Original Article

A Descriptive Analysis of Adverse Drug Reactions Among Hospitalized Patients in a Tertiary Care Teaching Hospital in India

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Abstract

Objective: The objective of this study is to analyze the adverse drug reactions (ADRs) in hospitalised patients in a tertiary care teaching hospital.

Methods: After obtaining institutional ethics committee approval, a cross-sectional study on ADRs reported at the hospital from October 2021 to February 2022 was carried out.

Results: There were 45 hospitalizations as a result of adverse drug reactions. Out of these, 28 (62.22%) were women and 17 (37.7%) were men. The majority of cases (62.5%) were moderate in terms of response intensity. Only one patient's estimate of causality (2.5%) was determined to be certain, placing 62.5% of instances in the likely group.

Conclusion: This study was carried out to educate practising doctors on the need of monitoring and reporting adverse Drug Reactions.

Keywords: Adverse drug reactions, Antihypertensive agents, Pharmacovigilance, Vitamin supplements

INTRODUCTION

Reporting of adverse drug reactions (ADRs) highlight significant safety concerns with pharmacological therapy. The documentation of these reports lead to modifications in the prescription medication trend and perhaps the withdrawal of the drug from the market. Serious adverse events can result in hospitalisation, an extension of the hospital stay, higher expenditures for investigations or treatments, poor work performance, birth deformities, and even risk to life that could result in death. ADRs may carry in the same physiological and pathological ways as other illnesses; as a result, it can be challenging or even impossible to tell the differences between them.

According to the World Health Organization (WHO), an adverse drug reaction (ADR) is "response to a medication, which is unpleasant and undesired, and which occurs at levels commonly used in man for prevention, diagnosis, or therapy of illness, or for the alteration of physiological function." [(1)]. Preclinical animal studies are insufficient to predict the safety in humans. Due to the small number of participants in the clinical trials in humans, the uncommon adverse effects cannot be identified. However, post-marketing surveillance may be used to investigate these side effects[(2)]. The tragedy of Thalidomide which was prescribed for the treatment of morning sickness in pregnancy, had caused a serious drug event which led to the creation of drug monitoring programmes. The drug Terfenadine's deadly cardiac arrhythmia which is a significant adverse effect was not addressed for more than ten years [(3)].

According to the data from 2014 Pharmacovigilance Programme of India (PvPI), 6.8% of patients experienced significant adverse events. Similar investigations have shown that hospital readmissions due to ADR were 3.7%, death was 1.8%, and hospital admissions owing to ADR were 3.4% [(4)].

Despite being the third-largest market for pharmaceuticals in the world, India had only reported 2% of all ADRs until 2013. PvPI raised the number of ADR monitoring centres, including private hospitals, from 90 to 150, which resulted in a rise in ADR reporting. India made history by becoming the first nation to submit Individual Case Safety Reports of

around 1,00,000 patients to Vigiflow, Uppsala Monitoring Centre. All healthcare professionals, including doctors, dentists, nurses, and pharmacists, must be informed to report ADRs as a part of their routine, even if they are unsure of the particular connection to the prescribed medicine.

Since all pharmaceutical mistakes may be avoided, sharing information is one of the most crucial strategies to do so. This can be done by raising awareness among medical professionals about the need to record and monitor adverse drug events. Hence, Pharmacovigilance plays a crucial role in the judicial use of medications.

MATERIALS & METHODS

With the approval of the Institutional Ethics Committee, we carried out a 5-months cross-sectional research from October 2021 to February 2022. Following oral informed consent, the patient provided information on ADRs. During this time, routine ward visits were conducted, and the voluntary reporting mechanism was made aware to all healthcare workers. The ADR information was recorded based on the treating physician's report. Patients' information, including their age, gender, IP number, weight, diagnosis, results of relevant investigations, and drug information, such as the drug's name, dosage, route of administration, frequency of administration, duration of therapy, types of ADR, treatment, and reaction outcome, was gathered from them and entered into the study proforma. Each patient who reported for the study was then assessed individually. The WHO-UMC Programme for International Drug Monitoring used VigiFlow to send the findings to the National Centre in Ghaziabad. It is an online system for managing Individual Case Safety Reports (ICSRs), created specifically for use by Regional Pharmacovigilance Centres.

