: without risk (15.3%), medium risk (40.4%) and high risk (44.3%). The total average DBI obtained was 0.97 (SD 0.86) and in the high-risk group was 1.7 (SD 0.78).

Comorbidities related to possible anticholinergic effects were found in 49.2% (n=90) of the patients. This percentage increased to 55.6% (n=50) by focusing on high-risk patients compared to medium-risk patients (32.2% n=29) and without-risk patients (12.2%, n=11). 87.4% of the comorbidities were neuropsychiatric symptoms.

Conclusion and relevance Most of the patients presented anticholinergic risk. Half of them had comorbidities that could be related to the effects of anticholinergic drugs. These comorbidities increased in direct proportion to anticholinergic risk.

It would be advisable to implement a hospital protocol to reduce the anticholinergic burden.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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5PSQ-140 PATIENT SAFETY CLIMATE IN A HOSPITAL PHARMACY DEPARTMENT

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Background and importance Patient safety should be a cross-cutting issue in all hospital services. It is important to assess patient safety culture in the units to implement improvement measures and offer quality and safe healthcare to patients.

Aim and objectives To analyse patient safety climate in a Hospital Pharmacy department.

Material and methods Descriptive, transversal study carried out through an anonymous survey in September 2021. All pharmacy staff were invited to participate. The survey applied was the Agency for Healthcare Research and Quality Hospital Survey SOPS Version 1.0-Spanish.

The survey has 42 items with five response options on a Likert-type scale from 1 (strongly disagree or never) to 5 (strongly agree or always).

A strength is considered if at least 75% of respondents rate the item positively, while it needs improvement if at least 50% rate it negatively. Items are grouped into 12 composite measures.

Data were analysed with an application available on the patient safety page of the Ministry of Health.

Results Response rate: 91% (44 surveyed). 69% technicians/nurses, 31% resident pharmacists/pharmacists. 56% worked 20–39 hours/week and the rest 40–59 hours; 46% had worked in the hospital for less than 1 year, 1 to 5 years (34%), 21 years or more (10%), 6 to 20 years the rest. 48% had been working in the unit for less than 1 year, 33% 1 to 5 years, 6 to 21 years or more the rest. 12% had direct interaction with patients.

Global results were: teamwork within units 69%, supervisor/manager expectations and actions promoting patient safety 64%, communication openness 57%, organisational learning-continuous improvement 51%, feedback and communication about error 47%, overall perceptions of patient safety 42%, nonpunitive response to error 39%, teamwork across units 39%, frequency events reported 38%, staffing 38%, management support 37%, handoffs and transitions 29%.

The overall grade on patient safety was perceived: very good 45%, excellent 30%, acceptable 20%, poor the rest.

Conclusion and relevance Eight need-of-improvement areas were perceived: management support and handoffs-transitions being the worst rated. Teamwork within units, supervisor/manager expectations/actions were the best perceived.

No strengths were found; however, the overall perception was rated as excellent or very good by the majority.

Assessing the baseline-state of safety climate is a good starting point for identifying areas for improvement.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-144 DEVELOPMENT AND VALIDATION OF CLINICAL RULES TO ADDRESS RISK PRESCRIPTIONS

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Background and importance The hospital is planning to implement a closed-loop medication system, including dose-dispensed medication, which legally requires pharmaceutical validation. An advanced system for pharmaceutical validation, built on clinical rules based on real-time data on patients' medication, laboratory data and diagnosis, is planned to be developed and implemented at the hospital. Pharmacists will be the first recipients of the alerts, only forwarding relevant alerts to the physician. The research project is called System Assisted Pharmaceutical Validation (SAPVAL). A challenge in developing clinical rules is to develop well-defined clinical rules that do not miss relevant risks or result in alert fatigue.

Aim and objectives The aim of the study was to determine a set of clinical rules and apply the rules to inpatient data to determine the prevalence and clinical significance of the generated alerts, as an element for a future system for pharmaceutical validation of inpatients' prescriptions at the hospital.

Material and methods Through a literature search and consultations with local experts, a set of clinical rules was determined. A retrospective cross-sectional study was performed to validate the clinical rules on a study population of 500 patients aged 65 years and older. The clinical rules were applied on patient data from the electronic health records the day after admission to the hospital, to determine the prevalence of risk prescriptions generated by the clinical rules. It was investigated whether the risks remained after 2 days. From the total generated alerts, 10% were randomly selected and assessed for clinical relevance by an experienced clinician.

Results A number of 62 clinical rules were defined and applied. Of these, 40 rules generated one or more alerts. The clinical rules generated 893 alerts in 338 (68%) out of 500 patients, and 84% of alerts remained 2 days after the patient was admitted to the hospital or at discharge. From the randomly selected alerts 24% were deemed clinically relevant.

Conclusion and relevance In summary, the clinical rules generated a large number of alerts for risk prescriptions in a majority of hospital inpatients aged over 65 years. The risk prescriptions were very likely to remain after 2 days and a quarter of them were clinically relevant.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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5PSQ-145 MEDICINAL PLANTS USE AMONG TUNISIAN PATIENTS: PREVALENCE AND PERCEPTION

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Background and importance According to the World Health Organization, 80% of the world's population uses medicinal plants. This allopathy alternative constitutes an accessible and inexpensive source of medicines. However, it is not without risks.

Aim and objectives This study aimed to: (1) assess the prevalence of the use of medicinal plants, (2) measure the perception about medicinal plants and (3) identify the most commonly used plants for self-medication among Tunisian patients.

Material and methods This was a cross-sectional monocentre study carried out in the largest hospital in Tunisia. The study was approved by the local ethics committees. The duration of the inclusions was 1 month. The sample size was calculated using EpiInfo software and was estimated to be 250 patients. Outpatients who agreed to participate in the study were interviewed face-to-face using a prevalidated questionnaire in Tunisian dialect. This questionnaire detailed sociodemographic data and information about the uses of medicinal plants. The collection site was the outpatient pharmacy. Statistical analysis was performed using PSPP.

Results The interview time was 1 to 5 min. A total of 336 patients were recruited. The average age was 52±13 years. The gender ratio (M/F) was 0.66. Sixty-four patients (19%) were illiterate. Most of the patients came from the departments of internal medicine (30.1%), neurology (17%) and cardiology (16.1%). One hundred and eight (32.1%) confirmed using medicinal plants, and among them 103 (95%) believed that this allopathy alternative is effective and accessible. One hundred and five (97%) patients believed that medicinal plants are beneficial for them. The most cited plants by patients were rosemary (17%), thyme (15%) and verbena (5%). The most popular form of use was a decoction (80%). The patients affirmed that plant material was sourced from the market (72%) or by simple harvesting (26%).

Conclusion and relevance This study showed a high prevalence of medicinal plant use among Tunisian patients. Aromatic plants were the most used for therapeutic purposes. Although patients strongly believe in the efficacy of these products, it is essential to ask the question regarding their safety.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-146 RISK MAPPING OF DRUG MANAGEMENT IN A PRISON

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Background and importance In France, since 1994, the responsibility for the health of prisoners has been transferred to the public hospital service.¹ The supply of drugs and stock management are thus organised by the hospital, under the responsibility of a pharmacist. Angoulême prison is attached to the Angoulême hospital centre. The last state of play of medication circuit in prison was carried out in 2006. Twenty-five percent of prisons did not have a pharmacist.² In 2018, Angoulême prison was inspected by the regional health agency. Several dysfunctions concerning drug management were highlighted. No pharmacist and pharmacy technician (PT) were identified to manage the medication circuit, despite the obligation by law.

Aim and objectives The aim of this study was to realise a risk mapping of drug management at the prison in order to implement corrective actions to improve this circuit and meet regulatory requirements.

Material and methods A preliminary risk analysis was chosen to carry out the risk mapping. The working group included a doctor, a pharmacist, a nurse, a PT, a health framework and a manager responsible for risk management.

Results The risk mapping concerned the stages of preparation and delivery of drugs. The initial criticalities of the scenarios were distributed as follows: 46.5% unacceptable (C1), 37.2% tolerable under control (C2) and 16.3% unacceptable (C3). After the implementation of corrective actions, the residual criticalities were distributed as follows: 97.7% C1 criticality and 2.3% C2 criticality. Ten corrective actions were identified by the working group, for example, the computerisation of prescriptions and the over-labelling of non-unit drug blisters.

Conclusion and relevance The preparation step is considered more risky. For the preparation stage 76% of the scenarios were classified as very vulnerable versus 58% for the delivery stage. The realisation of the risk mapping of drug management at prison made it possible to identify the potential dangers. The weekly nominative automated preparation of drugs by the pharmacy represents a major challenge.

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Conflict of interest No conflict of interest

5PSQ-147 A SYSTEMATIC RISK ANALYSIS METHOD APPLIED TO THE MEDICAL DEVICES MANAGEMENT PROCESS IN A HOSPITAL PHARMACY

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Background and importance During the COVID-19 pandemic, the management of medical devices was foreseen by repetitive and unforeseen breaks. To optimise management a risk analysis is necessary.

Aim and objectives The present study aimed to determine risks related to the medical devices management processes in our teaching hospital according to a failure mode and effects analysis (FMEA) method.

Material and methods Skilled health care professionals were recruited to form a multidisciplinary study team (pharmacists, nurses, administrative agent, and pharmacy technician). They proceeded to draft the process cartography. They defined all related failure modes that could occur indicating causes and consequences through brainstorming meetings. These failure modes were classified considering the criticality index (CI) calculated according to the indices: severity of the potential effect, detection probability, and likelihood of occurrence. Prioritisation was carried out considering the mean and the median values of CI as limits. Corrective and preventive actions were then proposed.

Results A total of 44 failures modes were defined accumulating 4176 points of criticality. CI values ranged from 12 to 336. The step of delivery processing exhibited the highest median CI with a value of 120 (min = 63 – max = 144) followed by the ordering step with a median CI value of 80 (min = 27 – max = 144). The highest CI was related to the

failure mode ‘erroneous estimate of need when defining the purchasing framework’ with CI value of 336. Sixteen (36%) failure modes were considered as critical, 6 (14%) as failure modes to control and 22 (50%) as acceptable. After prioritisation, three main axes to act were proposed: architectural reorganisation (by securing premises, organisation of flows, and strengthening of storage capacity), improvement of the medical device management software, and setting up a monitoring system for the conduction of the various purchasing frameworks.

Conclusion and relevance The FMEA method was a consensual tool that permits proposal actions reducing risks related to the medical devices management process. Optimising the prediction of needs, strengthening communication with user services, and securing access are essential to guarantee the availability of medical devices for the ultimate benefit of the patient.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-149 DURVALUMAB FOR THE TREATMENT OF NON-SMALL CELL LUNG CANCER: REAL-WORLD EXPERIENCE

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Background and importance Durvalumab is indicated for the treatment of locally advanced, unresectable non-small cell lung cancer (NSCLC) in adults whose tumours express PD-L1 on $\geq 1\%$ of tumour cells and whose disease has not progressed following platinum-based chemoradiation therapy (QT-RDT).

Aim and objectives To evaluate the effectiveness and safety of durvalumab in NSCLC according to the conditions of use indicated in the data sheet.

Material and methods An observational retrospective study was conducted. We identified all patients with advanced NSCLC treated with durvalumab from September 2018 to September 2021.

Patients’ demographics (sex, age), clinical (diagnosis, stage, Eastern Cooperative Oncology Group (ECOG), PD-L1 expression) and therapy-related data (cycles received, duration of treatment) were analysed. Adverse effects (AE) were recorded from electronic medical records.

Results 23 patients were included (6 women, 17 men) and mean age was 66 years (38–80).

Histology was squamous in 14 patients (60.87%) and adenocarcinoma in 9 (39.13%). Mean time from the end of QT-RDT and the initiation of therapy with durvalumab was 91 (36–146) days. Mean number of cycles received was 18 (4–27).

At the time of analysis 3 patients (13.04%) continued therapy with durvalumab, 8 (34.78%) completed 12 months of therapy and 12 (52.17%) discontinued. Progression was the main reason for discontinuation, specifically in 9/12 patients (75%).

At the end of the study, with an average follow-up of 17 (4–37) months per patient, 5 patients (21.74%) died. None of these patients completed 12 months of durvalumab (1 due to intolerance and 4 due to disease progression).

Neither median progression-free survival nor median overall survival were reached at the data cut-off date.

All patients except 4 presented AEs (83%). The most frequent were asthenia (48%), skin disorders (48%), gastrointestinal disorders (35%), musculoskeletal disorders (22%), cough (22%), respiratory tract infections (17%), hypothyroidism (3%). Others: dizziness, mucosal inflammation, anaemia, paraesthesia, sweats, renal disorders, weight gain, dysgeusia.

Conclusion and relevance 39.13% (9/23) of the patients presented progression of the disease during durvalumab therapy.

Mortality rate during the follow-up period was 21.74%. None of these patients completed 12 months of therapy with durvalumab.

Most AEs were mild, in accordance with those described in the clinical trials. One patient (4.35%) had to discontinue the treatment because of grade IV AE.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-151 OPTIMISATION OF THE SUBCUTANEOUS ADMINISTRATION OF DARATUMUMAB

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Background and importance Daratumumab, now indicated for first-line treatment of multiple myeloma, has been available in a formulation for subcutaneous (SC) injection since April 2021. SC administration must be carried out continuously over 5 min.

However, nurses who work in the hospital day care report musculoskeletal disorders, preventing continuous infusion and thus leading to drug misuse.

The increase of 55% between 2020 (IV) and 2021 (SC) of the preparation volumes of daratumumab for the period from 15 May to 15 September contributes to the challenge of this project.

Aim and objectives Determine an optimal and safe setup for subcutaneous administration.

Material and methods We carried out a market study by contacting hospitals and laboratories and analysing technical data sheets to preselect a general assembly.

We established a working group (2 nurses, 1 pharmacy technician and 2 pharmacists) to evaluate a suitable subcutaneous medical device according to these criteria: diameter and length of canula, dead volume, biocompatibility, cost and supplier, right use, fixation of medical device, practicality of nurses, security of nurses, feasible purging.

Results The use of an electric syringe pump (ESP) is essential for the setup. A 20 ml syringe compatible with ESP is filled with 15 ml daratumumab. A three-way flush valve for the extension tube is attached. A pre-filled syringe of 10 ml NaCl is used for flushing.

Several medical devices have been evaluated: a microperfuser, an infusion kit, an epicranial needle, a hypodermic needle and a secure hypodermic needle.

As a result, the microperfuser met all the selected criteria except for the cost, which is why we chose it.

Finally, the total cost of administration increased from € 1.23 to € 5.53, this means an additional cost of € 7272 for the hospital per year.

Conclusion and relevance This multidisciplinary work has allowed us to choose a subcutaneous administration setup for an anticancer treatment.

Despite the additional cost, this setup combines proper use and safety and will be proposed for evaluation in the hospital day care very soon.

As part of the improvement of the quality of life at work for nurses, occupational medicine is collaborating on this project.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-152 EFFECTIVENESS AND SAFETY OF ERENUMAB IN MIGRAINE PROPHYLAXIS

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Background and importance Migraine is the second most prevalent disease in terms of disability-adjusted life years (DALYs). Erenumab, a novel calcitonin gene-related peptide receptor antagonist, has been developed for migraine prevention.

Aim and objectives To evaluate the effectiveness and safety of erenumab in migraine prophylaxis.

Material and methods Retrospective, observational study in patients treated with erenumab from September 2019 to September 2021. Variables collected: demographic (sex, age), type of migraine, presence of aura, dose, Headache Impact Test-6 (HIT-6), baseline Migraine Disability Assessment Scale (MIDAS), number of previous treatments, migraine days measured in the last 3 months and duration of treatment. Effectiveness was evaluated by a monthly reduction of $\geq 50\%$ in migraine days measured at week 12 from start date. To analyse safety, adverse reactions were measured. Information sources: electronic prescription program ATHOS-Prisma and computerised medical record Diraya.

Results Thirty-seven patients were included, 81.1% women, mean age 43.6 ± 13.0 years. The percentage of patients who suffered from chronic migraine was 72.9% and episodic migraine 21.7% (67.5% had aura). The mean HIT-6 was 68.8 ± 4.1 and MIDAS was 60.1 ± 42.1 , with a median of 42 (IQR 33–60) days of migraine in the last 3 months prior to erenumab. Thirty-two patients (86.5%) started with a 70 mg dose while the rest started with 140 mg. Eighteen patients (48.7%) increased the dose and the median of previous treatments was 5 (IQR 4–7). Patients who achieved clinical response was 31 (83.8%), of whom 80.6% obtained a reduction of $\geq 50\%$ in the frequency of migraines. The median of patients' monitoring was 45 (IQR 24.4–63.3) weeks.

Of six non-responder patients, four of them increased erenumab dose, but only one had positive results. The main adverse effects were: constipation (24.3%), erythema (8%) and nausea and vomiting (2.7%). No patient discontinued treatment due to adverse effects.

Conclusion and relevance Erenumab is an effective and safe alternative in the prophylaxis of migraine refractory to other therapies. More and longer studies are needed to establish the

utility of this drug in clinical practice and their long-term safety.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-153 PERSISTENCE AND REASONS FOR DISCONTINUATION OF TREATMENT WITH APREMILAST IN DERMATOLOGICAL DISEASES

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Background and importance Apremilast is a selective inhibitor of type 4 phosphodiesterase taken orally that is indicated in psoriasis and psoriatic arthritis and whose response should be evaluated at 24 weeks of treatment.

Aim and objectives Evaluating the persistence and causes of treatment discontinuation in patients treated with apremilast in our hospital.

Material and methods We made a retrospective study (May 2017 to September 2021) in which all the patients treated with apremilast for at least 24 weeks were included. Data collected: sex, age, diagnosis, start date, last dispensation date and reason of discontinuation treatment if suspension occurred.

Apremilast's persistence was calculated in weeks by the Kaplan–Meier method. We used SPSS Statistics for analysis, considering a *p* value <0.05.

Results A total of 32 patients were included (24 with psoriasis and 8 with psoriatic arthritis). 50% of them were men (53.4 ± 11.32) years and the 15.62% were treated previously with biological drugs.

The persistence of apremilast was 52.68 weeks (IC 95% 32.85 to 72.44). 71.8% of the patients discontinued treatment during the study period. Discontinuations were mainly due to adverse events (60.8%) and inefficacy (26.1%). Among the adverse events, most were related to digestive system (71.43%), mainly gastrointestinal discomfort (50%) diarrhoea (35.7%), nausea and vomiting (14.3%), followed by depression (21.4%) and headache (7%).

50% of patients discontinued treatment before completing 24 weeks of treatment due to adverse events (75%) or inefficacy (25%). The remainder of the patients achieved at least 24 weeks of treatment, 3 of them (12.5%) stopped treatment before 52 weeks and the remaining 11 patients (34.7% of the total) were treated for more than 52 weeks. 9 patients (28.1%) are continuing treatment to the end of the study, with 7 of them being treated for more than 52 weeks.

Conclusion and relevance There is a high prevalence of adverse events with apremilast and this is the main cause of treatment discontinuation, follow by inefficacy. However, patients who have good tolerance also achieve a high persistence, thus illustrating the need to select patients who may take benefit of apremilast.

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Conflict of interest No conflict of interest

5PSQ-155 HOW IS CHEMOTHERAPY USED AT THE END OF LIFE IN A SECONDARY HOSPITAL?

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Background and importance Many studies have investigated how chemotherapy is used at the end of life but no clear recommendations have been given.

Aim and objectives Analyse treatment aggressiveness and clinical variables of oncohaematologic patients who receive chemotherapy at the end of life.

Material and methods Observational, retrospective study conducted in a secondary hospital during 2020. Inclusion criteria: patients who died in the hospital and were visited by oncologists or haematologists. Variables: demographic, prescription department, diagnosis and stages, last treatment received, administration via, date and performance status on the latest administration and time since the last administration until the patient died. Performance status was measured by the Eastern Cooperative Oncology Group (ECOG) scale. An aggressive treatment was one administrated 14 days before death. Data were collected from electronic health record.

Results Eighty-nine patients were included (64% men, median 71 (IQR 64–78) years). 82 patients were visited by the Oncology Department and 7 by the Haematology Department. Lung cancer (35%) was the most common diagnosis, followed by colorectal cancer (11%) and pancreatic cancer (8%). Other tumours were found in lower percentages. 86.5% of patients were diagnosed with advanced cancer. 71 patients received active treatment (50 intravenous, 13 oral, 3 oral + intravenous and 5 radiotherapy). The most common treatment was chemotherapy (70.4%), followed by immunotherapy (8.5%), radiotherapy (7%) and hormonotherapy (4.2%).

During the last administration 80%–90% of patients had ECOG 1–2 and 19.1% ECOG 3–4. Median days since the last administration until death was 44 (IQR 16–156) days. 19.1% of patients received treatment 14 days before death, 8% a month before death, 21.3% 2 months before death, 5.6% 3 months before death, 25.8% more than 3 months before death and 20.2% did not receive active treatment.

Conclusion and relevance The number of patients who received aggressive treatment was slightly higher than data published in other studies such as Earle *et al* (2003). Most of the patients belonged to the Oncology Department and had ECOG 1–2, advanced lung cancer being the most common diagnosis and chemotherapy the most common treatment. The main limitation of the study was the non-inclusion of patients who died outside the hospital. It would be interesting to continue this line of investigation.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-156 REASONS FOR SECUKINUMAB TREATMENT DISCONTINUATION

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Background and importance Secukinumab is an immunoglobulin G1 monoclonal antibody that selectively binds to interleukin 17A and inhibits its interaction with the IL-17 receptor. It is indicated in psoriasis (Ps), psoriatic arthritis (PsA) and ankylosing spondylitis in patients who do not respond adequately to conventional treatments.

Aim and objectives The aim of this study was to analyse the causes of secukinumab's treatment discontinuation.

Material and methods A retrospective study was performed in which all patients treated with secukinumab (between 2017 and 2021) were included. Data collected: sex, age, diagnostic, previous biological treatment, start date, date of the last dispensation, date of discontinuation treatment if suspension was occurred and reason for it. We used Excel to analyse the data.

Results A total of 64 patients were included (23 diagnosed with psoriasis, 24 with psoriatic arthritis and 17 with ankylosing spondylitis). 56.3%, were women, with a median age of 54 (IQR 42–60) years. 26.5% of patients used secukinumab as the first biological drug, with a median of two previous biological drugs. The global persistence of secukinumab was 27.3 (95% CI 21.7 to 32.9) months. A total of 37 patients (57.8%) discontinued treatment with secukinumab for different reasons. Primary failure was the main cause (43.2%), followed by adverse events (27.0%) and secondary failure (24.3%). The media persistence of patients who suffered a primary failure was 5.1 months versus 21.7 months for a secondary failure. Diarrhoea represented the most prevalent of the adverse events (44%), followed by infections (33%) and other causes like asthenia, fever or cefalea. Other reasons for discontinuation were other illness (5.4%), remission (2.7%) and unknown causes (2.7%).

Conclusion and relevance Secukinumab showed a moderate percentage of treatment interruption, the main cause being primary failure, followed by adverse events, with diarrhoea being the most common among them. However, patients with secondary failure or who go on treatment achieve a high persistence.

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Conflict of interest No conflict of interest

5PSQ-157 SEVERE NEUROTOXICITY OF ORAL IVERMECTIN: A SYSTEMATIC REVIEW OF CASE AND CASE SERIES REPORTS

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Background and importance Ivermectin is a broad-spectrum antiparasitic. It was tested to treat COVID-19 but no benefit

was found through large studies. Severe encephalopathy occurrence is known in patients treated with ivermectin and coinfecting by a large number of *Loa loa* microfilariae but there is a growing concern due to severe encephalopathy reports in other contexts.

Aim and objectives Assess the evidence about severe neurological toxicity cases after ivermectin use.

Material and methods Following the PRISMA recommendations for systematic reviews, a search combining terms associated with 'ivermectin' and 'drug toxicity' was conducted using the MEDLINE and LILACS databases for all relevant English- and Spanish-language articles from inception through 30 September 2021. Cases and case-control reports were included. We excluded articles not mentioning at least minimal information on 'ivermectin' or 'neurotoxicity' in a first screening phase. In a subsequent selection phase, articles were excluded if they reported data on paediatric or pregnant patients, intoxications, non-oral route administration or animal data. The outcome of interest was cases of severe neurotoxicity (SN) in adult/adolescent patients (>11 years) treated with ivermectin. Data were synthesised narratively.

Results 266 articles were assessed and 17 met the inclusion criteria. 6 cases and 11 cases series reports in patients treated for strongyloidiasis, onchocerciasis, loiasis and scabies infections reported SN occurrence such as consciousness disorders, seizure or convulsion, encephalopathy and coma. SN not only was associated with Onchocerciasis treatment in *Loa loa* coinfecting patients. *Chandler RE* reported 28 SN cases after ivermectin use outside the Onchocerciasis indication and *Nzolo D et al* reported cases of SN even with low blood levels of *Loa loa* microfilaria. 2 studies associated SN with the presence of ABCB1 mutation. *Baudou E et al* reported the case of patient with two human ABCB1 mutations who suffered SN and *Bourguinat C et al* showed homozygotic haplotypes associated with alterations in drug disposition in 2 cases.

Conclusion and relevance Although SN has traditionally been reported after extensive *Loa loa* infections this occurs in other contexts. SN after ivermectin use must be detected early to avoid fatal consequences. Authors related this toxicity with human ABCB1 nonsense mutations that allow ivermectin penetration into the central nervous system. This could be a future field of research.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-158 FOOD AND DRINK MANAGEMENT AS PART OF MEDICATION ADMINISTRATION SAFETY

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Background and importance Wrong timing or composition of food or drink with drug administration could have a significant impact on a drug's therapeutic value or safety. To provide better overall quality provided by health care professionals at the hospital this area should also be improved.

Aim and objectives This project formed part of a larger study focused on medication administration safety in hospital wards. Project goals consisted of identifying risk areas of nurse

medication administration. Analysis of the reality will serve as a base to develop suggestions leading to preventive and corrective actions with consequences for the quality of nursing care provided.

One of the risk areas of nursing care is timing drug administration with food as well as food and drink composition. The partial goal was to explore this reality and identify sub-optimal and potentially hazardous practices.

Material and methods The research was implemented in four selected cooperating hospitals, specifically in three of their wards – surgical, internal, and follow-up wards in the form of a prospective, multicentric, observation–intervention study. In the first part of this study, all nurses administering medications to all patients hospitalised in each of the above-stated wards during the observation period (morning, noon, evening) were observed by a team of unshadowed external investigators (pharmacist and nurse) for three consecutive days. Data were recorded onto a pre-prepared recording sheet and subsequently typed into a web database.

