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ADVERSE DRUG REACTIONS REPORTED AT A TERTIARY CARE HOSPITAL: A STUDY OF THEIR PATTERNS, CAUSALITY, PREVENTABILITY AND SEVERITY

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ABSTRACT

ADRs are among the top leading causes of death, adversely affect the quality of life by increasing hospital stay, treatment cost and morbidity. Spontaneous reporting of ADRs by health care professionals (HCP) helps in signal detection and enables regulatory agencies to formulate drug use guidelines, issue warnings or even ban/withdraw the drug from the market. Dissemination of knowledge regarding the patterns of ADRs seen in AMCs among HCP will enable to promote awareness on ADRs, help in early detection and encourage them to be more vigilant so as to prevent recurrence of ADRs. So we decided to conduct an observational study, with the following objectives. To determine the pattern of ADRs reported to AMC at PESIMSR, Causality assessment, Severity score and Preventability. We conducted an observational, retrospective, questionnaire based study in PESIMSR AMC, Department of Pharmacology. All ADRs reported to the AMC was collected by convenient sampling method . Data collected includes patient characteristics such as age, gender, details of the reaction, details regarding suspected drugs, treatment and outcome of ADR details as outlined in the standard CDSCO ADR notification form. Data was entered in SPSS ver 22. Descriptive statistics used and values are expressed in frequency and percentages. A total of 153 cases were taken for analysis. Among them 52% were males and 48%were females. The incidence of ADRs was higher (26%) among third and fourth decade than other age groups. Most frequent classes of drugs causing ADRs are antibiotics (44%) followed by analgesics (10%) and oral hypoglycemics (6%). The most frequently reported ADRs were cutaneous reactions. According to WHO scale for causality assessment 59% were possible ADRs. According to modified Hartwig Seigel's severity assessment scale, about 16%were assessed as severe reactions. 39% were probably preventable ADRs as assessed by modified Schummock and Thornton scale. Hospital-based ADR monitoring and reporting programs aims to identify and quantify the risks associated with the use of drugs. This study gives an insight to emphasize the awareness to the health care providers on vigilant monitoring of ADRs and promptly reporting the same so as to prevent the occurrence of the reactions in vulnerable population.

Keywords: Adverse drug reactions, patterns, WHO causality, Hartwig Siegel scale, Schummock and Thornton scale.

INTRODUCTION

Adverse drug reactions (ADRs) are an important public health problem in terms of mortality, morbidity as well as costs. Spontaneous reporting of ADRs by health care professionals (HCP) plays a major role in establishing the frequency of occurrence of known ADRs, detection of new, serious and even unknown reactions. This helps in signal detection and enables regulatory agencies to formulate drug use guidelines, issue warnings or even ban/ withdraw the drug from the market. A constant effort has been put by the concerned authorities in reinforcing reporting practices. However studies worldwide have shown gross under reporting with a median rate of around

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94% [1].

The pharmacovigilance programme of India (PvPI) was initiated by the central drugs standard control organization , New Delhi under the aegis of the ministry of health and family welfare, Government of India in July 2010. Currently 179 Adverse drug reaction monitoring centres (AMC) have been identified across the country [2]. India's contribution to the WHO global individual case safety reports database is only 3%. Over the last few years 149000 ADRS have been reported to the national co-ordinating centre at the Indian Pharmacopeia Commission, Ghaziabad [3].

One of the important aims of PvPI is to foster a culture of ADR reporting among not only the health care providers but also the consumers. ADRs are among the top leading causes of death [4], adversely affect the quality of life by increasing hospital stay, treatment costs and morbidity. This highlights the need for persistent monitoring of ADRs. Dissemination of knowledge regarding the patterns of ADRs seen in a AMC among health care providers will enable to promote awareness on ADRs, help in early detection and encourage them to be more vigilant so as to prevent recurrence of ADRs. Keeping this in mind, we decided to conduct an observational study with the following objectives.

Objectives

1. Pattern of ADRs reported to AMC at PESIMSR
2. Causality assessment of ADRs
3. Severity score
4. Preventablity

METHODS

This was an observational, retrospective, questionnaire based study conducted at PESIMSR AMC, Department of Pharmacology. The study period was between January 2016 to December 2016. The study was approved by the institutional human ethics committee. All ADRs reported to the AMC in the above period was collected by convenient sampling method. Data collected includes patient characteristics such as age, gender, details of the reaction, details regarding suspected drugs, treatment and outcome of ADR details as outlined in the standard CDSCO ADR notification form. ADRs were assessed for causality using the WHO causality assessment scale, preventability using Modified Schummock and Thornton scale and severity using Modified Hartwig and Siegel scale.

