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A PROSPECTIVE STUDY OF PATTERN OF ADVERSE DRUG REACTIONS REPORTED AT A TERTIARY CARE HOSPITAL

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Abstract

Introduction: Adverse drug reaction 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". 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.

Materials and Methods: A prospective, observational study was conducted over one year between January 2021 to December 2021, Department of Pharmacology, Fathima Institute of Medical Sciences, Kadapa. The ADRs reported were from patients attending out-patient department (OPD) and in-patient department (IPD), Fathima Institute of Medical Sciences, Kadapa. ADR data was collected in suspected ADR reporting form by Central Drugs Standard Control Organization (CDSCO), India from various departments. Analysis of data was done for ADRs collected by ADR monitoring centre of the teaching hospital for purpose of submission to Pharmacopoeia Commission (IPC), Ghaziabad that is functioning as a National Coordination Centre (NCC) for Pharmacovigilance Programme of India (PvPI).

Results: A total of 404 ADRs were collected from various departments of Fathima Institute of Medical Sciences, Kadapa during the study period (January 2021 to December 2021). Total number of ADRs reported was more in females (60%) than in males (40%). The percentage of ADR was highest in the age group 19-60 years (88%) followed by more than 60 years (8.5%) and age less than 19 years (3.5%) respectively.

Conclusion: Majority of adverse drug reactions in tertiary care level are preventable. Knowledge about drugs and background patient information can help to prevent easily preventable ADRs. More surveillance by ADR monitoring centre is advocated to ascertain the consistency of suspected ADRs. Regular and mandatory training of healthcare professionals on appropriate reporting of ADRs is needed to ensure reporting of ADRs thus establishing appropriate signals.

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Key Words: Adverse drug reaction, prophylaxis, surveillance, Knowledge.

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". 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.[1]

ADRs related hospitalizations have consistently increased which has caused an economic burden to the developing countries like India. ADRs are commonly encountered at hospital set up where poly pharmacy is practiced usually. India is the fourth largest pharmaceutical producer in the world and is recognized as an important clinical trial hub in the world.[2] 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.[3]

The cost for treating a single ADR in India and US is INR 690 and US $2500 respectively.5,6 Many factors play a crucial role in the occurrence of ADRs, including age, gender, race, pregnancy, breast feeding, kidney problems, liver function, and many other factors.[4] These factors enable medical practitioners to choose the best drug, dose and frequency of drug regimen.[5]

With this in background, the aim of our study was to characterize the pattern of ADRs reported through spontaneous reporting system at Department of Pharmacology, Fathima Institute of Medical Sciences, Kadapa.

MATERIALS AND METHODS

Study design: A prospective, observational study.

Study duration: January 2021 to December 2021.

Study Location: Department of Pharmacology, Fathima Institute of Medical Sciences, Kadapa.

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Evaluation of the data was done for various parameters which included patient demographics, drug and ADR characteristics and outcome of the ADRs. Causality assessment was done by WHO-UMC system. Severity assessment was done by modified Hartwig and Siegel scale.

RESULTS

A total of 404 ADRs were collected from various departments of Fathima Institute of Medical Sciences, Kadapa during the study period (January 2021 to December 2021). Total number of ADRs reported was more in females (60%) than in males (40%). The percentage of ADR was highest in the age group 19-60 years (88%) followed by more than 60 years (8.5%) and age less than 19 years (3.5%) respectively as depicted in Table 1.

Table 1: Patient demographics

Patient demographics	
Total number of ADRs reported	404
Gender-wise distribution	Females (60%)
	Male (40%)
Age wise distribution (in years)	<19 (3.5%)
	19-60 (88%)
	>60 (8.5%)

Table 2: Department wise distribution of ADRs

Department	**Percentage**
Psychiatry	50%
Medicine	24%
Dental	1%
Ear, nose and throat	4%
Gynecology and obstetrics	2%
Surgery	2%
Orthopedics	5%
Dermatology	4%
Chest and TB	5%
Pediatrics	3%

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Table 3: Distribution of ADRs among different classes of medicines

Department	Percentage
Antidepressant	50%
Antibiotic	24%
Antipsychotic	1%
Lithium	4%
NSAID	2%
Antihypertensive	2%
Anticonvulsant	5%
Asthma medicine	4%
Hormones	5%
Other	3%

Table 4: Organ system wise distribution of ADRs

Organ system wise	Percentage
CNS	25%
Skin and appendages	19%
GIT	15%
Ear, nose and throat	8%
Cardiovascular	5%
Psychological	4%
Genitourinary system	3%
Hematological	2%
Musculoskeletal	1%
Respiratory system	1%
Others	17%

Table 5: Causality assessment using WHO-UMC system

Causality Assessment	Percentage
Certain	7%
Probable	57%
Possible	31%
Unlikely	5%

Table 6: Severity assessment using modified Hartwig and Siegel scale

Severity assessment	Percentage
Mild	58%
Moderate	42%
Severe	0

DISCUSSION

This study was conducted for detection and analysis of adverse drug reactions occurring in out-patient and in patient department of diverse disciplines of a tertiary care hospital in Kadapa, Andhra Pradesh. The demographic details of the present study showed female gender predominance over males for ADRs.[5] This gender difference has been observed in several

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publications worldwide and several explanations have been investigated. Higher reporting of ADRs in females could signify higher percentage of females accessing healthcare services. It could also reflect a higher willingness to report ADRs among females as compared to males. However, no single risk factor could be identified. A higher percentage of ADRs occurred in adult population (19-60 years).[6] This corresponds roughly with female reproductive age. The pattern of demographics of ADRs reported in our hospital is comparable with the pattern of demographics reported in tertiary-care hospitals elsewhere in India.

Majority of the ADRs in this hospital were reported by psychiatry department (50%). A possible explanation could be active participation of the psychiatry department in reporting of ADRs. This finding could signify under-reporting of ADRs by other departments of the hospital.[8] More than 55% of the reported ADRs occurred due to antidepressant drugs and most ADRs involved the central nervous system (25.24%). This finding corresponds with higher reporting by psychiatry department. This observation is similar to the study done by Jayanthi et al in which higher frequencies of ADRs were noted among patients diagnosed with depression (34.5%) and central nervous system (58%) was predominantly affected.[9]

Most of the ADRs were probable and mild. This observation is in concordance with studies conducted in India where the ADRs reported were probable and mild. In a study conducted in Italy also they observed that ADRs were expected and non-serious. 42% of ADRs were moderate however no mortality was reported.[10]

Under-reporting of severe ADRs could correspond with overall under-reporting of ADRs. It is well known that even ADR, which is considered mild or predictable in nature can have a significant impact on patient. Hence, managing and preventing all types of suspected ADRs in patients is vital.

CONCLUSION

Majority of adverse drug reactions in tertiary care level are preventable. Knowledge about drugs and background patient information can help to prevent easily preventable ADRs. More surveillance by ADR monitoring centre is advocated to ascertain the consistency of suspected ADRs. Regular and mandatory training of healthcare professionals on appropriate reporting of ADRs is needed to ensure reporting of ADRs thus establishing appropriate signals.

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