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Research Article

# ADVERSE DRUG REACTIONS AMONG PATIENTS IN DEPARTMENT OF MEDICINE IN A TERTIARY CARE TEACHING HOSPITAL, KOLLAM

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**ABSTRACT**

**Objectives:** Pharmacovigilance practices are still in the infancy in India, more so in South India. adverse drug reactions (ADRs) are often underreported and the risks are higher in adults and elderly due to the association of comorbidities, self-medication, combination of indigenous systems of medicines and modern medicine, and so on. The present study was done with the objective to analyze the ADRs among patients in the general medicine department, Government Medical College, Kollam. The primary objective is to determine the prevalence and nature of ADRs and secondary objective to assess the causality, severity, and preventability of the ADRs.

**Methods:** In this cross-sectional study done in the Department of Medicine, Government Medical College, Kollam, 1000 patients of either sex were analyzed using CDSCO ADR reporting forms and the approved scales for causality, severity, and preventability.

**Results:** Among 1000 patients studied, the prevalence of ADRs was 7.6%. The most common system involved were dermatological (41%) followed by cardiovascular (18%) and gastrointestinal and neurology (16% each). Majority of the ADRs came under probable (48.7%) with a Naranjo score of 5 (40.8%), of moderate severity (65.8%) and not preventable (71.1%).

**Conclusion:** ADRs pose a major problem needing hospital stay or prolonging the duration of stay. Developing an ongoing ADR reporting system with continuous motivation and creating awareness among the healthcare professionals for reporting suspected ADRs will help to continue reporting and improving the patient safety. Improved communication of health-care professionals with the pharmacovigilance centers should be promoted for better patient healthcare.

**Keywords:** Adverse drug reaction, Medicine, Pharmacovigilance, ADR reporting, Patient safety.

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## INTRODUCTION

Adverse drug reactions (ADRs) constitute a major problem in society and drug therapy, as a health-care predicament as well as an economic burden. The risks are increasing due to polypharmacy, various comorbidities, multiple and intercurrent diseases, age-elderly and pediatric patients, drug characteristics, gender, race and genetics, and self-medication. Often this may lead to complications and hospitalization, some of which may even be fatal. Pharmacovigilance and ADR monitoring can play a vital role in detecting ADRs and empowering physicians to anticipate the possibility and circumstances of such adverse events, thereby protecting the user population from avoidable harm [1]. As far as India is concerned, ADR reporting rate is observed to be very low. There might be many factors responsible for this scanty reporting such as heavy patient load on prescribers, irrational prescribing, drugs dispensed without prescription, polypharmacy, use of many alternative systems of medicine, and unavailability of trained and motivated doctors and other paramedical staff for ADR reporting [2,3]. ADRs are associated with prolonged hospitalization, marked financial burden, and significant mortality. Many studies have reported that ADRs account for large numbers of hospital admissions [4-6]. Pharmacovigilance in India is still in infancy and ADR reporting rates is below 1% and requires more data. Incessant monitoring and systematic evaluation of prescribing practices are essential to understand the rationality of medical care and to communicate the message to the prescriber and regulatory authorities. There is a real dearth of studies addressing the knowledge, attitudes, and perception of healthcare professionals toward the pharmacovigilance system and ADR reporting, which is carried out in this country. In a country like India with multiethnic groups and a high rate of use of traditional and alternative medicine [8], practitioners can play a significant role in detecting and reporting ADRs associated with the use of such products.

The present study was carried out with the objectives to analyze the ADRs among patients in the Department of General Medicine, Government Medical College, Kollam to determine the nature and frequency of ADRs and to assess the causality, severity, and preventability of the ADRs.

### Objectives

*Primary objective*

The primary objective was to find out the proportion of ADRs among patients in the General Medicine department.

*Secondary objective*

To assess:

a. Causality using Naranjo's Scale
b. Severity using modified Hartwig and Siegel Scale
c. Preventability using modified Schumock and Thornton Scale of ADRs.

## METHODS

### Study design

This was cross-sectional study.

### Study setting

Department of General Medicine, Government Medical College, Kollam.

**Study population**
All patients of all genders who attended the outpatient department and those admitted as inpatients in the department of medicine.

**Sample size**
The sample size was determined by the formula $[Z_{1-\alpha/2}]^2$ p q÷$d^2$. proportion of patients showing ADRs in the reference study[7] was 8.9% Using this as p, the sample size was calculated as 972.

**Sampling technique**
All consecutive cases in the department of medicine till the sample size was satisfied.

**Study procedure**
After obtaining IRC and IEC clearance, CDSCO ADR reporting form reported by the physicians from the medicine department was collected for 6 months starting from June 2018. A detailed clinical history with symptoms, age, sex, and detailed elucidation of the drug used: including type of drug, dose of drug, date of starting the drug, duration of drug use, severity of adverse reactions, and any previous history of drug reaction are noted in the ADR monitoring form and the data analysed. Patient's case notes, medication charts, laboratory data, and other relevant documents of inpatients were reviewed wherever needed.

