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PREVALENCE AND PATTERNS OF ADVERSE DRUG REACTIONS IN A TERTIARY CARE HOSPITAL: A PROSPECTIVE OBSERVATIONAL STUDY

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ABSTRACT

Background: *Adverse drug reactions (ADRs) are unintended and harmful responses to medicines used in routine doses. ADRs contribute significantly to patient morbidity, reduced quality of care, and unplanned hospital admissions. Monitoring ADRs and strengthening pharmacovigilance practices are essential to improve patient safety.*

Aim: *To investigate the prevalence and patterns of ADRs in a tertiary care hospital and create awareness for safer medication use.*

Objectives: *(1) To assess the overall prevalence of ADRs among admitted patients. (2) To identify the types and severity of ADRs across patient populations. (3) To examine the association between drug classes and ADR occurrence.*

Methods: *A 3-month observational study was conducted in a tertiary care hospital in Erode. A total of 30 confirmed ADR cases were included. Data were collected through ward round participation using a case data entry form and ADR reporting form. ADRs were confirmed by physicians and analyzed using descriptive statistics.*

Results: *ADRs were equally reported in males and females (50% each). Most ADR cases occurred in the 20–30 years age group (23.3%). All ADRs were drug-based (100%). Risperidone was the most commonly implicated drug (26.8%), followed by iron sucrose (16.7%). The most frequently observed ADR was tardive dyskinesia (20%). Oral route was most common (53.4%). Augmented and bizarre ADR types were equally distributed (50% each). Most patients recovered (96.7%).*

Conclusion: *ADRs remain common in tertiary care settings and are strongly linked to medication exposure. Routine monitoring, careful prescribing, and improved patient awareness can reduce preventable ADRs. Strengthening pharmacovigilance systems and encouraging reporting are strongly recommended.*

Keywords: *Adverse drug reactions, pharmacovigilance, tertiary care hospital, ADR monitoring, patient safety.*

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INTRODUCTION

Adverse drug reactions (ADRs) are a major challenge in healthcare. The World Health Organization defines an ADR as a harmful and unintended response to a drug occurring at normal doses used for prevention, diagnosis, or treatment of disease or for modification of physiological function. This definition excludes adverse effects due to overdose, poisoning, drug abuse, or medication administration errors (Edwards & Aronson, 2000).

ADRs occur frequently in clinical practice and are recognized as a major cause of unplanned hospital admissions (Coleman & Pontefract, 2016). Certain ADRs are widely reported with commonly prescribed drug classes. For example, peripheral edema is a well-known adverse effect of calcium channel blockers such as amlodipine, caused due to arteriolar dilation without matching venous dilation. The reported frequency of peripheral edema with calcium channel blockers ranges widely, from 5% up to 70%, and management often requires dose reduction or withdrawal under medical supervision (Edwards & Aronson, 2000).

Another frequently observed ADR is dry cough due to ACE inhibitors. This cough may appear soon after initiation or even after weeks to months of therapy. The reported prevalence ranges between 5% and 35%. Risk factors include female gender, ACE genotype II, and Black/Asian ethnicity. In such cases, angiotensin receptor blockers (ARBs) are considered a suitable alternative as they offer similar cardiovascular benefits without affecting bradykinin breakdown (D'Cruz et al., 2012).

In addition to ADRs from expected pharmacological effects, medication-related harm may also arise due to prescription errors and inappropriate use of medicines. Medication errors are reported even in advanced healthcare systems and can lead to mild to severe adverse drug events (Khalil & Huang, 2020). Off-label drug use, especially in children, is another contributor to medication-related harm due to limited evidence for safety and appropriate dosing (Khalil & Huang, 2020).

Pharmacovigilance plays a crucial role in detecting and preventing ADRs. Spontaneous reporting systems like the Yellow Card Scheme in the UK and adverse event reporting systems such as FDA-AERS are important for post-marketing surveillance (de Vries et al., 2017). However, under-reporting remains a serious limitation globally, often due to lack of time, limited awareness, and complicated reporting procedures (Gahr et al., 2016).

