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Original Research Article

Analysing adverse drug reaction patterns observed during district residency program: a prospective observational study

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ABSTRACT

Background: Adverse drug reactions (ADRs) pose a substantial cost to global healthcare systems. The heterogeneous patient demographics and healthcare environments of district residency programmes (DRPs) provide special possibilities for detecting trends of ADRs. In order recognize recurring trends and related variables, this study will examine ADR incidents that occur during DRPs.
Methods: A prospective observational research with forty-three patients was carried out. Standardized reporting forms were used to gather data on ADRs, and descriptive statistical techniques were used to analyse the results. We evaluated medication information, patient demographics, and ADR features to seek for patterns and potential causes.
Results: Preliminary analysis revealed a diverse range of ADRs observed during DRPs, spanning various severity levels and therapeutic classes. Common ADRs included gastrointestinal disturbances, allergic reactions, and central nervous system effects. Factors such as patient age, polypharmacy, and comorbidities emerged as potential predictors of ADR occurrence.
Conclusions: The panorama of ADRs seen during DRPs is clarified by this study, underscoring the significance of careful monitoring, and reporting mechanisms in these initiatives. Gaining insight into ADR trends and related variables can help in improving patient safety, simplifying drug management plans, and directing future educational initiatives for medical professionals.

Keywords: Pharmacovigilance, Causality, ADR, Drug safety, Rural area, Reporting pattern

INTRODUCTION

Pharmacovigilance (PV) is the study of the identification, collecting, evaluation, comprehension, and avoidance of side effects regarding medication and vaccine-related issues.[1] PV's goal is to protect patients and medications by tracking and disclosing any adverse drug reactions (ADRs) connected to prescription medications.

An unfavourable and unexpected reaction to a medicine that occurs at levels typically used for disease prevention, diagnosis, or therapy, combined with altering physiological function, is refers to as an ADR by World Health Organization (WHO). In simpler terms, it refers to harmful and unintended effects caused by medications, even when taken as prescribed. These responses are a vital component of patient safety in the healthcare sector and can vary from minor pain to serious consequences.[2]

The incidence of ADRs reported worldwide is a significant public health concern. Over 180,000 ADRs are thought to occur annually, according to a recent meta-analysis of prospective ADR research, making ADRs the sixth greatest cause of mortality worldwide.[3] Moreover, it has been documented that 1 in 6 hospitalized patients 65 years of age or older would develop a new, serious adverse drug reaction while they are hospitalised.[4]

In India, the incidence of ADR has been observed to vary between 3.7% and 32.7%. A study conducted in Mysuru found that 3.7% of hospitalized patients experienced an adverse drugs reaction. Furthermore, ADR was the reason for 0.7% of hospital admissions, and 1.8% of those experienced fatal ADRs.[5] According to a Pune-based study, the overall prevalence of ADR was 4.75%, 3.6% of hospitalized patients had ADRs, and 1.72% of patient admissions were due to ADRs.[6] An further research conducted in Srinagar indicated that the total incidence of ADR was 6.23%.[7] The incidence of ADR development is impacted by the significant differences between developed and developing nations' illness prevalence, ADR reporting systems, drug usage patterns, and drug management systems.

To lessen the impact of ADRs, research on early diagnosis and prevention is essential. It's also important to motivate healthcare professionals to report ADRs.[8] Therefore, research on ADR is important for enhancing patient safety. WHO research states that 60% of ADRs are avoidable.[9] ADR reporting is less than 1% in India whereas it is 5% worldwide.[10]

Pharmacovigilance, which includes monitoring, managing, and preventing ADRs, mostly relies on spontaneous reporting. In the context of healthcare training and clinical experience, postings in different medical settings offer valuable opportunities to observe and document ADR occurrences. By adopting a new DRP posting to all postgraduate students in their respective departments from all medical colleges across India, NMC has paved the way for the aforementioned situation.

In order to document and assess ADRs observed in Belagavi during DRP posting, the initiative intends to spread awareness among patients and healthcare providers. By comprehensively analysing the observations, we aim to contribute to the body of knowledge surrounding ADRs, ultimately facilitating improved patient care and medication management strategies.

