VI Fórum Internacional sobre Segurança do Paciente
Erros de Medicação

DRUGS THAT ACT ON THE NERVOUS SYSTEM AND ANTI-INFECTIVES ARE THE MAIN CAUSE OF ADVERSE REACTIONS REPORTED ON A REGIONAL HOSPITAL:

An analysis of the clinical profiles of the events

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INTRODUCTION

Adverse reactions and incidents associated to medications cause death and threaten patients safety[1]. Evidences indicate that anti-infective drugs, and those which operate in the nervous system, are mostly linked with adverse events[2,3].

OBJECTIVE

To describe the frequency and the characteristics of the adverse drug reactions (ADRs) reports in a regional hospital and confront the clinical features of the events.

METHODS

❑ Study design

This is a quantitative, descriptive and comparative research carried out in a teaching hospital.

❑ Setting

We conducted the research in a teaching hospital, in the northwestern area of São Paulo State, in Brazil. The hospital contained a total of 174 beds, and 16 of them were in the intensive care unit. The hospital, which is a reference healthcare center for 13 cities, has an active risk management sector.

❑ Eligibility criteria

Through Anvisa's Notivisa system, it was accounted for, ADR[4] notifications from June 2012 to July 2014. The notifications with a Not Finalized Status or with insufficient data, were excluded.

❑ Variables and data sources/measurement

The notifications were divided in two groups:

Group 1	Group 2
Reactions associated to the anti-infective drugs and to those that operate in the nervous system.	Reactions linked to further therapeutic groups.

The cases of ADR were classified according to the criteria:

Drug classes	Anatomical Therapeutic Chemical (ATC)[5]
Patients involved	Gender and age
Organs affected	System organ classes[6]
Severity	Mild; Moderate; Severe[7]

❑ Bias

In order to minimize the risk of distortions and information bias, the multidisciplinary hospital staff was consulted to ascertain the causality of ADRs.

❑ Statistical methods

Data regarding the clinical features of the adverse reactions were compared between the two groups and were described as simple frequency and proportions.

❑ Ethical aspects

The research was approved by the Research Ethics Committee (Protocol no. 1.201.825/2015).

RESULTS

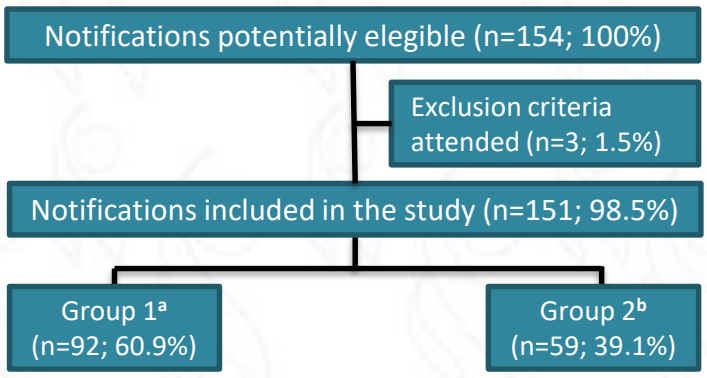

Figure 1. Notification selection flowchart

ª Reactions associated to the anti-infective drugs and to those that operate in the nervous system; ᵇ Reactions linked to further therapeutic groups (alimentary tract and metabolism, respiratory system, musculo-skeletal system, blood and blood forming organs, cardiovascular system, antineoplastic and immunomodulating agents, dermatologicals).

Table 1 - Distribution of the cases of ADR according to the group and characteristics.

Characteristics	Group 1 (%)	Group 2 (%)
Gender		
Male	35 (38)	21 (35.6)
Female	**57 (62)***	**38 (64.4)***
Age (years)		
≤ 25	15 (16.3)	16 (27.1)
26-59	**43 (46.7)***	21 (35.6)
≥ 60	34 (37)	**22 (37.3)***
Organ system affected[a]		
Skin and appendages	**31 (33.7)***	10 (16.9)
General cardiovascular	1 (1.1)	**14 (23.7)***
Nervous system	21 (22.8)	10 (16.9)
Severity		
Mild	16 (17.4)	11 (18.6)
Moderate / Severe	**76 (82.6)***	**48 (81.4)***

* Most cases in the group, according to the characteristic.
[a] Only the most relevant to the groups.

CONCLUSION

The ADR reports were shown to be recurrent in a hospital context. In addition, they support interventions that are important for patient safety. The characteristics of the notifications are based on vast knowledge about the effects of the drugs and concerning the clinical profile of the adverse events described.

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