Classification of Adverse Drug Reactions

ADRs are commonly classified into six categories (Edwards & Aronson, 2000):

- Type A (Augmented): Dose-related, predictable, common, low mortality
- Type B (Bizarre): Non-dose related, unpredictable, uncommon, higher mortality
- Type C (Chronic): Dose- and time-related due to cumulative exposure
- Type D (Delayed): Appears after some time of drug exposure
- Type E (End of use/Withdrawal): Occurs after stopping drug
- Type F (Failure): Unexpected therapeutic failure, often due to interactions

Importance of ADR Monitoring

ADRs contribute to preventable patient harm and increased healthcare burden. Proper medication history-taking helps identify previous ADRs and avoid re-exposure. Prevention strategies include selecting appropriate drugs for high-risk patients and ensuring treatment plans reduce adverse effects through monitoring and supportive therapy (Coleman & Pontefract, 2016).

Detection of ADRs requires careful observation because many reactions resemble disease symptoms or occur commonly in the population (Edwards & Aronson, 2000). Monitoring systems may include manual chart review, voluntary reporting, or computerized alert-based detection methods (Jha et al., 1998).

Pharmacovigilance and Reporting

Pharmacovigilance is defined as the science and activities related to detecting, assessing, understanding, and preventing adverse effects or other drug-related problems (Campbell et al., 2014). Major historical events like the sulfanilamide tragedy and thalidomide disaster highlight the importance of drug safety systems (Schep et al., 2009; Campbell et al., 2014).

In India, pharmacovigilance has evolved over decades. The Pharmacovigilance Programme of India (PvPI) was launched in 2010 and is coordinated by the Indian Pharmacopoeia Commission (IPC). The program operates through hundreds of ADR Monitoring Centres across the country (Kalaiselvan et al., 2016; Singh et al., 2023).

REVIEW OF LITERATURE

Recent evidence indicates that adverse drug reactions (ADRs) are frequent in clinical practice and a substantial proportion are preventable, making ADR monitoring and prevention a major patient-safety priority. Studies across different healthcare settings consistently report that ADRs contribute to morbidity, prolonged hospital stay, increased healthcare costs, and reduced quality of life. Importantly, many ADRs arise not only from unavoidable pharmacological effects but also from modifiable factors such as inappropriate drug selection, inadequate monitoring, and insufficient patient counseling.

Srisuriyachanchai et al. (2023) highlighted that gastrointestinal and dermatological (skin-related) reactions are among the most commonly observed categories of ADRs. Their findings also emphasized critical system-level barriers to prevention, including gaps in training of healthcare professionals, limited pharmacovigilance awareness, and insufficient resources for structured reporting. These shortcomings can lead to underrecognition of ADRs, delayed intervention, and missed opportunities for preventing recurrence. Strengthening professional education and improving reporting infrastructure were suggested as key strategies for improving ADR identification and management.

Similarly, Abu Esba et al. (2021) reported that immunological ADRs (such as hypersensitivity and allergic reactions) were frequently encountered, reflecting the clinical significance of immune-mediated drug responses. The study further identified inappropriate drug selection as one of the most common preventable causes, indicating that better prescribing practices—such as reviewing allergy history, considering drug interactions, and selecting safer alternatives—could reduce ADR incidence. This reinforces the importance of rational prescribing, medication review, and patient-specific risk assessment, particularly in individuals with known sensitivities or comorbidities.

The preventability of ADRs has been strongly supported by Hakkarainen et al. (2012), who estimated that approximately 43.5% of ADRs are preventable. This finding is significant because it suggests that nearly half of ADR events could potentially be avoided through improved clinical decision-making and monitoring. The study also noted that elderly patients are at higher risk, largely due to polypharmacy, altered drug metabolism, multiple chronic illnesses, and increased vulnerability to drug–drug interactions. Therefore, ADR prevention strategies should prioritize older adults by implementing medication reconciliation, deprescribing where appropriate, and close monitoring for early warning signs of toxicity.