Results During this study, 58 nurses administering 5330 solid oral drugs for 313 patients over 36 days were observed. We discovered that the timing of the food was suboptimal and potentially severe in 18.1% and 2.4% of cases, respectively. In order to ingest a drug, tea was used in 63% of cases, still water in 22% of cases and coffee with milk in nearly 5.8% of cases. Potentially significant drink–drug interactions were identified in nearly 1.5% of cases.

Conclusion and relevance We found that little or no attention was paid to appropriate food, drink and drug management on the wards. These primary data will be used for interventions in this study and as the base for further research.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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Section 6: Education and research

6ER-001 CAN PHARMACISTS IMPROVE THEIR PATIENT COMMUNICATION BY READING FICTION? NARRATIVE MEDICINE IN PHARMACY PRACTICE – A FEASIBILITY STUDY

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Background and importance Empathy is an essential part of good patient communication. However, pharmacists often provide information without taking patients' preferences into account. Narrative medicine is an innovative approach, where empathic skills are nurtured through close reading of literary texts and creative writing.

Aim and objectives The purpose was to investigate the feasibility of a narrative medicine course for pharmacists and to explore the experiences of the participating pharmacists.

Material and methods A 2-day course of narrative medicine was offered to Danish community and hospital pharmacists in

Summer 2020. The course capacity was set at 16 pharmacists. The course consisted of close reading of short literary texts about illness and related creative writing, facilitated by both experienced literary and health care professional lecturers. Pharmacists' empathy was assessed before and after participating in the course with the Jefferson Scale of Empathy (JSE). Feasibility was assessed focusing on acceptability, demand, implementation, practicality and limited efficacy using focus group interviews, participant observation and a satisfaction questionnaire.

Results In total, 8 pharmacists participated in the course. All pharmacists answered the questionnaire, and 5 focus group interviews were held with participants and lecturers. The practicality of the course can be optimised, as only half of the course capacity was filled. This could, however, be due to the situation with the COVID-19 pandemic, as the workload at the pharmacies was unpredictable in that period. The pharmacists accepted participation in the course, even though some of the sessions required a personal investment far from their normal routines and education. The pharmacists were, in general, very satisfied with the course and found it useful in their daily patient communication as it helped them to envision the life of each patient. As expected, no significant change was found in the JSE, but the pharmacists found the scale acceptable to complete.

Conclusion and relevance The course in narrative medicine was feasible on all assessed parameters, even though the course capacity was not fully utilised. A course in narrative medicine has potential for improving pharmacists' general communication with patients. Yet, the results should be tested in larger studies, including patient-reported outcomes, to provide distinct evidence on eventual effect.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

6ER-002 APPLYING REFLECTIVE MULTICRITERIA DECISION ANALYSIS TO UNDERSTAND THE VALUE OF THERAPEUTIC ALTERNATIVES IN THE MANAGEMENT OF ANAEMIA IN GYNAECOLOGIC SURGERY

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Background and importance Iron deficiency anaemia is the most prevalent nutritional deficiency, affecting 29% of women. It is common in patients undergoing elective gynaecological surgeries (18.1%) and up to 90% postsurgery, increasing the risk of negative outcomes and need for transfusions. Oral iron, especially ferrous sulphate (FS), is used as the most common treatment and intravenous iron is solely used in severe cases. Ferric carboxymaltose (FCM) has demonstrated clinical benefits above FS but it is not widely used due mostly to its high cost.

Aim and objectives Our objective was to assess the value of FCM versus FS for anaemia in patients undergoing benign gynaecologic surgery in our country. We followed a multicriteria decision analysis (MCDA) by using the EVIDEM framework that allows the incorporation of multiple stakeholders, including patients.

Material and methods The framework was adapted considering evidence retrieved with a PICO-S-T search strategy and grey literature. Criteria/subcriteria were weighted by relevance and an evidence-based decision-making exercise was developed to assign a score from -5 (in favour of FS) to +5 (FCM) to each alternative for each criterion. Weights and scores were multiplied to obtain the value of intervention relative to each criterion/subcriterion. Values were added to calculate the Modulated Relative Benefit-Risk Balance (MRBRB) on a -1 (FS) to +1(FCM) scale. Ten stakeholders (gynaecology/obstetrics, haematology, anaesthesiology, midwifery, hospital pharmacy, hospital management, and patients and patients' representatives) participated to collect different perspectives.

Results Weights were different among profiles: Compared Efficacy/Effectiveness (28% on average, 26.7% for hospital pharmacists (HP)) was the most relevant criterion. Compared Safety/Tolerability (18%, 24%) showed the greatest difference among all participants and HP. In general, participants were in favour of FCM in all criteria, as were HP, except for Economic Consequences (+1, -2.82). Lastly, the value of each criterion was calculated. The criterion with the highest impact was Compared Efficacy/Effectiveness (+0.178, +0.15). All profiles were in favour of FCM except Hospital Management. General MRBRB was +0.48; for HP, MRBRB was +0.34.

Conclusion and relevance From global and HP perspectives, FCM was the preferred alternative for treating anaemia in patients undergoing benign gynaecological surgery. MCDA can be a useful tool to incorporate diverse voices in the decision-making process, including professionals as well as patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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6ER-005 REDUCING INVASIVE DEVICE-RELATED BLOODSTREAM INFECTIONS: A CHALLENGE FOR THE PREVENTION OF HEALTHCARE-ASSOCIATED INFECTIONS

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Background and importance An infection is healthcare-associated (HCA) if it occurs during the care of a patient. Nosocomial infections (NI) are infections acquired in a healthcare setting. Bloodstream infections are the fourth most common NI in France and half the cases are associated with a vascular catheter. Reducing invasive device-related bloodstream infections is a major priority of the national programme: prevention of HCA infections.

Aim and objectives In our hospital we noticed an increase in healthcare-associated bloodstream infections (HCA-BSI) including those related to invasive devices. The objective of the study was to describe HCA-BSI acquired in our establishment

in order to reduce the number of infections related to invasive devices by promoting their correct use.

Material and methods We applied the methodology of the French network SPIADI to compare our results with those of the other hospitals monitored. Each positive blood culture corresponding to a HCA infection was analysed to define the portal-of-entry of the infection. For HCA-BSI related to invasive devices, data on vascular and urinary catheters were collected. The study was carried out between January and April 2020. The intensive care, paediatrics, nephrology, haemodialysis and surgery services were excluded (no electronic medical records).

Results We included 156 patients with HCA-BSI: 60% were aged over 65 years and 66% were immunosuppressed. HCA-BSIs (n=164) were most frequently identified in oncology (21%) and in haematology (17%). Urinary infection (44/164; 27%) and presence of a catheter (40/164; 24%) were mainly associated with HCA-BSI. *Enterobacteriaceae* were mostly responsible for HCA-BSI with a urinary portal-of-entry and staphylococci for central line-associated bloodstream infections (CLABSI). Implantable port catheters (IPC) were the most frequent cause of CLABSI (25/40; 62.5%). The incidence of HCA-BSI was comparable to that of other institutions, except for oncology, where it was higher (8.37 vs 3.65 per 1000 hospital days), and this was particularly the case for IPC (2.87 vs 0.96 per 1000 hospital days).

Conclusion and relevance In the light of these results, we implemented a strategy involving the reporting of surveillance data, the updating of protocols with professionals, practice observations, and the training of professionals in charge of handling invasive devices. The impact of all these measures will be assessed through the results of future monitoring.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

6ER-007 REAL-WORLD EFFECTIVENESS OF GENE THERAPY ONASEMNOGENE ABEPARVOVEC (ZOLGENSMA) FOR SPINAL MUSCULAR ATROPHY: A REVIEW

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Background and importance Spinal muscular atrophy (SMA) is an autosomal recessive neurodegenerative disorder. SMA I infants have a lifespan of <2 years if not treated. Zolgensma is an innovative drug of gene therapy strategy for SMA patients. Notwithstanding, there remains considerable uncertainty about the long-term sustainability of the Zolgensma clinical effect due to the narrow durability and limited sample size of clinical trials. Therefore, it is essential to measure its effectiveness to increase confidence in the technology use and its market access.

Aim and objectives Our study aimed to provide a critical review of the literature regarding the clinical outcomes in SMA infants in the real-world setting after the one-time Zolgensma dosing.

Material and methods A review of the literature was constructed, comprising five phases: (a) identifying the research question; (b) searching for relevant studies; (c) selecting

studies; (d) analysing data and (e) presenting the results. A comprehensive English-language literature search of the electronic databases PubMed and Science Direct was undertaken to identify published papers. Data were collected and analysed until May 2021.

Results In this review, we incorporated one retrospective and one prospective cohort study. In the ongoing prospective Long-Term Follow-Up (LTFU) study (13 patients), 100% of SMA I infants in the therapeutic-dose cohort were alive and free of permanent ventilation. It was reported that 20% of SMA I infants achieved the additional milestone of standing with assistance. The LTFU study has demonstrated that SMA I infants improved their Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND) scores (≥ 4 points). In the retrospective cohort study of SMA I (3 patients) and SMA II infants (4 patients), it was perceived that 43% of SMA patients had meaningful increases in the CHOP-INTEND score and 57% had increases in the Hamersmith Functional Motor Scale-Expanded (HFMSE) score.

Conclusion and relevance Despite the limited observation period, we conclude that Zolgensma is effective since no clinical regression or waning of effect had been reported. Nonetheless, several factors might still influence the duration of Zolgensma's effectiveness. As such, further research is needed to evaluate the persistence of the Zolgensma real-world effect in SMA infants.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

6ER-008 DEVELOPMENT OF A RISK-SHARING MODEL BASED ON THE CLINICAL PERFORMANCE OF ONASEMNOGENE ABEPARVOVEC (ZOLGENSMA)

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Background and importance Zolgensma is an innovative gene therapy for spinal muscular atrophy (SMA) infants. Nevertheless, the life-long clinical follow-up needed for understanding the long-term effectiveness of Zolgensma in combination with an exceptionally large single payment represents scientific and financial challenges for the pharmaceutical industry, regulators and payers. The so-called Performance-Based Risk-Sharing Arrangements-Performance Linked Reimbursement (PBRSA-PLR) are financial models that have been developed for reducing uncertainty through greater investment in evidence collection, while a technology is used within a healthcare system.

Aim and objectives The scope of this investigation comprised the development of a hypothetical PBRSA-PLR for Zolgensma Gene Replacement Therapy (GRT).

Material and methods A review of the literature was constructed, comprising five phases: (a) identifying the research question; (b) searching for relevant studies; (c) selecting studies; (d) analysing data and (e) presenting the results. A comprehensive English-language literature search of the electronic databases PubMed and Science Direct was undertaken to identify published papers. Data were collected and analysed until May 2021.

Results We propose an outcome-based scheme based on Zolgensma performance in terms of sustainability of the clinical effect. The relevant outcomes should be the subsequent for a given SMA infant: (a) overall survival and (b) event-free survival. We further suggest an annuity-based payment scheme to reduce the consequences of the annual budget impact with a pay-over-time of 5 to 15 years to increase patient access. More favourable outcomes could be achieved if SMA infants started treatment earlier. Thus, we propose a maximum 50% refund for Zolgensma early dosing in SMA infants (until 3 months old), and a maximum 25% refund for Zolgensma late dosing in SMA patients (after 3 months until 9 months old), if Zolgensma fails to meet the agreed-upon outcomes and pre-defined timing of outcome assessments.

Conclusion and relevance We conclude that it would be possible to mitigate uncertainty around the incremental budgetary impact and cost-effectiveness of Zolgensma GRT. Nonetheless, it should be outlined that innovative payment schemes should only be applied in circumstances where there is scope for such mechanisms to effectively reduce decision uncertainty so that the probability of long-term cost-effectiveness can be improved.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

6ER-011 COTRIMOXAZOLE: HOW FOLATE SUPPLEMENTATION COULD AFFECT TREATMENT EFFICACY

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Background and importance Cotrimoxazole (CTX) is an association of sulfamethoxazole and trimethoprim which acts synergistically to inhibit folic acid synthesis and block bacterial growth. It is used in the treatment of bacterial infections and in the prophylaxis of opportunistic diseases like toxoplasmosis and infection with *Pneumocystis jirovecii* in immunosuppressed patients. CTX causes myelotoxicity since it affects the same process in human cells. To prevent toxicity, folic or folinic acid can be administered. However, there is controversy as to whether this folate supplementation could affect the efficacy of cotrimoxazole.

Aim and objectives To determine if the co-administration of CTX and folates compromises efficacy of the treatment.

Material and methods A review of the published evidence on CTX and folate supplementation was conducted. An initial search was performed in PubMed and Google Scholar using the terms 'cotrimoxazole' and 'folates' and 'efficacy' supported by federal data sheets.

Results Regarding the use of folates as a supplement in bacterial infections, there is no evidence at all. Theoretically, as these bacteria intrinsically lack mechanisms to capture exogenous folates, it seems to be more appropriate to use folic acid before folinic acid due to its lipophilicity avoiding a possible passage of this molecule through the bacterial wall, which is lipophilic in nature. *P. jirovecii* is permeable to lipophilic folates and lacks an active transport mechanism to incorporate classical folates. Therefore, the administration of folinic acid, which is more lipophilic, could reduce the anti-folate activity of CTX meanwhile folic acid supplements do

not affect the activity of CTX. In the case of *Toxoplasma gondii*, the folate of choice is folic acid because the micro-organism can intake exogenous folate through the BT1 family transmembrane proteins which also have no affinity for folic acid.

Conclusion and relevance In general, theoretically folic acid supplementation can be used to prevent myelotoxicity as it does not interfere with the action of the antibiotic in the case of bacteria. However, in infections caused by more complex eukaryotic organisms such as other fungi or parasites with lipophilic cell walls or specific transmembrane proteins, each case must be evaluated on its own merits.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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6ER-012 EFFECTIVENESS OF IL-23 INHIBITORS IN PATIENTS WITH MODERATE-SEVERE CHRONIC PLAQUE PSORIASIS

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Background and importance Inhibitors of interleukin-23 (IL-23 inhibitors) have emerged as safe and effective options for the treatment of moderate-to-severe plaque psoriasis. These drugs are contributing to a rising standard for psoriasis outcomes through resolution of skin lesions and joint manifestations and improvement of patient quality of life

Aim and objectives To evaluate the effectiveness of IL-23 inhibitors in patients with moderate-severe chronic plaque psoriasis

Material and methods This was an observational study including patients with moderate-to-severe psoriasis who were treated for at least 36 weeks with IL-23 inhibitors. Data collected, obtained from digital clinical history, were: demographic characteristics and previous biological therapies. The severity of plaque psoriasis was assessed by the Psoriasis Area Severity (PASI). Efficacy was evaluated by estimating the proportion of patients achieving PASI 75, PASI 90 and PASI 100 responses at weeks 16, 24 and 36. Student's t-test for paired samples was used to determine the significant difference in outcome of patients between PASI at baseline and PASI response at weeks 16, 24 and 36. Data were analysed using IBM SPSS Statistics v.19.0

Results A total of 35 patients were included, 21 women (60%), mean age 50.6±13.8 years. IL-23 inhibitors used were: guselkumab (n=26, 74%) and risankizumab (n=9, 26%). All patients had chronic plaque psoriasis. Most of them had previously been treated with a biologic agent (n=33, 94%). 5 patients (14%) discontinued the anti-IL23 therapy due to inefficiency. Mean PASI at baseline was 10.1±5. IL-23 inhibitors decreased mean PASI from baseline to 3±3.3 (p=0.003), 2±3.8 (p=0.001), 1.3±2.9 (p=0.001) at 16, 24 and 36 weeks, respectively. At 16 weeks, PASI 75, 90 and 100 response was achieved in 50%, 31.8% and 22.7% of patients; at 24 weeks, PASI 75, 90 and 100 response was achieved in 86.4%, 54.5% and 40.9%, whereas at 36 weeks, PASI 75, 90 and 100 response was achieved in 100%, 77.3% and 72.7% of patients, respectively.

Conclusion and relevance IL-23 inhibitors show great results in the management of moderate-to-severe psoriasis in adults. Results of this real-life study are consistent with the pivotal trials.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

6ER-014 ANALYSIS OF THE EVOLUTION OF INTERLEUKIN-6 IN COVID-19 PATIENTS AFTER BEING TREATED WITH DEXAMETHASONE

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Background and importance Levels of interleukin-6 (IL-6) in patients with coronavirus disease 2019 (COVID-19) are particularly relevant before treatment with tocilizumab. According to the protocol established in our centre, levels of IL-6 above 40 pg/mL are required to start treatment with tocilizumab. Assessing the role of dexamethasone in the evolution of IL-6 during the first hours of the patient's hospital admission could help prevent premature use of tocilizumab.

Aim and objectives Assessing the evolution of IL-6 after the use of dexamethasone in patients diagnosed with COVID-19 and IL-6 >40 pg/mL.

Material and methods Descriptive, retrospective, observational study carried out between November 2020 and January 2021 in a second-level hospital. All patients with determinations of IL-6 were located. Those with IL-6 levels above 40 pg/mL were selected. Through a review of medical histories, COVID-19 patients who were treated with dexamethasone and with determination of IL-6 levels, both at the admission and within the following 96 hours, were chosen. Exclusion criteria: prescription of dexamethasone at least 24 hours before the first determination and use of tocilizumab before the first determination or between determinations. Data were subjected to Wilcoxon's test.

Results 41 patients met the criteria. 28 of them were men (66.7%) with a median age of 64 years (IQR 23). The median time between determinations was 48 hours (IQR 48). The median level of IL-6 at the time of the hospital admission was 85.6 pg/mL (IQR 110.9) and after being treated with dexamethasone it was 24.2 pg/mL (IQR 33.1). The median of differences was -66.1 pg/mL (IQR 67.3) and 87.8% of the patients experienced a decrease, observing a statistical association (p<0.01). 75.6% of the patients showed levels below 40 pg/mL and 21.9% showed levels within the reference range (<7 pg/mL). 12 patients (29.3%) were finally treated with tocilizumab, of which 7 (58.3%) still presented levels of IL-6 >40 pg/mL.

Conclusion and relevance Dexamethasone treatment reduced IL-6 levels to below 40 pg/mL in most patients in 48 hours.

IL-6 monitoring after dexamethasone treatment could help prevent inadequate use of tocilizumab.

It is necessary to research the benefits of tocilizumab for patients with low levels of IL-6.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

6ER-017

PREVENTION OF EXTRAVASATION BY THE LOCAL APPLICATION OF HYBRID AEROGEL MICROPARTICLES AS DRUG DELIVERY SYSTEMS FOR CERVICAL CANCER CHEMOTHERAPY

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Background and importance One of the most common cancers unique to women is cervical carcinoma which is caused by the human papillomavirus. Cisplatin is primarily indicated in the chemotherapeutic treatment of this cancer type, administered intravenously either as monotherapy or in combination with other antineoplastic agents. Due to lack of target tissue specificity and high drug toxicity, there are several side effects to the application of the drug. Furthermore, being given intravenously, several cases of extravasation have been reported, causing mild to severe degree of tissue damage. Silica–gelatin hybrid aerogels have been shown to be biodegradable and biocompatible with tissue cells and are promising platforms for local and non-invasive drug delivery.

Aim and objectives Our aim is to improve the chemotherapeutic approach by developing a model that locally delivers cisplatin to the cervix by using mucoadhesive aerogel microparticles which are further incorporated into suppositories and inserted intravaginally for subsequent release of cisplatin in a modified, controlled-release manner, thereby reducing toxic doses and extravasation caused by IV administration.

Material and methods The drug carrier vehicle was developed using the sol-gel method, including functionalisation with cisplatin and supercritical drying. In vitro cytotoxicity studies were carried out against HeLa cells and analysed via MTT assay.

Results The resulting vehicles are mesoporous containing 10–15 mg/g cisplatin in coordination bonds. The drug is predicted to be released on a pH responsive profile. Pristine particles showed 100% cell viability while cytotoxicity results showed that 1 mg/mL of the functionalised vehicle had the same anti-proliferative effect as 0.5 µg/mL free cisplatin.

Conclusion and relevance The aerogel microparticles are biocompatible with tissue models and appear safe for administration. Drug loading into these particles is expected to reduce the dosing of free cisplatin, hence reducing toxicity as well as being cost-beneficial. Extravasation could be prevented by this therapeutic approach and patients could self-administer them when formulated in suppositories, thereby reducing the number of inpatients in hospitals.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

6ER-018

USE OF ELTROMBOPAG IN ROUTINE CLINICAL PRACTICE

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Background and importance To investigate the use of eltrombopag in our centre and its suitability in routine clinical practice.

Aim and objectives To evaluate the use of eltrombopag in routine clinical practice and its compliance with the Summary of Product Characteristics (SmPC).

To measure the efficacy according to platelet count response and the need for other concomitant treatments.

Material and methods Observational, retrospective and descriptive study of adult patients who received treatment with eltrombopag from June 2020 to October 2021.

The following variables were collected from the electronic medical record: demographic data, indication for use, initial dose, platelet count and concomitant treatments related to hemostasis.

Efficacy was established according to platelet counts at 3 and 3 months after initiation of treatment, aiming for values between 50 000 and 150 000 platelets/µL.

Results Thirty-five patients (54% women), median age 68 (26–95) years, were included in the study. It was used on-label in 77% (27) of patients: primary immune thrombocytopenia (n=26) and severe aplastic anaemia (n=1). The uses off-label were: recovery of normal platelet counts in patients with oncohaematological diseases 11% (4), patients with hereditary bleeding disorders 6% (2) and due to secondary thrombopenias 6% (2).

60% (21) patients started with doses of 50 mg per day as indicated by the SmPC, 29% (10) started with a 25 mg daily regimen, 9% (3) with a dosage of less than 25 mg per day and 1 patient with 75 mg per day.

The mean platelet count at the start of treatment was 41 710 platelets/µL. Three months afterwards it was 113 910 platelets/µL; 10 patients had values above 150 000 platelets/µL, 6 had values below 50 000 platelets/µL and 6 discontinued treatment. After 6 months the mean was 97 090 platelets/µL; 7 had values higher than 150 000 platelets/µL, 6 had values lower than 50000 platelets/µL; 3 patients who had discontinued eltrombopag restarted it and two more discontinued it.

In 54% (19) of the patients, eltrombopag was started after cycles of corticosteroids, which were progressively withdrawn. 20% (11) required other adjuvant treatment after starting eltrombopag: prednisone (6), immunoglobulins (2), cyclosporine (2) or rituximab (1).

Conclusion and relevance Eltrombopag was used on-label in most patients and a high percentage started with the recommended dose according to the SmPC.

The evolution of the platelet count shows the efficacy of eltrombopag, with a minority of patients having platelet counts below 50 000 platelets/µL and only 11 patients requiring adjuvant treatment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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6ER-019 DETERMINATION OF DOXORUBICIN FROM THE EFFLUATE OF CELLS USING THE DRUGLOG SYSTEM

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Background and importance We have previously quantified and identified the content of doxorubicin both as a pharmaceutical and laboratory substance dissolved in complemented fluorobrite (chromophorous food media). In the present study we attempted to measure the same preparations in the effluate of cultured cell lines using the DrugLog device (Pharmacolog AB Sweden) as part of our quality assurance process.

Aim and objectives Demonstration of the suitability of this method to determine the concentration of doxorubicin in the above-specified preparation in a qualitative and quantitative manner.

Material and methods Triple-negative breast cancer cell lines MDA-MB-231 were cultured with a density of 1×10^5 cells/mL in Dulbecco's Modified Eagle Medium with 10% fetal bovine serum. Doxorubicin-complemented fluorobrite was used as culture media. After quantitative determination of the fluorobrite concentration with the Druglog, doxorubicin (as a second chromophore in our solutions) was added. For this purpose either Adrimedac (liquid form of doxorubicin, Doxorubicin Aurobindo (powder form) or Doxorubicin Sigma Aldrich (laboratory substance in powder form) in complemented fluorobrite was used. After calibration, concentration of the respective solutions was measured.

Results The three different preparations have shown the following results:

Adrimedac: relative deviation after day 1: 3.3% (n=18), day 2: 16.46% (18);

Doxorubicin Aurobindo: day 1: 1.84% (18); day 2: 8.89% (18);

Doxorubicin Sigma Aldrich: day 1: 22.4% (18); day 2: 32.6% (18).

According to our observation, the deviations were surprisingly large and the drug concentrations in all solutions were lower than expected, compared to the concentrations of doxorubicin in the preparations without cells. The preparations with the laboratory substance were the most rapidly degraded.

Conclusion and relevance From our results it can be concluded that the Druglog is suitable to provide reproducible quantitative measurements of doxorubicin concentrations from the effluate of cell preparations without further filtration of the solutions. In future experiments we will compare these results using a different method, in order to explain the difference in the deviations of doxorubicin in the solutions between the pharmaceutical and the laboratory grade of doxorubicin. This method can be used for further research of cytostatics preparations in hospital pharmacies.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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6ER-020 THE OCCURRENCE OF FLUID OVERLOAD IN CRITICALLY ILL PATIENTS: IS THERE A NEED FOR FLUID STEWARDSHIP?

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Background and importance Fluid infusion represents one of the cornerstones of intensive care unit (ICU) therapies. However, ICU-acquired fluid overload (FO) because of excessive fluid administration is common and is linked to worse long-term effects. Therefore, many groups conclude that fluid stewardship is needed to reduce unnecessary fluid administration in a timely manner and improve patient outcomes. In practice, however, maintaining a neutral fluid balance in a critically ill patient remains challenging, even after daily fluid balance monitoring. Data on fluid prescription and FO occurrence in our population is lacking. Likewise, the effect of even moderate FO on a patient's clinical state has been poorly described.

Aim and objectives In this study we quantified retrospectively the occurrence of moderate and severe FO during the first 5 days of ICU admission. In addition, we studied the effect of FO on mortality and mean SOFA (Sequential Organ Failure Assessment) score.

Material and methods Adult patients admitted to the ICU within the period 1 September 2019–18 March 2020 were included. FO was calculated as follows: $[\Sigma \text{daily (fluid intake (L)} - \text{total output (L))} / \text{baseline bodyweight (kg)}] \times 100$. Cut-off values of 5% and 10% defined moderate and severe FO, respectively. Univariate analysis was performed with a Chi-square test and Student's t-test. A multivariate regression model was used to adjust the association between FO and the outcome variables mean SOFA score and 28-day mortality for confounding factors.

Results FO occurred in 30.6% of the patients, which were mostly surgical patients. Moderate FO occurred more frequently in comparison to severe FO (27.1% vs 6.9%). In multivariate regression analysis FO was associated with a higher mean SOFA score (2.48; 95% CI 1.76 to 3.20; $p \leq 0.001$). Lastly, multivariate analysis revealed no association between FO and 28-day mortality (OR 1.19; 95% CI 0.59 to 2.41; $p = 0.625$).