METHODS

Over the course of three months, from May 2023 to October 2023, a prospective, non-interventional spontaneous reporting study was conducted during DRP posting in a civil hospital and PHC in Belagavi. Both proactive reporting strategies, like searching for any suspected ADRs, and passive strategies, such urging prescribers to report a suspected ADR, were used in this study. The study's objectives were communicated to the resident physicians, nurses, and pharmacists, who were also asked to record any cases involving suspected adverse drug reactions.

In accordance with the guidelines of institutional ethical committee, ethical approval was not required for this study due to nature of the research which is non-interventional. Therefore, no formal ethical approval process was pursued. Data were analysed by descriptive statistics using Microsoft excel version 2408.

We assessed the medication classes linked to the ADRs, the strength of the reaction, the causality evaluation of the collected ADRs, the age and sex demographics of ADR reporting, department-specific reporting, and the list of different ADRs reported to the pharmacology department. Through patient and reporter interviews, in-patient case notes, treatment plans, laboratory data reports, and ADR notification forms, all pertinent and essential information was gathered.

The study included all patients receiving care in an outpatient or inpatient department who experienced an adverse reaction at any point after starting therapy. The study excluded patients who were hospitalized for medication poisoning, whether it was intentional or unintentional. ADR forms with missing data were not accepted either.

The present study employed Naranjo's scale to evaluate causation, which comprises four categories: definite, probable, possible, and uncertain.[11] In addition, a modified Hartwig and Siegel scale was used in the study to categories the severity into three categories: mild, moderate, and severe.[12] The reporter, who could have been any healthcare practitioner, assigned the scale's initial score. However, the investigator confirmed the ratings provided by the reporter. Any questions or concerns that came up along the process were answered directly by the reporter.

RESULTS

Between May 2023 and October 2023, a total of 43 ADRs were reported from various clinical departments' outpatient and inpatient departments. The patients' ages ranged from three months to more than sixty years. Of the 43 patients, three were under the age of 20 (6.9%), 29 were in the 21–40 age range (67.5%), ten were in the 41–60 age range (23.2%), and one patient was over 61 (2.3%).

The patients' gender distribution revealed that there were 32 female patients (74.4%) and 11 male patients (25.5%), suggesting a preponderance of female patients (Figure 2). Out of 43 ADRs, the pulmonary department was reported to fourteen (32.5%) of them. Psychiatry (10 (23.2%), general medicine (8 18.6%), paediatrics (4 9.3%), dermatology (3 (6.9%), obstetrics and gynaecology (2 (4.6%), and surgery (2 (4.6%) were the next most common departments reported to ADRs (Table 1). At the time of reporting, seven of the 43 patients who had experienced ADRs seven had recovered, and 34 more were recovering; two patients had not recovered from the side effects. Despite the causality evaluation suggesting a possible link between the implicated drug and ADR, there were two occurrences of fatalities. There were 25 (58.1%) probable, 14 (32.5%) possible, and 4 (9.3%) doubtful/unlikely causal

linkages between the ADR and the suspected medication, according to Naranjo's causality rating scale. It was determined that there were mild 22 (51.1%), moderate 15 (34.8%), and severe 6 (13.9%) ADRs using the Hartwig and Siegel severity scale.

Table 1: Different types of ADR reported and their causation.

Name of ADR	Number of ADR
ATT - induced hepatitis	10
ATT - induced hyperuricemia	3
Olanzapine - weight gain	4
Olanzapine dyslipidemia	3
Haloperidol - extra pyramidal symptoms	2
Amitriptyline - dry mouth	1
Anti-rabies vaccine induced increasing pain at the injection site	2
Pentavalent skin plaque	1
Pentavalent-induced convulsion	1
Blood in stool following typhoid vaccine	1
Iron - hypersensitivity	3
Allopurinol - Stevens - Johnson syndrome	1
Azathioprine bone marrow suppression	1
Cefotaxime - anaphylaxis	1
Sulfasalazine - hypersensitivity	1
Perinorm - induced extra pyramidal symptoms	1
Streptomycin - induced ototoxicity	1
Ceftriaxone - Diffuse erythematous rash	1
Valproate - induced thrombocytopenia	1
Oxcarbazepine thrombocytopenia	1
Anti-snake venom induced urticaria	1
Streptokinase induced bleeding gums	1
Succinyl choline induced muscle rigidity and fever	1

