STATUS OF ADVERSE DRUG REACTION MONITORING, TECHNICAL DEFECTS AND PHARMACOVIGILANCE OF A PUBLIC TERTIARY HOSPITAL IN BRAZIL

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OBJECTIVES

The aim of this work was quantify and analyze the suspected Adverse Drug Reactions (ADRs) that occurs in a public tertiary hospital and describes technical defects (TDs) in four drug types available in Brazil.

METHODS

Descriptive, prospective and exploratory study held in 2010 (January 2010 to December 2010)

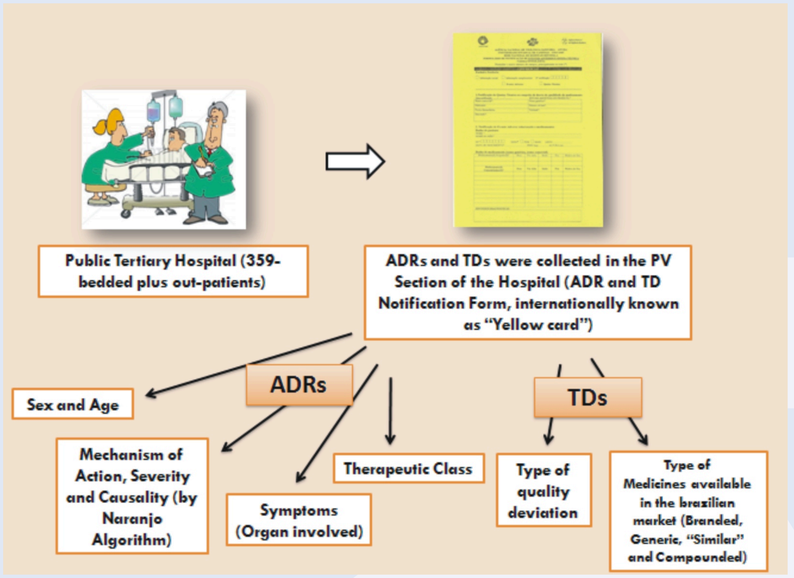


Figure 1. Description of the study development. ADRs= Adverse Drug Reactions; TDs= Technical Defects; PV=Pharmacovigilance.

SIMILAR DRUGS: *Similar drugs are the product authorized to be produced after of the patent period of the branded or innovator medicine. Both have the same active, concentration, dosage form, route of administration, dosage and therapeutic indication. By the other hand, the main difference between similar and generic medicine is that the first is represented by its own brand name and the second is represented by the active name.*

RESULTS

A total of 68 forms were analyzed, the ADRs accounted for 39.7% (27 forms) and TDs for 60.3% (41 forms). In relation to ADRs, the majority of patients who had suffered from ADRs were above 60 years (29.7%), with no difference about sex distribution (table 1).

Table 1. Sex and age wise distribution of ADRs.

Age Group (years)	Females	Males	No. of ADRs	Percentage (%)
0-14	01	01	02	7.4
15-29	02	04	06	22.2
30-44	04	02	06	22.2
45-59	03	02	05	18.5
≥60	03	05	08	29.7
TOTAL	13	14	27	100.0
Percentage (%)	48.1	51.9	100.0	-

The skin was the most affected organ (16 ADRs; 28.0%) and the therapeutic class mostly associated with ADRs was the general anti-infective for systemic use (11 ADRs; 40.7%) (figure 2 and 3).

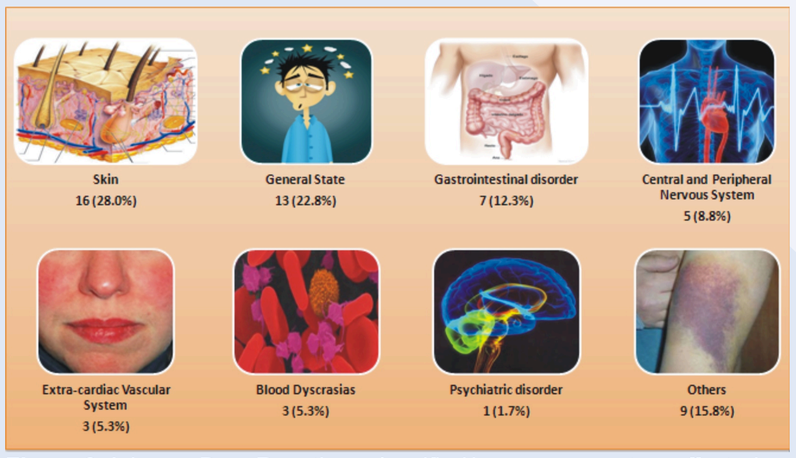


Figure 2. Adverse Drug Reactions classified by organ or system affected.