In addition, pharmacist participation plays a critical role in strengthening pharmacovigilance. Sriram et al. (2011) demonstrated that pharmacist involvement significantly improves both the rate and quality of ADR reporting. Pharmacists contribute by identifying suspected reactions, assessing causality, educating patients and healthcare workers, and ensuring accurate documentation. Their active role in medication safety programs supports timely reporting to pharmacovigilance centers and improves overall awareness of ADR patterns. Integrating pharmacists into multidisciplinary healthcare teams can therefore enhance detection, prevention, and reporting of ADRs.

Overall, the literature indicates that ADRs are not only common but also substantially preventable through improved prescribing practices, enhanced healthcare training, better monitoring, and active pharmacist involvement, especially among high-risk groups such as the elderly.

NEED FOR THE STUDY

Studying ADR patterns in a tertiary care hospital is essential for:

- improving patient safety and drug therapy outcomes
- identifying common ADRs and high-risk drugs
- supporting hospital quality improvement
- addressing lack of awareness among patients and the general population regarding ADRs and pharmacovigilance

AIM AND OBJECTIVES

Aim

To investigate the prevalence and patterns of ADRs in a tertiary care hospital and contribute to patient safety and awareness.

Objectives

1. To assess the overall prevalence of ADRs among admitted patients.
2. To identify the types and severity of ADRs in diverse patient populations.

3. To examine the association between drug classes and ADR occurrence.

MATERIALS AND METHODS

Study Site

Tertiary care hospital, Erode.

Study Design

Prospective observational study.

Study Period

Three months.

Sample Size

30 confirmed ADR cases.

Inclusion Criteria

- Male and female patients
- All age groups
- Inpatients and outpatients admitted/treated in the tertiary care hospital

Exclusion Criteria

- ADRs not confirmed by the physician

DATA COLLECTION PROCEDURE

ADR cases were identified through ward round participation. Patient and drug details were documented using a case data entry form. Identified ADRs were recorded in the ADR reporting form and confirmed by physicians. Data were analysed descriptively using frequencies and percentages.

RESULTS

Table 1. Summary of ADR Study Results

Parameter	Category	Percentage (%)
Age Distribution	20–30 years	23.3
	30–40 years	20.0
	70–80 years	20.0
Gender Distribution	Male	50.0
	Female	50.0
Occurrence of ADR	Drug-based ADR	100.0
	Disease-based ADR	0.0
Drugs Implicated (Most common)	Risperidone	26.8
	Iron sucrose	16.7
	Haloperidol	10.0
Common ADRs	Tardive dyskinesia	20.0
	Anaphylaxis reaction	10.0
	Rashes	10.0
Route of Administration	Oral	53.4
	Intravenous	43.3
	Intramuscular	3.3
Type of ADR	Augmented	50.0
	Bizarre	50.0
Outcome	Recovered	96.7
	Recovering	3.3

DISCUSSION

The present study explored ADR patterns among 30 patients in a tertiary care hospital. The highest ADR occurrence was observed in the 20–30 years age group, followed by 30–40 and 70–80 years groups. This aligns with findings reported among Indian patients in previous research (D'Cruz et al., 2012).

Gender distribution was equal, with 50% male and 50% female ADR cases, similar to the tertiary care hospital reporting pattern described by Abu Esba et al. (2021).

All ADRs identified were drug-based, confirming that medication exposure was the direct cause of observed adverse events. Risperidone was the most commonly implicated drug, and tardive dyskinesia was the most common ADR, reflecting the known adverse effect profile of antipsychotic medications.

Augmented and bizarre ADR types were equally distributed. Most patients recovered, indicating that early identification and appropriate clinical management can reduce serious outcomes. However, the study also observed a lack of awareness among patients regarding ADRs and pharmacovigilance, which may contribute to underreporting and delayed intervention.

CONCLUSION

This study concludes that ADRs are common in tertiary care settings and are primarily drug-related. Risperidone was the most frequently implicated drug, and tardive dyskinesia was the most frequently observed ADR. The study highlights the importance of:

- routine monitoring of drug indications, dose, and frequency
- strengthening pharmacovigilance and reporting culture
- improving patient awareness about ADRs

Further studies with larger samples are recommended to identify additional high-risk drugs and improve community-level awareness of ADR prevention and reporting.

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