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AN OVERVIEW: PHARMACOVIGILANCE IN A TERTIARY CARE FACILITY IN NEW DELHI

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ABSTRACT

Introduction: Adverse drug reactions (ADRs) are harmful, unintended drug responses occurring at standard therapeutic doses. They pose a major global health and economic burden, especially among older adults. Prevention is feasible through systematic interventions—particularly pharmacist-led—and by strengthening pharmacovigilance systems at national and international levels. Addressing ADRs effectively improves patient safety, reduces healthcare costs, and optimizes therapeutic outcomes. **Material and Methods:** ADRs that took place in admitted patients were taken into consideration for analysis. Information about ADR was collected in the ADR reporting form. **Result:** From January to July 2025, 32 ADRs were reported. The age of patients who underwent ADR ranged between 16 and 83 years. All the ADRs were divided into three categories based upon severity, and the highest number of ADR (85%) belong to the mild category, whereas 9% and 6% of ADR belong to the moderate and severe categories. **Conclusion:** ADR reporting is a critical component of pharmacovigilance, ensuring safe and effective use of medicines in real-world practice. Timely reporting by healthcare professionals, patients, and institutions helps identify risks that may not have been detected during clinical trials.

KEYWORDS: Adverse Drug Reactions, PvPI, pharmacovigilance.

INTRODUCTION

Adverse drug reactions (ADRs) are unintended, harmful responses to medications that occur at normal therapeutic doses used for the prevention, diagnosis, or treatment of disease. They represent a significant challenge in clinical practice, contributing to increased morbidity, mortality, and healthcare costs worldwide (Edwards & Aronson, 2000).

Pharmacovigilance (PV) is the science and set of activities related to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems. Its primary goals are to ensure safe and rational use of medicines, enhance patient care, and support informed regulatory decisions (Alomar et al., 2019). The World Health Organization (WHO) defines it as "the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem." (Safety of Medicines, 2002).

The present study aimed to analyse the factors that may be responsible or associated with the occurrence of ADRs at a healthcare centre.

MATERIALS AND METHODS

Adverse drug reactions (ADRs) that occurred in IPD patients between January and July 2025 were analyzed. The study design is a retrospective observational type. The data presented in the study were collected during ADR reporting using ADR reporting forms. All the collected data was categorized into various categories for presentation purposes. Bar graphs and pie charts were used to present the data, which were prepared using Microsoft Excel.

RESULTS

A Total of 32 ADRs have been reported during the mentioned period in IPD patients in a tertiary health care centre, New Delhi**.** Analysed results are shown as follows:

A) Age distribution: The patients who underwent the ADRs were distributed in different age groups. The distribution is shown in the figure 1. The mean age of patients reporting the ADRs is 53.16±20.14 years, ranging from 16 to 83 years.

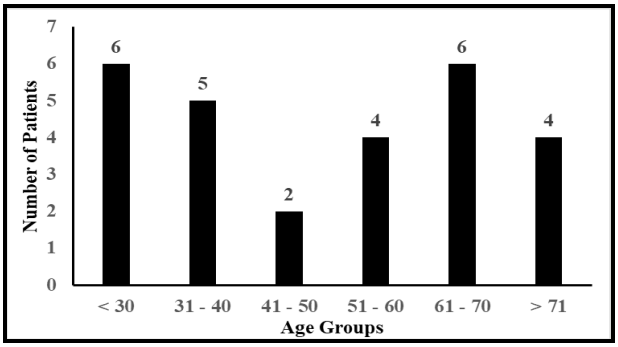

Figure 1: Shows the distribution of patients with ADRs according to age.

The age-wise distribution of patients experiencing adverse drug reactions (ADRs) shows variation across different age groups. The highest number of ADRs was reported in patients aged <30 years and 61–70 years (6 patients each), indicating a bimodal pattern with increased reporting among both younger and older populations.

B) Gender distribution: Out of 32 patients, 15 were male, and 17 were female. Table 1 shows the percent distribution of patients based on gender.

Table 1: Distribution of patients based on their gender.

Gender	Number of patients (%)
Male	15 (46.9)
Female	17 (53.1)

C) Specialty-wise distribution: Patients showing the ADRs were patients who were admitted under different specialities for the treatments. Figure 2 shows the distribution of patients according to the specialties in which they were admitted.