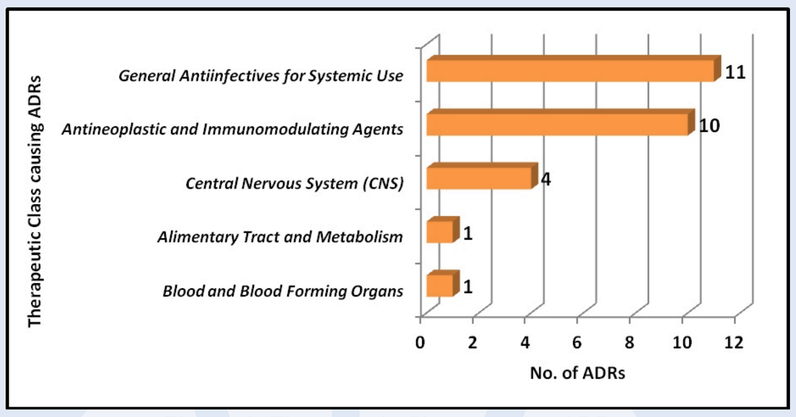


Figure 3. Therapeutic Class causing ADRs.

Table 2. Drugs causing ADRs.

Drugs	Number of ADR	Percentage (%)
Infliximab	03	11.2
Amphotericin B	02	7.4
Vancomycin	02	7.4
Cisplatin	02	7.4
Amoxicillin	01	3.7
Atazanavir	01	3.7
Bleomycin	01	3.7
Calcitriol	01	3.7
Carbamazepine	01	3.7
Carboplatin	01	3.7
Ciprofloxacin	01	3.7
Clozapine	01	3.7
Docetaxel	01	3.7
Etoposide	01	3.7
Gentamicin	01	3.7
Haloperidol	01	3.7
Isoniazid	01	3.7
Linesolid	01	3.7
Paclitaxel	01	3.7
Pyrazinamide	01	3.7
Rivastigmine	01	3.7
Warfarin	01	3.7

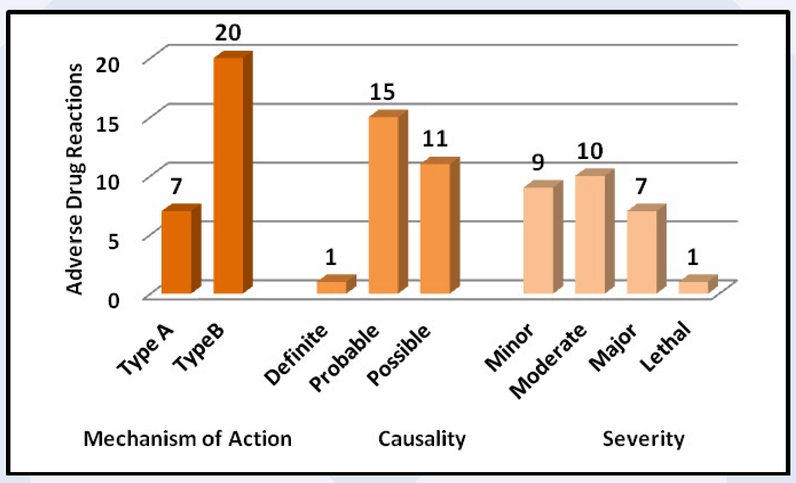


Figure 4. Mechanism of Action, Causality and Severity analysis of Adverse Drug Reactions.