Conclusion and relevance FO occurred in 30.6% of patients during the first 5 days of ICU admission. In most patients the FO was moderate and occurred after surgery. FO was associated with a higher mean SOFA score. No association was found between FO and 28-day mortality. A pharmacist-guided fluid stewardship protocol, focused on surgical ICU patients, would be a good start to improve these patients' outcomes.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

6ER-021 EVALUATION OF COVID MORTALITY DURING HOSPITAL ADMISSION IN PATIENTS RECEIVING ONCOLOGICAL TREATMENT

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Background and importance COVID-19 mortality changes depending on patients' characteristics. The literature describes similar mortality in general COVID-19 patients and those receiving cancer therapies. However, cancer treatments represent a heterogeneous group.

Aim and objectives To evaluate how different cancer treatments can affect COVID-19 mortality in patients requiring hospital admission.

Material and methods Retrospective observational analysis conducted from March 2020 to February 2021 in a tertiary hospital.

Bio-demographic data (sex, age) and clinical data (type of cancer, ECOG, comorbidities) were obtained from the hospital records.

All adult oncological patients admitted for COVID-19, who had received anticancer drugs at least 6 weeks prior to hospital admission, were included.

Patients were classified according to type of treatment: chemotherapy, immunotherapy, hormonal therapies, or targeted-treatment.

Results Of 5633 cancer patients treated at our centre, 108 (1.9%) met the inclusion criteria and were included.

59 (54.6%) were men, median age 64 (21–96) years, 50 (46.3%) had ECOG 0 or 1.

Treatment received: chemotherapy (62, 57.4%), immunotherapy (32, 29.5%), targeted-therapy (23, 21.2%), hormone therapy (3, 2.7%) or another antineoplastic agent (6, 5.55%). The most frequent comorbidities were: hypertension (50, 46.3%), dyslipidaemia (33, 30.6%) and diabetes (24, 22.2%).

Half of the patients with lymphoid neoplasms (22, 20.3%) received chemotherapy (13; 59.1%) or immunotherapy (11; 50%).

Of 20 (18.5%) patients with gastrointestinal, 13 (12.0%) with lung and 12 (11.1%) with head and neck cancer, respectively, 14 (70%), 9 (69.2%) and 10 (83.3%) had received chemotherapy.

Mortality rate for all patients admitted to hospital with moderate-severe COVID was 10.4%, while patients included in our study had a higher mortality (n=38; 35.1%).

Higher mortality was associated with immunotherapy (40.6%) and targeted-therapy (43.4%). Chemotherapy was less related with mortality (28.5%). Anti-CD20 was the mechanism of action most related with mortality (n=10; mortality: 60%).

Conclusion and relevance Although some evidence suggests that recent exposure to systemic anticancer therapy does not increase COVID-19 mortality, our results show that in a subgroup of moderate-severe hospitalised patients, cancer treatment does increase COVID-19 mortality.

Immunotherapy and targeted-therapy could be more related to higher mortality rates than chemotherapy. Specifically, anti-CD20 have significantly higher mortality than other drugs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

6ER-022 PHARMACOLOGICAL FACTORS RELATED TO HOSPITAL ADMISSIONS IN POLYMEDICATED ELDERLY PATIENTS

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Background and importance Poly medication is common nowadays due to an increasing aged population as well as chronic conditions. Medicines are associated with enormous health benefits but also with the potential to cause illness and death. Conversely, prescribed drugs can give a general idea of patients' health status and their conditions.

Aim and objectives The objective of this study was to investigate if there are pharmacological factors related to hospital admissions in polymedicated elderly patients (PEP).

Material and methods An observational retrospective case-control study in a hospital influence area of 450 000 inhabitants was done. PEP (those patients taking 15 or more drugs and aged over 65 years) during November 2019 were selected. Cases were those patients who were admitted to the hospital during 2020 (SARS-CoV-2-infected patients were excluded) and controls those who did not. Studied factors were gender, age, medications (classified at ATC level 3: pharmacological subgroup and total of prescribed drugs. Odds ratios were calculated by logistic regression analysis (method backwards: Wald). SPSS (v.20) was used.

Results 930 PEP were identified in 2019 November. 128 patients were admitted to the hospital during 2020 (cases). Only 3 of 20 factors had a statistically significant (SS) result (table 1).

Conclusion and relevance In this preliminary analysis of 930 PEP, B01A (antithrombotic drugs) and a number of total prescribed drugs were SS factor associated with a higher risk of admission, meanwhile N05A (antipsychotics) showed a protective trend.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

Abstract 6ER-022 Table 1 Odds ratio results from logistic regression analysis

Factor	OR	Lower 95% CI	Upper 95%CI	Factor	OR	Lower 95% CI	Upper 95%CI
A02B	1.46	0.427	4.991	N02B	0.814	0.513	1.291
A10B	1.246	0.816	1.904	N03A	0.715	0.443	1.154
A11C	0.875	0.535	1.431	N05A*	0.353	0.137	0.91
A12A	1.192	0.73	1.948	N05B	0.98	0.649	1.482
B01A*	1.95	1.004	3.824	N06A	1.002	0.671	1.497
C03C	1.088	0.72	1.642	R03A	0.997	0.628	1.583
C07A	1.206	0.8	1.818	R03B	0.881	0.541	1.435
C10A	0.988	0.626	1.561	Total	1.182	1.078	1.297
				prescribed drugs*			
H02A	0.875	0.431	1.778	Gender	1.011	0.651	1.57
M05B	1.016	0.581	1.776	Age	1.022	0.991	1.054
N02A	0.819	0.524	1.279				

CI, confidence interval; OR, odds ratio. *p<0.05.

6ER-023 STUDY OF THE USE OF CEFTAZIDIMA-AVIBACTAM IN A THIRD-LEVEL UNIVERSITY HOSPITAL

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Background and importance Ceftazidima-avibactam is a recently commercialised antibiotic recommended for the treatment of infections caused by Gram-negative aerobic microorganisms, some of which have lately developed resistance to many antibacterials. Its importance in the current clinical practice stems from the fact that it can be used in patients with limited therapeutic options where other antibacterials are ineffective.

Aim and objectives To evaluate the clinical indications and causal microorganisms for which ceftazidima-avibactam was prescribed in a third-level hospital and to assess whether resolution of the infection was achieved.

Material and methods Observational, descriptive and retrospective study of all the patients that have received antibiotic treatment with ceftazidima-avibactam from July 2017 to April 2021.

To evaluate the indications and resolution, the medical history of the patients was reviewed. The laboratory database was also checked to identify the causal microorganisms. Variables studied were: patient demographics, prescribing units, isolated microorganism, diagnosis and motive of suspension.

Results Sixty-six patients were included in this study (62% men), with a median age of 63 (16–86) years. Twenty-eight of these patients were hospitalised in intensive care units (42%), 7 in Haematology (11%), 6 in General Surgery (9%), 6 in Vascular Surgery (9%) and the remaining patients in other different units (29%). During the period of study, 9 patients died (14%).

The main causal agents isolated were *Klebsiella pneumoniae* producing extended-spectrum β -lactamase (ESBL) and carbapenemase in 19 patients (29%), *Pseudomonas aeruginosa* in 19 (29%, multiresistant in 16) and *Enterobacter cloacae* complex ESBL and carbapenemase in 12 (18%).

The infections for which the treatment has mainly been prescribed are bacteraemia in 23 patients (35%), surgical wound infection in 13 (20%), urinary tract infection in 10 (15%), intra-abdominal infection in 6 (9%) and pneumonia in 6 (9%).

Clinical resolution has been accomplished in 28 patients (42%) and microbiological resolution in 8 (12%). In 20 patients (30%), treatment has been suspended for de-escalation to a narrower-spectrum antibiotic. One patient (1.5%) was moved to another hospital, thus tracking was lost.

Conclusion and relevance Ceftazidima-avibactam achieved resolution of the infection in most patients. It was satisfactorily used to treat infections caused by resistant Gram-negative agents for which there were no other available options.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

6ER-024 POTENTIALLY DRUG-RELATED PROBLEMS IN A POLYMEDICATED POPULATION

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Background and importance Poly medication is becoming a growing problem nowadays in the general population. Drugs offer huge benefits treating acute and chronic conditions, but the more drugs are prescribed, the more potentially drug-related problems (PDRP) are found. Duplicities, prescription cascades, low therapeutic value drugs (LTVD), QT prolongation and anticholinergic potency are some of the main drug-related problems. Identifying target population with these problems can be a step forward to make pharmacological deprescription or modifications.

Aim and objectives The objective of this study was to investigate and quantify whether there are drug-related problems in a polymedicated population that belongs to a secondary level hospital as the first step of a pharmacist-led treatment revision.

Material and methods An observational transversal study in a hospital influence area of 450 000 inhabitants was done. Poly medication was defined as more than 15 prescribed drugs per patient. Sociodemographic and treatment data to quantify drug-related problems was extracted from digital clinical records. Excel (v. 2016) was used to process the data. Notes: duplicities were listed by comparing ATC level 5 (drug) and 4 (chemical subgroup); LTVD listed in local health-system documents; QT-prolonging drugs listed at CredibleMeds.

Results At September 2021, 2258 patients were found to be polymedicated. 1456 patients were female (64.5%). Median age was 75 (range 21–98) years. Drug-related problems found are listed in Table 1.

Abstract 6ER-024 Table 1 Drug-related problems found in the study population

Drug-related problem	Total (n)	Mean per patient (\pm 95% CI)
Duplicities	2270	1.005 (\pm 0.056)
Cascades	371	0.164 (\pm 0.056)
Low therapeutic value drugs	1295	0.574 (\pm 0.037)
QT-prolonging drugs	685	0.305 (\pm 0.041)
Anticholinergic drugs	897	0.397 (\pm 0.040)

Conclusion and relevance The results showed a high prevalence of PDRP, duplicities and LTVD being the most listed. This implies a high risk of adverse events or treatment misadequation. From this point with these data, a pharmacist-led revision programme could be a starting point to try to enhance treatment prescriptions.

REFERENCES AND/OR ACKNOWLEDGEMENTS

<https://ejhp.bmj.com/content/24/3/137.abstract>

Conflict of interest No conflict of interest

6ER-025 REAL-LIFE USE OF REMDESIVIR IN HOSPITALISED COVID-19 PATIENTS WITH SEVERE PNEUMONIA: AN OBSERVATIONAL STUDY FROM AN ITALIAN UNIVERSITY HOSPITAL

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Background and importance Since June 2020, the European Medicines Agency granted conditional approval to the antiviral drug Veklury (remdesivir) as a treatment for COVID-19 pneumonia. Many studies have shown conflicting results regarding its efficacy. Data from observational studies should be encouraged in order to provide valuable information about its real-life effectiveness.

Aim and objectives The aim of the study was to describe the effectiveness of remdesivir in terms of mortality rate and duration of hospitalisation in a cohort of patients admitted to an Italian University Hospital during the COVID-19 pandemic.

Material and methods We carried out a retrospective observational study at a 1600-bed University hospital in Northern Italy. Our cohort included all patients who received remdesivir between September 2020 and April 2021, corresponding to the second and third pandemic waves in Italy. As a primary endpoint, we measured the mortality rate at any time after initiation of therapy. Secondary endpoints included 30-day mortality and duration of hospitalisation. As a post hoc analysis, we compared patients requiring high-flow oxygen supplementation (HFO) after starting remdesivir and patients who did not require HFO (eg, NHFO group). High-quality data were extracted from the medical records and from the Veklury AIFA (Agenzia Italiana del Farmaco) monitoring register. Statistical analyses were carried out with R (R Core Team 2021).

Results The study sample included 528 patients, mainly men (68.4%) with a median age of 66.7 years. The overall mortality rate was 5.1%, while the 30-day mortality rate was 4.2%. In the post hoc analysis, 291 patients (55.1%) fell in the NHFO group. HFO therapy confirmed a stronger association with mortality (11.0% HFO vs 0.3% NHFO, $p < 0.001$). The NHFO group performed better in all the considered endpoints: rate of discharge to home, mortality, intensive care unit admission/transfer, and length of hospital stay.

Conclusion and relevance In our study, the mortality rate was similar to that reported in clinical studies. Since no reports of adverse drug reactions were notified, these data support remdesivir as a possible therapeutic option, given the positive benefit-risk profile. As expected, patients who required high-flow oxygen were at increased risk of negative outcomes. This seems to suggest that potential early use of remdesivir could optimise its clinical efficacy.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

6ER-026 EFFECTIVENESS AND SAFETY OF APREMILAST IN A THIRD-LEVEL HOSPITAL

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Background and importance Apremilast is indicated for the treatment of psoriatic arthritis (PA) alone or in combination with disease-modifying antirheumatic drugs (DMARD), and the treatment of moderate to severe plaque psoriasis (PP) in adult patients who failed to respond or have a contraindication, or are intolerant to DMARD or other systemic therapy, including biological.

According to the European Medicines Agency (EMA), reasons for discontinuation are the lack of response at 24 weeks, diarrhoea and nausea.

Aim and objectives The aim of the study was to assess the effectiveness and safety of apremilast in patients with PA or PP.

Material and methods Retrospective study performed in a third-level hospital. Patients who started apremilast between June 2016 and February 2021 were included, and their evolution was followed until August 2021. Demographic, clinical and treatment variables at baseline were collected. Efficacy and safety were analysed based on the general subjective assessment of the physician.

Data were obtained from medical records. Analysis was performed using Microsoft Excel.

Results A total of 47 patients were selected (38 PP and 9 PA). PP patients (13 women, median age 53.5 (22–82) years), 16 had received prior non-biological systemic treatment, 11 biological, 9 topical and 2 phototherapy. PA patients (6 women, median age 46 (28–70) years), 8 had received DMARD and 1 biological.

Apremilast was effective in 24 patients (19 PP and 5 PA) at 6 months. In PP, 8 achieved total whitening and 11 partial. In PA, 4 achieved a moderate disappearance of pain and 1 mild. 7 patients discontinued before 6 months due to adverse effects (AE), it not being possible to determine the response.

At the end of follow-up, 8 patients (7 PP and 1 PA) continued with apremilast, with a median of 21 (8.6–30.9) months. The drug was discontinued in 31 PP patients after a median of 3.4 (0.5–24.8) months (12 lack of response (LR), 11 loss of efficacy (LE), 3 vomiting, 2 diarrhoea, 1 headache and 1 death) and 8 PA patients after a median of 6.2 (3.7–10.8) months (4 LR, 3 LE and 1 diarrhoea).

Conclusion and relevance Apremilast has been effective in half of the patients at 6 months, but less than a quarter remain on treatment.

Regarding the safety profile, 8 patients discontinued due to AE, the gastrointestinal AE being the most common.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

6ER-027 BLOOD CYTOKINE EVALUATION IN PATIENTS WITH INTRAVITREAL RANIBIZUMAB FOR NEOVASCULAR AGE-RELATED MACULAR DEGENERATION

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Background and importance Inflammation is involved in the development and pathogenesis of age-related macular degeneration (n-AMD) although the roles that the inflammation-

related cytokines play in it are not yet defined as some of them are pro-angiogenic. Local and systemic inflammatory molecules are being proposed as potential biomarkers of n-AMD progression.

Aim and objectives The aim of this study was to evaluate cytokine values after the ranibizumab loading phase in patients with n-AMD.

Material and methods Prospective, observational study of n-AMD patients with criteria to initiate treatment with ranibizumab. A blood test was performed at the initial visit (prior to the first administration of ranibizumab) and after finishing the loading doses (4 months). Demographic, clinical and blood analytical parameters (C-reactive protein (CRP), β 2-microglobulin, tumour necrosis factor (TNF), interleukins rIL-2, IL-5, IL-6, IL-8 and IL-10) were obtained through electronic medical records. Statistical analysis was performed using Student's t-test (SPSS Statistics V.26, IBM Inc.).

Results A total of 45 patients were included (40% men). Mean age was 80 ± 8 years. 41 patients responded to treatment (14 partially), 2 did not respond to treatment and 2 did not finish the loading phase. Visual acuity obtained a statistically significant improvement in responder patients (EDTRS: 56 ± 17 vs 63 ± 16 , $p < 0.002$).

In responders, changes in cytokine serum levels did not reach statistically significant differences between the initial visit and after the loading phase ($p > 0.05$): TNF (8.97 ± 2.78 vs 9.04 ± 3.75 pg/mL), CRP (0.323 ± 0.387 vs 0.324 ± 0.332 mg/dL), β 2-microglobulin (2.77 ± 0.92 vs 2.85 ± 0.95 mg/L), IL-6 (6.6 ± 3.3 vs 6.5 ± 6.1 pg/mL), rIL-2 (516.0 ± 213.9 vs 529.6 ± 224.9 U/mL). Although IL-8 (51.46 ± 66.5 vs 85.95 ± 115.1 pg/mL) showed an increase after the loading phase, it did not reach statistical significance ($p = 0.088$). IL-5 and IL-10 remained undetected over time in both responders and non-responder patients.

Conclusion and relevance Changes at the end of the loading phase in IL-6 and IL-8 have been described previously with the administration of anti-angiogenics. In our case, no differences were detected, probably due to the low sample size. More studies will be necessary to determine the prognostic potential of the change in systemic cytokines as a response parameter in patients treated with anti-angiogenics in AMD.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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Conflict of Interest No conflict of interest

6ER-028 MARKET EXCLUSIVITY EXPIRY HAS LIMITED EFFECT ON PRICES OF BRAND-NAME ORPHAN DRUGS

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Background and importance R&D and market entry for orphan medicinal products (OMPs) are incentivised with a 10-year market exclusivity period as stated in Regulation (EC) No 141/2000. Notably, OMP prices often remain high after market exclusivity expiry (MEE). This has led to societal debate on OMP pricing. However, transparency on the

purchase prices of OMPs is lacking due to confidentiality issues. Research on OMP prices is needed to support policymaking.

Aim and objectives Our research aimed to explore trends in both list prices and purchase prices of brand-name OMPs before and after market exclusivity expiry in Western European countries.

Material and methods Annual average list prices and purchase prices of brand-name OMPs from a number of university hospitals were collected. The selection of OMPs was in accordance with our research protocol – published EJHP. To capture confidentiality constraints, the annual average price in the year of market exclusivity expiry (MEE=0) was set as index year ($p=100\%$) for list prices and purchase prices separately. Proportions were then created to illustrate price trends over time. **Results** 14 OMPs were included. A first analysis including four hospitals demonstrated that 2 years after market exclusivity expiry (MEE+2), list prices had dropped on average by 2.01% compared to list prices in the year of market exclusivity expiry (MEE=0) and purchase prices increased on average by 0.09% compared to purchase prices at MEE=0. Three years after market exclusivity expiry (MEE+3), list prices dropped on average by 0.56% compared to list prices at MEE=0 and purchase prices increased on average by 0.09% compared to purchase prices at MEE=0.

Conclusion and relevance List prices of brand-name OMPs have dropped very modestly in the first years after market exclusivity expiry compared to the list prices at the times of market exclusivity expiry. The purchase prices of brand-name OMPs even increased slightly on average in the first years after market exclusivity in our dataset. This potentially implies a lack of incentives for pharmaceutical companies to lower prices after market exclusivity expiry. Additional data collection is required to draw more robust conclusions.

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Conflict of interest No conflict of interest

6ER-029 DEVELOPMENT OF A LUDO-PEDAGOGIC TRAINING PROGRAMME FOR THE MANAGEMENT OF A ROBOTISED SYSTEM FOR CYTOTOXIC COMPOUNDING

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Background and importance A robotised system was acquired to automate part of the chemotherapy production. Continuous training of operators is a challenge and we observed an increase of disparity in operators' knowledge over time. Less trained operators became reluctant to use the system.

Aim and objectives To create a short, playful, standardised and sustainable training on the robot and to evaluate its impact on our operators.

Material and methods The Kern cycle was used to set up the training created with LearningDesigner software. Participants answered a survey on their knowledge about technology. Knowledge about the robot was assessed by a 0-to-24 scale

Abstract 6ER-029 Table 1

Criteria (mean (SD))	Before	After	6 months
Knowledge (0–24)	13.7 (5.7)	18.5 (3.1) ($p=0.002$)	18.4 (4.1) ($p=0.004$)
Confidence (0–100)	48.5 (40.1)	75.6 (19.2) ($p=0.013$)	60.2 (38.1) ns
Motivation (0–100)	57.6 (39.2)	86.6 (11.7) ($p=0.024$)	70.4 (33.6) ns

questionnaire. Operators were classified as mentor or apprentice. Motivation and confidence were recorded on 0-to-100 scales. These three criteria were also assessed after the training and after 6 months. Satisfaction was collected on a six-point Likert scale.

Results Three games were created for a 1 hour 30 min training with pairs of players. (1) Game ‘knowing the manufacturing steps’: the 16 steps of the process were printed on cards to put back in the right order. (2) Game ‘knowing the criteria for using a molecule with the robot’: fake Pokémon cards presenting a molecule and its specificities (stability, viscosity, usual dosage, etc.) were created. Teams should guess if the molecule can be used with the robot and why. (3) Game ‘knowing how to handle errors during production’: inspired by the ‘Who Wants to Be a Millionaire?’ TV show. Four answers were suggested, issued from real-life problems. A debriefing followed every game. Seven mentor/apprentice teams participated. Participants strongly agreed that objectives, structure and subject were appropriate (80%), playful and interactive (83%). Table a presents the results (p is for before/after or before/6 months. ns, non-significant).

Conclusion and relevance For this complex tool, we created a short and playful training appreciated by operators. We showed an improvement of knowledge with a remembrance until 6 months. Confidence and motivation slightly decreased over time, highlighting the importance of adding a coaching during daily practice.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

Section 7: Post congress additions

11SG-009 IMPLEMENTATION AND EVALUATION OF TELEPHARMACY DURING THE COVID-19 PANDEMIC IN AN ACADEMIC MEDICAL CITY: PAVING THE WAY FOR TELEPHARMACY

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Background and importance A leading public healthcare institution implemented a disruptive innovation of telepharmacy in pursuit of compliance with the National COVID-19 Response Framework. It emerged and proved to be an essential and critical pillar in suppression and mitigation strategies. Telepharmacy innovation resulted in pharmacy staffing protection and provided uninterrupted access and care continuum to the pharmaceutical services, both for COVID-19 and collateral care.

Aim and objectives To evaluate the impact of implementing telepharmacy during the COVID-19 pandemic on the safety of pharmacy staff and patients.

Material and methods The Pharmacy Department redesigned a new workflow that combined both on-site and remote staff through a secured VPN access to our health information system (HIS) (figure 1). This new design prevents any direct interaction between pharmacist and patient or with other health care providers, and at the same time the new changes will not compromise patient safety and medication distribution.

Results The Pharmacy Department has the capacity to switch all outpatient prescriptions to be requested through the online portal and a total of 14 618 medication shipments were home delivered from 15 March to 10 June 2020. 14 618 medication shipments were delivered out of 25 520 online requests submitted; the difference between the number of delivered prescriptions and received requests was due to repeated submissions by patients or because the refill due date did not arrive.

WhatsApp Business has been initiated for direct communication between patients and pharmacists. A total of 10 030



Abstract 11SG-009 Figure 1

Abstract 11SG-009 Table 1

Parameter	Online refill
March 2020	3340
April 2020	9413
May 2020	4990
10 June 2020	7777
Total number of requests during 2019	488
Total number of requests in 2020	25 520
Total shipped 15 March to 10 June 2020	14 618
WhatsApp sent message	14 633
WhatsApp received message	26 613
Orders verified by remote access (outpatient)	4650
Orders verified by remote access (inpatient)	5380

inpatient pharmacy and outpatient pharmacy orders were verified through remote access.

Conclusion and relevance In conclusion, the implementation of telepharmacy via the utilisation of medication home delivery services, remote access, and modification of the previous workflow was associated with promising outcomes in terms of efficient, high-quality pharmaceutical care delivery while avoiding medication distribution disturbances as well as containing the spread of the pandemic among staff and patients, thus ensuring their safety during this crisis.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

2SPD-003 TELEPHARMACY IN ONCO-HAEMATOLOGIC PATIENTS: A 7-MONTH EXPERIENCE

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Background and importance Telepharmacy delivers pharmaceutical care services from a distance through information and communication technologies, avoiding patient attendance at the hospital. Until now, our hospital Onco-haematology Pharmacy Unit dispensed oral and subcutaneous treatments only in person. These onco-haematologic patients are usually a very fragile population.

Aim and objectives To describe the telepharmacy system for onco-haematological patients implemented at our hospital and its results in terms of activity and patient satisfaction.

Material and methods In collaboration with medical services and supported by the hospital management staff, onco-haematologic patients with oral or subcutaneous drugs prescribed and at least one of the following criteria were included: medical consultation through telemedicine, chronic stable disease with good adherence or paediatric haematologic patients whose dose adjustments require laboratory results.

A separate room with computer, mobile phone, webcam and headphones was set up. One oncology pharmacist and one pharmacy technician were allocated part time. Delivery of the dispensed treatment to the patient was arranged through community pharmacies and their regular distributor. Confidentiality was warranted through all the delivery process.

During a 7-month period, a satisfaction survey that enquired about the service and graded several items from 1 (very unsatisfied) to 5 (very satisfied) was conducted with a sample of 40 patients. Patients subjected to the survey were randomly selected by date of attendance (last day of the month from June to September) until the target of 40 completed surveys was attained.

Results During this period, 8494 patients attended the Onco-haematology Pharmacy Unit and 19.8% (n=1681), an average of 10 patients per day, were via telepharmacy. Of the 40 patients surveyed, 88.4% were very satisfied with the information received about their treatment during the telematic pharmaceutical consultation, 95.3% were very satisfied with the confidentiality maintained during the telematic pharmaceutical consultation, 90.7% were very satisfied with the conditioning of the medication for delivery and 93% were very satisfied with the overall experience. The lowest grade obtained in the

overall responses was a single score of 3 for the conditioning item.

Conclusion and relevance According to the results obtained, telepharmacy in onco-haematologic patients is a high-value practice that fulfils the needs of these selected patients and it is thought highly of by them.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

2SPD-012 IMMUNOTHERAPY IN PATIENTS WITH NON-SMALL CELL LUNG CANCER: EFFECTIVENESS AND SAFETY IN REAL LIFE

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Background and importance The high cost of immunotherapy makes it necessary to assess health outcomes in real life, which can help in decision-making.

Aim and objectives The current study aimed to analyse the effectiveness and safety of immunotherapy in second-line treatment in adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) in real life.

Material and methods Retrospective and observational study. All patients with locally advanced or metastatic NSCLC treated with nivolumab, pembrolizumab and atezolizumab monotherapy as second-line treatment between April 2017 and April 2020 were included.