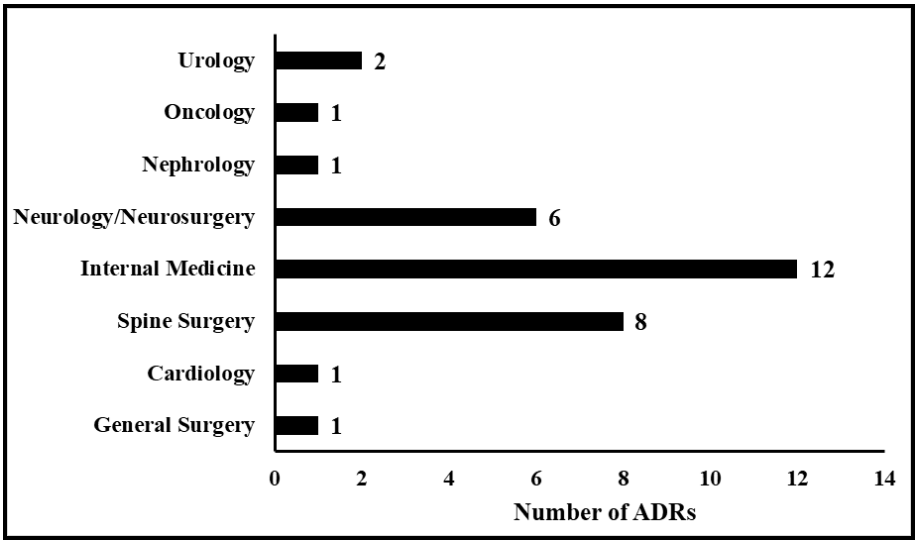

Figure 2: Shows specialty-wise ADR distribution.

D) Drug category distribution: Drugs showing the reaction belong to different classes. Table 2 presents the distribution of drugs by class.

Table 2: Distribution of Drugs showing ADRs.

Drug Class	Number of ADR (%)
Antianaemic	9.375
Anticoagulant	3.125
Cephaosporin	31.25
Glycopeptide	15.625
Monoclonal antibody	6.25
Neuroprotective drug	3.125
Antibiotics	25
Fluroquinolones	3.125
Analgesic and Antipyretics	6.25
Antianaemic	9.375

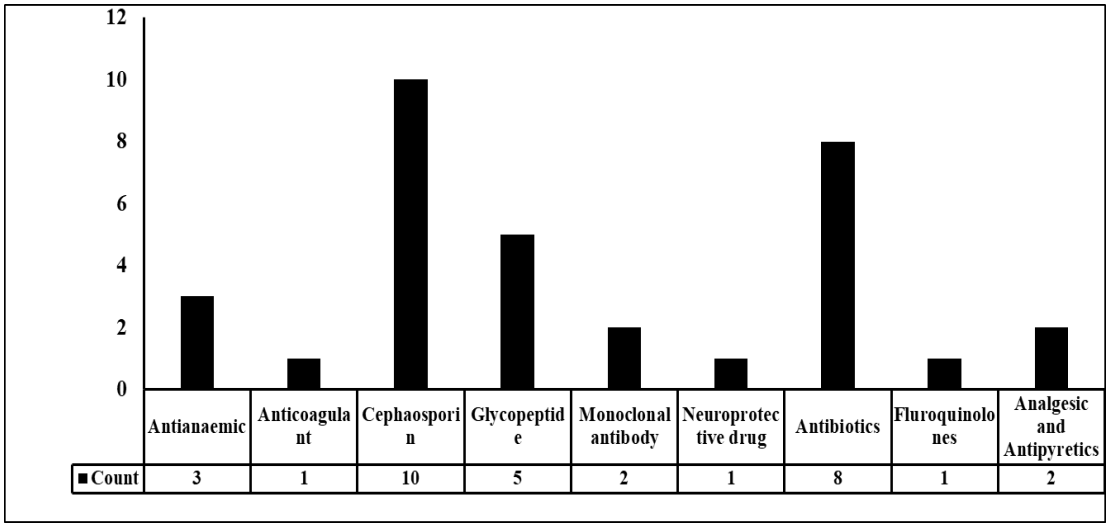

Figure 3: Shows the distribution of ADRs among Drug categories.

E) Seriousness of ADR: ADRs were categorized into Mild, moderate, and Severe based on reactions reported and events that took place. Figure 4 shows the percentage distribution of ADR based on severity.

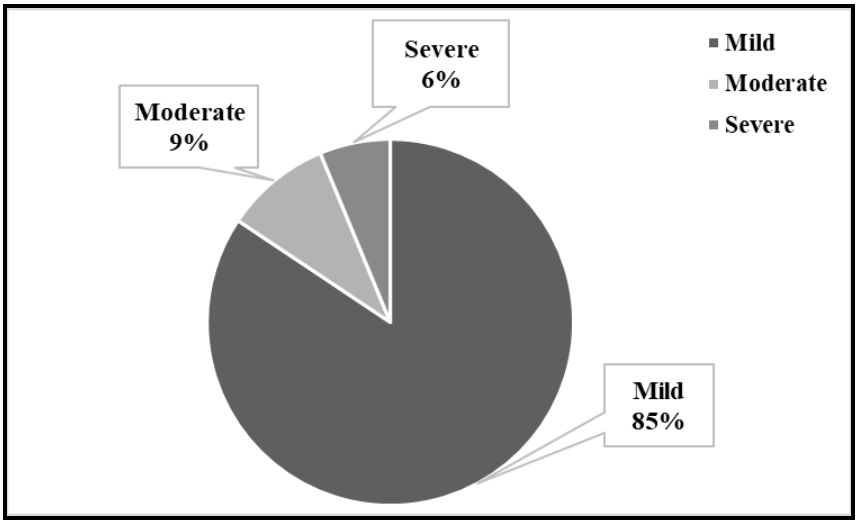

Figure 4: Shows the distribution of ADRs according to the severity.

