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A CROSS SECTIONAL STUDY OF ADVERSE DRUG REACTIONS IN A TERTIARY CARE TEACHING HOSPITAL

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ABSTRACT

The aim of this study was to carry out Adverse Drug Reactions (ADRs) monitoring in various departments of a tertiary care teaching hospital. Methods: A cross sectional study was carried out on ADRs in a tertiary care teaching hospital in Potheri from June to December 2013 after Institutional Ethics Committee approval. Result: Total 32 ADRs were reported. Among them, 46.87% were in males and 53.12% were in females. The majority of ADRs were due to antimicrobial agents (71.78%) followed by antiepileptics (18.75%). Maximum number of patients (81.25%) was reported with dermatological manifestations. Highest number of ADRs was reported from the department of medicine (37.5%). As per Naranjo's probability scale, 50% reports were assessed as possible and 46% as probable. 75% reports were documented as moderate according to Modified Hartwig's criteria for severity assessment. The present study was done to emphasize the importance of pharmacovigilance among practicing physicians.

KEYWORDS: Adverse Drug Reactions, Tertiary care teaching hospital, pharmacovigilance

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INTRODUCTION

Adverse Drug Reaction (ADR) is defined as "Any noxious change, which is suspected to be due to drug, occurs at doses normally used in man, requires treatment or decrease in dose or indicates caution in future use of the same drug"[1]. Morbidity and mortality due to ADR are becoming a challenge to the health care system [2]. Approximately 25% of ADRs have been reported in inpatients admitted to the hospital. This could be attributed to a multitude of factors like polypharmacy, drug interactions, lack of awareness, easy accessibility of drugs and increased co-morbid disease conditions [3,4]. The unexpected ADRs for the new drugs are yet to be well documented; hence the ADR monitoring system will be beneficial for the treating physician. Some adverse drug reactions have been identified after use by a large number of people in phase IV clinical trial, so the documentation of ADR is more emphasized [5]. In India, ADR monitoring system is still primitive due to lack of awareness and interest in reporting by the health care professionals [6]. Active ADR monitoring could be done by a voluntary reporting system in a hospital set-up. Pharmacovigilance plays an essential role in providing information about adverse drug reactions and drug safety in a hospital. Hence, it is considered as essential to study ADRs in our hospital.

MATERIALS AND METHODS

A cross sectional study was conducted for a duration of six months from June to December 2013 at SRM Medical College Hospital and Research Centre. The study was approved by the institutional ethics committee. ADR details were obtained after the oral informed consent from the patient. During this period regular ward rounds were carried out and the health care professionals were also encouraged to report ADR through voluntary reporting system. The ADR information was collected based on the treating physician's report. The patients were assessed individually, patient information such as age, sex, IP number, weight, diagnosis, relevant investigations and drug information such as name of the drug, dose, route of administration, frequency of administration, duration of therapy, types of adverse drug reaction, treatment and outcome of the reaction were collected and the data was documented in the study proforma. The reported ADRs were assessed for causality using Naranjo's probability scale. The total score was calculated, based on the score, it was categorized as certain (score >9), probable (score 5-8) and possible (score1-4) [7]. The severity of ADRs were assessed by using Modified Hartwig's criteria into seven levels. Level 1 & 2 classified as mild category, level 3 & 4 considered as moderate and level 5, 6 & 7 grouped as severe category [8].

RESULTS

During the period of this study, 32 ADRs were reported. Of these groups 15 (46.87%) were male and 17(53.12%) were female. The more number of ADRs were reported in 8 (53%) male patients in the age group of 36 to 59 years and in 11 (64.7%) female patients in the age group of less than 35 years (Table: I).

Table I
Age and gender distribution in reported ADRs

Age group	Male	Female
Less than 35 years	3(20%)	11(64.7%)
36-59 years	8(53%)	3(17.6%)
More than 60 years	4(26%)	3(17.6%)
Total	15(46.87%)	17(53.12%)

Out of 32 ADRs, the major preponderance of drugs were antimicrobial agents 23 (71.87%). Among them, Ciprofloxacin 7 (30.43%), Ceftriaxone combinations 5 (21.73%), Cotrimoxazole 4 (17.39%), Cefotaxime 3 (13%), Metronidazole 2 (8.69%), Vancomycin and Clindamycin 1 each (4.34%) followed by antiepileptic drugs like Phenytoin, Carbamazepine 3 each (50%) and Non-steroidal anti-inflammatory drugs like Diclofenac sodium and Paracetamol 1 each (50%) and radio contrast dye Iopamide 1 (3%) (Table: II).