Outcomes collected were: demographic variables: age and sex and clinical variables: diagnosis, stage, performance status score according to Eastern Cooperative Oncology Group (ECOG), PD-L1 expression and treatment variables: treatment start and end date and administered doses.

The primary endpoints were: overall survival (OS) and progression-free survival (PFS). All adverse effects (AE) were recorded according to CTCEA v4.3 criteria.

Data were collected from the electronic clinical history and electronic prescribing software. The Kaplan–Meier method was used to calculate PFS and OS. SPSS v17 was used to perform statistical calculations.

Results 104 patients were included in this study: N=40 nivolumab, N=29 pembrolizumab and N=35 atezolizumab. Median age was 62.93±9.20, 64.92±11.69 and 59.86±11.60 years, respectively. 74.7% were men and 67.8% were ECOG-1.

Nivolumab showed an OS of 6.4 months (95% CI 2.81 to 9.98) and a PFS of 3 months (95% CI 1.14 to 4.25), pembrolizumab-treated patients had a median OS of 8 months (95% CI 3.05 to 12.94) and median PFS of 3.5 months (95% CI 2.4 to 4.6). The use of atezolizumab demonstrated an OS of 6.33 months (95% CI 4.4 to 9.1) with a PFS of 3.2 months (95% CI 2.6 to 7.2).

82.5% of patients suffered from some AE to nivolumab, 76.9% to pembrolizumab and 80.9% to atezolizumab. Asthenia was the AE that occurred most frequently and was common to all three drugs.

Conclusion and relevance Safety was similar for all drugs, and the effectiveness in terms of OS was a little higher for pembrolizumab, which could be related to the fact that patients treated with this antibody had PD-L1 expression >1%. However, it will be necessary to expand the sample size to

generate quality information that can help in decision-making in real-life clinical practice.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

2SPD-022 RELEVANCE OF UNIVERSAL KIT COMPOSITION AND ECONOMIC VALUE OF NON-USED MEDICAL DEVICES

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Background and importance The Universal Kit (UKIT) is composed of sterile medical devices (MD) which are essentials for large surgical operations. The UKIT composition was established years ago to meet the demands of different specialties' surgeons. UKIT is annually purchased by public tender procedure from specialised companies. Recently, we have noticed an increasing annual consumption which impacts on hospital expenditures.

Aim and objectives Evaluate relevance of UKIT qualitative and quantitative composition by listing and calculating economic losses of remaining non-used MD.

Material and methods This was a 1-month prospective observational study (from 31 May 2021 to 30 June 2021) conducted in the Central Operating Theatre (COT). The operating programme is equally allocated between certain surgical specialties: urology and neurosurgery, visceral surgery and gynaecology, traumatology and thoracic surgery. Checklist of UKIT components is manually filled during surgery procedures. Non-used MD are listed and economic value is calculated based on unit prices (UP) of public tender procedure attributed in 2020. The data were analysed using Excel.

Results The UKIT composition (UP=€ 24.01) consists of: two mounted scalpel blades 23 (UP=€ 0.032), 20 Gazin compresses (UP=€ 3.78) and five abdominal compresses (UP=€ 1.89). Each surgical department uses an average of 7 UKIT/week which corresponds to 371 UKIT/year. A total of 2226 UKIT (€ 53 446) are used per year in the COT.

The economic losses are estimated per year as: urology € 293.09; neurosurgery € 293.09; visceral surgery € 81.99; gynaecology € 81.99; thoracic surgery € 222.60; traumatology € 222.60. The overall economic losses are estimated at € 1195.36 per year in COT, which represent 2.2% of the annual budget allocated to UKIT.

Conclusion and relevance UKIT qualitative composition seems relevant despite the short study duration. The UKIT quantitative composition should be adjusted according to surgical specialties in order to optimise hospital expenditures. The re-sterilisation of non-used MD could be an interesting alternative which should be examined and validated by the Committee of Medicines and MD.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

3PC-032 OPTIMISING ANALGOSEDATION IN THE INTENSIVE CARE UNIT DURING THE SARS-COV-2 PANDEMIC

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Background and importance The pandemic caused by SARS-CoV-2 evidenced the need for expediting the dispensation and usage process, poorly automated, of narcotic drugs and for optimising the most commonly used perfusions available in the hospital (midazolam, dexmedetomidine, propofol, fentanyl). With this intervention, significant improvements in efficacy and safety were expected, considering the fact that perfusions decrease the risk of infection, medication errors and the workload and exposure of nurses.

Aim and objectives To elaborate a physicochemical and microbiological stable fentanyl perfusion and to adapt the presentations of drugs (midazolam, dexmedetomidine, propofol, fentanyl) used for analgo-sedation in COVID-19 patients admitted to the intensive care unit (ICU).

Material and methods

1. A multidisciplinary team formed by intensive care doctors, nurses and clinical pharmacists was created in October 2020 to discuss areas of improvement and effort optimisation.
2. All midazolam and propofol presentations were changed for others of larger volume available on the market. A dexmedetomidine perfusion 2000 mg/250 mL was standardised thanks to previous stability data collected.
3. A new fentanyl perfusion was prepared and validated in sterile conditions after a literature systematic review, microbiological controls in *tryptic soy broth* (TSB) and thioglycollate broth, and a microbiological risk matrix were done.
4. Fentanyl perfusions were stocked in Pharmacy and individually dispensed according to the infusion speed of each patient. Control numbers were assigned to every preparation to maintain the narcotics' traceability.

Results Each perfusion consisted of 1500 µg fentanyl (10 vials 150 µg/3 ml=1 perfusion) diluted in 100 mL sodium chloride 0.9%. The final stability given was 30 days at room temperature (all culture replicates in TSB and thioglycollate broth at days 0, 9 and 30 were negative). The daily number of preparations depended on the epidemiology of the disease. However, a median value of 13 perfusions was dispensed up to a total of 21 ICU beds.

Conclusion and relevance This model can be extrapolated to other Pharmacy Services as long as volumetric pumps, trained professionals and horizontal laminar flow cabinets are available. The intervention met some of the demands created during the pandemic and helped to slightly attenuate the pressure on healthcare professionals.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-022 TO VACCINATE OR NOT TO VACCINATE: IMPACT OF A PUBLIC HEALTH ACTION ON VACCINE HESITANCY

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Background and importance Vaccine hesitancy is one of the top 10 threats to global health according to the World Health Organization.¹ A part of the Swiss population is hesitant to vaccinate against COVID-19.²

Aim and objectives The aim of this study was to conduct a public health action with hesitant to vaccination and measure its impact on vaccine hesitancy and on vaccination rate.

Material and methods Vaccine hesitancy and barriers to vaccination were measured and identified using a pre-test questionnaire. Only non-vaccinated volunteer participants were included, and they were invited to a 1-hour online session using motivational interviewing techniques, animated by a physician and a pharmacist. Two weeks after the session, they were asked to fill a post-test and 2 months later, their vaccine status was requested. Data collection was conducted from April to August 2021.

Results 31 adults participated for a total of 11 online sessions (2.8 participants/session). Majority were women (68%, n=21) and aged between 35 and 60 years (71%). 10 (32.3%) were public health professionals and 21 (67.7%) were not. Prior to the study, 54.9% did not consider vaccines safe (19.4% post-study), 87.1% were concerned about vaccine side effects (64.5% post-study) and 51.6% considered vaccines to be effective (83.9% post-study). Before the study, participants were classified as certainly willing to vaccinate (3.2%), probably (9.7%), probably not (35.5%), certainly not (12.9%), do not know/other (38.8%) and the degree of confidence in vaccination was 4.5 ± 2.2 (scale 1–10). After the study, the confidence increased to 6.3 ± 2.4 (+29%). Following the study, 52% (n=14) were effectively vaccinated. Among reasons that motivated to vaccinate: vaccination will help with containing the pandemic (5/14) and benefit-risk ratio is positive for the vaccine (5/14). 48% (n=13) were not vaccinated mainly for the following reasons: doubt about the effectiveness (2/13) and fear of side effects (2/13). Opinion on vaccines was moved mainly by having personal questions answered and feeling not judged for having a different opinion on vaccination.

Conclusion and relevance In this study we could reduce vaccine hesitancy by increasing the degree of confidence in the vaccine and our action effectively convinced half the participants to get vaccinated.

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Conflict of interest No conflict of interest

4CPS-025 ADEQUACY OF HEPATITIS B REACTIVATION PROPHYLAXIS IN PATIENTS TREATED WITH RITUXIMAB

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Background and importance The Spanish Agency for Medicines and Health Products (AEMPS) in July 2014 made recommendations on the prophylaxis related to the reactivation of hepatitis B secondary to immunosuppressive treatment, particularly with rituximab (RTX), after observing a reactivation frequency higher than that found with classic chemotherapy.

Aim and objectives To determine the degree of compliance with the recommendations of the AEMPS in our centre after several years.

Material and methods All patients treated with RTX from August 2014 to May 2020 were included. Compliance with serological screening was measured through the registration of the following markers of the hepatitis B virus (HBV) carried out in the Microbiology Service: HBsAg, anti-HBc IgG antibodies and HBV-DNA levels.

To determine the degree of compliance of prophylactic treatment, tenofovir and lamivudine dispensations were reviewed. As demographic variables of the study population, gender and age were recorded.

Results 230 patients received RTX and a serological study of HBV infection was carried out in 210 (91.3%). 50.5% (106/210) of the patients were women and the median age was 52.14 (IQR43.01–67.64) years. Of these, 35 patients (16.67%) had positive anti-HBc and 2 positive HBsAg. The HBV-DNA was positive in 27 of them (77.14%) and in all cases it was less than 2000 IU/mL (median 153 IU/mL, IQR 56–447 IU/mL). Of these 35 patients with positive serology and an indication for prophylaxis, only 15 (42.85%) received treatment with tenofovir, with a median duration of 267 (IQR 248.5–471) days. 2 patients with negative serology also received prophylactic tenofovir (median 475.5 days, IQR 335.75–595.25 days). Only 2 patients completed at least 12 months of prophylactic treatment after completing RTX according to the recommendations. 5 patients finished tenofovir before the end of RTX and of the remainder (10) 4 did not achieved a complete month after finishing RTX and 6 had a median duration of treatment of 141 (IQR 127.25–153.25) days.

Conclusion and relevance In our centre, hepatitis B screening in patients receiving immunosuppressive treatment with rituximab is high, but prophylactic treatment is prescribed in less than half of the candidate patients and generally does not meet the recommendations for duration after completion of treatment with rituximab.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-027 **DESENSITISATION PROTOCOL FOR LIPOSOMAL AMPHOTERICIN B: A CASE REPORT**

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Background and importance Liposomal amphotericin B (ANBL) is an effective and safe treatment, however non-IgE-mediated hypersensitivity reactions have been described.

Aim and objectives To describe the ANBL desensitisation protocol in a patient with leishmaniasis who developed a demonstrated hypersensitivity reaction to the drug.

Material and methods A 16-year-old male, 85 kg, with severe corticoid-dependent eosinophilic asthma, was admitted for prolonged fever, cholestatic hepatitis, splenomegaly and thrombocytopenia. Visceral leishmaniasis was diagnosed and ANBL treatment was started at 3 mg/kg intravenously (IV) to be administered over 2 hours.

During the perfusion the patient presented back pain and headache, which subsided when the perfusion was interrupted. Later, the perfusion was restarted at a slower rate; however, he developed erythematous plaques, discomfort, tachycardia and fever, as a result of which the perfusion was stopped.

The ANBL prick test was negative. It has been described that in non-IgE reactions there is a release of cytokines that trigger the symptoms of fever, hypotension, etc. Desensitisation to the antigen produced by the initial cytokine cascade is possible.

Second-line alternatives for leishmaniasis were not considered adequate, so it was decided to restart ANBL with a desensitisation protocol, which consisted of administering the drug in three steps, progressively increasing the infusion rate and concentration until administration of the full dose was reached. Low initial doses of antigen produce progressive depletion of activating signals and inhibition of mediator release, thus reducing clinical reactivity.

Results In our case, desensitisation consisted of only two steps: 1/10 dilution at a concentration of 0.2 mg/mL (25 mg/125mL) and the full dose at 1 mg/mL (250 mg/250mL) of ANBL in 5% glucose serum because there are no stability data for a more dilute preparation of ANBL (1/100).

The first dilution was administered in five perfusion rhythms starting at 2.5 mL/hour in 15 min, given good tolerance, the speed was progressively increased every 15 min: 5 mL/hour, 10 mL/hour, 20 mL/hour up to 40 mL/hour. Subsequently, the full dose of ANBL was administered in four rhythms, starting at 10 mL/hour, and increasing to 20 mL/hour, 40 mL/hour to 60 mL/hour, which was maintained until the full dose was reached. Premedication with paracetamol plus IV dexchlorpheniramine was necessary.

Conclusion and relevance The use of an ANBL desensitisation protocol has proven to be a safe option, which has allowed the administration of treatment without the appearance of adverse effects.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-029 **PEMBROLIZUMAB, NIVOLUMAB AND ATEZOLIZUMAB: INCREMENTAL COST-EFFECTIVENESS RATIO**

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Background and importance The high cost of immunotherapy makes it necessary to evaluate the results in real life, and the study of costs and economic evaluation can be useful tools to guide clinical decisions.

Aim and objectives To make an incremental cost-effectiveness ratio (ICER) analysis among the different available immune checkpoint inhibitors to treat non-small cell lung cancer (NSCLC) as second-line monotherapy.

Material and methods Retrospective and observational study. All patients with locally advanced or metastatic NSCLC treated with nivolumab, pembrolizumab and atezolizumab monotherapy as second-line treatment between April 2017 and April 2020 were included. Outcomes collected: treatment start and end date, administered mean dose, and mean number of cycles administered.

The drug costs were calculated based on the notified price. A 7.5% discount was applied for these prices as laid down in Spanish Royal Decree 8/2010 and 4% was charged as VAT (value add tax). In addition to the pharmacological costs, resource use was estimated: treatment administration in day hospital. Cost/cycle and overall cost (mean number of cycles administered multiplied by pharmacological and associated costs) were calculated. The endpoint was overall survival (OS).

Data were collected from the electronic clinical history, electronic prescribing software and pharmacy management programme. The Kaplan-Meier method was used to calculate OS. SPSS v17 was used to perform statistical calculations. We calculated the ??? for each strategy.

Results 104 patients were included in this study: N=40 nivolumab, N=29 pembrolizumab and N=35 atezolizumab.

Regarding effectiveness: the median OS was 6.4 (95% CI 2.81 to 9.98) months for patients treated with nivolumab; pembrolizumab-treated patients reached 8 months median OS (95% CI 3.05 to 12.94) and atezolizumab-treated patients achieved 6.33 months median OS (95% CI 4.4 to 9.1).

The overall cost of each treatment was: € 49 640.19 for pembrolizumab, € 42 887 for nivolumab and € 28 678.44 for atezolizumab.

ICER: nivolumab vs atezolizumab: € 2 435 753.14/life years gained (LYG); pembrolizumab vs atezolizumab: € 150 623.35/LYG; pembrolizumab vs nivolumab: € 50 648.92/LYG.

Conclusion and relevance The need to promote efficiency in the selection of treatments is one more reason to carry out an exhaustive comparative drug evaluation that includes the economic one. The effectiveness in terms of OS was greater for pembrolizumab; however, the cost analysis showed a greater benefit for atezolizumab.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-032 **HOW TO IMPROVE THE APPROPRIATE PRESCRIPTION OF ANTICOAGULANTS DURING UNEXPECTED EMERGENCY ROOM ADMITTANCE TO THE HOSPITAL? A CASE SERIES REPORT USING PHARMACY PRACTITIONERS**

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Background and importance Serious medication errors can be made during unexpected hospital admittance through the emergency ward. In particular, anticoagulants portray a great risk for patients when proper medication reconciliation is absent. We started using pharmacy practitioners (PPs) to improve this process on the emergency ward. We report here the results of two case series with respect to accuracy in the medication reconciliation on the emergency room (ER) ward.

Aim and objectives To investigate if appropriate embedding of PPs in the process of medication reconciliation during unexpected admittance to the hospital could lead to fewer medication errors downstream in other hospital wards.

Material and methods A PP was embedded in the ER ward team during office hours (08:00 to 17:00) to perform the medication reconciliation of unexpectedly admitted patients instead of ER physicians.

The two case series of admitted patients were chosen in a post-propter design. As a zero measurement, a case series of patients (ZMCS) in a pilot phase was used (October-December 2019). This pilot phase was done to collect data on hospital administration in order to show that PPs could be embedded to do this task. This retrospective dataset consisted of 40 patients, unexpectedly admitted on the ER ward and for whom the ER physicians performed the medication reconciliation. A prospective case series of patients was then performed during the period October-December 2020 under the same conditions and used as the experimental case series (EXCS) to compare with the ZMCS. The number of medication errors in the EXCS divided by the number of medication errors during the ZMCS was our main outcome parameter expressed as a percentage.

After ER admittance patients were transmitted to several other specialist wards.

Results Our results showed a 40% reduction in medication errors downstream in the specialist wards when the PPs were involved in the medication reconciliation process in the EXCS compared to the medication reconciliation done by ER physicians in the ZMCS.

Conclusion and relevance We conclude that PPs can make a valuable contribution to reduce the number of medication errors downstream in the hospital when embedded in the ER ward team.

REFERENCES AND/OR ACKNOWLEDGEMENTS

We acknowledge the ER hospitality during this case series investigation.

Conflict of interest No conflict of interest

4CPS-036 **IS OUR PROTOCOL FOR THE USE OF TOCILIZUMAB IN COVID PATIENTS ADEQUATE?**

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Background and importance Tocilizumab (TCZ) has been a key pillar in the management of pulmonary hyperinflammation in patients with SARS-CoV-2 pneumonia. The incessant publication of new studies assessing its effectiveness and the ideal time of use means that in-hospital protocols are constantly being reviewed and updated.

Aim and objectives To describe the clinical characteristics of hospitalised patients with SARS-CoV-2 pneumonia treated with TCZ and their evolution, and to compare our results with those of the primary endpoint (28-day mortality) of the RECOVERY study.

Material and methods Retrospective observational study of patients administered TCZ between October 2020 and February 2021 in a tertiary hospital. Criteria for TCZ use were PAFI <300 and meeting two of the following three criteria: C-reactive protein (CRP) >150 mg/L, D-dimer >1500 ng/mL and ferritin >2000 ng/mL, and not having contraindications for its use.

Each patient received a single dose of 400 mg if weight <75 kg and 600 mg if weight >75 kg.

Demographic data, comorbidities and days from symptom onset to TCZ administration were collected. Follow-up of analytical data (CRP, D-dimer and ferritin pre- and post- (15 days) TCZ administration). Clinical evolution was evaluated by mortality rate at 28 days.

Statistical analysis: Stata/MP v16.0. Student's t-test was used for comparison of quantitative variables.

Results 39 patients were included, 25 (64.1%) were male, median age 74 (IQR 61–80) years. 61.5% had hypertension, 33.3% obesity, 41% diabetes mellitus, 17.9% chronic kidney disease, 12.8% heart disease. The median time from symptom onset to TCZ administration was 10 (IQR 7–15) days.

The medians prior to and at 15 days of TCZ administration were, respectively: 152.5 mg/L (IQR 89–220.8) and 1.7 mg/L (IQR 0.65–4.2) CRP ($p < 0.001$); 2300 ng/mL (IQR 1195–4889) and 1124 ng/mL (IQR 567–1439) D-dimer ($p = 0.1726$); 1242 ng/mL (IQR 647–2705) and 851 ng/mL (IQR 268–1384) ferritin ($p = 0.1294$). Mortality at 28 days was 64.1%.

Conclusion and relevance Our sample size is smaller than that of the RECOVERY study; however, the days of symptoms until TCZ administration (10 vs 9) and the median CRP prior to TCZ (143 vs 152.5 mg/L) in both studies are very similar. Our mortality is much higher (64.1% vs 29%). We found a statistically significant difference between our pre- and post-CRP data.

With this result, the in-hospital protocol was modified and new criteria for TCZ administration in COVID patients became oxygen saturation <92% or PAFI >300 and CRP >75 mg/L, with no contraindications for use.

In subsequent studies we will test whether this update helps to improve mortality outcomes.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-050 USE OF GALCANEZUMAB IN PATIENTS WITH MIGRAINE IN A TERTIARY HOSPITAL: HEALTH RESULTS

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Background and importance Galcanezumab, a humanised monoclonal antibody that binds calcitonin gene-related peptide, has demonstrated a significant reduction in monthly migraine headache days.

Aim and objectives To perform a first preliminary evaluation 3 months after using galcanezumab in patients with migraine.

To compare the health results with the ones in the pivotal clinical trials REGAIN and EVOLVE.

Material and methods A retrospective, descriptive study was conducted. Data were collected from patients with migraine who had started treatment with galcanezumab from February 2020 to July 2021.

The data collected were: sex, age, type of migraine (episodic (EM) or chronic migraine (CM)), number of previously used preventive drugs, presence of analgesia abuse, dosage, date of start and end of treatment, reason for end of treatment, number of monthly migraine headache days (MHD) prior to treatment, and number of MHD after 3 months. All the information was obtained from the electronic medical record.

Results 59 patients with a diagnosis of EM or CR were analysed (81.4% women), with a mean age of 53.8 ± 12.2 years. 76.3% had CM (45) and only 14 patients suffered from EM. Patients had tried a mean of 4.2 preventive drugs. At least 44.1% of patients presented analgesia abuse.

All patients received the same posology: 120 mg monthly (with a 240 mg loading dose) of galcanezumab.

17 patients stopped treatment, the main reasons were: inefficacy (70.6%), stability (17.6%), no adherence (5.9%) and toxicity (5.9%). 6 patients were excluded from the study on account of them not having received the re-evaluation after 3 months of treatment. The mean of MHD in patients with EM was 11.6 before treatment and 5.2 after (-6.5 MHD). The mean of MHD in patients with CM was 16.5 before treatment and 8.2 after (-8.3 MHD). So, 69.2% and 57.5% of patients with EM and CM, respectively, reduced the number of MHD by at least half.

Conclusion and relevance For patients with EM, the results were better than in the pivotal clinical trial EVOLVE (-4.7 vs -6.5 MHD). The same was the case for patients with CM, the results are better than in REGAIN (-4.8 vs -8.3 MHD). Galcanezumab seems to present a better effect than expected in clinical trials. This is, however, a first preliminary evaluation, and a follow-up would be necessary to see the long-term effect.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-062 RITUXIMAB PHARMACOKINETICS CHARACTERISATION IN PLASMA AND URINE IN A PATIENT WITH NEPHROTIC SYNDROME

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Background and importance Rituximab (RTX) is a monoclonal antibody used to treat various conditions including glomerular diseases (GD) as an off-label indication. There is high variability in RTX pharmacokinetics (PK) and it has scarcely been studied in cases of nephrotic syndrome (NS) (Foguero *et al*, 2019). We report the PK analysis of RTX in a case of GD and measure RTX excretion in urine.

Aim and objectives We present a 72-year-old male with hypertension, dyslipemia and obesity (81 kg) diagnosed with membranous nephropathy in September 2020. Usual medication included magnesium, amlodipine and ezetimibe.

Material and methods In October 2020 the patient suffered severe NS (proteinuria: 16 g/24 hours, hypoalbuminaemia: 2.1 g/mL, hypercholesterolaemia: 406 mg/dL) and RTX was prescribed, according to available knowledge at the time: 1 g days 1 and 15.

Routine blood and 24-hour urine samples were collected. RTX was measured in serum with an ELISA kit: Lisa-Tracker-Rituximab (Theradiag). The quantitative determination of RTX in urine was performed using in-house standards and urine samples diluted to 1/100 in Phosphate-Tween Buffer.

RTX's PK analysis was done using a monocompartmental model and nonlinear regression (Winnolin). RTX maximum concentration (C_{max}), distribution volume (V_d), clearance (Cl) and half-life (t_{1/2}) were determined.

Results RTX plasma concentration: 0 µg/mL at day 1 (d1) (pre-dose), 26.38 µg/mL at d 7. 7.93 µg/mL at d15 (pre-dose), 64.99 µg/mL at d15 (post-dose) and 3.72 µg/dL at d28.

RTX urine concentration: 0.18 µg/mL at d1 (pre-dose), 2.12 µg/mL at d7 and 0.18 µg/mL at d15.

PK analysis: C_{max}=92.0 µg/mL, V_d=135.1 mL/kg, Cl=1.075 mL/kg/hour, t_{1/2}= 88.91 hours=3.7 day.

By d7 there were 93.2 mg of RTX in the body and 17.8 mg were eliminated that day. Considering a 1500 ml/24 hour urine production, 3.18 mg of RTX were excreted at d7, 3.4% of RTX in plasma was excreted by urine every 24 hours and urine excretion justified 17.9% of RTX elimination.

Tacrolimus was initiated in December 2020 due to persistent NS.

Ten months after RTX administration the patient remains in complete remission (proteinuria: 0.5 g/24 hours, serum albumin: 3.8 g/ml, serum cholesterol: 237 mg/dL).

Conclusion and relevance The patient's RTX V_d was increased which may be due to NS-related oedema; C_{max} was lower, Cl was increased and t_{1/2} was notably shorter than reported values, which can be justified by RTX elimination in urine. RTX PKs are altered in cases of NS, leading to a reduced exposure. RTX may be aberrantly eliminated in urine in cases of NS and its concentration can be measured with ELISA.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-070 STUDY OF CARDIOVASCULAR TOXICITY ASSOCIATED WITH IBRUTINIB TREATMENT

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Background and importance Ibrutinib treatment has been associated with the development of unwanted cardiovascular (CV) and bleeding events, which may lead to the loss of a line of treatment in patients with so few therapeutic options.

Aim and objectives The objective of this study was to evaluate the rate of events related to cardiovascular toxicity during treatment with ibrutinib.

Material and methods Observational, retrospective study carried out between July 2015 and September 2021, which included all patients treated with ibrutinib. Clinical and demographic variables: age at the start of treatment, sex, diagnosis, previous therapeutic lines, duration of treatment, death, dose reduction and suspension of treatment. Previous CV risk factors were recorded: diabetes mellitus (DM), arterial hypertension (AHT), dyslipidaemia; and the underlying CV pathologies: heart failure (HF), atrial fibrillation (AF), ventricular tachyarrhythmia (VT). The appearance of new CV events related to ibrutinib treatment was recorded: AF, HF, VT, AHT and bleeding events. The rates of their appearance were calculated, excluding patients who had been treated for a period of less than 6 months.