These ADR reporting forms were evaluated using causality, severity, and preventability scales. The causal relationship between the ADR and the suspected culprit drug was assessed using the Naranjo *et al*. probability scale [11] and severity was assessed using the Hartwig *et al.* severity scale [12]. The preventability of ADR was assessed using a modified Schumock and Thornton scale [13].

## RESULTS AND DISCUSSION

The study population taken was 1000 patients who were outpatients and inpatients in the Department of Medicine, Government Medical College, Kollam. Of these 1000 patients, 76 had some sort of ADR during their medication period. Hence, the prevalence of ADR according to the study is 7.6%. This was similar to Baniasadi *et al.*'s [15] study and less compared to the study by Shareef *et al*. [7]. The reason may be the higher workload of health care professionals, the lack of awareness of proper ADR monitoring and reporting, and its benefit on patient management.

Most of the ADRs were reported in males. (56.6% males and 43.4% females) (Fig. 1). This was in accordance with the studies of Shareef *et al*., Baniasadi *et al*., and Palaniswami *et al*. [16]. The mean age of the population was 51.3 years and more than half falls were above 45 years age, majority in the age group 55–65 years (Fig. 2). This was in accordance with previous studies. According to the study, the elderly are more prone for ADRs. This may be due to their various comorbidities such as diabetes, hypertension, and cardiovascular comorbidities, and multidrug therapy associated with that [10].

A total of 100 ADRs were reported from 76 patients since many presented with more than one ADRs. The most common system involved were dermatological (41%) followed by cardiovascular (18%) and gastrointestinal and neurology (16% each) (Fig. 3). The most common ADR reports were itching and rashes. This may be because proton pump inhibitors are almost always prescribed with antibiotics. Hence, gastrointestinal tract (GIT) ADRs were low compared to the obvious dermatological ADRs which are hard to miss out. ADR reporting was inadequate due to a lack of workforce, unawareness that every ADR even milder ones have to be reported, how to report, etc.

The most common class of drugs involved in ADR was antibiotics (33.33%) followed by psychotropic drugs (24%). Concomitant drug therapy was present in majority (60.52%) (Table 1). This study shows similarity with the study made by Sriram *et al*; and Harugeri *et al*. which has shown that antibiotics were found to be the most common class of drug causing ADRs.

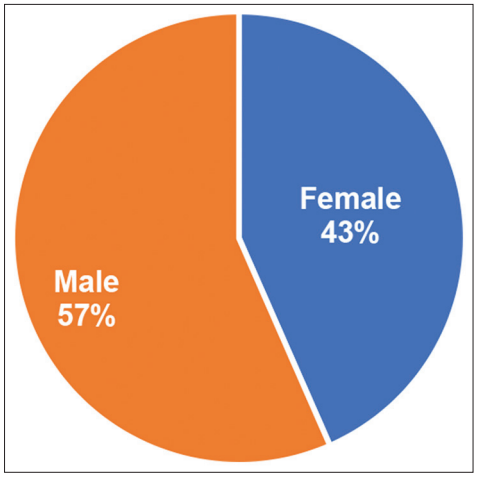


**Fig. 1: Sex distribution**

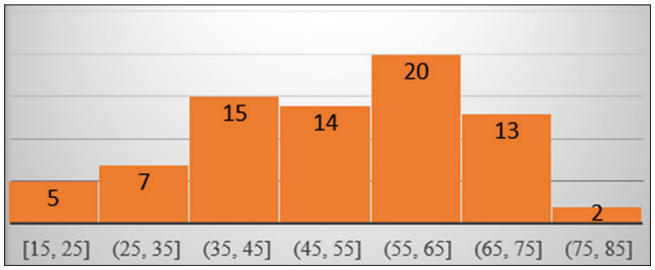


**Fig. 2: Age distribution**

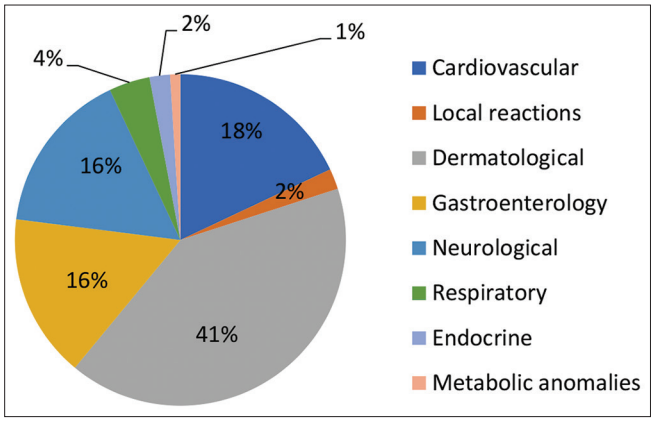


**Fig. 3: Common systems affected**

**Table 1: Frequency of ADR in drug groups**

| Suspected drug group | Frequency | Percentage |
|---|---|---|
| Anticancer | 1 | 1.33 |
| Antibiotic | 25 | 33.33 |
| Antitubercular | 9 | 12.00 |
| Psychotropic drugs | 18 | 24.00 |
| NSAIDs | 9 | 12.00 |
| GIT drugs | 1 | 1.33 |
| Endocrine | 2 | 2.66 |
| CVS drugs | 10 | 13.33 |
| Total | 75 | 100 |

