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A Cross Sectional Study Analysis of Adverse Drug Reactions Encountered At Tertiary Care Hospital

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Abstract

Background: Adverse drug reactions are due to hazards of drug therapy and can occur with any class of drugs. The aim of this study was to evaluate and record adverse drug reactions reported from various departments of a tertiary care hospital.

Methods: A Cross Sectional study conducted in a tertiary care hospital. ADRs reports collected and analyzed for causality, severity and preventability by international standardized scales.

Results: Total of 50 patients were reported to experience ADR during study period. Out of50 patients, 32 (64.00%) patients were males while 18(36.00%) patients were females. Mean age of patients was 45.23±12.48 Yrs. According to Naranjo's causality assessment, 64% of reactions were probable, 26% were possible

Conclusions: Adverse Drug Reactions are common and some of them resulted in increased healthcare cost due to need of some interventions and increased length of hospital stay. The health system should promote the spontaneous reporting of ADR's. The proper documentation and periodic reporting to Pharmacovigilance Centres is required to ensure drug safety.

Keywords: Adverse Drug Reactions, Causality, Pharmacovigilance, Spectrum, Spontaneous reporting

Introduction

The World Health Organization (WHO) defines ADR as "a response to a drug that is noxious and unintended and occurs at doses normally used in man for the prophylaxis diagnosis or therapy of disease, or for modification of physiological function". [1]

Adverse drug reaction is the major limitation in providing health care to patients at a global level. The overall rate of ADR - 6.7%. ADR account for 5% of all hospital admissions. Also occurs in 10-20% of hospitalized patients. They are the fourth leading causes of death. All drugs are having the potential to cause ADR. [2]

ADRs related hospitalizations have consistently increased which has caused an economic burden to the developing countries like India. [3]

ADRs are commonly encountered at hospital set up where poly pharmacy is practiced usually. [4] India is the fourth largest pharmaceutical producer in the world and is recognized as an important clinical trial hub in the world. Due to introduction of many drugs in the country, it has become essential to have an effective Pharmacovigilance system nationwide in order to

protect interest of public health. The main function of this programme involves data collection and analysis of ADRs. [5]

Therefore this present research topic is selected to know the patterns of ADR collected in tertiary care hospital which is helpful to the Physicians in their practice.

Material and Methods

A cross sectional study and spontaneous reporting study involving active methods and passive methods was carried out in all departments of S M S M C Jaipur and tertiary care teaching hospital.

The details of ADRs like age, gender, suspected drug, type of ADR and causality assessment were noted and data is entered in excel sheet and subjected for statistical analysis. While collecting data, patient identity was kept anonymous.

Statistical analysis : The data analysis was done using Epi-info software. Descriptive statistics was applied and results were expressed in percentages.

Results

Table 1: Socio-demographic profile

Mean age (Yrs)	45.23±12.48 Yrs.
Male : Female	32 : 18
Rural : Urban	27 : 23

Total of 50 patients were reported to experience ADR during study period. Out of50 patients, 32 (64.00%) patients were males while 18(36.00%) patients were females. Mean age of patients was 45.23±12.48 Yrs.

Table 2: Department wise distribution

Department	No of patients
Skin	23 (46.00%)
Medicine	12(24.00%)
Surgery	8 (16.00%)
Other department	7 (14.00%)

In terms of departments, more number of ADR's were from Medicine (29%) followed by Surgery (16%) and OG (16%)

Table 3- Division of ADRs based on Pharmacological classification of drugs

Drugs	No of patients
Antibiotic	32 (64.00%)
Analgesic	4(8.00%)
Anti-cancer	6 (12.00%)
TCA	2 (4.00%)
Enzymes	1 (2.00%)
Anesthetic agent	2 (4.00%)
Others	3 (6.00%)

The drugs mostly accounted were antibiotics (64.%) especially Cephalosporins .

Table 4- Causality assessment of ADRs (Naranjo's scale)

Drugs	No of patients
Definite (≥9)	5 (8.00%)
Probable (5-8)	32(64.00%)
Possible (1-4)	13 (26.00%)
Doubtful (≤0)	0 (0.00%)

According to Naranjo's causality assessment, 64% of reactions were probable, 26% were possible.

Discussion

In this study 50 ADR's were reported. Majority of ADRs were seen in adult age group which was comparable with the previous study by Sharma et al where it was 50.4%. [6]

It is likely that this population is attending hospital more frequently and is a major population receiving drug therapy. The number of ADRs were high in Skin department, General Medicine and General Surgery departments due to amplified use of antibiotics in these departments for the treatment and prophylaxis of

various diseases and also since the patients admitted were with multiple comorbidities requiring poly pharmacy (Bar 1) these results in concurrence with the observation done by Vora et al. [7]

The most frequent ADRs were due to the antibiotics which could be associated with increased frequency of prescription of antibiotics. Among the ADRs, major proportions of adverse reactions were seen with Betalactam antibiotics which were similar to the observation by Rodriguez-pena et al, as well as by Raut et al. [8,9]

Since Beta-lactam antibiotics is the one of the most common antibiotics used by the practicing doctors. [10] In accordance with previous studies by Misbah M et al, Oshikoya et al, Shareef et al and Suthar et al, the present study showed the predominance of cutaneous manifestations [11-14]

According to Naranjo's scale most of the ADR's were probable, since re-challenge was not done in many patients due to ethical issues we didn't get definite relationship. The causality assessment of the reported ADRs according to the Naranjo's scale revealed that no reactions were certain and most of them were probable with a lesser number of possible ADRs. This data is in correlation with the study of Jose et al. [15]

As per Hartwig criteria, most of the ADR reports were moderate in nature - patients required discontinuation of offending drug and treatment for ADR's. Majority of the patients recovered completely from the ADR since most of the reactions were moderate this result was in accordance with Shamna et al and Kala et al were majority was moderate reactions followed by mild and severe ones. [16,17]

Conclusion

Adverse Drug Reactions are common and some of them resulted in increased healthcare cost due to need of some interventions and increased length of hospital stay. The health system should promote the spontaneous reporting of ADRs. The proper documentation and periodic reporting to Pharmacovigilance Centres is required to ensure drug safety

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