Results A total of 66 patients were included (median age 72.7 (47–90) years, 68.2% men). 75.8% suffered from chronic lymphocytic leukaemia, 10.6% from mantle cell leukaemia, 12.1% from Waldenstrom macroglobulinemia and non-Hodgkin lymphoma as off-label use. 34.8% first-line treatment, 33.3% second-line, 15.1% third-line, 10.6% fourth-line, 6.1% fifth and subsequent lines. The mean duration of treatment was 22.6 [7.3–80.2] months. 63.6% keep the treatment going, 21.2% progressed and 15.5% died during treatment. 37.9% (25) did not have any risk factor at the beginning of the treatment, 22.7% (15) had two basic risk factors, and 10.6% (7) had three risk factors. 9.1% (6) had underlying CV pathology. During treatment, 34.8% (23) of patients developed some CV episode associated with ibrutinib use: 13.6% (9) AHT, 12.1% (8) AF, 7.6% (5) bleeding events, 1.5% (1) HF and 1.5% (1) VT. The dose was reduced in 2 patients and ibrutinib was suspended in 2 patients (3%).

Conclusion and relevance This study shows that 65% of patients do not develop any type of cardiovascular toxicity. Only a small percentage of patients need a dose reduction or suspension of treatment due to cardiovascular adverse events, requiring a multidisciplinary approach in the proper management of the drug.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-073 DESENSITISATION TO IBRUTINIB IN A PATIENT WITH SERIOUS LATE REACTION: A CASE REPORT

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Background and importance The use of a desensitisation protocol (DP) allows tolerance to drugs to which a hypersensitivity reaction has occurred, allowing treatment options which in some cases are the only ones available.

Aim and objectives Describe the use of a DP for ibrutinib in a patient with limited treatment options.

Material and methods 67-year-old woman with stage IV chronic lymphatic leukemia, not a candidate for transplantation, with a history of relapse to previous treatments. After 14 months of treatment with ibrutinib with good tolerance, a serious late reaction arose with a generalised purpuric rash of several days of evolution, and arthromyalgia that required hospitalisation and drug discontinuation, with subsequent clinical resolution.

Intradermal test for differential diagnosis of allergy versus late cutaneous adverse reaction was not conclusive for sensitisation to ibrutinib and a DP was proposed based on Phadke *et al.*¹

Results Ibrutinib capsules were dispersed in purified water. A DP was performed with both hospital and home administration. Daily doses were administered 1 hour apart (table 1).

Abstract 4CPS-073 Table 1

No.	Administration	Dispensed dose	Interval (min)
1	Hospital	0.042 mg/0.42 mL (0.1 mg/mL)	60
2	Hospital	0.084 mg/0.84 mL	60
3	Hospital	0.168 mg/1.68 mL	60
4	Hospital	0.336 mg/3.36 mL	60
5	Home	0.630 mg/6.30 mL, 5 doses	24 hours (5 days)
6	Hospital	0.672 mg/0.67 mL (1 mg/mL)	60
7	Hospital	1.344 mg/1.35 mL	60
8	Hospital	2.688 mg/2.70 mL	60
9	Hospital	5.376 mg/5.40 mL	60
10	Home	10.710 mg/1.70 mL (10 mg/mL), 5 doses	24 hours (5 days)
11	Hospital	10.750 mg/1.75 mL	60
12	Hospital	21.504 mg/2.15 mL	60
13	Hospital	43 mg/4.3 mL	60
14	Hospital	86 mg/8.6 mL	60
15	Home	140 mg (1 capsule)	24 hours (5 days)
16	Hospital	280 mg (2 capsules)	60
17	Home	280 mg (2 capsules), 5 days	24 hours (5 days)
18	Hospital	420 mg (3 capsules)	60

The patient returned to the usual treatment with good tolerance.

Conclusion and relevance The DP allowed continuation with ibrutinib, with safety and good tolerance, without loss of this therapeutic option.

REFERENCES AND/OR ACKNOWLEDGEMENTS

1. Phadke NA, *et al.* Immediate reaction to ibrutinib amenable to oral desensitization. *J Oncol Pharm Pract* 2021;**27**(7):1802–1805.

Conflict of interest No conflict of interest

4CPS-091 ANALYSIS OF PHARMACEUTICAL INTERVENTIONS RELATED TO HIGH-RISK-DRUGS IN THE EMERGENCY DEPARTMENT

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Background and importance Medication errors are frequent in the emergency department (ED) and the most common drugs involved are high-risk-drugs (HRD), which are drugs that are more likely to cause serious or even fatal harm to patients when used incorrectly.

Aim and objectives Describe the evolution of pharmaceutical interventions in the ED related to HRD in two comparable time periods and evaluate the acceptance degree.

Material and methods Retrospective observational study. All interventions performed in the ED during the periods between July and December 2019 and 2020 were included. The primary endpoint was the percentage of interventions related to HRD and their acceptance percentage. Secondary endpoints were: percentage of interventions related to HRD according to therapeutic group,^{1, 2} their acceptance percentage, and the main reasons for intervention (>15%). Interventions were recorded through the electronic prescription programme and were communicated to the responsible physician. The data were processed using Excel 2013.

Results A total of 165/494 (33.4%) and 234/731 (32.0%) HRD interventions were performed in 2019 and 2020, respectively. The acceptance percentages were 108/165 (65.5%) and 173/234 (73.9%). The main HRD therapeutic groups on which we intervened and their acceptance percentage in the periods of 2019 and 2020, respectively, were: heparin and parenteral anticoagulants (23.6% (61.5%) and 20.1% (83.0%)), insulins (12.1% (60.0%) and 15.0% (71.4%)), oral anticoagulants (10.9% (66.7%) and 13.2% (83.9%)), opioids (8.5% (71.4%) and 7.7% (77.8%)), antipsychotics (7.9% (69.2%) and 6.8% (68.8%)), diuretics (7.3% (50.0%) and 16.7% (61.5%)), sedatives (6.7% (63.6%) and 4.3% (90.0%)), antibiotics (6.1% (80.0%) and 1.3% (100%)), narrow-margin antiepileptics (4.2% (71.4%) and 5.6% (69.2%)) and other groups (<5%). The main intervention reasons (>15%) on the most prevalent therapeutic groups (>10%) were in the 2019 and 2020 periods, respectively: heparin and parenteral anticoagulants (need for treatment (66.7% and 57.4%)); insulins (need for treatment (60.0% and 41.2%), medication reconciliation (15.0% and 23.5%), inadequate dose (10.0% and 17.6%)); oral anticoagulants (medication reconciliation (55.6% and 41.9%), inadequate dose (11.1% and 19.4%)); diuretics (medication reconciliation (50.0% and 43.6%) and renal insufficiency (16.7% and 12.8%)).

Conclusion and relevance The percentage of interventions related to HRD was similar in both periods; however, there was an increase in acceptance degree in the 2020 period. More than a half of HRD interventions were performed on parenteral heparin, insulins, oral anticoagulants, and diuretics. The most prevalent reasons for intervention were the need for additional treatment and medication reconciliation. It seems that the intervention of pharmacists in the ED could improve the safety in the use of HRD.

REFERENCES AND/OR ACKNOWLEDGEMENTS

1. ISMP-Spain list of HRD in hospitals.

2. MARC project.

Conflict of interest No conflict of interest

4CPS-095 APPROPRIATENESS OF EMPIRICAL ANTIBIOTIC THERAPY FOR CERVICITIS AND URETHRITIS PRESCRIBED AT THE EMERGENCY DEPARTMENT

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Background and importance Sexually transmitted diseases are the most common cause of urethritis and cervicitis. *Neisseria gonorrhoeae* and *Chlamydia trachomatis* are frequently involved in the development of these infections. Guidelines have recently updated treatment recommendations due to the increasing prevalence of antimicrobial resistance.

Aim and objectives To assess the appropriateness of empirical antibiotic therapy for cervicitis and urethritis prescribed in the emergency department (ED).

Material and methods We designed an observational, descriptive and retrospective study. Inclusion criteria: adult patients with suspected cervicitis or urethritis who attended the ED of a tertiary hospital in 2020. Patients with suspected pelvic inflammatory disease, prostatitis and those who required hospital admission were excluded.

Recommendations for the empirical treatment include the combination of ceftriaxone 500 mg intramuscularly (single dose) plus azithromycin 1000 mg oral (single dose) or ceftriaxone 500 mg intramuscularly (single dose) plus doxycycline 100 mg oral twice daily for 7 days.

Appropriateness of empirical antibiotic therapy was evaluated taking into account four aspects: indication, dosing, duration of therapy and route of administration. In this way, patients could be classified as undertreated or overtreated.

Data were obtained from the electronic medical record, the electronic prescription program and the discharge summary. Ethical approval was obtained from the institutional review board.

Results 176 patients were included, mean age was 28.9 years (SD 7.7) and 90.9% were men. The most commonly prescribed treatment was the combination of ceftriaxone and azithromycin (83.0%).

The percentage of patients that received inadequate treatment was 72.7%. The total number of drug errors was 148.

The most frequent cause was undertreatment (55.5%) related to underdosing (50.7%), particularly with regard to ceftriaxone. The percentage of errors related to indication was 10.8%, dosing 85.8%, duration 3.4% and route of administration 0%.

33.3% of the patients treated with doxycycline did not collect the medication at the pharmacy to complete the antibiotic course.

Conclusion and relevance A high percentage of patients who attended the ED for cervicitis or urethritis received an inappropriate empirical antibiotic regimen. The main reason was undertreatment due to underdosing. The use of a standard order set could optimise antimicrobial therapy.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-100 INTRADIALYTIC PARENTERAL NUTRITION EFFECTS ON ALBUMIN LEVELS IN MALNOURISHED HAEMODIALYSIS PATIENTS

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Background and importance Malnutrition is one of the strongest predictors of mortality and morbidity in haemodialysis patients. Albumin levels are used as an indicator of its severity and concentrations under 3.8 g/dL indicate severe malnutrition. As first-line treatment, guidelines recommend nutritional counselling and oral nutrition supplements. Furthermore, parenteral nutrition during regular haemodialysis sessions, known as intradialytic parenteral nutrition (IDPN), is an option for patients who can not tolerate oral or enteral routes for nutrition supplements.

Aim and objectives The aim of this study was to evaluate the effects of IDPN on albumin concentrations in malnourished haemodialysis patients.

Material and methods Observational retrospective study carried out with patients who had been in treatment with IDPN in the last 5 years, from April 2016 to April 2021. Age, sex, height, weight, body mass index, IDPN start and end dates, and albumin levels were collected to create database. Statistical evaluation was done using R commander software.

Results In this 5-year period, the total number of patients was 7 (N=7). Initial albumin levels were under 3.8 g/dL in 100% of the patients and the mean was 2.7 ± 0.58 g/dL. Mean duration of IDPN was 36 (3–150) days. Albumin concentrations increased in all patients and the mean increase was 0.80 ± 0.32 g/dL. In addition, 42.9% of the patients (n=3) attained albumin levels higher than 3.8 g/dL.

Conclusion and relevance IDPN has shown an improvement in albumin concentrations among haemodialysis patients; however, further investigations are required to establish a relation with mortality and morbidity.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-105 CARDIOVASCULAR RISK FACTORS IN PATIENTS WITH HIV INFECTION WITH ANTIRETROVIRAL TREATMENT

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Background and importance Cardiovascular disease (CVD) is a major cause of morbidity and mortality in HIV patients. Recent studies suggest that the increased incidence of CVD is due to increased patient longevity, chronic inflammation and immune activation associated with HIV infection and antiretroviral therapy (ART) itself, which may contribute to increased cardiovascular risk (CVR).

Aim and objectives To establish the frequency of cardiovascular risk factors (CVRF), as well as to estimate the incidence of CVR in patients with HIV.

Material and methods Observational, retrospective study with all HIV patients with ART who were followed up by

the Infectious Diseases Unit during 2020 at the Outpatient Unit.

The role of the hospital pharmacist in the treatment of these patients is the prevention, identification and management of the side effects associated with ART.

The variables gathered were: age, gender, AIDS prevalence, time since diagnosis, time and current ART.

The CVRF were evaluated following the criteria of the European Society of Cardiology: age, male gender, smoking, hypertension, diabetes, dyslipidaemia, obesity.

The Framingham scale adapted to the HIV population was used to determine the risk of CVD at 10 years: low risk (<5%), moderate (5–10%), high (10–15%) or very high ($\geq 15\%$) of myocardial infarction or coronary death.

Results 950 HIV patients were included (73% male, mean age 52 years). Most of the patients had long-term infection, 25% with AIDS criteria and on ART for an average of 14 years. 98% were receiving ART, 16% with non-nucleoside analogues, 40% with protease inhibitors and 47% with transcriptase inhibitors.

The prevalence of CVRF was: age >45 years 78.5%, smoking 44%, hypertension 26.3%, diabetes 18.1%, HDL-cholesterol (HDL-C <35 mg/dL) 16.1%, total cholesterol (C-total >240 mg/dL) 10.8% and obesity 15.1%. There was a higher prevalence of CVRF associated with the male gender, which was statistically significant in diabetes, lower HDL-C and higher triglycerides ($p < 0.05$).

Regarding the CVR assessment by the Framingham scale, the mean was 10.6% (95% CI 9.9% to 11.1%). CVR was significantly higher in men than in women (12.21% vs 6.25%, $p < 0.001$).

Conclusion and relevance Classic CVRF are very common in patients with HIV, which carries a high risk of CVD. Therefore, it is advisable to improve the primary control of modifiable CVRF in HIV patients and to assess the use of drugs with a better CVR profile.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-126 REAL-WORLD PERSISTENCE WITH FAMPRIDINE AMONG MULTIPLE SCLEROSIS PATIENTS

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Background and importance Fampridine is the only pharmacological agent approved for walking impairment in multiple sclerosis (MS). Medication persistence is an important element in determining the success of any long-term therapy and real-life utilisation data are especially important to optimise resources.

Aim and objectives To evaluate the persistence of fampridine in MS patients, reasons for discontinuation and the influence of predictive factors.

Material and methods Observational, retrospective, longitudinal study. All adults with MS treated with fampridine were included. Persistence, defined as the duration of time from initiation to discontinuation of therapy, was calculated as the count of days from the index prescription to the date of the final dispensing or end of the observation period (August

2021). Persistence after the first year of treatment was also assessed.

Sociodemographic and clinical factors (age, age of diagnosis, DM phenotype, baseline Expanded Disability Status Scale (EDDS), treatment with disease-modifying therapies (DMTs) and anti-spasticity agents and walking support request) were collected from medical record. Persistence and adherence (measured as medication possession ratio (MPR)) data were collected from drug dispensation records (FarmaTools).

For the analysis of persistence a survival analysis with the Kaplan-Meier estimator was performed. Influence of covariates was evaluated according to a Cox regression model. All statistical analyses were performed using SPSS V24.0. Significance level was 0.05.

Results Fifty-one patients were included. Mean±SD age of MS diagnosis was 37.3±12.6 years. 62.7% female. At the start of the treatment, mean±SD age was 49.7±10.0 years. Phenotypes were relapsing-remitting (49%), secondary progressive (41.2%) and primary progressive (9.8%). 68.6% were on treatment with DMTs and 60.8% with anti-spasticity agents. 58.8% required support to walk. Baseline EDDS was 5±1.3. Median adherence in first year was 98.5±4.5%.

Median persistence duration was 1.756 days (95% CI 1.405 to 2.107). Median time to suspension was 84 days (IQR 28–262). Medication suspension rate in first year was 31.4% and overall medication suspension rate was 13/100 patients-year (95% IC 8.1 to 17.9). Discontinuation reasons were lack of efficacy (57.9%), adverse effects (23.1%) or both (14.3%). Cox model showed only influence of age of DM diagnosis HR=1.05 (95% CI 1.01 to 1.07; p=0.007).

Conclusion and relevance A high percentage of patients abandon treatment with fampridine, mainly due to lack of efficacy. Most discontinuations occur in the first year of treatment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-129 ADJUST DOSES OF ANTIBIOTICS IN PATIENTS WITH RENAL INSUFFICIENCY

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Background and importance Antibiotics constitute one of the main groups of drugs prescribed for hospitalised patients. Many of them present renal elimination, which is why in cases of impaired renal function is necessary to adjust the dose.

Aim and objectives To evaluate physician acceptance of pharmacist recommendation (PR) in patients with renal insufficiency.

Material and methods Prospective interventional study from June to September 2021. We included all patients who started antibiotic treatment with a glomerular filtration rate less than 50 mL/min. Data were collected from the electronic medical record (DIRAYA) and the prescription program (PRISMA). Dose adjustment recommendations were made based on the antibiotic datasheets and the Sanford Guide to Antimicrobial Therapy.

Data collected: sex, age, clinical service, prescribed antibiotic.

Recommendations were reported in the clinical course of the patient. In the case of severe kidney failure, the prescribing doctor was notified directly. Descriptive statistics were used to analyse the results.

Results 40 patients (60% men) were analysed, with a median age of 78 (range 48–92) years. 42 dose adjustment recommendations were made. The antibiotics evaluated were: piperacillin/tazobactam (22), meropenem (9), amoxicillin/clavulanic (7), vancomycin (2), ertapenem (1) and ceftazidime (1). Clinical services involved were: Internal Medicine (19), Urology (10), Cardiology (3), Digestive (3) Oncology (3), Traumatology (3) and Pneumology (1).

The rate of acceptance of PR was 79.5%: 67.7% dose reduction and 33.3% dose increase. 7.1% of the PR cannot be valued due to a change in treatment.

Conclusion and relevance The hospital pharmacist plays an important role in the correct, effective and safe use of antibiotic therapy, especially, as occurs in our study, in elderly patients. Thanks to the pharmacist-doctor communication, the number of recommendations made decreased over time in certain clinical areas due to the correct dose adjustments by the prescribing doctors.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Sanford Guide to Antimicrobial Therapy.

Conflict of interest No conflict of interest

4CPS-130 ANALYSIS OF THE DIFFERENT CardioVERSION STRATEGIES IN THE EMERGENCY DEPARTMENT IN A SECONDARY HOSPITAL

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Background and importance Acute atrial fibrillation (AF) is the most common arrhythmia managed in the emergency department (ED). Conversion to normal sinus rhythm can be performed by electrical (ECV) or pharmacological cardioversion. ECV is more effective and it is the method of choice for haemodynamically unstable patients or new onset AF; however, pharmacological cardioversion does not require anaesthesia and it is easier to attempt.

The choice to pursue rhythm control is an individualised one according to the clinical profile of the patient and the therapeutic options available.

Aim and objectives To analyse the strategies to restore sinus rhythm for ED patients with acute AF and the results obtained.

To analyse the time from AF onset to restoration of sinus rhythm.

Material and methods Observational, retrospective, multidisciplinary study. Inclusion criteria: patients >18 years treated at the ED (June 2020–February 2021) with diagnosis of AF in which it was decided to restore sinus rhythm.

Variables demographic, comorbidities (chronic renal failure, diabetes, obesity), haemodynamic stability (yes/no), structural heart disease, type of cardioversion (ECV or pharmacological), drug used in pharmacological cardioversion, conversion to normal sinus rhythm (yes/no), time to restoration of rhythm, rescue cardioversion if failure.

Results For a total of 186 patients with a diagnosis of acute AF in the ED, 83 (45%) patients were eligible to pursue rhythm control. Mean age 66 ± 13 years, 58% women, 47% with comorbidities. Haemodynamically unstable patients 11%, 34% had structural heart disease.

Seven patients underwent ECV. Pharmacological cardioversion (92%): 55% amiodarone, 41% flecainide, 3% vernakalant, 1% propafenone.

Time from AF onset to restoration of sinus rhythm: <2 hours in 100% of ECV; amiodarone 45% of patients <2 hours, 17% 2–6 hours, 21% 6–12 hours, 17% >12 hours; flecainide 52% <2 hours, 44% 2–6 hours; vernakalant 100% <2 hours.

Cardioversion failed in 25% of patients. Rescue therapy: 67% alternative cardioversion strategy and 33% rate control approach.

Conclusion and relevance Although the gold standard therapy is ECV, it was underused in our sample of patients.

In addition, amiodarone was the most widely prescribed drug, although the time to restore sinus rhythm was shorter with other therapies (excluding flecainide).

More trials comparing different strategies are needed to better understand the optimal management of acute AF.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-136 PERSISTENCE OF FIRST-LINE BIOLOGICAL THERAPY IN PATIENTS WITH CROHN'S DISEASE

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Background and importance Treatment of patients with moderate-severe corticosteroid-dependent or corticosteroid-refractory Crohn's disease (CD) consist of biologically synthesised monoclonal antibodies. Due to the limited number of available drugs, optimal treatment monitoring is important to increase drug persistence and to maintain clinical remission.

Aim and objectives To describe the prescribed biological drugs in patients with CD and to compare the persistence of these treatments in first-line in comparison with subsequent therapies.

Material and methods A descriptive, observational, cross-sectional study was conducted in May 2021. All patients with CD and biological therapy were included. Data were obtained from the hospital information system. The following data were recorded: age, sex, prescribed biological drug, months since the treatment was started, dose and frequency, previous biological treatments and concomitant immunosuppressive therapy. Values are expressed as percentages and means (range).

Results A sample of 84 patients was obtained. The mean age was 48 (19–88) years and 43 (51.19%) were men.

Sixty-seven (79.76%) patients were on first-line treatment, 26 (38.81%) were prescribed adalimumab (ADA), 40 (59.70%) infliximab (IFX) and 1 (1, 49%) ustekinumab (UTK). Seventeen (20.24%) patients were on subsequent lines of treatment, 8 (47.06%) were prescribed ADA, 2 (11.76%) IFX and 7 (41.18%) UTK.

Forty-three (64.18%) patients who were on first-line treatment and 9 (52.94%) on subsequent lines of treatment were receiving concomitant immunosuppressive therapy.

The mean duration of treatment in first-line was 67 (0–167) months and in subsequent lines of treatment was 31 (4–97) months.

Sixteen (23.88%) patients who were on first-line treatment and 9 (52.94%) on subsequent lines of treatment received the drug at a higher dose or frequency than that indicated in the technical data sheet (intensified treatment).

Conclusion and relevance IFX was the most used monoclonal antibody in first-line, followed by ADA. However, ADA was the most prescribed in subsequent lines of therapies, followed by UTK.

In our study, first-line treatments maintained longer clinical persistence. However, more clinical data are needed to conclude that first-line treatments are most effective.

Subsequent therapies were less persistent despite being intensified in a greater number of patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-140 ANTIMICROBIAL STEWARDSHIP PROGRAMME IN ONCOLOGY PATIENTS THROUGH A MULTIDISCIPLINARY TEAM

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Background and importance Antibiotic stewardship programmes (ASPs) aim to improve clinical outcomes in patients with infections and reduce adverse effects related to the use of these drugs, including the emergence of bacterial resistance.

In cancer patients, the development of infections is one of the most important causes of morbidity and mortality, which is why the consumption of antimicrobials is notable in this group of patients. For this reason, it is essential to optimise antimicrobial treatment both in therapeutic target and duration.

Aim and objectives To describe the actions carried out by the ASP in the oncology unit and analyse the degree of acceptance of these interventions.

Material and methods Prospective single-centre study to evaluate the interventions carried out by non-imposing counselling of the ASP team. The duration of the study was 3 months (April-July2021). During this period all inpatient antimicrobial prescriptions from the oncology unit were reviewed in a weekly meeting.

The intervention consisted of an evaluation of the adequacy of the prescription to the hospital antibiotherapy guide, review of the risk factors for multidrug-resistant microorganisms, and verification of the concordance between prescribed dose and renal function. In the case of discrepancy, an individualised proposal is made in a multidisciplinary meeting made up of experts from oncology, infectious diseases and pharmacy.

Demographic, biochemical, microbiological and clinical variables of the patient are collected through the electronic medical record.

Results Sixty-seven patients (51% female) with mean age 62 ± 11 years were included. A total of 101 antimicrobials corresponding to 85 prescriptions were reviewed.

The most prescribed antibiotics were piperacillin/tazobactam (22), ceftriaxone (16), cotrimoxazole (15), amoxicillin/clavulanate (8) and metronidazole (5).

The sources of infection were respiratory (26.2%), urinary (21.3%), intra-abdominal (21.3%), skin and soft tissue (9.8%), catheter-associated (6.6%) and unclear (14.8%).

Recommendations were made to continue treatment (67.8%), discontinue for excessive duration (10.3%), de-escalate (9.2%), discontinue for unnecessary antimicrobial (8.0%) and escalate (4.6%).

The acceptance rate was 98.8%.

Conclusion and relevance The recommendations made by the ASP team were almost entirely accepted by the responsible clinician. Advice from a multidisciplinary team of experts in the field benefits these patients in optimising their antimicrobial therapy.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-152

CHARACTERISATION OF A COMPOUNDED VORICONAZOLE SOLUTION FOR NEBULISATION AND DESCRIPTION OF ITS USE IN THE CLINICAL SETTING

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Background and importance Voriconazole is the primary treatment for invasive pulmonary aspergillosis. Antifungal nebulisation has advantages, but there are no commercial antifungal pharmaceutical presentations for nebulisation.

Aim and objectives To physicochemically characterise a compounded voriconazole solution for nebulisation and to describe its use in a cohort of patients.

Material and methods Voriconazole solution for nebulisation was prepared in the Pharmacy Department. Accord, Kern and Normon vials were used.

Clinical data from patients treated with nebulised voriconazole in our hospital were retrospectively collected.

Voriconazole concentration in plasma was determined using high-performance liquid chromatography.

Results Voriconazole vials containing 200 mg of powder for solution for infusion were diluted with sterile water for injection (19 mL). The solutions were adequate for nebulisation (pH 4.97, 7 and 5; osmolarity 359, 503 and 313 mOsm/kg, respectively). Syringes containing 40 mg/4 mL were dispensed.

Ten patients received nebulised voriconazole, 9 adults and 1 child; median age was 35 years (minimum 5 and maximum 69 years), all men. Five patients had cystic fibrosis and 8 had undergone lung transplantation (LT) 7 (0–84) months ago. 6 patients had respiratory distress and 2 were colonised. Treatment was started on the hospital floor (5), intensive care unit (3) or outpatient department (2).

Fungi detected were *Aspergillus spp* (5) (*A. flavus* (4)), *Scedosporium spp* (4) and *Purpureocillium spp* (1).

Treatment was started due to lack of response to systemic treatment (4), toxicity (4), avoiding drug-drug interactions (2), post-LT prophylaxis (1) and booster oral voriconazole effect (1).

Doses (40 mg for adults, 10 mg for children) were administered every 12–24 hours (2–3 days in the case of colonisation) during a median of 130 (26–911) days.

Three patients died, 3 fungal infections resolved, 2 had colonisation without exacerbations, there was one case of voriconazole resistance and the patient using voriconazole as prophylaxis had a successful evolution.

No adverse events were reported, only mild pruritus in a patient with a history of allergy (treatment withdrawal was not required).

There were 11 voriconazole plasma measurements for 6 patients. Voriconazole was only detected in 2 patients receiving oral voriconazole.