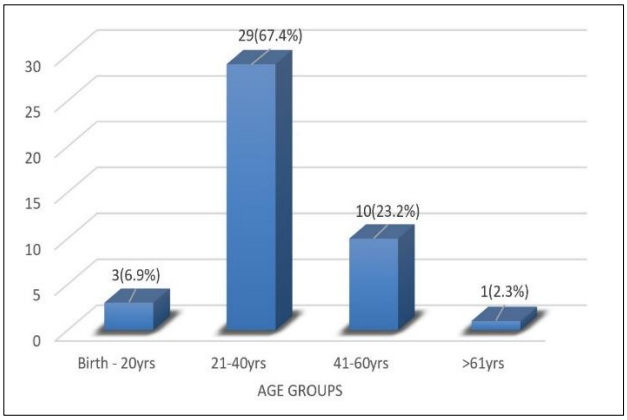

Figure 1: Age distribution in reported cases of adverse drug reaction.

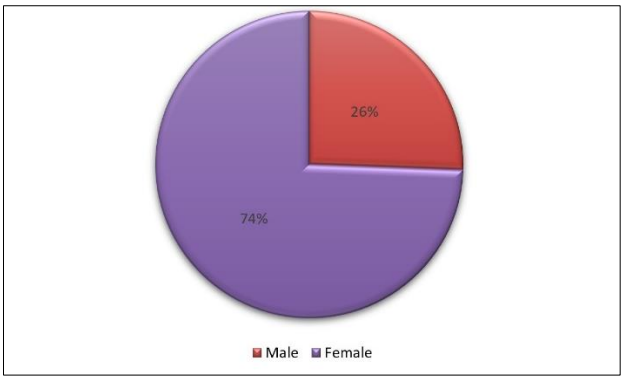

Figure 2: Gender distribution of ADR reporting.

DISCUSSION

Majority of medications have both potential beneficial and detrimental effects. The best strategy to manage these side effects is to use a multifaceted strategy that includes treatment, rehabilitation, and prevention. Like in a study by Daulat et al, 67.4% of the patients in this investigation were between the ages of 21 and 40.[13] The gender distribution of the patients showed that there were 32 female patients (74.4%) and 11 male patients (25.5%), which is different from previous research where there was a male predominance.

The most frequent suspected ADR was hepatitis caused by ATT. In the current study, the pulmonary medicine department accounted for 14 (32.5%) of the ADRs, with psychiatry 10 (23.2%) and OBGY 2 (4.6%), and surgery 2 (4.6%) accounting for the least number of ADRs. This was not the case in research by Gupta et al where the dermatology department accounted for the majority of ADRs.[14] The current study found that 51.1% of the patients experienced mild ADRs, with severe (13.9%) and moderate (34.8%), following. In different research conducted in 2015, Ramakrishnaiah et al discovered that moderate ADRs (59%) made up the majority of cases, mild ADRs (37%) and severe ADRs (4%).[15] The results of the current study are consistent with a study by Ramakrishnaiah et al as 25 cases were considered probable based on the probability scale.[15]

Strength of our study is as follows: hospitals must have a constant ADR monitoring system since the medication that caused. Our study's strength is that hospitals need to have an ongoing ADR monitoring system in place because the medications that resulted in the ADRs are frequently utilised. The knowledgeable medical practitioners themselves provided the information that was gathered. This team of specialists must stay up to date on any developments or news about drug safety. This study was severed with that purpose.

Limitations of the study was that the information was gathered through spontaneous reporting. A more effective way to get information would be through active monitoring. Other shortcomings of this trial included its

short duration, lower frequency of adverse drug reactions, restricted patient follow-up, and single centre design.

CONCLUSION

There is a serious underreporting issue with the pharmacovigilance programme in India. Spreading awareness through initiatives aimed at all levels of healthcare staff and putting in place workable pharmacovigilance programmes in hospitals are crucial steps in stopping this ADRs can be prevented and their effects can be lessened when they do occur through the implementation of patient monitoring, training courses on the primary causes of ADRs, and proper prescription practices in action. Patient education about ADRs can raise awareness among medical professionals and patients, which in turn can improve patient outcomes. We conclude that the majority of ADRs are caused by injectable iron, antitubercular medications, pentavalent vaccines, and psychiatric pharmaceuticals; middle-aged individuals are most frequently impacted by ADRs.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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