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HOSPITAL DE VILA FRANCA DE XIRA, EPE

THERAPEUTIC DRUG MONITORING WITH BIOLOGICAL DRUGS IN THE TREATMENT OF INFLAMMATORY BOWEL DISEASE

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Background

Inflammatory Bowel Disease (IBD) is characterized by a chronic inflammation of the gut mucosa. About one-third of patients show primary non-response (PNR) 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 optimizing therapy for these patients.

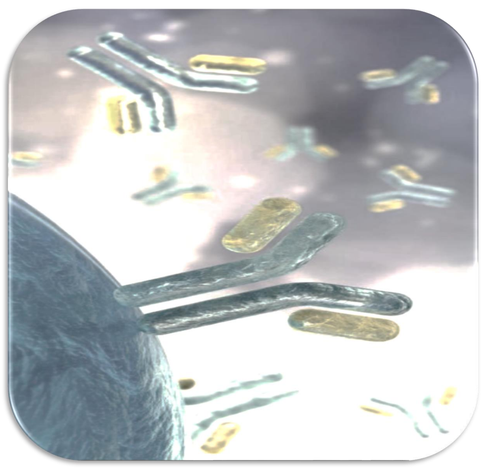
Objective

Assessing the outcome of **optimizing** biologic **drug therapy regimens** based on serum dosing results in IBD patients.

Materials and Methods

An observational, descriptive and retrospective study was conducted from **April 1, 2018 to August 31, 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 PNR, as well as patients with secondary loss of response (SLR) to biological agents and the subsequent therapeutic optimization (increased dose, interval reduction or therapeutic switch).

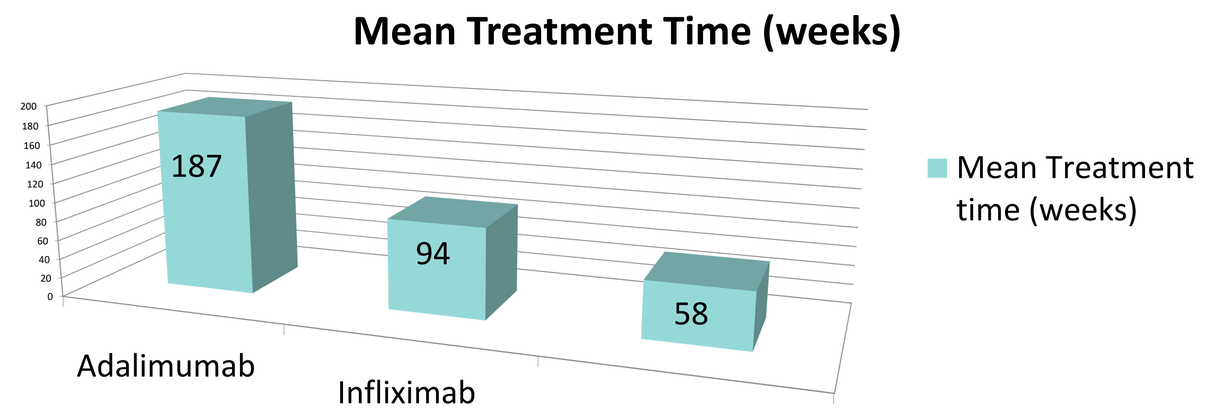
KEYWORDS: Pharmaceutical Intervention; Therapeutic Optimization; Therapeutic Drug Monitoring; Biological Drugs.

References:
1. Papamichael et al., Appropriate Therapeutic Drug Monitoring of Biologic Agents for Patients With Inflammatory Bowel Diseases, 2019 Aug;17(9):1655-1668
2. Portaria n.º 351/2017,de 15 Novembro

Results

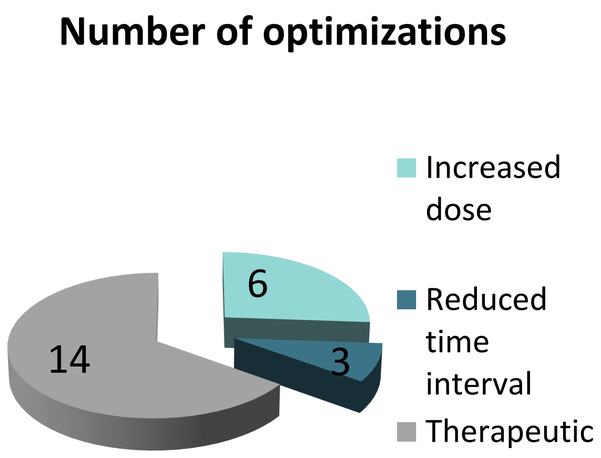
58 patients remained in the first line of treatment. 12 patients needed one switch and 1 patient undergone 2 switches. The average number of drugs administered per patient was 1,2.

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 35 weeks of average treatment.



20 patients (28%) had undergone 23 therapeutic optimizations by SLR, distributed as follow: **6 increased doses, 3 reduced time interval and 14 therapeutic switches.** The time to SLR was, in weeks, 189,5 for Adalimumab, 53,3 for Infliximab and 18 for Vedolizumab.

Conclusion

TDM allowed therapeutic optimization of biological agents, enabling the maintenance of **patients on the selected regimen for more time**, and an **early switch** in PNR. The limitation with the greatest impact was the real-time access to the serum dosing results.
Serum determination of drug concentrations and antidrug antibody levels may be a **good strategy** for **maintenance** and/or **optimization of therapy**.