Conclusion and relevance The characteristics of the compounded voriconazole solution are adequate for nebulisation.

Compounded voriconazole solution is well tolerated and it is not absorbed into the systemic circulation.

Nebulised voriconazole could be an interesting therapeutic option to treat pulmonary infections and/or colonisations.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-164

DURABILITY OF ORAL DUAL ANTIRETROVIRAL THERAPY IN HIV PATIENTS

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Background and importance Dual antiretroviral therapy (DAT) is currently used as initial treatment in naïve patients or as a maintenance therapy in those who are virologically suppressed. The simplification of antiretroviral regimens is associated with a reduction in treatment toxicities and costs and an adherence improvement. However, there are a lack of studies reporting data on DAT effectiveness beyond clinical trials.

Aim and objectives To assess the durability and reasons for discontinuation of DAT in HIV-infected patients.

Material and methods This was a retrospective, cohort study. Adult HIV-infected patients who started a treatment with DAT between 2015 and 2019 in a general hospital were included. Sociodemographic data, HIV-1 RNA copies at baseline and treatment data (DAT combination, previous treatment, time to discontinuation and reason for discontinuation) were collected from clinical records. Treatment durability was assessed using the Kaplan-Meier analysis up to 48 weeks.

Results Fifty-one patients were included: 31 patients were male, mean age was 49±11 years. Mean time from HIV diagnosis was 16.2±9.1 years, 20 patients had a previous classification Centers for Disease Control and Prevention (CDC) stage C and 15 had a history of intravenous drug use. Thirty-six patients were previously treated with a three-drug regimen, 8 with a DAT, 5 with an antiretroviral monotherapy and 2 were treatment-naïve. Thirty-seven patients were virologically suppressed at baseline. DAT combinations were: integrase inhibitor (INI) plus nucleoside reverse transcriptase inhibitor (NRTI) or non-nucleoside reverse transcriptase inhibitors (NNRTI) (n=29), boosted protease inhibitor (PI/b) plus NRTI or NNRTI (n=15) and INI plus PI/b (n=7). Thirty-nine patients maintained DAT at 48 weeks and mean treatment

duration was 40.5 ± 14.8 weeks. The reasons for discontinuation were: lack of effectiveness (n=1), treatment simplification (less-pills regimen) (n=3), abandonment (n=2), drug-drug interactions (n=2), kidney failure (n=1), death (n=1) and follow-up losses (n=2).

Conclusion and relevance A broad spectrum of DAT combinations were used according to patients' characteristics. Although 14 patients were not at virological suppression at baseline, DAT showed a high durability at 48 weeks and only 2 patients discontinued due to lack of effectiveness or toxicity.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-177 A QUALITATIVE STUDY ON PHARMACIST PRESCRIBING FOR PATIENTS WITH CHRONIC KIDNEY DISEASE

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Background and importance Chronic kidney disease (CKD) has a high risk of morbidity and mortality. The available evidence worldwide demonstrates that non-medical prescribing by pharmacists in various clinical specialties is a safe and effective approach. There is lack of evidence of information on the implementation and development of pharmacist prescribing for patients with CKD.

Aim and objectives Aim was to explore the development, implementation and evaluation of pharmacist prescribing for patients with CKD in the UK.

Material and methods This study used a qualitative semi-structured interview. The development of the theory-based semi-structured interview tool followed a rigorous iterative process using findings from the literature, underpinned by the Consolidated Framework for Implementation Research (CFIR) and reviewed independently by an expert panel. A date/time for a telephone interview was arranged following receipt of signed consent. All interviews were transcribed verbatim. Interview data were analysed thematically. The Francis method of checking for data saturation was used. Ethical approval was granted by RGU School of Pharmacy.

Results Data saturation was reached after 14 interviews. Demographic details included: 11 female, 7 had >16 years experience in the profession, all had secondary care as their main practice setting and 8 had >11 years as a prescriber. The interviewees were generally very positive about their prescribing practice and they articulated that they were prescribing in a variety of settings. CFIR helped identify themes related to facilitators and barriers to advancing prescribing practice. There was enthusiasm for the future

Abstract 4CPS-177 Table 1 Themes and interviewee illustrative quotes for facilitators and barriers to advancing prescribing practice

Themes	Quote
Facilitators – management support	"I think because I've built a rapport with the team and get lots of support from them." [Pharmacist 13]
Barriers – no renal specific training	"We could have better course around use of medications in patients with CKD." [Pharmacist 3]

development of prescribing practice including further establishment of clinics and taking responsibility for groups of patients.

Conclusion and relevance This work provides information relating to the current status of the development of pharmacist prescribing practice in the UK. Further 'deep dive' case study work will help explore the practice of leading edge advanced and consultant level practitioners to learn even more about practice development.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-181 CLINICAL-PHARMACEUTICAL MEDICATION COUNSELLING FOR PNEUMOLOGICAL PATIENTS IN OUTPATIENT AND INPATIENT AREAS

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Background and importance This project focused on direct interaction between hospital pharmacists and patients, through clinical pharmaceutical counselling. Drug safety and patient well-being are promoted and possible user errors and uncertainties concerning the medication and interactions are communicated directly. During the consultation patients were given the opportunity to ask questions, express uncertainties and receive information regarding their medication. Two different settings for the project (outpatient and inpatient) allowed investigation of which questions were of primary concern in these different situations.

Aim and objectives Most *chronic obstructive pulmonary disease* (COPD) patients have up to at least three comorbidities in addition to their primary pneumological disease. These can affect the heart, bones, metabolism and/or psyche, among others. Therefore polymedication is almost inevitable. Clinical-pharmaceutical counselling of patients is intended to promote adherence and medication safety. Especially for these patients, adherence to therapy is crucial and close monitoring of the medication is essential. This patient-oriented service is intended to be a tool for optimal drug therapy, since it has already been shown that clinical-pharmaceutical interventions, such as the targeted education of patients, can reduce adverse drug events and readmissions.

Material and methods A guideline with predefined questions about health status, medication scheduling, intake modalities, uncertainties, and a final satisfaction survey was created in order to be able to offer a comparable consultation to all patients. Prior to the consultation, patient records were reviewed and the medication was checked for possible interactions using drug interaction software programs.

Results It could be shown that the consultation for the inpatient area was related to medication changes during the stay and the expected benefits from those changes, thus promoting the patients' medication knowledge for the time after hospital discharge, whereas most outpatients' questions were about self-medication and over the counter (OTC) drugs. In this cohort some examples of severe drug interactions could be found.

Conclusion and relevance In summary, this medication consultation benefits the patients by increasing their knowledge regarding their medicine which leads to better adherence and

therefore less rehospitalisation, therefore showing a high impact for the work of clinical pharmacists.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-191 SWITCH TO BENRALIZUMAB FOR SEVERE EOSINOPHILIC ASTHMA

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Background and importance Mepolizumab and benralizumab are monoclonal antibodies directed against anti-IL-5 and anti-IL5R, respectively, and their use reduces exacerbation rate and maintenance oral corticosteroid requirements in severe eosinophilic asthma.

We observed that a minority of patients treated with mepolizumab experienced a suboptimal response and switched to benralizumab which provides a more complete depletion of eosinophils.

Aim and objectives To study the effectiveness and safety of benralizumab in patients with severe refractory uncontrolled eosinophilic asthma after failure of mepolizumab.

To compare patients' annual asthmatic exacerbations after switching to benralizumab.

Material and methods Observational, retrospective study of patients with severe eosinophilic asthma treated with benralizumab for at least 6 months with prior mepolizumab therapy in a tertiary level hospital. The study was conducted until October 2021.

Data collected: sex, age, adherence level, duration of treatment with mepolizumab, pulmonary function tests: forced expired volume in the first second (FEV1), FEV1/forced vital capacity ratio (FEV1/FVC); blood eosinophil value, points for the Asthma Control Test (ACT) and number of exacerbations. The average of variation in these parameters 24 weeks before and after starting treatment with benralizumab was analysed. Adverse events were also collected. Statistical analysis was performed using the Student's t-test.

Results 30 patients previously treated with mepolizumab after its failure or lack of asthma control, started treatment with benralizumab. 21 were women with a median age of 53 (17–80) years.

The average level of adherence, according to the dispensing registry, was $90.62 \pm 6.70\%$.

The median duration of treatment with mepolizumab was 13 (3–39) months.

FEV1 increased by 8.26 ± 3.90 mL ($p < 0.01$), FEV1/FVC ratio increased by 3.24 ± 1.43 ($p < 0.01$) and ACT improved by 4.84 ± 0.25 points ($p < 0.001$). Eosinophilia decreased from 160.43 ± 94.7 to 24.26 ± 20 cells/ μ L ($p < 0.001$).

Annual asthmatic exacerbations were reduced from 2.19 (1–6) to 0.57 (0–3) ($p < 0.0001$).

1 patient did not respond to benralizumab and was switched to dupilumab after 6 months.

Adverse events due to benralizumab were recorded in 3 patients, and in 2 of them treatment had to be definitively discontinued. Adverse effects were: moderate erythema nodosum, allergic reaction, hot flashes and back pain.

Conclusion and relevance We report substantial and clinically meaningful improvements in exacerbation rate, asthma control and ACT scores. Benralizumab may be an effective alternative for those patients with lack of asthma control with mepolizumab.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-199 EVALUATION OF FREMANEZUMAB RESPONSE IN MIGRAINE PROPHYLAXIS

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Background and importance Fremanezumab is a humanised monoclonal antibody (IgG2) that binds to the calcitonin gene-related peptide (CGRP). CGRP is a neuropeptide that, in addition to modulating nociceptive signals, is a vasodilator that is associated with migraine. CGRP levels have been found to increase significantly during migraine and normalise with headache relief.

Aim and objectives To study the effectiveness and security of fremanezumab in migraine prophylaxis after 3 months of treatment.

Material and methods Retrospective observational study. All patients with more than 3 months of fremanezumab treatment in our hospital were included.

Data collected: sex, age, previous biological therapy, dosage regimen, moderate-severe migraine days per month and score on the Headache Impact Test-6 (HIT-6), Migraine Disability Assessment Scale (MIDAS) and any adverse event.

Results Forty-five patients were included with a median age of 43 (23–70) years of whom 39 (86.7%) were women. Effectiveness data could be extracted for 35 of them.

No patient had any other previous biological treatment for migraine. 32% of patients were treated with fremanezumab 675 mg once every 3 months and the remainder with 225 mg monthly.

Patients presented pre-baseline versus after 3 months (mean \pm standard deviation): 17.7 ± 7.2 vs 10.9 ± 9.4 migraine days/month ($p < 0.001$); MIDAS scale: 94.8 ± 80.4 vs 82.3 ± 102.7 ($p > 0.1$) and HIT-6 scale: 65.4 ± 9.8 vs 63.2 ± 11 ($p > 0.01$).

Treatment was effective (reduced by half the number of migraine days per month) in 53% (20 patients). 5.7% of patients (n=3) were discontinued due to a response of less than 30%. Of the 3 patients who did not respond, 2 switched to galcanezumab and 1 to botulinum toxin.

31% patients presented some type of adverse event. Most of them were due to reactions in the area of administration, asthenia and gastrointestinal disorders, and all were of mild-moderate intensity.

Conclusion and relevance Fremanezumab has demonstrated consistent efficacy in some patients by achieving a fast reduction in the number of migraine days per month, although the reduction in pain and disability was not shown to be statistically significant.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-215 PERSISTENCE AND THERAPEUTIC ADHERENCE TO FIRST-GENERATION JANUS KINASE INHIBITORS IN RHEUMATOID ARTHRITIS PATIENTS

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Background and importance First-generation Janus kinase inhibitors (JAKi), tofacitinib and baricitinib, are approved in adults with moderately to severely active rheumatoid arthritis (RA) who have not responded or tolerated previous treatment lines. Real clinical data about persistence and therapeutic adherence to these treatments is scarce.

Aim and objectives (i) To assess and compare first-generation JAKi persistence in clinical practice. (ii) To compare whether therapeutic adherence to tofacitinib and baricitinib influences treatment persistence.

Material and methods This was a retrospective study which included all RA patients treated with tofacitinib and/or baricitinib between October 2017 and May 2021 in a tertiary hospital. Demographic, clinical and pharmacological data were collected from electronic medical and pharmacy claim records. Kaplan-Meier survival analyses and log rank test were performed to calculate and compare treatment persistence. We assessed drug adherence with the medication possession ratio (MPR). Effect of therapeutic adherence on treatment persistence was evaluated with a linear regression model. Statistical analyses were performed using Stata 15 software.

Results We included 136 cases (61 were treated with tofacitinib (44.9%) and 75 with baricitinib (55.1%)) corresponding to 105 RA patients. They were mostly women (86.7%) with a mean age (\pm SD) of 63 (\pm 13) years. At treatment initiation, patients had a mean DAS28-ESR (\pm SD) of 5.1 \pm 1.2. Study patients had previously received a median (range) of 3 (0–8) biologic agents for RA.

During the study period, 40 (29.4%) and 38 (27.9%) patients treated with tofacitinib and baricitinib, respectively, discontinued the treatment.

Mean treatment persistence was 363 days (95% CI 2 to 1282) in the tofacitinib group and 406 days (95% CI 8 to 1300) in the baricitinib group. There were no statistically differences in treatment survival (HR 1.01; 95% CI 0.59 to 1.71; $p=0.97$).

Mean MPR was 91.0% in both groups. There was no correlation between therapeutic adherence and persistence ($p=0.21$).

Conclusion and relevance Our results show no significant differences in treatment persistence and adherence between tofacitinib and baricitinib patients. In our cohort, medication adherence was high and did not influence treatment persistence.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-217 CLINICAL, ECONOMIC AND ORGANISATIONAL IMPACT OF PHARMACISTS' INTERVENTIONS IN ONCOLOGICAL CARE PATIENTS

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Background and importance Clinical pharmacy is considered an integral discipline in the health care system to improve patients' health outcomes by optimising therapy and reducing drug-related problems (DRP), which are highly detected in oncological patients with complex therapies.

Aim and objectives Evaluate the clinical, economic and organisational impact of pharmaceutical interventions (PI).

Material and methods An observational, prospective and interventionist study was conducted in an oncology unit from October 2020 to March 2021. Clinical pharmacists identified, during medication review, relevant DRPs, which were subsequently classified according to the Overhage & Lukes severity scale, which led to a PI. All PIs were analysed to evaluate clinical, economic and organisational impact through the multidimensional tool CLEO.

Data were collected in an Excel database through the systematic review of inpatients via an electronic medical record program (HPHCISv.3.8). Variables collected were demographic, DRP detected, severity, PI recommended and its acceptance and later implementation.

The relationship between clinical, economic and organisational IPs relevance and DRP severity was assessed throughout with Spearman's correlation coefficient.

Results During the study period, 153 patients were included (50% female) with a mean age of 66 years. In one-third of the patients, 114 DRP and IP were recorded. The most common DRP identified were 'supratherapeutic dosage' (25.4%), 'untreated indication' (21.1%) and 'subtherapeutic dosage' (13.2%). Medication errors were considered significant in 68.4% of cases. PIs were mainly related to dose adjustment (35.1%) and untreated indication (22%). They were accepted in 78.1% of cases.

Clinical impact of PIs was 'major', 'moderate' and 'minor', in 4.4%, 16.4% and 79.2%, respectively. Regarding the economic and organisational dimension, 33.3% of PI would decrease the costs of care and 80.7% would be favourable on the quality of medical care.

The severity of the medication error and the clinical, economic and organisational significance of the PI were correlated with a medium statistical reliability level (Spearman's $\rho=0.343$; $\rho=0.439$ and $\rho=0.487$, respectively).

Conclusion and relevance The present study proves clinical pharmacists play a key role for detecting DRPs during medication review, whose severity relates to significant clinical, economic and organisational relevance. PIs allow an improvement of the quality standards of medical care while having a positive impact on cost saving in the clinical process. Including a clinical pharmacist as an essential member of the

multidisciplinary group would lead to an improvement in the care process.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-237 MEASURING ADHERENCE TO ANTIRETROVIRAL TREATMENT: CORRELATION AND CONCORDANCE BETWEEN TWO INDIRECT METHODS

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Background and importance Adherence is one of the most important variables for achieving the benefits of antiretroviral treatment (ART) since effectiveness and safety of current treatments are optimal.

Adherence can be measured by direct methods, which consist of measuring the substances in biological samples, or by indirect methods based on patient interviews and dispensing records.

Indirect methods have the advantages of simplicity, an easier application in daily clinical practice and lower costs.

Aim and objectives The objectives of this study were to describe ART adherence in people living with human immunodeficiency virus (HIV) and to analyse the correlation and the concordance between two indirect methods used to measure adherence: a simple single item rating scale answered with a visual analogue scale (SIRS-VAS) and the medication possession rate (MPR).

Material and methods Multicentre (5 centres), observational, prospective and cross-sectional study. We enrolled adult people living with HIV (PLHIV) on ART.

The adherence was measured using two indirect methods. One was a SIRS-VAS about the percentage of ART taken in the previous month. The other method was the MPR, calculated over the previous 6 months from dispensing records.

$MPR (\%) = (\text{days covered with dispensed medication} / \text{time interval}) * 100$.

For studying the adherence as a qualitative variable, different cut-off points were established on the SIRS-VAS and the MPR (95%, 90%, 85% and 80%), classifying participants as 'adherent' or 'non-adherent'.

Spearman correlation coefficient (r) was studied between quantitative variables. Cohen's kappa concordance coefficient (κ) was studied between qualitative variables.

P values under 5% were considered statistically significant.

Results We enrolled 128 participants, aged 20–81 years ($\bar{x}=46.9 \pm 11.7$); 112 men, 14 women, and 2 non-binary people.

The mean \pm SD MPR was $96.8 \pm 7.0\%$. The mean \pm SD SIRS-VAS score was $96.9 \pm 5.8\%$. There was a modest correlation between both measures ($r = 0.31$, $p < 0.001$).

We observed the following qualitative concordance results between both measures:

Adherence cut-off point	κ	p
95%	0.318	0.000
90%	0.280	0.001
85%	0.127	0.145
80%	-0.030	0.724

Conclusion and relevance According to the results of both the SIRS-VAS and the MPR the adherence to ART in our population is optimal. The correlation between the SIRS-VAS and the MPR was only modest. The concordance between both measures was higher for people with high adherence results.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-239 IMPACT OF KNOWLEDGE ABOUT HUMAN IMMUNODEFICIENCY VIRUS (HIV) TRANSMISSION ON THE QUALITY OF LIFE OF PEOPLE LIVING WITH HIV

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Background and importance Prejudices about sexually transmitted infections and misinformation about their transmission cause people living with human immunodeficiency virus (HIV) to continue to suffer social stigma. Social stigma can have a significant impact on mental health, global health, adherence to antiretroviral treatment and the quality of life (QoL) of these individuals.

Aim and objectives The aim of this study was to analyse the impact of knowledge about HIV transmission on the QoL of people living with HIV (PLHIV) to justify future interventions.

Material and methods Multicentre (5 centres), observational, prospective and cross-sectional study. We included adult PLHIV on antiretroviral treatment. Participants with less than 3 months since diagnosis were excluded.

The QoL was quantified using the validated WHOQOL-BREF questionnaire, consisting of 26 questions, directly scored from 1 to 5, with the exception of questions 3, 4 and 26, which are inversely scored. Results are directly proportional to the QoL. This questionnaire is divided into components: 'Self-Perception of QoL' (SPQoL), 'Self-Perception of Health' (SPH), 'Physical Health' (PH), 'Psychological' (Ps), 'Social Relationships' (SR) and 'Environment' (E). Results for each component are achieved by totalling the values of the items that comprise it.

Knowledge about HIV transmission was evaluated using an *ad hoc* questionnaire of 20 statements, to be responded to with 'true' or 'false'. Results were the percentages of correct answers, considering as optimal knowledge results greater than or equal to 80%.

Associations between quantitative and qualitative variables were analysed with Student's t-test or Mann-Whitney U test, based on normality tests. P values under 5% were considered statistically significant.

Results We enrolled 133 participants, aged 20–81 years old ($\bar{x}=46.8\pm 11.7$); 115 men, 16 women and 2 non-binary people.

The mean WHOQOL-BREF score was 3.54/5 (SPQoL=3.7/5; SPH=3.6/5; PH=3.5/5; Ps=3.6/5; SR=3.3/5; E=3.6/5).

The knowledge evaluation obtained an average of 87.1 \pm 10.6% of correct answers. 104 participants (78.2%) had optimal knowledge.

PLHIV with suboptimal knowledge reported worse QoL ($\Delta\bar{x}=9.1$, 95% CI 3.4 to 14.9; $p=0.002$) including SPQoL ($\Delta\bar{x}=0.6$, 95% CI 0.2 to 0.9; $p=0.001$), PH ($\Delta\bar{x}=2.4$, 95% CI 0.7 to 4.2; $p=0.006$), SR ($\Delta\bar{x}=1.3$, 95% CI 0.3 to 2.3; $p=0.011$) and E ($\Delta\bar{x}=2.9$, 95% CI 1.1 to 4.6; $p=0.002$).

Conclusion and relevance The results of this study justify the need for health education interventions in PLHIV who have suboptimal knowledge about HIV transmission in order to improve their quality of life.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-242

HUMAN IMMUNODEFICIENCY VIRUS PRE-EXPOSURE PROPHYLAXIS: ANALYSIS, FOLLOW-UP AND PANDEMIC EFFECT

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Background and importance In 2019, the National Health System (NHS) approved funding for the indication of pre-exposure prophylaxis (PreP) as an strategy to prevent human immunodeficiency virus (HIV) infection in high-risk populations. The hospital pharmacy (HP), together with the Sexually Transmitted Infection (STI) centre, has created an interdisciplinary circuit where these individuals are closely monitored.

Aim and objectives To characterise the user population of the HIV PrEP programme and assess the adequacy of the circuit, as well as the impact of the SARS-CoV-2 pandemic.

Material and methods Retrospective observational study of the PrEP programme from November 2019 to April 2021 carried out in the provincial STI treatment centre and the HP.

The following were assessed: compliance with inclusion criteria, adherence to treatment and causes of discontinuation, toxicity, acquisition of STIs and interactions. Also variations during confinement and degree of involvement by COVID.

Results 169 males, aged 39.6 \pm 10.0 (range 19–64) years, all met at least one inclusion criterion in the last year: 75.7% (n=128) men who have sex with men (MSM) with more than 10 different sexual partners, 71.6% (n=121) MSM anal sex without condoms, 17.1% (n=29) MSM drug use, 10.7% (n=18) MSM with multiple PreP, 74.0% (n=125) MSM with at least one STI and one engaged in prostitution.

30 clients discontinued medication: 33.3% (n=10) stopped risky practices, 20.0% (n=6) digestive toxicity (main adverse effect), 3.3% (n=1) poor adherence, 16.7% (n=5) client

choice and 26.7% (n=8) drop out of follow-up. Mean adherence was 94.5 \pm 11.4.

No patients acquired HIV during treatment, but other STIs were found (several users reported reduced of condom use): 36.7% (n=11) *Treponema pallidum*, 56.7% (n=17) *Chlamydia trachomatis*, 63.3% (n=19) *Neisseria gonorrhoeae* and 36.7% (n=11) *Mycoplasma genitalum*.

This was a young population that does a lot of physical exercise and after the clinical interview it was discovered they were abusing protein shakes and anabolic steroids, therefore they were warned about it.

During the confinement, 41 users were in treatment. Of the 37 who continued, 4 suffered from COVID.

Conclusion and relevance The programme meets the requirements of the NHS, with high adherence to treatment and a good safety profile.

Patients continued with PreP during confinement and there was a significant number affected by COVID.

Clinical pharmaceutical follow-up has allowed preventive and corrective interventions, but more emphasis should be placed on the use of condoms and avoiding anabolic steroids given the possible renal repercussions.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-245

INAPPROPRIATE ANTIBIOTIC DOSAGE ADJUSTMENTS IN PATIENTS WITH RENAL IMPAIRMENT: A CROSS-SECTIONAL ANALYSIS

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Background and importance Adequate dose titration in patients with renal impairment is crucial to avoid adverse effects and to achieve therapeutic goals. Dose reduction at baseline is not recommended to achieve desired plasma levels and to prevent the development of resistance.

Aim and objectives To assess the inadequacy of prescribed antibiotic doses according to renal function and to identify the medical services involved.

Material and methods Cross-sectional, descriptive study. All patients over 18 years of age with antibiotics prescribed on the day of the cut-off requiring adjustment according to renal function were included; patients admitted to the intensive care unit were excluded. The variables age, sex, prescribing specialty, antibiotic, dose and glomerular filtration rate were collected. Each prescription was reviewed according to our teaching hospital guidelines. Medical history and electronic prescription program were used for data collection.

Results 227 prescriptions for 200 patients (54% men, mean age 68 years) were reviewed. 9.7% of these prescriptions were not correctly adjusted for glomerular filtration rate. Of these, piperacillin/tazobactam was the most commonly prescribed antibiotic with an inadequate dose (45.5%), followed by amoxicillin/clavulanate (27.3%), meropenem (13.6%), vancomycin (9.1%) and gentamicin (4.5%).

The type of adjustment required would have been: dose adjustment (50%), interval modification (27.3%), and both (22.7%). 72.7% of these prescriptions were underdosed and 27.3% overdosed.

In terms of prescribing specialties, Internal Medicine had the highest rate of inadequacy (72.7%), followed by Digestive Medicine (9.1%).

34 of the 227 prescriptions reviewed (15%) required dose adjustment due to glomerular filtration rate below 30 mL/min, of which 35.3% were inappropriately prescribed (20.6% with piperacillin/tazobactam and 14.7% with amoxicillin/clavulanate). Furthermore, 52.9% of them required a first loading dose different from the maintenance doses and in 88.9% of them this was done incorrectly as in most cases the filtrate-adjusted dose was prescribed directly.

Conclusion and relevance A small but not negligible percentage of patients with renal failure do not receive a correct dose. Training physicians in proper prescribing and optimising the pharmaceutical validation process in these patients is essential to ensure their correct use. In addition, this study identifies the need to follow a protocol on the correct initial loading doses and the time required for their adjustment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-253 DIFFERENCES BETWEEN PHARMACEUTICAL INTERVENTIONS PERFORMED ON ANTIMICROBIALS IN MEDICAL AND SURGICAL SERVICES

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Background and importance The increasing in-hospital use of antimicrobials requires pharmacists' involvement in multidisciplinary teams. Pharmaceutical interventions (PI) are essential to optimise antimicrobials' effectiveness and safety.

Aim and objectives To describe PI performed on antimicrobials in different hospitalisation services.