STATISTICAL ANALYSIS

Data was entered in SPSS ver 22. Descriptive statistics used and values are expressed in frequency and percentages.

RESULTS

A total of 153 ADRs were reported to the AMC over a period of 1 year. On analyzing the demographic data we found that 52% of ADRs were among male patients and rest among females as in fig 1. The incidence of ADRs is depicted in fig 2 and was found higher (26%) among third and fourth decade than other age groups. Department of general medicine reported 34% of all ADRs followed by the dermatology (16%) and emergency medicine (13%) departments at our hospital.

Among the ADRs reported 5 were serious ADRs. Anaphylaxis was reported in 3 patients , steven Johnson syndrome in 1 and hyperkalemia in 1 patient. Cutaneous adverse drug reactions were the most common type of ADRs (50%) followed by gastrointestinal manifestations such as vomiting and epigastric pain. The types of cutaneous reactions were generalized pruritus, rash and erythema.

The most frequent class of drugs causing ADRs were antibiotics (44%) followed by analgesics (10%) and oral hypoglycemics (6%). Among antibiotics third generation cephalosporins were most often implicated followed by flouroquinolones. Tramadol followed by Diclofenac were the common analgesics while glimepride was the commonest hypoglycemic agent with ADRs.

The causality assessment using the WHO scale is as shown in table 1. On evaluation of the severity of ADRs by Hartwig and Siegel scale it was evident that most of the ADR reported in the study, were of mild severity. Details of the severity assessment are given in the Fig 3. On evaluation of the preventability of ADRs using modified Schumock and Thornton scale, we found that 39% were probably preventable. Refer Table 2 for further details.

Table 1. Causality assessment of ADRs by WHO scale

Type	Number of ADRs	Percentage
Possible	91	60
Probable	54	35
Certain	8	5

Table 2. Preventability assessment of ADRs by Modified Schumock and Thornton scale

Type	Number of ADRs	Percentage
Definitely preventable	91	5
Probable preventable	54	39
Not preventable	8	57