More Technical Defects were seem in generic drugs (36.4%) and the most common defects observed were breaks/cracks/leaks (20.9%) and lack of product inside drug packaging/ volume less than that reported in the label (20.9%) (figure 5 and 6). In this hospital is bought more similar and generic drugs (estimated: 47.7 similar, 36.4% generic, 11.7% branded and 3.2% compounded drugs).

ACKNOWLEDGEMENTS: CNPq e FUNCAMP

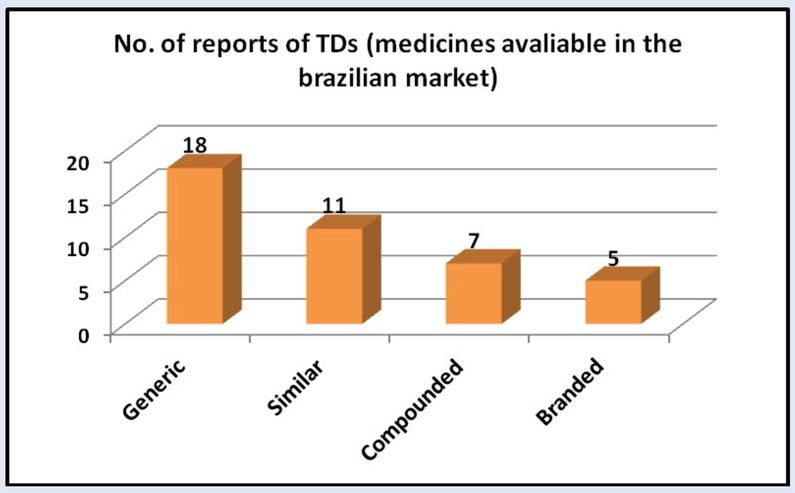
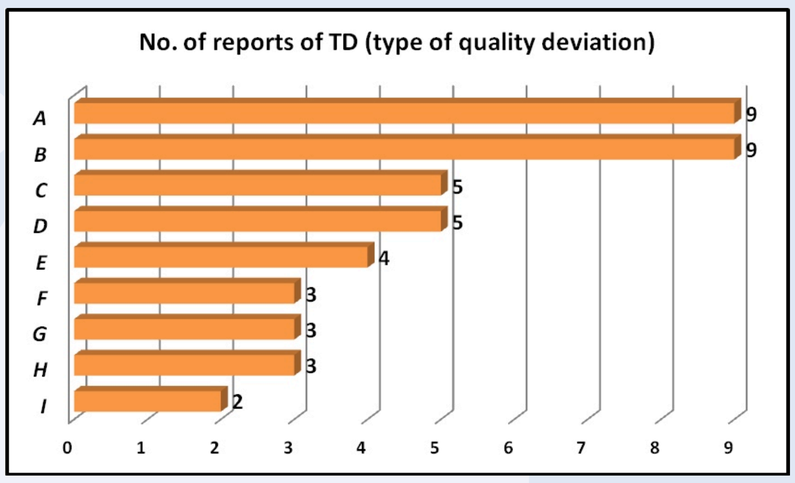


Figure 5. Number of reports of Technical Defects classified according to the drug type available in the Brazilian market.



Legend:

A-Breaks / cracks / leaks

B-Lack of product inside drug packaging/ volume less than that reported in the label

C-Anatomical problems in the drug packaging

D-Lack of essential information or identification

E-Foreign body

F-Poor quality of information

G-Organoleptic changes

H-Changes in physicochemical properties in liquid/ semi-solid products

Changes in physicochemical properties in solid products

Figure 6. Number of reports of Technical Defects classified according to the type of quality deviation.

CONCLUSION

Type B, probable and moderate seriousness dermatological reactions was the most common Adverse Drug Reactions in this hospital and general anti-infective drug for systemic use was the most common therapeutic class involved in Adverse Drug Reactions mainly in people older than 60 years old.

The most common Technical Defects observed was related to breaks/ cracks/ leaks and lack of product inside drug packaging/ volume less than that reported in the label, found in more than one generic produts.

Every drug has a risk and besides detecting adverse events, it is essential their prevention, mainly through the monitoring of clinical/ hospitals pharmacists, and also ensure the quality by the drug control authority.