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ADVERSE DRUG REACTIONS: AN ACTIVE MONITORING STUDY IN A TERTIARY CARE HOSPITAL

Tamilselvan T*	Professor and Head, Department of Pharmacy Practice, Nehru College of Pharmacy, Thrissur, Kerala, 680588, India.*Corresponding Author
Celia Thomas	Doctor of Pharmacy Interns, Department of Pharmacy Practice, Nehru College of Pharmacy, Thrissur, Kerala, 680588, India.
Jesna Thankachan	Doctor of Pharmacy Interns, Department of Pharmacy Practice, Nehru College of Pharmacy, Thrissur, Kerala, 680588, India.
Keerthana KS	Doctor of Pharmacy Interns, Department of Pharmacy Practice, Nehru College of Pharmacy, Thrissur, Kerala, 680588, India.
Mashhal	Doctor of Pharmacy Interns, Department of Pharmacy Practice, Nehru College of Pharmacy, Thrissur, Kerala, 680588, India.
Rajasree.S	Assistant Professor, Department of Pharmacy Practice, Nehru College of Pharmacy, Thrissur, Kerala, 680588, India.

ABSTRACT Identification of Adverse drug reactions is a key factor to improve the overall health outcome. The study aimed to assess the adverse drug reactions reported in hospitalized patients. The study was conducted for 6 months to assess the incidence of adverse drug reactions where the assessment of various parameters was done using Naranjo, modified Schumock and Thornton, and modified Hartwig and Siegel scale. A total of 500 cases were analyzed, out of which 38 adverse drug reactions were reported. The demographic details showed that geriatric male patients have a greater number of adverse drug reactions than females. It was found that rashes were the most commonly seen adverse drug reaction and most of occurred adverse drug reactions were found to be probable. Drugs acting on the central nervous system showed a greater number of adverse drug reactions and the most affected system was found to be the skin. Occurrence of adverse drug reaction was also found and the causality, preventability, severity, seriousness, and outcome were found using various scales. A prospective study was conducted to assess the knowledge among the healthcare providers by circulating questionnaire survey forms to 200 healthcare providers. The practice of adverse drug reaction reporting is poor among healthcare providers due to various reasons like lack of knowledge, unavailability of reporting form, not knowing where and how to report, and lack of time. However, this study reveals that there is a greater need to create awareness and promote reporting of adverse drug reactions for better health outcomes.

KEYWORDS : Adverse drug reactions, Pharmacovigilance, Naranjo scale, Schumock and Thornton scale, Hartwig and Siegel scale.

INTRODUCTION

Drugs have been used for ages for the successful management of human illness. Unfortunately, most of the drugs have contributed to the occurrence of various iatrogenic diseases[1].The use of drugs always carries a certain amount of risk which may be intended or unintended[2]. Health care professionals should be well aware of the burden that adverse drug reactions play in the health service which marks the importance of post-marketing surveillance thereby ensuring continues drug safety[3].

Adverse drug reactions (ADR) are a major concern all over the world. An ADR is defined by the World Health Organization as "any noxious and unintended response to a drug that occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease or the modification of physiological function". This definition excludes overdose, drug abuse, drug administration errors, and treatment failure. An Adverse drug event (ADE) is 'any untoward medical occurrence during the administration of drugs.' Thus, an ADR can also be considered an ADE, but not all ADEs are ADRs[2,3].

One of the major deficiencies of the spontaneous reporting program is underreporting. It has been reported less than 10 percent of drug-related unwanted events are notified to pharmacovigilance centers. Underreporting varies due to various factors like increased reporting of new drugs compared to old drugs, reporting of more serious adverse reactions, reporting of a greater number of Type B reactions, the influence of sponsor, etc. Specific drug-related problem promotes further reporting which may not be necessarily related to actual frequency. The influence of the general public around the adverse reaction reporting scheme is also a major factor[2,4].

