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Research Article

# PATTERN OF SUSPECTED ADVERSE DRUG REACTIONS IN A TERTIARY CARE HOSPITAL – A CROSS-SECTIONAL STUDY

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**ABSTRACT**

**Objective:** The objective of the study was to study the pattern of suspected adverse drug reactions (ADRs) in a tertiary care hospital.

**Methods:** This is a cross-sectional study conducted in the Department of Pharmacology of a Tertiary Care Teaching Hospital, Kerala. As part of pharmacovigilance activities, the ADRs were collected in Central Drug Standard Control Organization Suspected ADR reporting form from various departments during a period of 3 months and recorded in Pharmacovigilance register maintained by the pharmacology department. As part of our study, we collected the details such as patient's initials, age, gender, reporting department of hospital, description of the ADR, duration of the reaction, name of suspected ADRs, and outcome from the Pharmacovigilance register. Descriptive statistics will be used for data analysis by statistical package for the social science for windows 16.

**Results:** Two hundred and twenty-two ADR from 141 patients obtained during a period of 3 months. The maximum ADR reports were in age group more than 50 years of age. The skin and appendages were most affected followed by gastrointestinal tract. Antineoplastic drugs accounted for 59.7% of drug class suspected for ADRs followed by use of more than one drug (14.1%). Among antineoplastic drugs, cyclophosphamide and carboplatin accounted for majority causes of ADR. The antibiotics accounted for 12.7% of all drugs. Among the antibiotics penicillin and cephalosporins caused most of the ADRs.

**Conclusion:** The maximum number of ADR reported in our study was with the use of antineoplastic drugs and most common ADR reported was alopecia.

**Keywords:** Adverse drug reactions, Pharmacovigilance, Antineoplastic drugs.

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## INTRODUCTION

Adverse drug reactions (ADRs) have been implicated as the major cause of mortality and morbidity worldwide. Drugs prescribed for various diseases are often the cause of major ADRs among the patients. ADR as defined by WHO is "any noxious, unintended, undesired effect that occurs at dosage used in human for prophylaxis, diagnosis, and therapy" [1]. It has been reported that ADRs account for about 5% of all hospital admissions and these occur in 10–20% of hospitalized patients [2]. These ADRs are the challenge in healthcare, having huge impact in determining cost and quality of patient morbidity. Drug toxicity act as a limitation in providing improved patient recovery. Early detection, monitoring, and evaluation of ADRs pave way for active surveillance of drug related problems. By doing this unintended and unwanted effects can be curtailed to a limit. ADR monitoring helps to ensure that patients are getting safe and efficacious drugs [3].

Pharmacovigilance aims to provide safety with use of medicine and assessment of risk benefit profile. With this aim international drug monitoring program was launched in which India is now an active member. Under Central Drug Standard Control Organisation the Pharmacovigilance Program of India is currently active and is keeping eye on drug use in the country [4].

ADR monitoring is still infancy in India. The health care providers and stakeholders need to be educated the importance of detecting and reporting ADR. Polypharmacy increases the incidence of ADR and can be reduced by skilful prescription by the doctors [5]. Hence, information on ADR will enhance ability of prescribers to manage ADRs more effectively and most of the ADRs are preventable if strict vigilance and monitoring are undertaken. This study is undertaken to bridge gap in the literature relating to ADRs reported in Kerala [6].

## METHODS

This was a cross-sectional study conducted in the Department of Pharmacology of a Tertiary Care Teaching Hospital, Kerala, India. As part of Pharmacovigilance activities, the ADRs were collected in Central Drug Standard Control Organization Suspected ADR reporting form from various departments (general medicine, pulmonary medicine, psychiatry, dermatology, and radiotherapy) during a period of 3 months starting from October 2016 to December 2016 and recorded in Pharmacovigilance register maintained by the pharmacology department. As part of our study, we collected the details (patient's initials, age, gender, reporting department of hospital, description of the ADR, duration of the reaction, name of suspected ADRs , and outcome) from the Pharmacovigilance register.