ADR: Adverse drug reactions, NSAIDs: Nonsteroidal anti-inflammatory drugs, GIT: Gastrointestinal tract

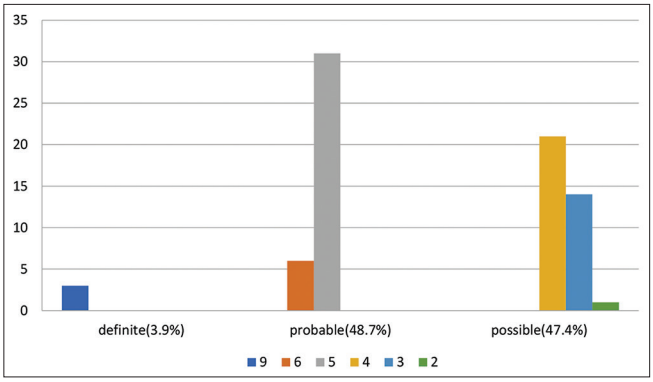


**Fig. 4: Causality criteria using Naranjo's score**

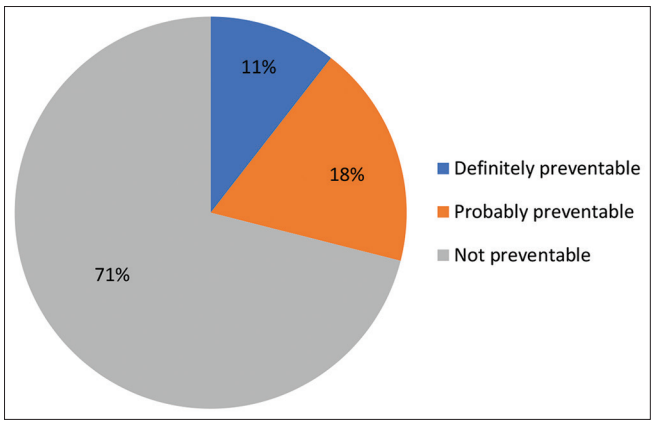


**Fig. 5: Preventability criteria using Modified Schumock and Thornton scale**

**Table 2: Severity levels assessed using the Hartwig severity scale**

| Severity | Severity levels | Frequency | Percentage |
|---|---|---|---|
| Mild (n=24; 31.6%) | 1 | 3 | 3.95 |
| | 2 | 21 | 27.63 |
| Moderate (n=50; 65.8%) | 3 | 40 | 52.63 |
| | 4a | 3 | 3.95 |
| | 4b | 7 | 9.21 |
| Severe (n=2; 2.6%) | 5 | 1 | 1.31 |
| | 7 | 1 | 1.31 |
| Total | | 76 | 100 |

These ADRs were evaluated using causality, severity, and preventability scales [9]. The causal relationship between the ADR and the suspected culprit drug was assessed by using the Naranjo probability scale. the majority of the ADRs came under probable (48.7%) with a Naranjo score of 5 (40.8%) (Fig. 4).

The severity of ADR observed was assessed using the Hartwig severity scale. The majority of ADR was of moderate severity (65.8%) which required the withdrawal of the suspected drug and symptomatic management of ADRs (level 3–52.63%) (Table 2).

The preventability of ADR is assessed using a modified Schumock and Thornton scale. 71.1% of ADRs were not preventable (Fig. 5).

## CONCLUSION

In modern medicine, ADRs are inevitable due to the wide use of drugs. Proper monitoring and reporting will ensure patient confidence and health care benefits. Most of the ADRs reported were probable and not preventable. Majority were of moderate severity which required discontinuation of drugs, symptomatic management, and alternate drugs. Developing an ongoing ADR reporting system with continuous motivation even by using incentives [14] and creating awareness among the healthcare professionals for reporting suspected ADRs will help to continue reporting and improving the patient safety. Improved communication of health-care professionals with the Pharmacovigilance centers should be promoted for better patient healthcare. Continuous and proper awareness programs which can be group discussions, posters, charts, and CME programs by ADR monitoring centers will help to promote reporting of ADRs.

## AUTHOR'S CONTRIBUTION

The study design and concept were done by Dr. Beena JS and Dr. Reeja R. Dr. Beena JS wrote the paper, performed data collection, performed data analysis, drafted the manuscript, and contributed to the final manuscript. Dr. Reeja R and Dr. Rakesh co-wrote the paper, drafted the manuscript, and contributed to the final manuscript. Dr. Resma helped in data collection and made it feasible. Dr. Bindulatha Nair R supervised the research and contributed to the final manuscript.

## CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

## AUTHOR'S FUNDING

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