All mild and moderate ADRs were successfully controlled by administration of Injection Avil 25mg, and Injection Hydrocort 100mg, and severe ADRs were managed through appropriate clinical management, such as symptomatic treatment. In general, suspected drugs were withdrawn in all cases without resulting in long-term complications. The relatively low proportion of severe ADRs suggests effective monitoring and timely intervention in the clinical setting.

Type of ADR: Table 3 shows the frequency of types of ADR that have taken place. Out of all ADRs, one ADR has shown a drug-drug interaction.

Table 3: Distribution of ADRs based on types of ADR.

Type of ADR	Frequency
TYPE A- Augmented	31
TYPE B- Bizarre	0
TYPE C- Chronic	0
TYPE D- Delayed	1
TYPE E- End of use	0
TYPE F- Familial	0
Type G-Genotoxicity	0
TYPE H- Hypersensitivity	0
TYPE U- Unclassified	0

DISCUSSION

The present study provides an in-depth analysis of ADRs that occurred in IPD patients during the period from January to July 2025.

Overall, the findings suggest that ADRs are more frequently reported at the extremes of age (Routledge et al., 2004), particularly among younger adults and the elderly. Increased ADRs in older patients may be due to polypharmacy and age-related physiological changes, (Beijer & de Blaey, 2002) whereas higher reporting in younger individuals may reflect higher drug exposure or better reporting awareness (Edwards & Aronson, 2000).

This indicates a slightly higher representation of female patients compared to males. The near-equal gender distribution suggests that the study population was relatively balanced, although a marginal predominance of females was observed. Such a pattern has been reported in several pharmacovigilance and adverse drug reaction (ADR) studies (Zopf et al., 2008), where females are often found to report ADRs more frequently than males. This difference may be attributed to variations in pharmacokinetics, hormonal influences, body composition, and healthcare-seeking behavior between genders (Rademaker, 2001).

The higher frequency of ADRs in Internal Medicine and surgical specialties such as Spine Surgery and Neurology/Neurosurgery may be attributed to the complexity of cases, presence of multiple comorbidities, polypharmacy, and prolonged hospital stay in these departments (Pirmohamed et al., n.d.). Patients admitted under medical specialties often receive multiple drugs simultaneously, increasing the risk of drug–drug interactions and ADRs. Conversely, the lower number of ADRs reported from other specialties may reflect shorter treatment duration, more protocol-driven therapy, or possible underreporting (JOSE & RAO, 2006).

The distribution of adverse drug reactions (ADRs) according to drug class shows that cephalosporins were the most frequently implicated drug class, accounting for 31.25% of the reported ADRs. This was followed by penicillin antibiotics (18.75%) and glycopeptides (15.62%). The predominance of antibiotic-related ADRs highlights the extensive use of antimicrobials in hospitalized patients, particularly for prophylactic and therapeutic management of infections, which increases the likelihood of hypersensitivity reactions and other drug-related adverse events.

Antianemic drugs contributed to 9.37% of ADRs, while monoclonal antibodies, analgesics, and antipyretics each accounted for 6.25%. These findings may be associated with their known adverse effect profiles and increasing use in chronic and inpatient care. Other drug classes, including anticoagulant/antithrombotic agents, neuroprotective drugs, beta-lactam antibiotics, and fluoroquinolones, each contributed 3.12% of the ADRs, indicating comparatively lower involvement.

Overall, the results suggest that antibiotics were the leading contributors to ADRs, consistent with existing pharmacovigilance data (Lhamo et al., 2025). This underscores the need for judicious prescribing, close monitoring, and robust antimicrobial stewardship programs to minimize the risk of ADRs (Patel et al., 2014).

These findings are consistent with reports from pharmacovigilance studies, which show that the majority of ADRs occurring in hospitalized patients are mild to moderate and preventable with early detection and appropriate management.

Overall, the severity pattern underscores the importance of continuous ADR monitoring systems, which facilitate early identification and prompt management, thereby reducing progression to severe or life-threatening reactions.

After the depth analysis, we were able to note that there is also a need to observe drug-to-food interaction. Absence of data on drug-to-food interaction is a drawback of ADR reporting

CONCLUSION

Pharmacovigilance is an essential discipline that safeguards public health by ensuring that the benefits of medicines outweigh their risks. In the modern era of precision medicine, advanced therapeutics, and rapid vaccine development, its role is more critical than ever. A strengthened global pharmacovigilance ecosystem, supported by digital health innovations and patient engagement, will be key to advancing medication safety in the 21st century.

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Conflict of Interest: There is no conflict of interest among authors.

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