The study was initiated after getting approval from Institutional Research Committee, Institutional Ethics Committee and Permission Letter from Principal, Superintendent, and Head of the Department of Pharmacology. Census sampling method was used and all patients of either sex or of any age whose ADR entered in the Pharmacovigilance register were taken for the study. The data were sorted, coded, and entered in Microsoft excel and descriptive statistical analysis was done using epi info 7.

## RESULTS

Two hundred and twenty-two ADR from 141 patients were obtained during a period of 3 months. The maximum ADR reports were in more than 50 years of age (52.5%) followed by 20–50 years age group (44.7%).

Demography is summarized in Table 1. The ADRs lasted for more than one-week duration in 73% of patients as shown in Fig. 1. As depicted in Fig. 2, when the offending drug was discontinued or continued with reduced dose, reactions subsided in 51 patients (36.2%) and was persisting in nine patients (6.4%). The reintroduction of offending drug was done in 14 patients (9.9%). Out of 141 patients, data about concomitant drug was available in 44 patients who received at least one concomitant drug. Most of the patients (63%) had no relevant medical history. The categorization of seriousness of ADR is shown in Fig. 3, where 46% of ADRs required hospitalization or prolonged treatment for their ADRs and 4% of ADRs required intervention to prevent permanent impairment. The outcome of ADRs were recovering in 51.8% patients, continuing in 40.4% patients, and recovered in 7.8% patients which are shown in Fig. 4.

The reported ADRs were summarized based on the WHO-adverse reaction terminology System Organ Class, as shown in Fig. 5. The skin and appendages were most affected followed by gastrointestinal tract. Alopecia and vomiting were the most common dermatological and gastrointestinal ADR reported, respectively. As shown in Fig. 6, antineoplastic drugs accounted for 59.7% of drug class suspected for ADRs followed by drug class which has more than one drug use (14.1%). Among antineoplastic drugs, cyclophosphamide and carboplatin accounted for majority causes of ADR. The antibiotics accounted for 12.7% of all drugs. Among the antibiotics penicillin and cephalosporins caused most of the ADRs.

## DISCUSSION

This study shows a descriptive analysis of ADRs reported to Department of Pharmacology of a Government medical college in Kerala from October 2016 to December 2016. Two hundred twenty-two ADRs were reported from 141 patients. The majority of ADR occurred in elderly population. Due to variable and unpredictable pharmacokinetics, extremes of ages have critical impact on occurrence of ADR [7]. There was a female preponderance in the study population which was consistent with several other studies [6-10]. Literature review shows that anatomical and physiological variations in the females alter the pharmacokinetic and pharmacodynamics of the drugs and predispose them to more ADRs [11]. In this study, the skin and appendages