RESULTS

Microsoft Excel programme performs a descriptive analysis of the ADR data obtained and presents the results as percentage comparisons. There were 45 hospitalizations as a result of adverse drug reactions. Out of these, 28 (62.22%) were women and 17 (37.7%) were men (Fig. 1). 8 patients (17.77%) belonged to the elderly age group, 35 patients (17.77%) from the adult age group and 2 patients (4.4%) from adolescents age group (fig.2). 25 (55.5%) females aged between 18 to 60 years were found to be the majority in reporting the ADRs in this research, followed by 10 (22.2%) men aged between 18 to 60 years.

The highest number of Adverse Drug Reactions (ADRs) were recorded by Department of Medicine (33.3%) and Paediatrics (6.66%), followed by Obstetrics and Gynaecology department (17.7%). 16 (35.5%) ADRs were caused by antibiotics like fluoroquinolone, metronidazole, penicillin, and beta-lactams. 2 (4.44%) ADRs were caused by iron sucrose. 4(8.88%) ADRs were caused by NSAIDs, Tramadol and Paracetamol. 3(6.66%) ADRs were due to statins (atorvastatin), 2(4.44%) ADRs were due to antipsychotic (olanzapine, alprazolam) and 1(2.2%) ADR was due to hormonal therapy (Fig.3). Most of the instances (62.5%) were minor in terms of the reaction's intensity (Fig. 4). Only one patient's evaluated of causality (2.5%) was determined to be certain, placing 62.5% of instances in the likely group (Fig. 5). Antibiotics and NSAIDs caused skin lesions including urticaria and erythematous rash that occurred in majority of the ADR instances (Tables 1 and 2).