Table II
Drugs and its formulation in reported ADRs

Drug class	Route	Number of ADRsN= 32
Antimicrobials		23(71.87%)
Ceftriaxone with Sulbactam	IV	2(8.69%)
Ceftriaxone	IV	2(8.69%)
Ceftriaxone with Tazobactam	IV	1(4.34%)
Cefotaxime	IV	3(13%)
Cotrimoxazole	Oral	4(17.39%)
Ciprofloxacin	IV/ Oral	7(30.43%)
Metronidazole	IV/ Oral	2(8.69%)
Vancomycin	IV	1(4.34%)
Clindamycin	IV	1(4.34%)
Antiepileptics		6(18.75%)
Carbamezapine	Oral	3(50%)
Phenytoin	Oral	3(50%)
NSAIDs		2(6.25%)
Paracetamol	Oral	1(50%)
Diclofenac Sodium	IM	1(50%)
Iopamide	IV	1(3%)
Total		32

Based on the system wise analysis in this study, dermatological reactions were most frequent such as urticaria 20 (62.5%) followed erythematous skin lesion 6 (18.75%) (Table: III).

Table III
Types of reactions in reported ADRs

Reactions	Drugs	Number of ADRs N = 32
Urticaria	Ceftriaxone with Sulbactam, Ceftriaxone, Ceftriaxone with Tazobactam, Cefotaxime, Phenytoin, Ciprofloxacin, Cotrimoxazole, Metronidazole,	20(62.5%)
Erythematous skin lesion	Diclofenac Sodium, Cotrimoxazole, Paracetamol,Phenytoin, Carbamezapine,Clindamycin	6(18.75%)
Chest tightness and pain	Metronidazole, Iopamide	2(6.25%)
Throat irritation	Ciprofloxacin	1(3%)
Facial edema	Cefotaxime	1(3%)
Rigor	Vancomycin	1(3%)
Lip edema	Cotrimoxazole	1(3%)

In causality assessment, only 1 (3%) was identified as certain, 15(46.87%) as probable and 16(50%) as possible ADRs (Figure: I). In severity assessment, 8 (25%) ADRs subsided without any intervention (mild), 24 (75%) ADRs subsided after intervention (moderate) and no severe ADR were identified (Figure: II).

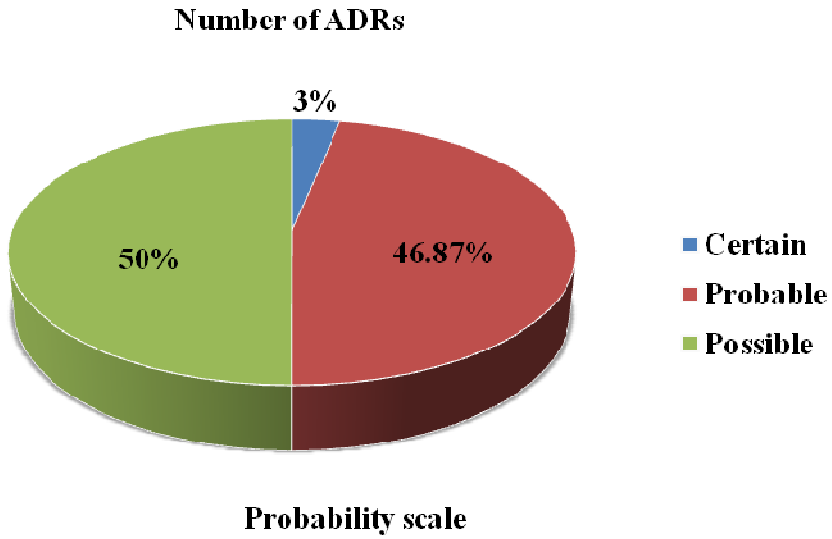

Figure I
Causality assessment of reported ADRS (in percentage)