ADR is directly linked to the knowledge, assessment, and practice of healthcare professionals (HCP). HCPs should be well aware of ADR and assessment and practice ADR to prevent any drug-related reactions[6].

Knowledge among health care providers is necessary to decrease the rate of occurrence of ADRs thereby ensuring improved quality of pharmacotherapy[6]. Although many studies have evaluated the KAP of pharmacovigilance, it is important to assess and compare the public and private setups such as to address the issue of underreporting of ADRs and assess the causation of it[7].

The incidence of ADR varies with studies that show incidences ranging from low (0.15%) to high (30%)[6]. The prevalence rate varies widely because of the difference in the surveillance program, criteria for causation, study population etc[1].ADR in hospital patients can be classified into two types: those that result in admission to the hospital and those that occur in inpatients after admission to the hospital. Approximately 2% - 20% of reported hospitalizations are because of an ADR and at least one ADR has been reported to occur in 10% -20% of hospitalized patients[8].

ADRs are the most important cause of morbidity and mortality.

In India,0.7% ADRs results in hospital admission,1.8% ADRs are fatal. The occurrence of ADR adversely affects the patient's quality of life, which causes patients to lose confidence in their doctors[16]. It also increases the cost of patient care. So, the study was aimed to assess the adverse drug reactions reported in hospitalized patients.

MATERIALS AND METHODS

The study was conducted in a 750 bedded multispeciality tertiary care hospital for 6 months. Patients of all age groups and both genders were included in the study. The study was approved by Institutional Ethics Committee. The patient case sheets were reviewed to collect data and incomplete case sheets were excluded from the study. A total of 500 cases were screened from inpatient wards and the medical record department. In which 38 ADRs were reported. All data were collected in ADR reporting forms including demographic details, drugs causing the type of ADRs, and management. The causality assessment of ADRs has been done using Naranjo's scale. Severities of the reactions were done using Hartwig and Seigel Scale. Preventability of the reported ADRs was assessed using the modified Schumock and Thornton Scale [17].

Data Analysis

All the collected data were analyzed by using statistical software SPSS version 21.0. The categorical variables were represented as percentages and frequencies. Descriptive statistical analysis was used to analyze basic demographics.

RESULTS AND DISCUSSION

A total of 500 cases were screened from inpatient wards and the medical record department. In which 38 ADRs were reported. All data were collected in ADR reporting forms including demographic details, drugs causing the type of ADRs, and management. The causality assessment of ADRs has been done using Naranjo's scale. Severities of the reactions were done using Hartwig and Seigel Scale. Preventability of the reported ADRs was assessed using the modified Schumock and Thornton scale.

Demographics Of Subjects

The age of the study group was categorized into three groups. The highest number of ADRs were reported in the age group of more than 60 years and followed by the age group of 20 to 59 years (44.7%). Out of 38 patients, males 24 (63.2%) reported a greater number of ADRs compared to females 14 (36.8%). (Table 1)This observation was consistent with the study conducted by Sriram et al which shows that majority of ADR is in the geriatric population (56%) followed by adults (33%) and pediatrics (11%)[6].

Table 1: Demographics of Subjects

Sl. No	Demographics	Frequency	Percentage
Age Group			
1	0 - 19	3	07.89
2	20 - 59	17	44.74
3	>60	18	47.37
Gender			
4	Male	24	63.16
5	Female	14	36.84

Details Of Adverse Drug Reactions

In this study, the majority of the adverse reactions were rashes (21.1%). The study conducted by RJ Lihite et al also supports this observation. In their study, cutaneous ADR was higher as compared to others[9]. Also, the result was supported by the study conducted by R Arulmani et al in which rashes were found to be 35 (21.3%)[7]. (Fig-1) The maximum number of ADRs were reported from the Neurology department 8(21.1%) compared to other departments. This result was consistent with the study carried out by Palaniswamy S et al but different from the study carried out by Dilip C et al where the highest percentages of ADRs were reported from general medicine departments[12,14].

