ANALYSIS TO THE PROFILE OF MEDICINES SUSPECTED OF CAUSING ADVERSE DRUG REACTIONS TO PATIENTS OF A FEDERAL HOSPITAL IN RIO DE JANEIRO

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Introduction

Medicines are importants therapeutics resources for the treatment and prophylaxis of many diseases. Its efficacy and safety are proven based on pre-clinical and clinical tests that are carried out before its commercialization. However, clinical trials may have limitations. Therefore, post-marketing surveillance of medicines is of fundamental importance for the health of the population, since when used by a large part of the population, they can cause Adverse Drug Reactions (ADRs) not predicted in the tests previously carried out[1].

ADRs are defined as any response to a drug that is harmful and unintended, occurring at doses normally used in humans for prophylaxis, diagnosis and treatment of diseases[2]. They are considered a public health problem as they have a major impact on morbidity and mortality, in addition to causing additional costs to health systems[3]. Furthermore, it is the subject of study in Pharmacovigilance, the science responsible for detecting, evaluating, understanding and preventing adverse effects or any other problem related to medications[4]. A pharmacovigilance system will make it possible to understand the profile of adverse drug reactions in order to prevent and reduce morbidity and mortality related to them. Currently, it is estimated that ADRs could have been avoided in around 50% of cases, generating a positive impact on patient care and reducing healthcare system costs[5-7].

Material and Methods

A retrospective descriptive observational study was carried out, with a quantitative approach, where all notifications (spontaneous or active search) of suspected Adverse Drug Reactions reported to ANVISA by the Risk Management Area of the Federal Institute of Traumatology and Orthopedics in Rio de Janeiro during the period 2021 to 2022. The variables studied will be demographic data such as the patient's age and gender and the medications suspected of causing adverse drug reactions. The results found were expressed as relative frequency. The present study is a part of the research project entitled “Assessment of causality algorithms for adverse drug reactions” approved by the Research Ethics Committee of the Federal Fluminense University (CAAE 64881922.1.1001.5243) and by INTO (CAAE 64881922.1.2001.5273).

Results and Discussion

In the period from January 2021 to December 2022, INTO's Risk Management Area made 106 notifications of Adverse Reactions to Medicines to ANVISA. Of the total, 54 notifications occurred in 2021 and 51 occurred in 2022. Notifications were more frequent in male individuals, representing 53% of the total when compared to females, which corresponded to 47% of notifications. These results corroborate the study conducted by Melo and collaborators[8] with 59.7% of reactions occurring in males. In terms of age, a division was made by age groups, which were divided into children (0 to 11 years old), adolescents (12 to 18 years old), adults (19 to 59 years old) and elderly people (60 years old or more). It was observed that adults have a higher frequency of reports of adverse reactions to medications, totaling 51% of reports. This

result is in agreement with the research carried out by Lima, Almeida and Rezende[9], as it was observed that the age group from 19 to 59 years old was the most reported, corresponding to 54.5% of these. The 106 reports analyzed involved 26 different medications suspected of causing adverse drug reactions. The suspected drugs were grouped into seven groups according to the Anatomical Therapeutic Chemical classification, with the class of general anti-infectives for systemic use being the most predominant, representing 69.2% of the suspected drugs. Lima, Almeida and Resende[9] also reported that the main class to which the suspected medications belonged were general anti-infectives for systemic use (44.6%), with Vancomycin being the most recurrent (31.2%). Loução, Sanches and Carraro[10] also report that Vancomycin was the most frequent anti-infective for systemic use in their research, with 8.3% frequency.

Conclusion

In the period between 2021 and 2022, 106 reports of adverse drug reactions reported to ANVISA were identified at the Institute under study. Such notifications were more frequent in male individuals, aged between 19 and 59 years. Twenty-six different medications suspected of causing ADRs were identified. It is noteworthy that the class of general anti-infectives for systemic use was the most predominant, with Vancomycin being the drug most frequently identified as suspected of causing an adverse drug reaction.

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