PHARMACOVIGILANCE OF BIOLOGICAL THERAPIES FROM THE OUTPATIENT DEPARTMENT

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BACKGROUND AND IMPORTANCE

Pharmacovigilance has an essential role in monitoring outpatient treatments. As healthcare professionals we have the responsibility to report suspected adverse drug reactions (ADRs), so these data can be analysed by pharmacovigilance centres to determine the causality of possible unknown risks or changes in the severity and frequency of those already known.

In the last decade, the rise of biological therapies as standard treatment in a huge array of pathologies in outpatient practices has led us to focus our project on them.

AIM AND OBJECTIVES

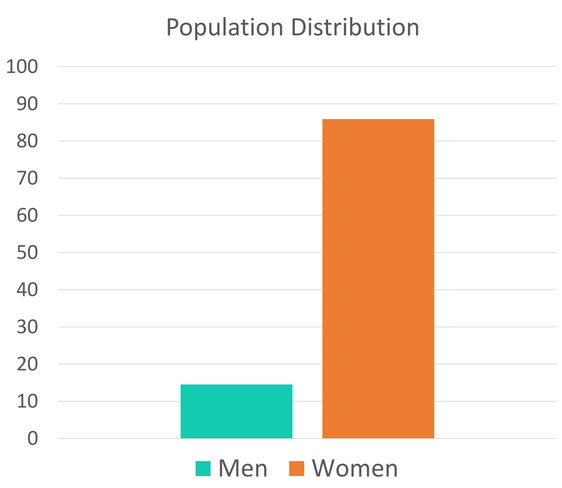
Analyse suspected ADRs reported to the National Pharmacovigilance System of the Agency of Medicines and Health Products (AMHPS), from the outpatient department in a central Hospital Pharmacy.

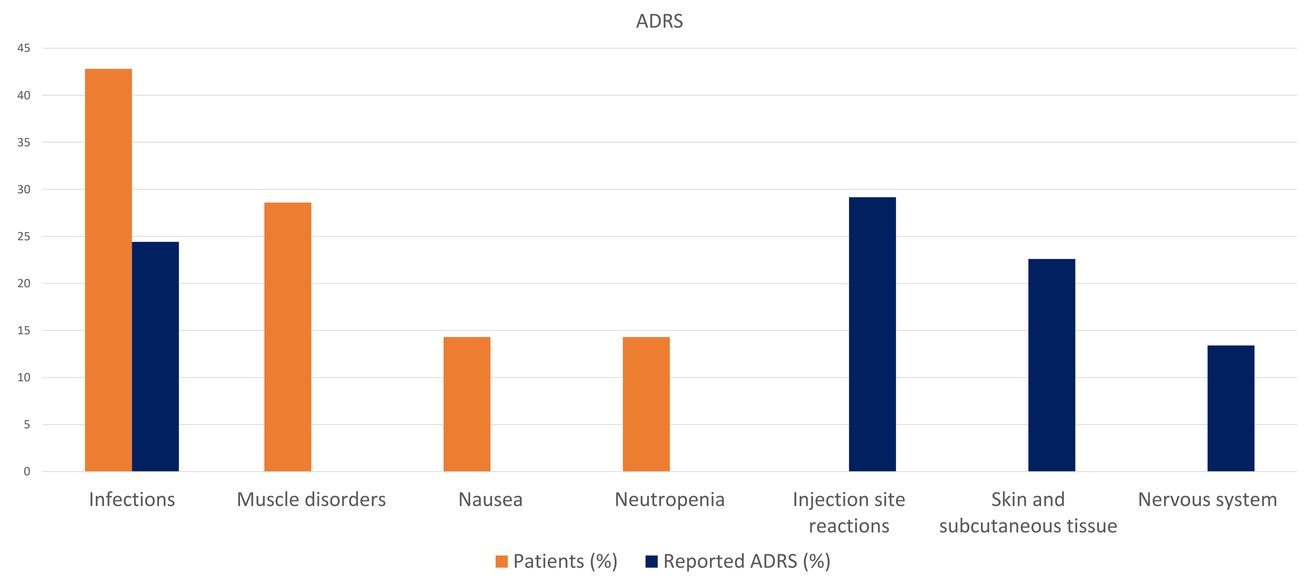
MATERIAL AND METHODS

- Single-centre observational retrospective study Three-month period [July 2022 - September 2022].
- Data collected: age, sex, treatment, indication, date of initiation, ADRs type and duration.
- Results were compared with the AMHPS National database, which is updated every 3 months.

RESULTS

In these months, we reported seven suspected ADRs. Most of them were reported in women (85,8%), with a mean age of 49,6 years (32-64). The biological therapies suspected of triggering ADRs were adalimumab, sarilumab, etanercept, abatacept, erenumab and galcanezumab. The adverse reactions reported were mostly related to the presence of infections (42,8%), followed by muscle disorders (28,6%), nausea (14,3%) and neutropenia (14,3%). Among the biological therapies used, the one associated with the highest number of notifications was sarilumab (28,6%) and the most frequent indication was rheumatoid arthritis (57,14%).





CONCLUSION AND RELEVANCE

Comparing the results with the AMHPS database, we observe in our population a greater number of notifications for sarilumab, being the one with the fewest national notifications, probably related to its recent authorization and not being used in first-line treatments. On the other hand, in the overall number of national ADRs notifications, infections are not the most frequent ADR, being in the first place injection site reactions.

It is important to be aware of the role of pharmacists and all healthcare professionals in contributing to the detection of ADRs. Collecting this data and taking a global view of it by healthcare institutions allows to improve safety in outpatient treatments.