To analyse differences between sociodemographic variables and mortality depending on type of service and PI performed. **Material and methods** Retrospective observational study in a 750-bed university hospital. PI analysed from October 2020 to March 2021. Registered variables: PI type, service, age, length of stay (LOS) and mortality.

Statistical analysis: Wilcoxon or Kruskal-Wallis test for quantitative variables; Chi-square test for qualitative variables.

Results Total PI performed: 16 913, 3145 (18.6%) on antimicrobials. PI at medical services 2449 (77.9%), surgical 696 (22.1%). Table 1 details the services with the most PI performed.

	Medical	Surgical	P value
Age	77 (65–86)	68 (56–79)	p<0.001
LOS	16 (8–28)	17 (9–35)	p=0.036
Mortality	444 (18.6%)	31 (4.6%)	p<0.001

	Effectiveness	Toxicity	Administration/ information	Monitoring	P value
Age	72 (60–81)	79 (67–87)	72 (59–83)	76 (64.5–86)	p<0.001
LOS	17 (8–31)	16 (9–28)	15 (8–29)	17 (9–30)	p=0.129
Mortality	66 (12.5%)	149 (18.2%)	166 (16.7%)	94 (13.2%)	p=0.007

Conclusion and relevance The most common type of PI was administration/information, except in geriatrics where monitoring was predominant.

Toxicity prevention is the second most frequent PI type in medical services; while effectiveness optimisation is second in surgical ones.

LOS in surgical services is longer than medical services, with higher mortality in medical services.

Patients with PI to prevent toxicity present higher mortality and, together with monitoring-requiring ones, are older.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-255 FREQUENCY OF CONSUMPTION OF COMPLEMENTARY AND ALTERNATIVE MEDICINE AMONG HIV PATIENTS: A MULTICENTRE CROSS-SECTIONAL STUDY

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Background and importance Consumption of complementary and alternative medicine (CAMs) has increased among human immunodeficiency virus (HIV) patients. CAMs are of questionable safety and efficacy and may interact with antiretroviral

Abstract 4CPS-253 Table 1

	Optimisation of treatment effectiveness	Toxicity prevention	Administration enabling and/or information	Pharmacotherapy monitoring	P value
Medical	353 (14.4%)	692 (28.3%)	807 (33.0%)	597 (24.4%)	p<0.001
Surgical	187 (26.9%)	143 (20.6%)	222 (31.9%)	144 (20.7%)	
Geriatrics	81 (11.0%)	198 (26.8%)	209 (28.3%)	251 (34.0%)	p<0.001
Infectious	91 (14.7%)	194 (31.2%)	219 (35.3%)	117 (18.9%)	p<0.001
Other surgeries	67 (25.0%)	54 (20.2%)	95 (35.5%)	52 (19.4%)	p<0.001
Traumatology	57 (23.7%)	37 (15.4%)	83 (34.4%)	64 (26.6%)	p<0.001
ICU	18 (12.1%)	27 (18.1%)	56 (37.6%)	48 (32.2%)	p=0.005
Internal	21 (14.1%)	35 (23.5%)	48 (32.2%)	45 (30.2%)	p=0.226

Abstract 4CPS-255 Table 1

Parameter	Value
Patients, n	209
Age, years (SD)*	47.3 (10.3)
Male, n (%)	176 (84.2)
HIV viral load undetectable, n (%), CD4 >200 cells/mm ³ , n (%)	136 (65.1), 160 (76.6)
ART type, n (%) NNRTI, PI, Raltegravir, Elvitegravir, Dolutegravir	47 (22.5), 32 (15.3), 25 (12.0), 37 (17.7), 48 (23.0)
HCV coinfection, n (%)	10 (4.8)
Most frequent CAMs, n (%) Green tea, Black tea, Red tea, Fish oil, Ginger, Cannabis, Field horsetail [P1]	71 (34.0), 41 (19.6), 34 (16.3), 28 (13.4), 26 (12.4), 24 (11.5), 21 (10.0)

*Median (range).

treatment (ART). There are no data about the frequency of CAMs consumption in the Spanish HIV population.

Aim and objectives This study aimed to explore CAMs consumption and drug-drug interactions (DDI) in a cohort of HIV patients.

Material and methods Cross-sectional multicentre study conducted between June and November 2018 in nine Spanish hospitals. Data collected: demographics, current ART, adherence (patients' self-report), CAMs consumption, virological and immunological current status. A structured questionnaire was used to assess CAMs consumption.

Identification of DDI was performed using the University of Liverpool database and classified in three categories: no clinically significant interaction, potential interaction requiring close monitoring/change (moderate) and contraindication (severe).

Results 420 patients were included; 347 (82.6%) male, aged 47(±10.4) years; 337 (80.2%) Caucasian, 209 (49.8%) taking 86 different CAMs. Table 1 shows the characteristics of patients taking CAMs and the most consumed CAMs. Ninety (21.4%) patients took ≥3 CAMs and 34 (8.1%) took ≥5 CAMs. At least one DDI was identified in 34 (16.3%) patients, all being moderate. Most frequent CAMs involved in DDI were magnesium (n=8), multivitamins (n=7) and cat's claw (n=3). In 68 (79.1%) CAMs no information was found.

Conclusion and relevance A high frequency and variety of CAMs consumption was observed in the Spanish HIV population, with green tea, black tea, red tea, fish oil and ginger being the most consumed products.

In 16% of patients a DDI with the ART requiring close monitoring/treatment change was detected. However, in almost 80% of CAMs no information about potentials DDI was found.

These results highlight the need to provide adequate information about these products to HIV patients as part of their pharmaceutical care due to their unawareness of potential drug interactions.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-257 EFFECTIVENESS AND SAFETY OF NINTEDANIB AND PIRFENIDONE IN PATIENTS WITH IDIOPATHIC PULMONARY FIBROSIS

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Background and importance Idiopathic pulmonary fibrosis (IPF) is a progressive disease with a poor prognosis. Nintedanib and pirfenidone are the only drugs indicated for this pathology. In pivotal clinical trials these drugs reduced the decline in forced vital capacity (FVC), which is consistent with a slowing of disease progression.

Aim and objectives Evaluation of the effectiveness and safety of nintedanib and pirfenidone in IPF in a second-level hospital.

Material and methods A descriptive study was designed in patients diagnosed with IPF treated with nintedanib or pirfenidone for at least 11 months. The following data were recorded: sex, age, dose, duration of treatment, initial FVC, FVC at 12 and 24 months, and death from any cause. The Electronic Medical Record (Selene), outpatient pharmacy software Farmatools and IBM SPSS Statistics were used. Patient data were collected between 1 January 2015 and 1 September 2021. To evaluate the effectiveness, the decline in FVC was used as the main variable. Dose reduction, time until dose reduction, and treatment discontinuation were used to evaluate safety.

Results Thirty patients were included: 23 (76.7%) men and 7 (23.3%) women, mean age 67 (49–83) years. A total of 16 (53.3%) patients received nintedanib and 14 (46.7%) pirfenidone. Mean duration of treatment was 2.8 (0.9–5) years. Mean FVC at the beginning of treatment was 2.47 L (95% CI ±0.71 L) and at 12 months the mean FVC was 2.40 L (95% CI ±0.65 L). In 16 patients it was possible to record a second FVC measurement at 24 months with a mean of 2.26 L (95% CI ±0.65 L). Death was recorded in 10 (33.3%) patients (5 (50%) in the nintedanib group and 5 (50%) in the pirfenidone group). Of all the patients, 6 (20.0%) had to reduce the dose (4 (66.7%) in the nintedanib group and 2 (33.3%) in the pirfenidone group). The mean treatment time until dose reduction was 6 (1–19) months. Four (13.3%) patients discontinued treatment due to adverse effects, all with nintedanib.

Conclusion and relevance FVC decreased slightly after 1 year of antifibrotic treatment and followed the same pace for 2 years. These results were comparable to those obtained in the pivotal clinical trials.

The safety of the treatment is acceptable, although one-fifth part of the patients had to reduce the dose due to adverse effects, and at least 1 in 10 patients had to abandon the treatment due to intolerance.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-264 ANALYSIS OF MEDICAL TREATMENT, RISK FACTORS AND RECURRENCE OF *CLOSTRIDIODES DIFFICILE* NOSOCOMIAL DIARRHOEA

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Background and importance The frequency of *Clostridioides difficile* infection (CDI) has been increasing worldwide to become one of the most common hospital-acquired infections. The clinical picture is diverse and ranges from asymptomatic status through various degrees of diarrhoea, to the most severe colitis. Evidence about risk factors and predictive tools can help to achieve optimal clinical management.

Aim and objectives Analyse medical treatment and risk factors of patients with CDI in order to optimise therapy and try to predict recurrence

Material and methods A retrospective descriptive study for patients with CDI between January 2012 and September 2021. The variables, collected from electronic medical records and electronic prescribing system were: age, sex, toxin polymerase chain reaction (PCR), treatment, days to end diarrhoea, severity infection measured with analytical parameters such as leukocytes $>15000/\text{mm}^3$, creatinine $>1.5 \text{ mg/mL}$, albumin $<2.5\text{g/dL}$, recurrence, patients with bowel comorbidities, deaths. Risk factors were: antibiotics consumption 3 previous months, hospitalisation 6 previous months, immunosuppressive treatment. Risk of recurrence (RR) defined with GEIH-CDI scores as: low risk 0–1 (10% RR), medium risk 2–3 (20% RR), high risk >4 (40% RR). Score defined as: <70 years (0 points), 70–79 years (1 point), >80 years (2 points), any episode in the last year (2 points), toxin PCR-positive (1 point), persistent diarrhoea after 5 days (2 points).

Results Total patients: 40 (55% men), mean age 66.2 ± 18.5 years, toxin PCR-positive 35 (81%), oral vancomycin 24 (60%), metronidazole 2 (5%), vancomycin plus metronidazole 14 (35%), fidaxomicin (second line) 7 (17%), mean days to end diarrhoea 6.06 ± 3 , mild or moderate disease 31 (77.5%), severe disease 7 (17.5%), fulminant disease 2 (5%), recurrence 8 (20%), patients with bowel comorbidities 24 (60%), deaths 2 (5%). Risk factors: antibiotics consumption 3 previous months 34 (85%), hospitalisation 6 previous months 31 (77%), immunosuppressive treatment 8 (20%). RR according to GEIH-CDI score: low risk 16 (40%), medium risk 14 (35%), high risk 10 (25%).

Conclusion and relevance Treatment was optimal in general, although there were 2 patients treated only with metronidazole. Most patients had risk factors for infection, the most important being antibiotics consumption and previous hospitalisation, it this matches with the proportion of patients with comorbidities. Recurrence was similar to high risk of recurrence measured with GEIH-CDI score, which demonstrates the utility of this tool to predict recurrence.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-265 CHRONIC COMPLEX PALLIATIVE PAEDIATRIC PATIENT AT-HOME CARE UNIT: PHARMACOTHERAPEUTIC PROFILE AND ANALYSIS OF SIALORRHOEA TREATMENT

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Background and importance Analysing the patients' characteristics in one paediatric palliative care unit is significant, as there are few such units in our hospitals. Sialorrhoea is one of the commonly associated symptoms in these patients and its treatment frequently presents a challenge for healthcare professionals.

Aim and objectives To describe characteristics of patients followed in a Chronic Complex Palliative Paediatric Patient at-Home Care Unit (CCPPHCU) of a university hospital.

To analyse the treatment of sialorrhoea.

Material and methods Observational, retrospective and transversal study included patients in the CCPPHCU during April 2021. Data were collected from the electronic medical history. Sociodemographic, clinical and pharmacotherapeutic variables were registered.

Patients with sialorrhoea were registered if they needed pharmacological treatment and/or surgery. Data collection included the number of drugs and the treatment with trihexyphenidyl, scopolamine, glycopyrrolate and botulinic toxin.

A descriptive analysis was performed.

Results Thirty-six patients were included, with a mean age of 9.5 (± 5.5) months (7 months–19 years) years and 20 (55.6%) of them were males.

A rare illness was the main diagnostic in 33.3%. Mean time in the CCPPHCU until analysis: 22.5 months (± 14.5) (10 days–4.1 years). 80.6% of patients developed convulsions, 66.7% constipation, 58.3% sialorrhoea and 55.6% spasticity.

Mean number of drugs was 6.9 (± 3.9) (1–16). 50% of the patients underwent speech therapy. 66.7% took laxatives, 66.7% anticonvulsants and 25% antispasmodics. At least one magistral preparation was prescribed in 16.7%.

Amongst patients with sialorrhoea, 81% required drug treatment and 19% only speech therapy. 52.4% were treated with 1 drug, 9.5% with 2, and 19% with ≥ 3 drugs. 71.4% took trihexyphenidyl at some point, 33.3% scopolamine, 19% glycopyrrolate and 4.8% botulinum toxin. Among patients receiving drug treatment, the first-line was trihexyphenidyl in 82.4%, scopolamine in 11.8% and glycopyrrolate as a magistral formula in 5.9%. Of those treated with >1 drug, 83.3% used scopolamine as a second-line. None underwent surgery to prevent hypersalivation.

Conclusion and relevance Seizures, constipation, sialorrhoea, and spasticity are common symptoms in patients in our CCPPHCU, often requiring medication.

In the case of patients with sialorrhoea, the majority required pharmacological treatment, with trihexyphenidyl being the most used as first-line, followed by scopolamine and glycopyrrolate.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-272 INTEGRATION OF THE HOSPITAL PHARMACIST INTO A MULTIDISCIPLINARY DYSPHAGIA SCREENING TEAM IN AN INTERMEDIATE AND LONG-STAY HOSPITAL

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Background and importance Dysphagia can occur due to a wide range of medical conditions including acute or progressive neurological disorders, trauma or surgery, with secondary effects such as dehydration and malnutrition causing an increase in morbidity and mortality rates. Dysphagia screening and assessment of swallowing function by a multidisciplinary care team is essential to identify, diagnose and manage patients with dysphagia.

Aim and objectives To analyse the results of dysphagia screening and the benefit of including a hospital pharmacist in the multidisciplinary dysphagia screening team in an intermediate and long-stay hospital.

Material and methods A prospective study of dysphagia screening and subsequent interventions was performed over a 2-week period in all patients hospitalised in an intermediate and long-stay hospital. The multidisciplinary team responsible for dysphagia screening consisted of a registered nurse and a physician with the integration of a hospital pharmacist and nutritionist. The Eating Assessment Tool-10 (EAT-10) questionnaire was used as a direct-scoring screening test for dysphagia together with the standardised Volume-Viscosity Swallow Test (V-VST) in all patients with an EAT-10 score ≥ 3 . After confirming the condition, different dietary and pharmaceutical interventions were performed. The following data were collected from the medical record program EKON: age, sex, primary diagnosis, diet and texture.

Results 86 patients (57% men) were included in the study with a mean age of 74 (39–102) years. The mean EAT-10 score was 8 ± 9 points with 33 patients (38%) testing positive for being at risk of presenting dysphagia. Of these patients at risk, the V-VST detected dysphagia and the necessity of a nectar consistency in 21 patients (64%), a honey consistency in 2 patients (6%) and a pudding consistency in 2 patients (6%). Dietary and pharmaceutical interventions were made in 17 patients (68%) of those diagnosed with dysphagia, including modifications of the diet texture, tailoring of medical formulations available or drug administration mixed with more textured food.

Conclusion and relevance Dysphagia screening in intermediate and long-stay hospitals is not common practice even though there is a high prevalence and important clinical repercussions in these settings. A hospital pharmacist plays an important role as part of the multidisciplinary team making the necessary pharmaceutical interventions needed in patients with dysphagia.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-002 ADVERSE EVENTS REPORTED AFTER ADMINISTRATION OF BNT162B2 AND MRNA-1273 COVID-19 VACCINES AMONG HEALTHCARE WORKERS

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Background and importance Since December 2019, the world has faced a new disease known as COVID-19. On 11 March 2020, the World Health Organization officially declared the COVID-19 pandemic. Given the health emergency, vaccine development progressed rapidly, but with limited safety data under real-world conditions.

Aim and objectives To describe and compare the incidence of adverse events with the BNT162b2 and mRNA-1273 COVID-19 vaccines, taking into account the number of doses and subjects previously positive for SARS-CoV-2 infection.

Material and methods A retrospective observational study was conducted in a tertiary hospital between March and April 2021. Data were collected through a questionnaire sent by email to hospital staff. Demographics and data regarding the occurrence of adverse events were collected, indicating which vaccine was administered. Statistical analysis was performed using SPSS software. Groups were compared using the Chi-square test and Fisher's exact test when necessary.

Results 1249 respondents completed the survey (25% of all hospital staff); 52% (650) received BNT162b2 vaccine and 48% (599) mRNA-1273. 14 402 adverse reactions were recorded. 6896 were local: 3939 were with mRNA-1273 and 2957 with BNT162b2 (6.6 vs 4.4 reactions per patient); and 7506 were systemic: 4460 with mRNA-1273 and 3046 with BNT162b2 (7.4 vs 4.7 per patient). The occurrence of **local reactions** was 95.8% after the first dose/89.1% after the second dose with mRNA-1273 versus 89.7%/82.5% with BNT162b2. For **systemic reactions**, this proportion was 64.3%/93.3% versus 46.8%/73.2% (p value < 0.05).

In terms of severity, 379 patients (63.3%) with mRNA-1273 confirmed a severe reaction versus 222 (34.2%) with BNT162b2 and 60 patients (10%) with mRNA-1273 confirmed an urgent reaction versus 33 (5.1%) with BNT162b2 (p value < 0.001). For both vaccines, there was no difference in the occurrence of local or systemic reactions between patients seropositive and seronegative for SARS-CoV-2.

Conclusion and relevance The results are consistent with the limited data available to date, confirming that although these are not particularly serious adverse effects, they do occur in a large majority of vaccinated persons and in greater numbers after administration of the mRNA-1273 vaccine. The Hospital Pharmacy Service is a key agent in pharmacovigilance within the healthcare system and must be aware of the safety profile of new drugs. This study is an essential tool to detect and prevent adverse events.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-005 ANALYSIS OF THE USE OF MONOCLONAL ANTIBODIES FOR THE TREATMENT OF COVID-19 IN CLINICAL PRACTICE: A WEAPON IN THE FIGHT AGAINST THE PANDEMIC, ALONGSIDE VACCINATION

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Background and importance Vaccines are emerging as a fundamental tool in the prevention of COVID-19 disease but are not decisive in treating it, once contracted. Anti COVID-19 monoclonal antibodies (MAB) define a valuable and parallel resource for the treatment of coronavirus infection so it is useful to monitor the usage data, adverse reactions (ADRs) and percentage of hospitalisations after treatment.

Aim and objectives Purpose of the work was to provide data on safety and efficacy of anti-COVID MAB in consideration of their use in current clinical practice.

Material and methods Using a home-made database, the pharmacy extrapolated and reprocessed the data relating to the reports of patient recruitment by local and hospital clinicians, the number of patients who were treated, the specific therapies administered (bamlanivimab, bamlanivimab/etesevimab or casirivimab/imdevimab) and ADRs reported by doctors. In parallel, the infectious diseases department monitored the percentage of patients who still needed hospitalisation after the infusion of MAB.

Results Most of the recruitment reports were received from general doctors (82% vs 18% from hospitals) and, from March 2021 to September 2021, 104 patients were treated: 48 patients (46.2%) with bamlanivimab/etesevimab, 55 (52.9%) with casirivimab/imdevimab and 1 (0.9%) with bamlanivimab. 67% of patients were not vaccinated while 33% received at least one dose of vaccine (58%: first dose; 42%: two doses). The main comorbidity found was the cardiocerebral/vascular type. Following outpatient dosing, 2 ADRs have been reported: an emetic episode after bamlanivimab infusion and a subacute antero-septal myocardial infarction with acute pulmonary oedema occurring within hours after administration of casirivimab/imdevimab and in the presence of a septic event of bacterial origin. 9% of patients treated with anti-COVID-19 MAB still required hospitalisation due to COVID-19; the other patients recovered completely.

Conclusion and relevance Together with the home care protocol and vaccines, MAB constitute a valid weapon in the early phase of COVID-19 disease. It is an important opportunity because it allows the virus to be faced in an active way, without waiting for the worsening of the patient's clinical condition, and with a synergistic approach of hospital and territory that join forces against this great infectious disease challenge.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-024 EFFECTIVENESS AND SAFETY OF DURVALUMAB IN THE TREATMENT OF UNRESECTABLE LOCALLY ADVANCED NON-SMALL-CELL LUNG CANCER (LA-NSCLC)

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Background and importance Unresectable locally advanced non-small cell lung cancer (LA-NSCLC) long-term survival is poor. Durvalumab is approved as consolidation treatment in unresectable LA-NSCLC, without progression after chemoradiotherapy including platinum, with PD-L1 $\geq 1\%$.

Aim and objectives To analyse the effectiveness and safety of durvalumab in the treatment of unresectable LA-NSCLC compared with the results of the pivotal study (PACIFIC). Secondary objective was influence of PD-L1 expression on effectiveness.

Material and methods Retrospective observational study of patients with unresectable LA-NSCLC treated with durvalumab in a tertiary hospital (August 2018–October 2021).

Variables studied (electronic medical history): sex, age, Eastern Cooperative Oncology Group (ECOG), smoking, PD-L1, histology, disease stage. Variable to evaluate effectiveness: progression-free survival (PFS) from the start of treatment. For safety: adverse events (AE) and toxicity grade according to the Common Terminology Criteria for Adverse Events v5.0. Statistical analysis performed with SPSS v.23 software.

Results Thirty-one patients were included, mean age 66.45 (± 9.45) years, male (74.2%), smokers (64.5%), ex-smokers (35.5%), World Health Organization (WHO) performance status: ECOG 0 (74.2%), ECOG 1 (25.8%). Disease stage IIIA (25.8%), IIIB (48.4%), IIIC (25.8%), squamous histology (41.9%), adenocarcinoma (41.9%) and unspecified (16.1%).

41.9% received induction chemotherapy. Most common chemotherapy was cisplatin-vinorelbine (48.4%). Durvalumab was initiated a median of 55 (35–70) days after chemoradiotherapy. After initiating durvalumab, the median follow-up was 15 (5–22) months. Received a median of 13 (8–26) cycles. 35.5% (n=11) of patients completed 12 months of treatment, 29% (n=9) remain on treatment. Treatment discontinuation was 22.6% (n=7) due to disease progression and 12.9% (n=4) due to severe toxicity. 51.6% (n=16) presented toxicity associated with durvalumab: 68% (n=11) grade 1–2 toxicity. Main AEs: thyroid (19.32%) and cutaneous (22.54%) alterations.

Median PFS was 14 (95% CI 7.59 to 20.4) months, with a PFS rate at 12 months (PFS12m): 70.6%. PFS12m was: 25% in PD-L1 <1% (n=4); 50% in PD-L1 1%–49% (n=10) and 73.33% in PD-L1 $\geq 50\%$ (n=15).

Conclusion and relevance Our results showed, compared with the PACIFIC study, a lower median PFS (14 vs 17 months) and a higher PFS12m (70.6% vs 55.7%), results that seem comparable. In terms of safety, the results are similar to those of the PACIFIC study, so there is a good safety profile in our patients. The data analysed showed a lower effectiveness in PD-L1 <1%. However, a larger sample and follow-up are required to obtain conclusive results.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-054 ENDOPTHALMITIS AFTER INTRAVITREAL INJECTION WITH ANTI-ANGIOGENIC DRUGS: A RARE BUT SERIOUS COMPLICATION

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Background and importance Endophthalmitis is a serious complication, which is becoming more frequent due to population ageing and the steady increase of intravitreal injections with anti-angiogenic drugs (IAD).

Aim and objectives To analyse the incidence of endophthalmitis in patients who received IAD, to describe the population affected and to classify endophthalmitis.

Material and methods A retrospective observational study was conducted from January 2017 to December 2020. Patients who received any IAD (aflibercept or ranibizumab) and developed endophthalmitis were included.

Aflibercept was preloaded in syringes in a safety cabinet (SC) while ranibizumab was ready to use. IAD was performed in a 'clean room', 5% povidone iodine or 0.05% chlorhexidine eye drops (in patients allergic to iodine) prepared in a SC by the Pharmacy Service were administered in the conjunctival sac, a blepharostat was placed and the drug was administered. Antibiotic eye drops were recommended according to the 'Spanish Vitreo-Retinal Society'.

Patients who developed endophthalmitis were admitted to hospital. Cultures were taken, intravitreal, topical and/or systemic antibiotic treatment was administered. The need for vitrectomy was assessed individually, requiring follow-up until resolution.

Endophthalmitis was classified by: (1) time: acute (less than 6 weeks since the procedure) or chronic (more than 6 weeks), (2) aetiology: infectious (positive culture) or non-infectious (negative culture) and (3) severity: good or bad prognosis (according to clinical criteria).

Results 12 057 IAD (7765 aflibercept, 4292 ranibizumab) were administered and 7 endophthalmitis (incidence 0.058%) were recorded, always after using aflibercept.

All cases were acute (always within 10 days after last IAD), 4 infectious (3 with *Staphylococcus epidermidis* and 1 with *Micrococcus luteus*) and 3 non-infectious. One case (14%) ended up with a bad prognosis.

Mean age was 63 (46–85) years, 4 males and 3 females. The average length of stay in hospital was 12 (7–21) days. Vitrectomy was performed in 4 patients. Average number of IAD received until development of endophthalmitis was 5 (2–11); 6 patients (85%) developed it after 3 or more IAD.

Conclusion and relevance Endophthalmitis after IAD is an acute, usually infectious, potentially hazardous and infrequent complication (0.019%–0.58%, incidence rate similar to previously reported). It always occurred with aflibercept, so drug handling, even under sterile conditions, might be a risk factor.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-071 REAL-WORLD RESULTS OF EFFECTIVENESS AND SECURITY OF ERENUMAB AND GALCANEZUMAB IN MIGRAINE PATIENTS

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Background and importance Migraine is a very disabling and prevalent disease that needs new therapies to reduce episodes and improve patient's quality of life. Erenumab and galcanezumab are subcutaneous monoclonal antibodies recently approved for migraine prophylaxis in patients with previous treatment failures.

Aim and objectives To assess the effectiveness and security in real-world conditions

Material and methods Observational retrospective study that included patients with the funded indication to start erenumab and galcanezumab in Spain (8 or more migraine days/month and three or more previous treatment failures) that were in treatment with any of them between October 2020 and September 2021. To evaluate the effectiveness, we recorded the average number of migraine days per month (NMDM) and the score of Headache Impact Test (HIT-6) for each patient at the beginning and at the end of the study period. Effectiveness is established in episodic migraine (EM) when there is a minimal reduction in the average NMDM of 50% and in chronic migraine (CM) when NMDM are reduced at least 30% with a decrease of minimum 5 points on HIT-6 score from the baseline value.