Fig 1. Gender wise Distribution of ADRs among patient

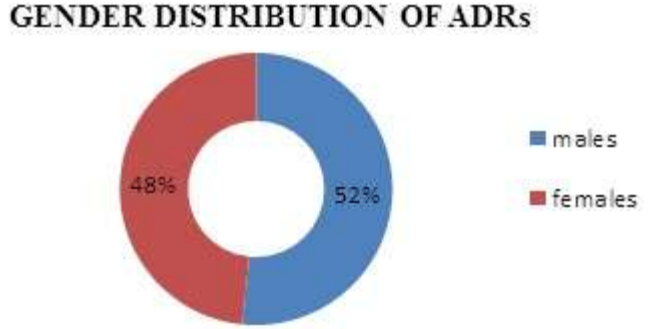


Fig 2. Age wise Distribution of ADRs among patients

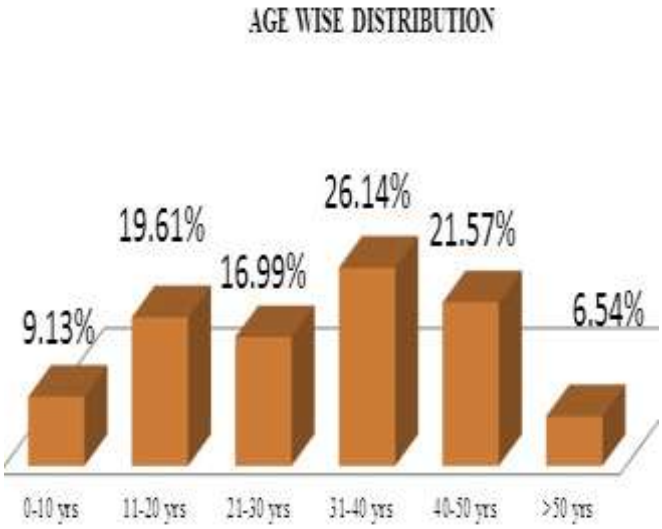
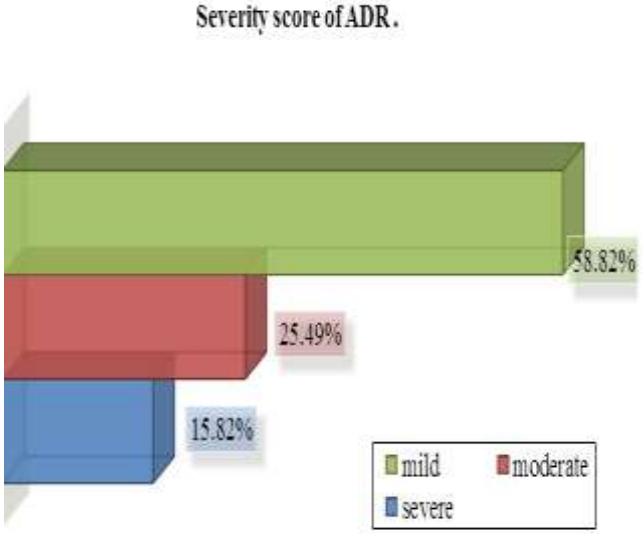


Fig 3. Severity of ADRs by Hartwig and Siegel scale



DISCUSSION

A total of 153 inpatients were suspected to have ADRs over the period of 1 year in our hospital and were more commonly seen in males(52%) similar to other studies [5-6]. In contrast to other studies ADRs are more commonly seen in third and fourth decade (26%) than elderly age group people [7].

The department of general medicine reported more number of ADRs which was comparable to other studies [8]. The most common organ class involved in our study was skin and subcutaneous tissue which was as per other studies [9-10]. Similar to other studies antibiotics (40%) followed by analgesics (10%) class of drugs were associated with more number of ADRs [11-12].

The percentage of probable ADRs at 35% was less compared to other studies [13-15]. Majority of ADRs were of possible causality which could be attributed to the fact that information on dechallenge and rechallenge most often is missing [16]. Similar to other studies mild ADRs were more common (58.82%) than moderate ADRs [17]. Probably preventable ADRs was 38.56% in our study which is higher compared to other studies [6,18].The findings of this study thus highlight the need for spreading awareness on pharmacovigilance and also to institute measures for both Secondary and primary prevention of ADRs at our health care centers.

Since reporting rate is low ADR reporting should be made mandatory in all hospitals. Spontaneous reporting of ADRs by all stakeholders should be encouraged. Consumer reporting of ADRs could go a long way in gathering data of all marketed drugs. According to a study on consumer reporting by Rehan *et al.*, missing informations were found to be a deterrent in analyzing and signal detection [19]. The study also highlights the need for improving awareness among consumers to overcome these deterrents. The government should ensure that the pharma companies comply with the rules and regulations of drug safety reporting and monitoring. Reporting of certain number of ADRs should be made a mandatory exercise during post graduation and internship training for all students in the medical and allied fiellds. Conducting educational interventions like CMEs/workshops at regular and repeated intervals. Inclusion of topics related to ADR and pharmacovigilance as part of the curriculum for medical and allied subjects cannot be over emphasized.

Research on Novel data mining technologies should be encouraged. The role of social media in our day to day life is enormous. Automated pharmacovigilance research from social media data though with a lot of challenges is pinned to have a massive impact in the future [20].

While suspecting, diagnosing and documenting ADRs is important we should also aim at preventing the recurrence of ADR. Therefore issuing alert cards to patients should be encouraged and should be made a mandatory practice.

Primary prevention [21]

It should aim at preventing the occurrence of an ADR. Entering patient's medical records in an electronic database enables the pharmacist as well as the physicians to monitor ADRs and also evaluate patients condition [22]. Implementing online prescription format will help to reduce the medication errors which are another important cause for ADRs.

CONCLUSION

Hospital based ADR monitoring and reporting programs aims to identify and quantify the risks associated with the use of drugs. This study gives an insight to emphasize the awareness to the health care providers on vigilant monitoring of ADRs and promptly reporting the same as to prevent the recurrence of the adverse drug reactions in population. Also highlights need to adopt methods of primary prevention of ADRs.

CONFLICT OF INTEREST

None declared

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