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# A RETROSPECTIVE OBSERVATIONAL STUDY OF ADVERSE DRUG REACTIONS IN A TERTIARY CARE TEACHING HOSPITAL.

Pharma

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## ABSTRACT

**Introduction:** Adverse Drug Reactions (ADRs) are unintended and harmful responses to medications and constitute a major cause of morbidity, mortality, and increased healthcare costs worldwide. **Objective:** To analyze the pattern of ADRs reported over a three-month period in a tertiary care teaching hospital. **Methods:** This retrospective observational study was conducted from January to March 2025. Spontaneously reported ADRs were analyzed for patient demographics, suspected drugs, and clinical manifestations. **Results:** A total of 108 ADRs were reported. Middle-aged adults and males were more commonly affected. Antibiotics were the most frequently implicated drug class, and neurological and gastrointestinal symptoms predominated. Majority ADRs were found to be Probable on Causality assessment by WHO-UMC scale. **Conclusion:** Strengthening pharmacovigilance systems and promoting awareness among healthcare professionals can significantly improve patient safety.

## KEYWORDS

Adverse drug reactions, pharmacovigilance, clinical manifestations

## INTRODUCTION

Adverse Drug Reactions (ADRs) are recognized as a major public health concern worldwide and contribute significantly to patient morbidity, prolonged hospital stays, and increased healthcare costs. According to the World Health Organization (WHO), ADRs are defined as noxious and unintended responses to drugs occurring at doses normally used in humans for prophylaxis, diagnosis, or therapy[1].

ADRs are a significant cause of hospital admissions and are associated with considerable morbidity, mortality, and economic burden. Large prospective and meta-analytic studies have demonstrated that ADRs account for a substantial proportion of hospital admissions and in-hospital adverse outcomes[2,3].

In tertiary care hospitals, the risk of ADRs is further increased due to polypharmacy, multiple comorbidities, and the use of high-risk medications. Patients admitted to such settings often require complex therapeutic regimens, increasing the likelihood of drug–drug interactions and adverse outcomes[4].

Pharmacovigilance plays a crucial role in the detection, assessment, understanding, and prevention of ADRs. Spontaneous reporting systems form the backbone of pharmacovigilance programs worldwide and are essential for identifying new, rare, and serious adverse drug reactions[6]. Continuous monitoring and systematic analysis of reported ADRs help identify high-risk populations, commonly implicated drugs, and characteristic clinical patterns, thereby promoting safer and more rational prescribing practices[7].

This study was undertaken to evaluate the pattern of ADRs reported in a tertiary care teaching hospital over a three-month period, with emphasis on patient demographics, suspected drugs, and clinical manifestations of ADR.

## MATERIALS AND METHODS

This retrospective observational study was conducted from January to March 2025 at Pravara Rural Hospital, Loni, a tertiary care teaching hospital. All spontaneously reported ADRs during the study period were collected using a standardized ADR reporting form. Data collected included patient age, gender, suspected drug(s), and clinical presentation of the ADR.

Patients were categorized into predefined age groups. Data were entered into Microsoft Excel and analyzed descriptively using frequencies and percentages. Patient confidentiality was strictly maintained.

## RESULTS

A total of 108 ADRs were reported during the study period. The highest number of ADRs was observed in the 41–60 (37.0 %) years age group, followed by the 21–40 (23.1 %) years age group (Fig. 1). Males (60.2 %) were more commonly affected than females (39.8 %) (Fig. 2). Antibiotics (46 %) were the most frequently implicated drug class, followed by analgesics (37 %) and cardiovascular drugs (28 %) (Fig. 3). The most commonly observed clinical manifestations included headache, rash, nausea, dizziness, and diarrhea (Fig. 4).
On Causality assessment by WHO-UMC criteria, we found majority ADRs belong to the category of Probable (41.7%) (Fig. 5).