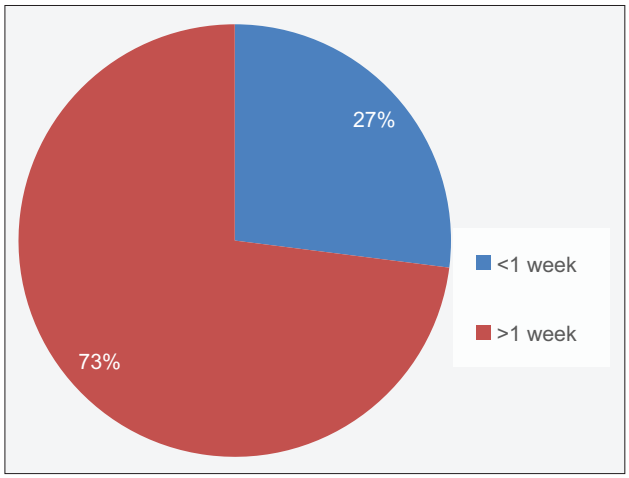


**Fig. 1: Duration of adverse drug reactions**

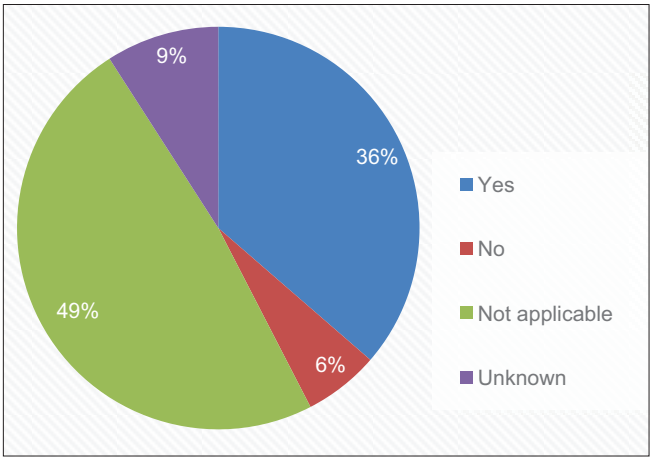


**Fig. 2: Reaction abated after drug stopped or dose reduced**

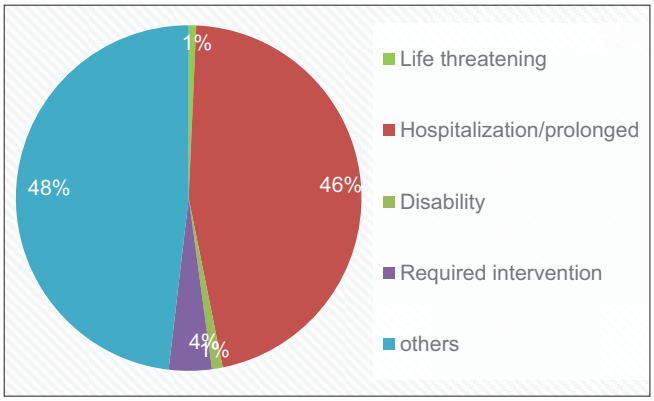


**Fig. 3: Seriousness of reaction**

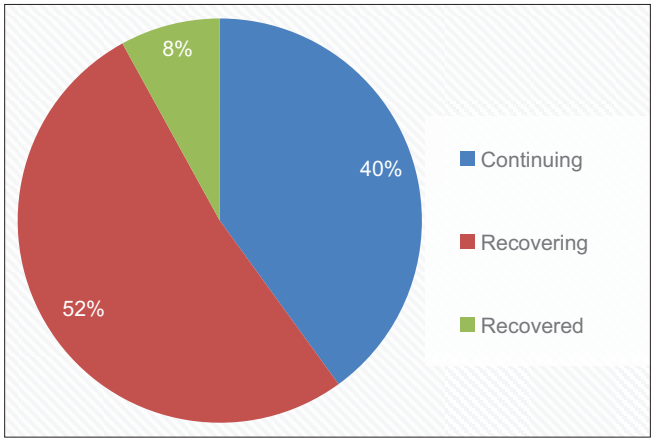


**Fig. 4: Outcome of adverse drug reactions**

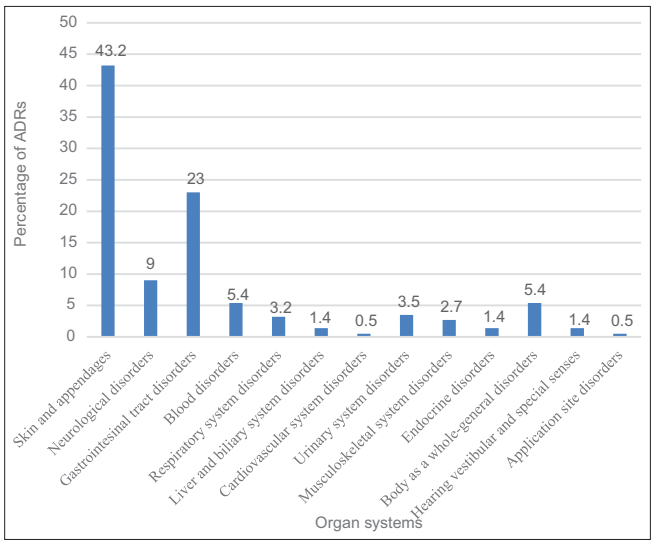


**Fig. 5: Distribution of adverse drug reactions reports based on system organ class**

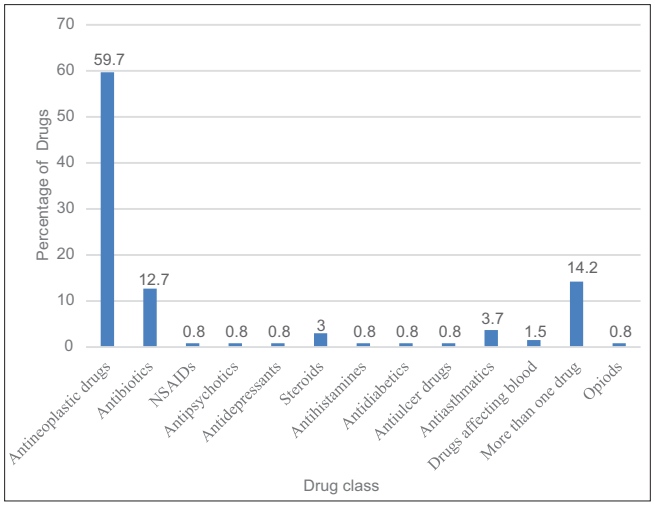


**Fig. 6: Distribution of adverse drug reactions based on drug class**

**Table 1: Demographic data**

| Variables n=141 (%) | |
|---|---|
| Gender | |
| Male | 47 (33.3) |
| Female | 94 (66.7) |
| Age (years) | |
| <20 years | 4 (2.8) |
| 20–50 years | 63 (44.7) |
| >50 years | 74 (52.5) |

were the most commonly affected organ in this study which was supported by several studies [12-14]. Alopecia was the most common dermatological ADR reported. Among all the drugs implicated for the occurrence of ADR, antineoplastic drugs accounted for 59.75% in which majority was due to cyclophosphamide and carboplatin. This finding was supported by Sharma *et al*. where alopecia was the commonest adverse effect and docetaxel, carboplatin, paclitaxel, and cyclophosphamide caused majority of ADRs [15]. The second commonest class of drugs causing ADR was use of more than one drug. Polypharmacy plays an important role in the occurrence in the development of adverse drug interactions. In this study, 44 patients received at least one concomitant drug which significantly the risk of ADR. Alomar *et al*. stated that too many medications amount to increased risk of ADR [11]. In this study, antibiotics accounted for only 12.7% of total drugs causing the ADR. This finding was different from previous studies where antibiotics were the commonest class of drugs causing ADR [3,14].

### Limitations

The main limitation of this study is that it represents only the ADRs reported to the Department of Pharmacology that was entered in Pharmacovigilance register and we collected only the details of ADR occurred during 3 months duration. Hence, this report does not reveal complete picture of ADR in this tertiary care teaching hospital.

## CONCLUSION

The maximum number of ADR reported in our study was with the use of antineoplastic drugs and most common ADR reported was alopecia. Polypharmacy increased the incidence of ADR in our study. Most patients were recovering at the time of reporting. This study suggests that spontaneous reporting of ADR should be practiced by all clinical departments of tertiary care hospital for monitoring and assessment of ADR. Skilful prescription should be advised to reduce the burden of ADR by reducing polypharmacy.

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## AUTHORS' CONTRIBUTIONS

Lima Koruthara Mohanana – Protocol preparation, data collection, data analysis, manuscript preparation, editing, review. Dhanya Thirookaran Harichandran – Protocol preparation, data collection, data analysis, manuscript preparation, editing, review, and correspondence. Sanalkumar K B – Protocol preparation, manuscript preparation, editing, and review.

## CONFLICTS OF INTEREST

Nil.

## SOURCE OF FUNDING

Nil.

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