Results A total of 339 patients (80.27% women; mean age 46.7±11.4 years) were included. Before starting the prophylaxis, the average number of MDM of the previous 3 months were 21±7.4 days and the HIT-6 score was 66.20±5.82 points. After a mean follow-up period of 6.7±4.6 months per patient, patients that reached a response for each group according to the mentioned criteria were collected in the following table:

	Erenumab (n=182)		Galcanezumab (n=157)	
EM (n=39)	CM (n=143)	EM (n=31)	CM (n=126)	
Patients with response (n, (%))	14 (35.89)	48 (33.56)	16 (51.61)	40 (31.75)

Only 12 (3.54%) patients discontinued treatment because of adverse effects (AE): 10 (83.33%) were in treatment with erenumab, and 2 (16.67%) with galcanezumab.

Conclusion and relevance We found in our study a higher proportion of responsive patients for each drug and type of migraine than did most clinical assays. In general these drugs are well tolerated, but it seems that erenumab has more limiting AE than galcanezumab in our population study. More real-world studies are needed to confirm these findings.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-101 MEDICATION ERRORS IN UNIT-DOSE DRUG DISTRIBUTION SYSTEM: QUALITY CONTROL

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Background and importance The need to improve the quality of the unit-dose dispensing system was detected due to an increase in errors.

Aim and objectives Quantitative and qualitative analysis of errors in the dispensing of unit-dose drugs to implement measures to reduce them.

Material and methods Prospective study, 2 months duration, in a tertiary hospital. The drug trolleys of two randomised nursing units were chosen from 16 hospitalisation units (589 beds) where unit-dose dispensing was reviewed daily. The review was conducted by a pharmacist and a pharmacy technician, using a protocol for quality control of the unit-dose dispensing system, which is based on the comparison of medication listings per patient with the drug content of the drug trolleys. Finally, the pharmacist makes a quantitative analysis: number and error rate (number of dispensing errors for every 100 changes); and qualitative analysis: type of error. The data obtained are analysed monthly.

Results 247 dispensing errors were detected, with a mean of 2823 (± 124) revised changes per day. The median error rate was 1.23 (IR 0.48–1.99), the first month being 1.61 (IR 1.13–3.07), and 0.45 (IR 0–0.91) in the second month. The median error rate in the manually filled plants was 1.56 (IR 0.67–2.21) versus 0.92 (IR 0.57–1.24) in trolleys dispensed by automated dispensing cabinets. Filling the drug trolleys with an incorrect number of units was the most repeated error (44.13%, n=109), followed by the omission of introducing a medication (17.81%, n=44) and introducing a medication not prescribed (13.77%, n=34).

Conclusion and relevance From the error analysis we can conclude that:

1. A reduction in potential dispensing errors was achieved, as the error rate decreased from 1.94 to 0.59 from the first to the second month.
2. Increasing automated dispensing cabinets could help reduce errors, as plants filled without the help of electronic systems have a higher error rate (1.34 vs 1.16).
3. There is a need to educate the pharmacy technicians about the impact of their work on the safety of hospitalised patient care, insisting on the need to check the number and name of the drugs introduced.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-105 INSULIN PERFUSION IN NEONATOLOGY: WHICH ONE IS THE SAFEST?

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Background and importance Glycaemic alterations are highly prevalent in premature newborns during the first days of life. Particularly, hyperglycaemia has been reported as an independent risk factor for increased mortality and morbidity. This condition requires the use of insulin infusions for its treatment. However, this drug presents problems of adsorption to plastic that is intensified with low insulin concentrations and infusion rhythms used in neonates, conditioning the decrease and also the ignorance of the doses actually administered to the newborn. There is no consensus on the appropriate insulin preparation and administration.

Aim and objectives To determine the combination of variables for the preparation and administration of insulin infusions that provides higher accuracy and lower probability of error.

Material and methods An experimental study was carried out with the aim of determining which variable (additive (albumin yes/no), solution (sodium chloride solution, NaCl 0.9%/glucose 5%), operator (1/2), preconditioning (yes/no), purge (yes/no), concentration (0.05–0.1 UI/mL), infusion rate (0.3–0.7 mL/h) and infusion duration (1 hour/24 hours)) most influences the concentration and dose of insulin administered. The determinations were made with immunoassay using IMMULITE 1000 equipment. Previously, an ad hoc calibration was developed, adjusted to the range of doses commonly used in neonatal insulin infusions. Finally, a screening model using Plackett-Burman designs was developed to calculate insulin recovery and determine the variables with the most influence.

Results 24 experimental infusions were made, using combinations of different variables. After analysing the total of the samples, each of the recovery values obtained were entered in the screening model. The variables that achieved higher insulin recovery values were the additive (albumin - yes) and the solution (NaCl 0.9%). The model can explain 48.16% of the variation in insulin recovery, in which the additive has a standardised effect four times greater and the solution two times greater than the rest of the variables that do not exceed 1. (Figure 1: Pareto diagram)

Conclusion and relevance The additive and the solution seem to be the most important determining factors for the recovery of insulin in the preparation of the infusions. The addition of albumin and preparing the infusions with sodium chloride solution 0.9% as solution results in a greater recovery of insulin.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-111 PHARMACEUTICAL INTERVENTION: AVOIDING INTERACTIONS BETWEEN ANTIRETROVIRALS AND VITAMIN SUPPLEMENTS/ANTACIDS

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Background and importance Integrase inhibitors (raltegravir, dolutegravir, elvitegravir, bictegravir and cabotegravir) should be administered 2 hours before or 6 hours after taking medications containing polyvalent cations, such as antacids or multivitamins. Simultaneous coadministration of integrase inhibitors and polyvalent cations contained in antacids or vitamin supplements results in their reduced absorption due to a chelation process.

Aim and objectives To analyse the effectiveness of a pharmaceutical intervention to prevent the potential interaction between integrase inhibitors and vitamin supplements or antacids.

Material and methods Retrospective study conducted between May and September 2021. Patients were included if they were on treatment with ART containing an integrase inhibitor, both naive and continuation, and if they attended the pharmacy outpatient service during the study period.

Demographic (sex and age) and pharmacological variables were collected. It was also documented whether patients were taking their treatment adequately and, if not, whether they were committed to modifying their medication management.

Results One hundred and thirty-five patients treated with *anti-retroviral* therapy (ART) containing raltegravir, dolutegravir, elvitegravir, bicittegravir or cabotegravir were interviewed. Mean age was 47 years and 72% were men.

33% of the patients confirmed that they took a multivitamin and mineral complex daily and 21% took antacids occasionally.

Pharmaceutical advice was given to these patients using infographics to help them understand how to take their treatments properly (taking ART 2 hours before or 6 hours after multivitamins or antacids). 80% of these patients were not taking their therapy properly due to lack of information and 100% of them committed to following the pharmaceutical advice in order to improve the effectiveness of their treatment.

Two months later, the counselled patients were contacted by telephone and 92% confirmed that they were following the pharmacist's recommended guidelines. The remaining 8% could not be contacted.

Conclusion and relevance This study shows a large population that takes non-prescription drugs and is uninformed. Patients should be adequately interviewed during dispensing of treatment to find out what other non-prescription medicines they are taking in order to effectively prevent drug-drug interactions and to optimise ART.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-119 A DESCRIPTIVE, RETROSPECTIVE ANALYSIS OF HIGH-DOSE INTRAVENOUS VITAMIN C ADMINISTRATION IN CRITICALLY ILL COVID-19 PATIENTS

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Background and importance Proinflammatory cytokines seem to have an influence on the course and severity of a COVID-19 infection. The use of high-dose vitamin C (HDVC) represents a possible adjunctive therapy approach for the treatment of critically ill COVID-19 patients owing to its immune-modulating, anti-inflammatory and antioxidant properties.

Aim and objectives To determine the impact of adjunctive HDVC therapy on inflammatory markers such as interleukin-6 (IL-6).

Material and methods **Setting:** A descriptive, retrospective analysis with critically ill COVID-19 patients admitted to the

intermediate care unit (IMCU) and intensive care unit (ICU) in a public hospital.

Adult ICU-hospitalised patients with COVID-19 were included with those who were to receive, besides the standard of care, either:

1. HDVC (treatment group with 7.5 g/day VC up to 10 days)
2. Low-dose VC (LDVC with 1g/day VC up to 10 days)
3. No additional VC (control group).

All data were obtained from the patients' medical records from November to December 2020 and from March to May 2021.

Results Data were collected from 83 critically ill patients with confirmed COVID-19 infection. 40 patients were administered HDVC, 24 patients received LDVC and 19 patients did not receive any VC.

The mean age of the patients in the treatment group was 57.3 years, in the LDVC group 62.1 years and in the control group 55.8 years. The average IMCU and ICU length of stay was 17.4 days for patients in the HDVC-group, 21.4 days in the LDVC-group and 21.5 days in the control group. 68% from the HDVC group survived and were discharged from hospital. In the LDVC group 58% survived and in the control group 42%. Lower levels of IL-6 in the HDVC-group as compared with the LDVC-group and control group were detected.

Conclusion and relevance Our findings have demonstrated that the use of HDVC can lead to a clinical benefit due to decreased levels of IL-6. Additional investigations should be encouraged in order to further characterise adjunctive HDVC treatment in COVID-19 infection. Unlike some previous studies, our results have shown no detrimental effects of HDVC on glomerular filtration rate and serum creatinine levels.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-120 IMPACT OF THE COVID-19 PANDEMIC ON THE USE OF ANTIMICROBIALS IN PRIMARY AND HOSPITAL CARE

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Background and importance The characteristics of the patient who requires health care are different between primary care (PC) and hospital care (HC). The COVID-19 pandemic has impacted on public access to health services. Therefore, prescribing patterns and consumption of antimicrobials in both contexts could have changed.

Aim and objectives To assess the impact of the COVID-19 pandemic on antimicrobial consumption in PC and HC.

Material and methods Descriptive cross-sectional study that evaluated the antimicrobial consumption (ATC J01) in adult patients 1 year before (March 2019–February 2020) and 1 year after (March 2020–February 2021) the arrival of the COVID-19 pandemic.

Antimicrobial consumption rates were expressed in defined daily doses per 1000 inhabitants-day (DID). In PC we included the reference population of our area and in HC the number of patients discharged. The impact was assessed by the difference in DID between both periods and care settings.

Data on antimicrobial prescribing in PC were obtained from a public database with anonymised data on the total number of items of each drug prescribed. Hospital data were obtained from the clinical unit of pharmacy.

Results Between March 2020 and February 2021 antimicrobial consumption decreased -36.0% (7.3 vs 11.4 DID) in PC and increased $+37.5$ (16.5 vs 12.0 DID) in HC, both compared to the same period of the previous year.

The most prescribed antimicrobials in PC before the COVID-19 pandemic were amoxicillin, amoxicillin/clavulanate, doxycycline, azithromycin, ciprofloxacin, and between March 2020 and February 2021 these were amoxicillin/clavulanate, amoxicillin, doxycycline, ciprofloxacin and azithromycin.

The most prescribed antimicrobial used in HC before the COVID-19 pandemic were amoxicillin/clavulanate, levofloxacin, piperacillin/tazobactam, ceftriaxone and ciprofloxacin, and between March 2020 and February 2021 these were amoxicillin/clavulanate, ceftriaxone, azithromycin, piperacillin/tazobactam and meropenem.

Comparing the COVID period with the previous year, in PC the antimicrobial that most decreased in consumption was phenoxymethylpenicillin (-66.59%). Amoxicillin decreased by -52.13% , clarithromycin (-50.60%), moxifloxacin (-45.98%), levofloxacin (-44.42%), amoxicillin/clavulanate (-35.55%) and azithromycin (-29.05%). For HC the antimicrobial that most increased in consumption was azithromycin ($+721.42\%$), followed by amoxicillin ($+602.00\%$), ceftriaxone ($+184.34\%$), vancomycin ($+116.9\%$) and amikacin ($+88.79\%$). Meropenem DID increased by $+52.94\%$.

Conclusion and relevance The COVID-19 pandemic has impacted on the increase in antimicrobial use in HC along with a proportional decrease in PC.

Antimicrobial prescription patterns in PC remain stable. The increase in amoxicillin/clavulanate over amoxicillin may be related to non-contact patient care (telemedicine).

In HC, antimicrobial stewardship strategies can help return the consumption of broad-spectrum antibiotics to acceptable levels.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-148 TANDEM PROJECT: TRANSITIONS OF CARE AND MEDICATION RECONCILIATION IN HIGH-RISK PATIENTS

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Background and importance The implementation of medication reconciliation programmes is a quality standard in health centres according to the recommendations of national and international patient safety organisations to reduce medication errors during transitions of care.

Aim and objectives Main objective was to implement a medication reconciliation programme in high-risk patients admitted to a tertiary hospital. Secondary objective was to promote patient safety by detecting medication errors that occur during transitions of care.

Material and methods Selection of high-risk patients by two clinical pharmacists physically present in the Emergency Department.

At admission, pharmacists make an advanced medication review and interview the patient or carers to obtain a complete and accurate home medication list. When a potential prescribing error is detected, the pharmacist makes a pharmacotherapy recommendation (PR) to the physician.

At discharge, pharmacists review the medication list on the discharge plan and interview patients via telephone within 72 hours post-discharge to confirm that they have understood the new treatment plan. If the pharmacist detects an error, he/she makes a PR directly to the patient.

The impact was measured with the number of PR and the severity of the detected prescribing errors according to the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) severity index at admission and discharge.

Results Between February 2018 and September 2021, a total of 789 patients were included in the programme (53.3% women, mean age 81.3 years (SD 9.65)). Mean number of home medications at admission was 11.2 (SD 4.30). Pharmacists made a total of 1140 PR to physicians (1,5 per patient). Main types of prescribing errors were: omission of a drug (37.3%), wrong drug (23.6%), wrong dose (21.0%) and wrong frequency (11.2%). A total of 707 (62.0%) prescribing errors could have caused harm to the patient (NCC MERP severity index, Category \geq E). Physician acceptance rate was 92.5%.

At discharge, 277 patients were interviewed by a pharmacist via telephone; 46.9% did not understand at least one aspect of the discharge medication list. Pharmacists made 336 PR to patients and 64.6% of the detected errors could have caused harm.

Conclusion and relevance We have successfully implemented a medication reconciliation program in high-risk patients that allows us to detect medication errors at admission and discharge.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-150 IMPLEMENTATION OF A PROGRAM FOR OPTIMISING THE USE OF ANTIBIOTICS (PROA) IN THE PAEDIATRICS EMERGENCY CARE UNIT OF A THIRD-LEVEL HOSPITAL

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Background and importance Programs for optimising the use of antibiotics (PROA) have been demonstrated to be useful tools to guarantee the rational use and adequacy of antibiotics, while decreasing the risk of developing treatment resistances.

Given the extensive use of antibiotics and, in order to expand the program, we decided to study the possibility of including the paediatric emergency care unit as part of the PROA.

Aim and objectives The main objectives of the study were:

To identify the need for a PROA in the paediatrics emergency care unit of a third-level hospital by analysing the current situation.

To analyse the adequacy of the antibiotics prescribed (indication and duration) according to the local guide of the centre.

Material and methods A cross-sectional study in the Paediatrics Emergency Care Unit was used as pilot test. The day the study was completed, the relation of registered children in the unit was obtained via an informatic program. Both demographic (age and weight) and clinical (symptomatology, complementary tests, diagnosis and discharge treatment) were registered. For each patient, adequacy of the prescribed antibiotic, indication and dose adjustment to weight and age, were analysed.

Results From the 114 assessed patients, 16 (14%) were treated with antibiotics and recruited for follow-up. The most common diagnosis was tonsillitis (25%), acute bronchitis (19%) and otitis media (19%), being the remaining percentage cases of appendicitis, urinary tract infections, nasopharyngitis, cellulitis and laryngitis. From the 16 prescribed treatments, 12 were susceptible of recommendation. The main identified causes for treatment modification were an excessive duration (50%), an inadequate dose for either shortage (25%) or excess (8%) or a suboptimal antibiotic choice (17%).

Conclusion and relevance Results showed a low adequacy of the antibiotic treatments, thus evidencing the need for a PROA that improves the prescription quality and guarantees patient safety. Members from the PROA group must ensure education about antibiotics prescription, emphasising the features of children as a population group and sharing the local antibiotic guide from the hospital.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-154 IMPACT OF THE COVID-19 PANDEMIC ON ANTIMICROBIAL CONSUMPTION AND ANTIMICROBIAL RESISTANCE

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Background and importance Recent studies have reported an increase of antimicrobial use during the COVID-19 pandemic.

The impact of overuse on the propagation of antimicrobial resistance could be an indirect adverse consequence of the pandemic.

Aim and objectives To describe the impact of the COVID-19 pandemic on antimicrobial prescription trends and analyse the relationship with the evolution of antimicrobial susceptibility.

Material and methods Descriptive study to investigate the prescription of antimicrobials (ATC group J01) and the evolution of resistance before and after the COVID-19 pandemic in adult patients admitted to a tertiary-care hospital.

Antimicrobial use was expressed into defined daily doses per 100 discharges (DDD/100D). We compared first-wave COVID (March-June 2020) versus pre-COVID (March-June 2019).

Antimicrobial sensitivity (EUCAST v11.0) was evaluated as a percentage of resistant bacterial strains isolated between January and June 2021 versus the pre-COVID situation (January-December 2019).

Results During the first wave, 4465 adult patients were admitted to the hospital versus 5318 in the same period of 2019). In this context antimicrobial consumption increased +79.09% (735.85/410.89 DDD/100D).

The most important changes in antimicrobials consumption compared to the pre-COVID period are detailed in table 1.

Abstract 5PSQ-154 Table 1

Antimicrobial	COVID/pre-COVID (DDD/100D)	Increase DDD/100D (%)
Amoxicillin	60.23/2.19	+2650.98
Azithromycin	107.73/5.69	+1791.68
Cefotaxime	0.99/0.18	+461.22
Ceftriaxone	139.24/28.97	+380.67
Vancomycin	24.25/8.33	+199.40
Aztreonam	2.61/0.92	+185.49
Meropenem	43.29/24.39	+77.48
Cefuroxime	14.6/9.23	+60.77
Linezolid	27.57/17.19	+60.40
Cefixime	2.72/1.82	+49.32
Piperacillin/tazobactam	49.81/33.75	+47.58
Amoxicillin/clavulanate	95.23/79.96	+19.09

Abstract 5PSQ-154 Table 2

Microorganism	No. isolated January-December 2019	No. isolated January-June 2021	Antimicrobial	Sensitivity January-December 2019 (%)	Sensitivity January-June 2021 (%)	Pearson's Chi-square significance
<i>Escherichia coli</i>	4085	1648	No change			
<i>Klebsiella spp</i>	1095	425	Gentamicin	93	86	p=0.000
			Cefuroxime	78	73	p=0.036
			Cefotaxime	81	76	p=0.028
			Nitrofurantoin	87	81	p=0.010
			Aztreonam	74	70	p=0.226
			Ceftazidime	81	77	p=0.076
			cefepime	82	78	p=0.069
<i>Pseudomonas aeruginosa</i>	507	195	Gentamicin	83	78	p=0.114
<i>Staphylococcus aureus</i>	878	400	No change			
<i>Enterococcus faecalis</i>	572	266	No change			
<i>Enterococcus faecium</i>	146	87	Nitrofurantoin	92	83	p=0.120
			Ampicillin	12	6	p=0.305

The most important changes in bacterial sensitivity are detailed in table 2.

Conclusion and relevance Important increase in hospital antimicrobial consumption was observed, especially for the beta-lactams and carbapenems.

Minimal changes in antimicrobial susceptibility was observed, detected only in *Klebsiella spp*, *Pseudomonas aeruginosa* and *Enterococcus faecium*.

Antimicrobial stewardship strategies can help to keep the consumption of antimicrobials within acceptable levels.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

6ER-006 PARACETAMOL VERSUS IBUPROFEN FOR TREATMENT OF PERSISTENT DUCTUS ARTERIOSUS CLOSURE IN PRETERM INFANTS: IBUPAR-TRIAL

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Background and importance Haemodynamically significant patent ductus arteriosus (hsPDA) is a common cause of morbidity and mortality in preterm infants. Currently, the first-line therapy for hsPDA is ibuprofen, but this treatment has potentially life-threatening side effects. Paracetamol has been proposed as an alternative to ibuprofen, but there is still insufficient clinical evidence to make a standard recommendation.

Aim and objectives To evaluate the efficacy and safety of the standard treatment of hsPDA with ibuprofen versus paracetamol in the closure of hsPDA.

Material and methods Non-inferiority, randomised, multicentre, double-blind clinical trial was designed to evaluate the efficacy and safety of intravenous (IV) paracetamol versus IV ibuprofen in preterm patients with a gestational age (GA) ≤ 30 weeks diagnosed with hsPDA in four Spanish hospitals. Patients were randomized 1:1 to 10 mg/kg ibuprofen followed by 5 mg/kg at 24 and 48 hours or 15 mg/kg paracetamol every 6 hours for 3 days. If ductus size was >1 mm after the end of the 3-day course of the assigned treatment, another 3-day course of the same treatment was administered. If not, efficacy, ibuprofen and/or surgical closure were evaluated. The primary endpoint was ductus closure after the first treatment course.

Results The clinical trial is currently ongoing. The results presented correspond to an interim analysis with the objective of evaluating possible relevant safety warnings. A total of 91 patients have been recruited (approximately one-third of the scheduled recruitment). The populations of both groups have been comparable, with a mean GA of 26 weeks. For the main variable, ductus closure after the first treatment course, an intention-to-treat analysis revealed no statistically significant differences between the groups (62.8% vs 42.2%, $p=0.053$). Applying the random stop method to assess the need to continue or stop the study, a p value <0.978 was obtained, the limit for assuming a lack of power. Likewise, no differences were found in the main safety variables.

Conclusion and relevance Given the data obtained in the intermediate analysis, it is essential to continue with the

planned recruitment. At the moment, with the results of this analysis and the previous literature, it is not yet possible to establish a clear recommendation on the use of paracetamol in hsPDA.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

6ER-013 ANALYSIS OF PATIENTS' MORTALITY IN SARS-COV-2 INFECTION DURING THE FIRST MONTH OF HOSPITAL ADMISSION

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Background and importance As of December 2019, the world is facing a pandemic caused by the SARS-CoV-2 coronavirus (COVID-19). Symptoms resulting from the infection vary widely, ranging from asymptomatic disease to pneumonia and life-threatening complications.

Aim and objectives The aim was to study the impact of the active oncohaematological process on the severity and short-medium term mortality of COVID-19 infection.

Material and methods Observational retrospective study, carried out in a Spanish tertiary-level hospital. All patients diagnosed with COVID-19 and hospital admission between March 2020 and June 2021 were included. Variables collected were demographics, comorbidities; situation during hospitalisation (defining severe situation as admission to intensive care unit (ICU) or intubation) and mortality at 14 and 30 days after hospital admission. Data were obtained through the digital medical record and managed by R software (V.4–2021).

Results We included 1924 patients in the non-oncological group, 47.5% (915) men with a median age of 67 years and interquartile range (IQR) of 53–77. 128 patients (6.23%) were included in the active oncohaematological group, 58.6% were men (median age 72 (IQR 63–78) years). The most prevalent oncohaematological processes were: lung cancer (16.4%), colorectal (15.6%), bladder (10.9%), breast (10.2%) and prostate (8.59%). Metastases were present in 42.2% of patients. The main comorbidities presented by oncohaematological patients with statistical significance versus non-oncological patients were diabetes mellitus (30.5% vs 19.4%), dyslipidaemia (46.9% vs 32.2%), hypertension (52.3% vs 42.0%), chronic renal failure (18.0% vs 8.73%), chronic obstructive pulmonary disease (22.7% vs 9.94%), obesity (14.1% vs 15.2%) and heart failure (13.3% vs 10.6%). In the oncohaematological group, 44.5% were in a serious condition during their admission. The number who died compared to non-oncohaematological patients was 23.4% versus 13.6% at day 14 and 29.7% versus 18.1% at day 30. The two main neoplasms in the deceased patients were lung cancer (26.3%) and colorectal cancer (21%). Univariate analysis showed a relative risk of 1.72 (1.23–2.4) and 1.64 (1.23–2.17) mortality at 14 and 30 days, respectively, for COVID-19 in patients with active oncohaematological processes versus non-oncohaematological processes.

Conclusion and relevance The data reflect a higher mortality at 14 and 30 days due to COVID-19 in the oncohaematological population (72% and 64%, respectively). The oncohaematological population has a higher percentage of comorbidities

associated with the total that may also influence this increased risk of mortality.

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6ER-015 MUTATIONS IN THE FACTOR VIII GENE IN OUR HAEMOPHILIA A POPULATION

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Background and importance Haemophilia A (HA) is a haemostasis disorder with an incidence of 1:5000 male births and X-linked recessive inheritance. The genetic alteration determines the blood amount of FVIII, which will predict the severity: mild (between 5% and 40%), moderate (1% to 5%) and severe (<1%). Severe haemophilia is present in 60% of haemophiliacs.

Intron 22 and intron 1 inversion represent the main molecular alterations in patients with severe HA (45%–50% and 0.5%–5%).

The development of inhibitors is associated with the treatment and the genetic alteration. 20%–30% of severe HA develop inhibitors. The mutations with the highest incidence of inhibitors are large deletions, with a 42%a–74% prevalence.

Aim and objectives To describe the FVIII gene's mutation in the haemophilic population in Tenerife and to see the

correlation between the genotype and the phenotype of the disease, as well as the influence on the inhibitor's development.

Material and methods Observational, retrospective and descriptive study. We checked the patient's clinical history, the mutations and the inhibitor's record.

Results 44 patients (aged 1, 81 years) were analysed; 21 severe (47.7%), 2 moderate-severe, 4 moderate and 17 mild. The diagnosis was confirmed by molecular biology (polymerase chain reaction (PCR)) in 32 patients (severe and moderate): intron 22 inversion was identified in 14 patients (43.8%), exon 5 substitution in 3 (9.4%), exon 14 insertion in 2 (6.25%), substitution of other exons in 6 (18.75%), small deletions in 4 (12.5%) and exon 4 insertion in 1 (3.12%).

7 patients (15.9%) developed alloantibodies: in 1 patient these are still active and the rest have managed to erase them.

In contrast to the studies performed, the mutations that prevail in the presence of the inhibitor are intron 22 inversions, with an incidence of 71.4%, rather than deletions, with an incidence of 28.6%.

Conclusion and relevance The data on the most prevalent molecular alteration in HA are consistent with those of our patients in Tenerife, since most of them present inversion of intron 22. However, the mutations associated with the development of inhibitors do not coincide with those described in the literature, since most of them are inversions of intron 22.

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