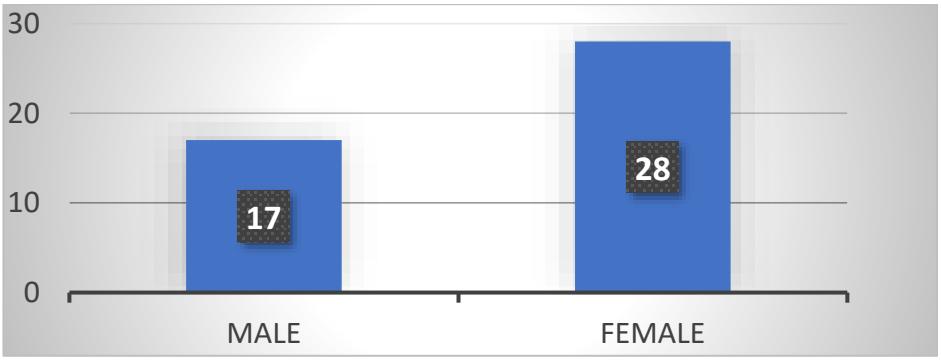

Fig. 1: Distribution of gender in reported adverse drug reactions

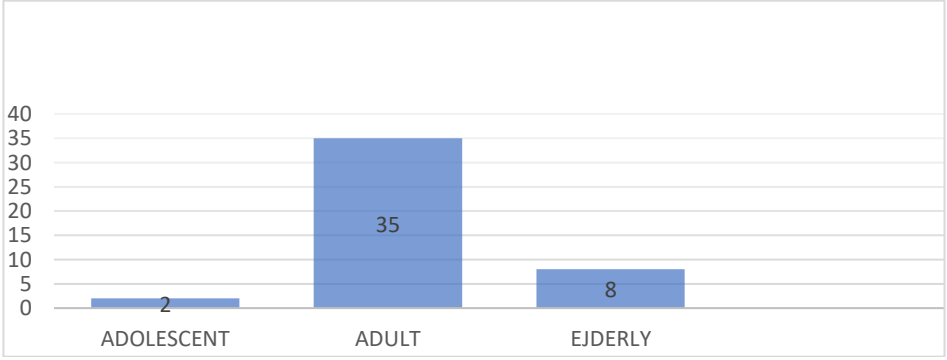

Fig. 2: Distribution of age in reported adverse drug reactions

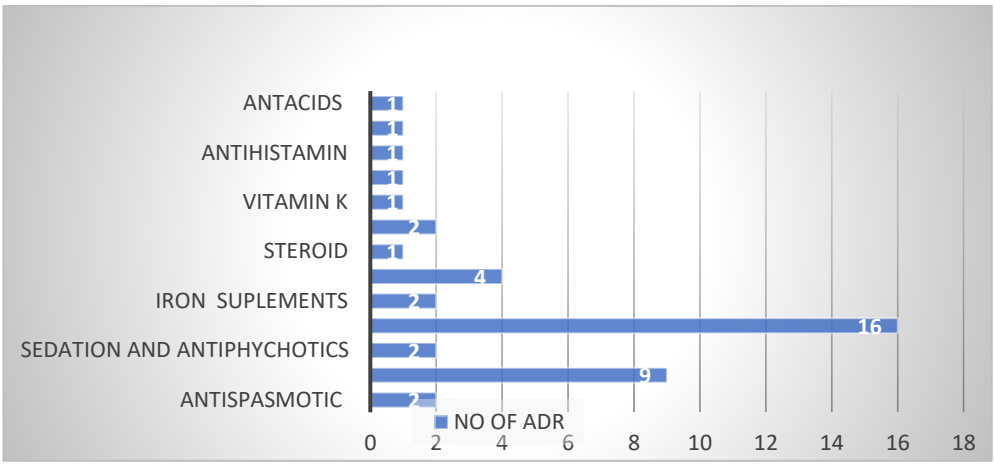

Fig.3: Drugs in reported adverse drug reactions

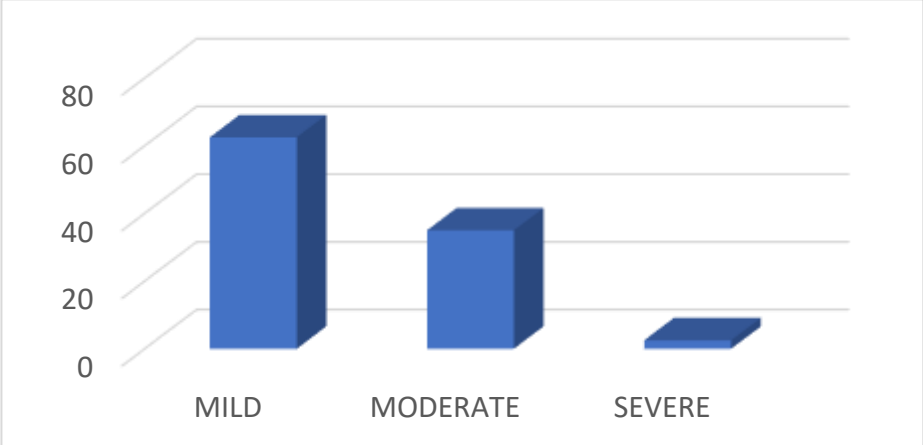

Fig.4: Severity of adverse drug reaction

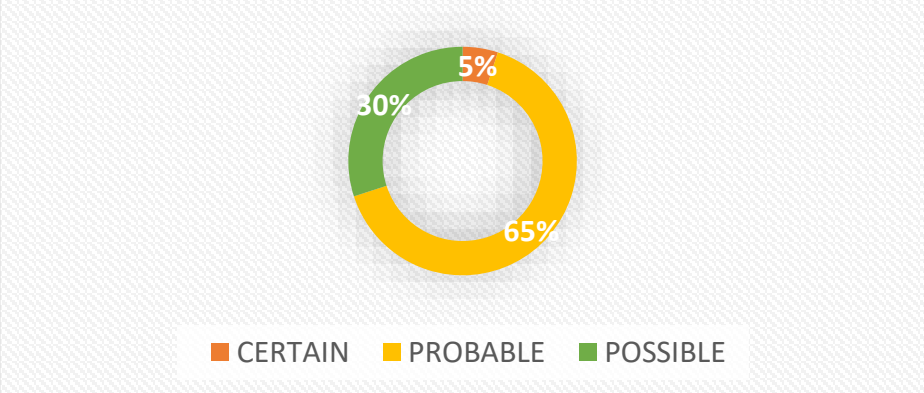

Fig.5 Causality assessment in reported adverse drug reactions

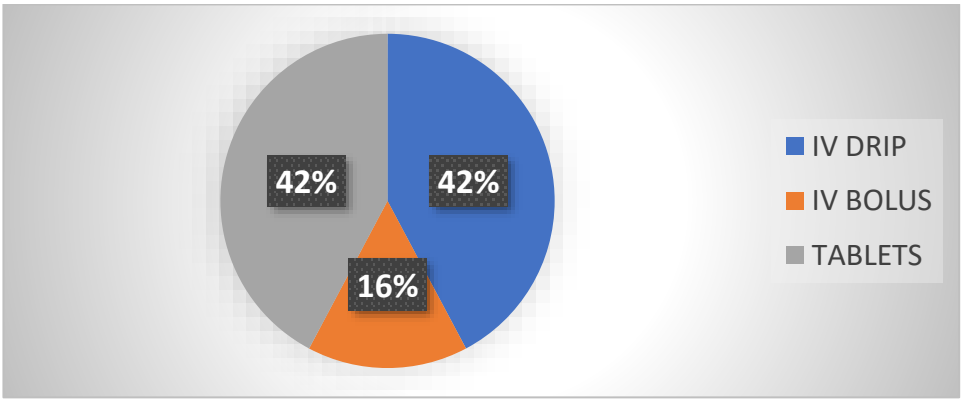

Fig.6: Route of drug administration in ADR patients

Table :1 - List of ADR reported in various departments

List of ADR reported according to system	
Departments reported ADR	NO OF ADR
Medicine	15
Surgery	15
Obstetrics and Gynaecology	8
Peadiatrics	3
Psychiatry	2
Orthopeadics	2