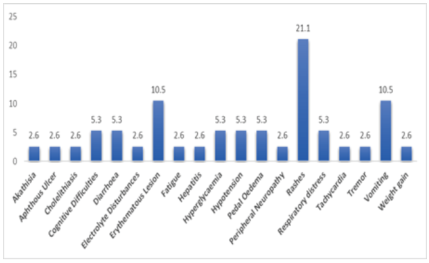

Fig 1: Percentage of Reported Adverse Drug Reactions

Among the suspected drugs causing ADRs CNS drugs accounted for 21.1% of the total cases followed by Antibiotics (15.8%) and Analgesics (13.2%). According to Rajesh Reddy et al and Murthy S N et al majority of ADRs were caused by antimicrobial agents followed by CNS drugs[13,9].

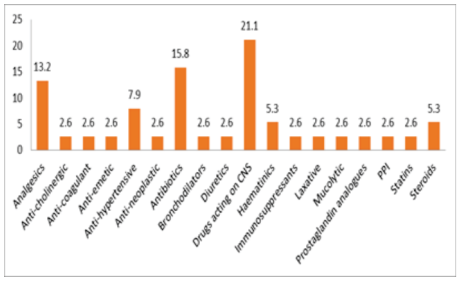

Fig 2: Percentage of Reported Adverse Drug Reactions by Class of Drugs

In 26 (68.4%) cases the suspected drug was withdrawn while the dose was reduced for the suspected drug in 6 (15.8%) and no change was made in 6 (15.8%). According to the Naranjo scale, 28 (73.7%) were probable and 8 (21.1%) were possible ADRs. Similar findings were noted from Rajan A et al, Dilip C et al where most of the reported ADRs belonged to probable, followed by possible category11,12

Table 2: Causality Assessment of Suspected ADR

Sl. No	Causality	Frequency	Percentage (%)
1.	Definite	1	2.6
2.	Probable	28	73.7
3.	Possible	8	21.1
4.	Doubtful	1	2.6

The severity and preventability of the reactions were assessed using 'Hartwig and Seigel' & 'modified Schumock and Thornton Scale'. The results are depicted in Table 5. According to Hartwig Scale, the study reveals majority of ADRs were mild 23 (60.5%) followed by moderate reactions 13 (34.2%), and only two of the reactions were severe. No fatal cases were reported. This finding is consistent with the study conducted by Rajan A et al and R Arulmani et al11,7. Withdrawal of drug 26 (68.4%) was the mainline of management of ADRs as compared to no change to the dose of suspected drug 6 (15.8%) and dose alteration of suspected drug 6 (15. 8%). Reported ADRs were assessed for their preventability by using the Modified Schumock and Thornton scale. Results revealed that 17 (44.7%) of ADRs were probably preventable while 13 (34.2%) were not preventable and 8 (21.1%) were preventable.

Table 3: Assessment of ADR Severity and Preventability

Sl. No	SEVERITY		PREVENTABILITY			
	Category	Frequency	Percentage	Category	Frequency	Percentage
1.	Mild	23	60.5	Definitely preventable	8	21.1

2.	Moderate	13	34.2	Probably preventable	17	44.7
3.	Severe	2	5.3	Not preventable	13	34.2
	Total	38	100.0	Total	38	100.0

CONCLUSION:

Adverse drug reactions are inevitable risk factors associated with the use of medicines. Proper attention to dosage, precipitating factors and renal function can reduce the risk of adverse reactions to some extent. In our study, adverse drug reactions reported were commonly due to centrally acting drugs and Antibiotics. The commonest organ system affected was the skin. This study also shows that most of the reported ADRs during hospital stays were managed by withdrawing the offending drug and specific treatment. However, the practice of ADR reporting was poor among all healthcare professionals due to a lack of knowledge about ADR reporting forms and lack of time. Pharmacists can play a major role in the area of Pharmacovigilance to strengthen the National Pharmacovigilance program and ensure the safe and effective use of medication.

Conflict Of Interest:

There are no conflicts of interest among the authors in this study.

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