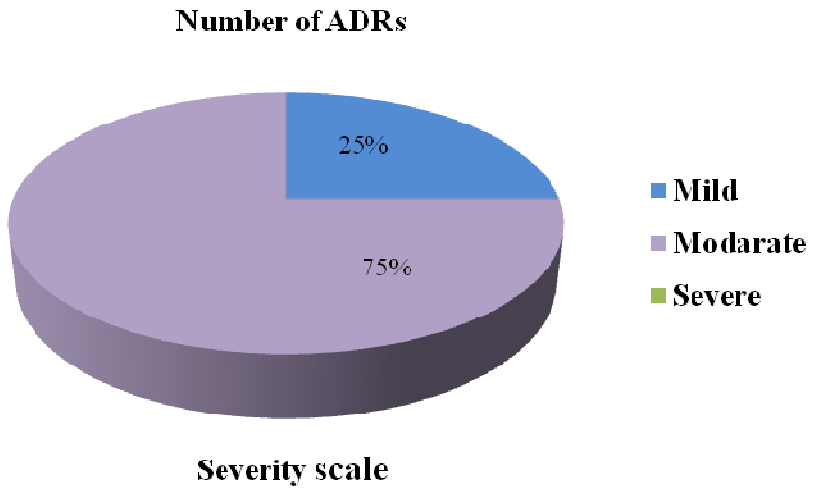

Figure II
Severity of reported ADRs (in percentage)

The majority of ADRs were reported from the department of general medicine 12 (37.5%) followed by general surgery 7 (21.87%) (Table:IV).

Table IV
ADRS reported from various departments

DEPARTMENTS	Number of ADRs
Medicine	12(37.5%)
Surgery	7(21.87%)
Obstetrics& Gynecology	3(9.37%)
ENT	2(6.25%)
CTVS	1(3%)
Dermatology	3(9.37%)
Urology	4(12.5%)

DISCUSSION

In the present study, total of 32 ADRs were reported which was similar to the study done by Malhotra et al [9]. In a previous metaanalysis study, 10.9% of patients developed ADR during hospitalization [10]. The low incidence rate in the present study could be due to lack of awareness in the patients to notify and report these ADRs to health-care workers and concerned authorities. Rademaker et al, described in their study about the increased frequency of ADR in females due to immunological and hormonal differences [11]. The current study was also comparable with the previous one. According to Mandavi et al, ADR among elderly population was 10% [12]. In the present study, it was 21.87%, which could be due to polypharmacy, lack of time and attention by the care givers to identify the ADR in this population. In this study, according to causality relationship, 50% were reported as possible because information on drug withdrawal may be lacking or unclear, it could have been explained by disease or other drugs and there was a reasonable time relationship to drug intake. 46.87% were reported as probable. Only one patient (3%) was admitted for evaluation of erythematous rashes for tablet Cotrimoxazole with relevant past drug history for the same drug (rechallenge). Hence this was reported as certain for causality assessment, whereas a study done by Mandavi et al showed 88.6% as probable [12]. In the present study, the severities of the reactions were mild to moderate; 25% patients did not require any intervention; 75% patients required medical interventions such as antihistaminics, corticosteroids. All the reactions were already well documented, no new ADR was observed. None of the reactions were recognized as severe. The most frequent ADR was due to the use of antimicrobial agents in 23 (71.87%) patients which could be associated with increased frequency of prescription of antimicrobial agents. Our results were also similar to the previous studies [13]. Guidelines for antimicrobial agents use should include the available evidence on risk of antibiotic-associated adverse events in individual patients which can be incorporated into clinical practice in the future. The second most common ADR was due to antiepileptic drugs 6 (18.75%), could be due to genetic variations [14]. Systematic screening for antiepileptic drug ADR may aid in identification of toxicity and help to reduce adverse effects in epileptic patient [15]. One female patient developed chest tightness and breathlessness after intravenous infusion of radio contrast Iopamide even after a test dose. Out of 32 ADRs, 26 (81.25%) patients had dermatological symptoms like urticaria, and erythematous rashes, which were in accordance to the observation by Shalini chawla et al [16] and was contradicting with previously published studies [12, 17]. The admission rates were high in medicine and surgery department because the patients admitted were with multiple co-morbid conditions requiring polypharmacy, which might have influenced the rise in ADR. In conclusion, the results of this study indicate that all the patients should be well-informed for the importance of ADRs to avoid detrimental consequences. The awareness of ADRs among the health care professionals should be emphasized to reduce the morbidity and mortality rate. Despite some limitations like short duration confined to six months, this study has provided the basis for future larger studies.

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CONFLICT OF INTEREST

Conflict of interest declared none.

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