ADRs: Adverse drug reactions

Table:2 – Reactions due to ADRs

ADRs	Drugs reported
Swollen lips	Vitamin K
Urticaria	Pantoprazole, Paracetamol, ciprofloxacin, Cefoperazone, Amoxicillin
Erythematous skin lesion	Cephalosporines, ciprofloxacin, Tramadol
Facial edema	Iron sucrose, Metronidazole
Pedal edema	Telmisartan, Amlodipine
Breathlessness	Ceftriaxone, Iron sucrose, Ciprofloxacin

ADRs: Adverse drug reactions

DISCUSSION

India stands third in drug marketing and second in population, yet just 2% of adverse drug reactions are recorded. This study was conducted to highlight the significance of ADR documentation. There is a significant increase in prevalence of ADR among female patients (62.2%) compared to male patients (37.7%) out of the 45 patients reported during this investigation, which was consistent with a study conducted by Saravanan et al.[5]. The maximum incidences were documented to be in the general medicine and surgery departments due to an increase in patient intake, which is consistent with the finding made by Vora et al.[6,7]The spontaneous reporting method in India had increased the reporting rates but have not reached the reporting levels of western counterparts[8]. Hypertensives, Ofloxacin, Amoxicillin, Ciprofloxacin, Aceclofenac, Tramadol, Paracetamol and Vitamin K were the medications that were commonly associated with ADR. The patients who were hospitalised due to ADR for more than a week had to incur the additional treatment cost for the adverse reaction as well as an indirect cost of loss of wages, travel and expenditure for the care giver.Our study's demographic information revealed that women outnumbered men (55.5%), which was consistent with findings from previous research that have been published in the literature. According to Raut et al. and Rodriguez-Pena et al.[9,10], the majority of ADRs were due to beta-lactam antibiotics. Beta-lactam is one of the most commonly prescribed antibiotics in clinical practice. In this study, the majority of reactions were mild (62.5%), then moderate (35%) and 3% were severe. Research by Shamna et al.[11] found a similar percentage of responses. The severity of the responses were evaluated using the Modified Hartwig's criteria for severity evaluation, and patients who encountered them were asked to discontinue the drug immediately. Patients who experienced mild to moderate reactions were treated with antihistamines and steroids as needed, while those who experienced severe reactions were hospitalised. All patients who experienced ADRs recovered fully after treatment.The patients were instructed to reveal their history of adverse reaction for the concern drug to their treating physician in order to prevent such responses in the future. In accordance with a research conducted by Mandavi et al., which had identified 88.6% as likely [12,13], the causality evaluation of the reported ADRs in this investigation indicated that 62.5% of responses were classified as Probable according to the Naranjo scale.

When we examined the presentation of responses, over 75% had cutaneous reactions such as urticaria, and erythematous rashes, which was consistent with studies conducted by Jose et al. and Chawla et al.[14]. Three patients received the causality evaluation for the medication ciprofloxacin as definite. When we looked at the different medication responses, we saw that the majority of the cephalosporin and NSAIDs resulted in urticaria and erythematous reactions. According to a research by Sharma et al., 40% and 35% of the cutaneous ADRs were caused by antibiotics and NSAIDs, respectively[15]. Numerous studies have suggested that aberrant drug metabolism and clearance from the body may be the source of altered liver and renal function tests, which may lead to severe cutaneous ADRs.

CONCLUSION

The purpose of this study is to highlight the need of health care practitioners being aware of ADRs and emphasize reporting them to the ADR centre. To educate healthcare professionals on the value of reporting ADRs. Regular pharmacovigilance programmes should be conducted periodically. Above all, the patient should get good counselling to avoid self-medication and to disclose to the treating physician any past drug allergies they may have had. Many undesirable responses in patient care can be minimised with systematic, thorough monitoring and documenting of ADRs, which will also result in efficient medical management.

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Conflict of interest: Nil

Ethical approval: Obtained

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