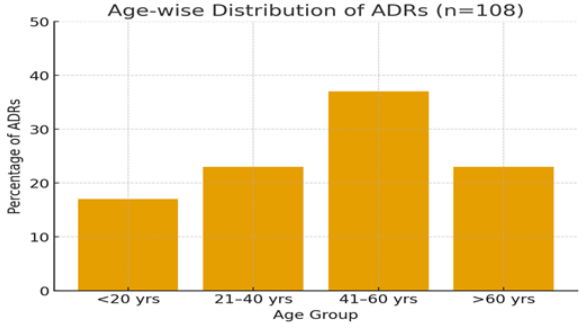


**Figure 1 - Age-wise distribution.**

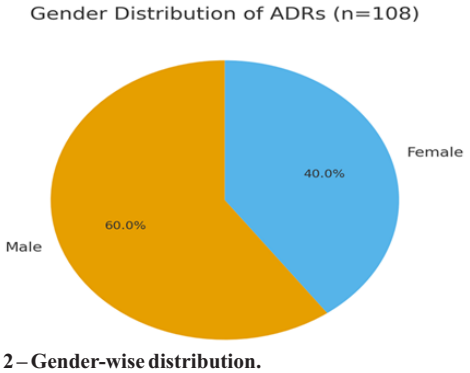


**Figure 2 – Gender-wise distribution.**

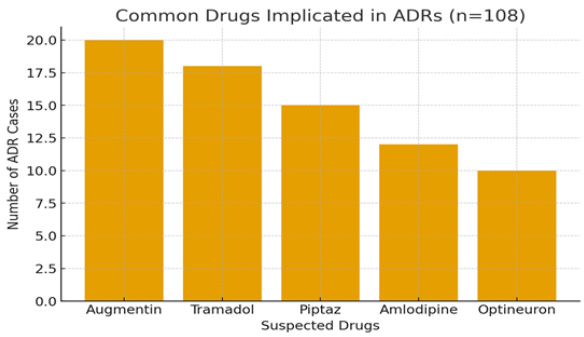


**Figure 3 – Drugs Implicated.**

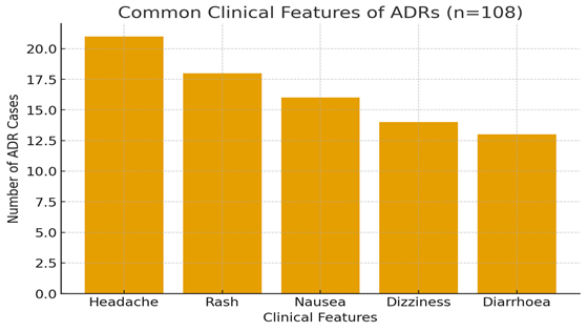


**Figure 4 – Common Clinical Features of ADR.**

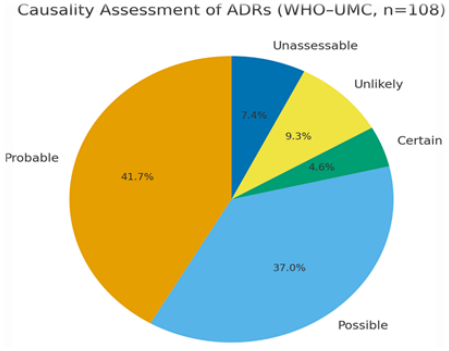


**Figure 5 – Causality Assessment of ADR.**

## DISCUSSION

The present study provides valuable insights into the pattern of adverse drug reactions (ADRs) reported in a tertiary care teaching hospital. Understanding such patterns is essential for strengthening pharmacovigilance activities and improving patient safety.

In the present study, the majority of ADRs were reported among middle-aged adults (41–60 years). Similar findings have been reported by Pirmohamed et al. and Sriram et al., who observed that middle-aged patients constitute a significant proportion of ADR cases in hospital-based studies[3,7]. Increased drug exposure, presence of chronic comorbidities, and frequent healthcare utilization in this age group may explain this observation.

However, some studies have reported contrasting results. Routledge et al. observed a higher incidence of ADRs among elderly patients, attributing this to age-related changes in pharmacokinetics and pharmacodynamics, polypharmacy, and reduced physiological reserve[8]. The relatively lower proportion of ADRs in the elderly population in the present study may be due to underreporting or cautious prescribing practices in older patients.

A male predominance in ADR occurrence was observed in the present study. Similar observations have been reported in Indian studies by Arulmani et al., where males accounted for a higher proportion of reported ADRs[9]. Sociocultural factors, differences in healthcare-seeking behavior, and higher hospital admission rates among males may contribute to this finding. In contrast, studies by Lazarou et al. and Pirmohamed et al. reported a higher incidence of ADRs among females, suggesting that gender-related susceptibility to ADRs remains inconsistent and may vary across populations[2,3].

Antibiotics were the most commonly implicated drug class in the present study. This finding is consistent with reports by Murthy et al. and Saha et al., who identified antimicrobials as leading contributors to ADRs in tertiary care hospitals[10,11]. The widespread empirical use of antibiotics and their potential for hypersensitivity reactions may explain this observation. In contrast, some studies have reported cardiovascular drugs or non-steroidal anti-inflammatory drugs as the most common causative agents, reflecting variations in prescribing patterns across institutions[12].

Neurological and gastrointestinal manifestations were the most frequently reported ADRs in the present study. Similar patterns have been reported by Modi et al. and Sriram et al., who noted that these systems are commonly affected due to their sensitivity to drug effects[7,13]. Cutaneous reactions were also frequently observed, possibly due to their easy recognizability and higher likelihood of reporting.

The Causality assessment finding showed that majority ADRs belong to category of Probable which was 41.7 % followed by Possible (37 % ). This finding is consistent with the studies done by Saha et al and Murthy et al. [11,13], stressing the importance of vigilance, timely reporting, and strengthening pharmacovigilance (PvPI).

Underreporting of ADRs remains a major limitation of spontaneous reporting systems. Lopez-Gonzalez et al. identified lack of awareness, time constraints, and uncertainty regarding causality as major factors contributing to underreporting[5]. Continuous education and sensitization of healthcare professionals are essential to improve reporting rates and strengthen pharmacovigilance programs.

## CONCLUSION

This study underscores the significance of ADR monitoring in tertiary care hospitals. Middle-aged adults and males were more frequently affected, with antibiotics being the most common causative agents. Most ADRs involved the nervous system and gastrointestinal tract.

Strengthening pharmacovigilance activities, encouraging spontaneous reporting, and promoting rational prescribing practices are essential to minimize the burden of ADRs and improve overall patient safety.

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## DECLARATIONS

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Conflict of Interest: None declared

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