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Original Research Article

A study on drug utilization, evaluation and monitoring of adverse drug reactions in the cardiology department of a tertiary care hospital

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ABSTRACT

Background: Cardiovascular diseases require complex pharmacotherapy, increasing the risk of Adverse Drug Reactions (ADRs). Monitoring drug utilization and ADRs is essential to enhance patient safety.
Methods: A prospective observational study was conducted over 3 months (April 2025-June 2025) in the Cardiology Department of a tertiary care hospital. Fifty inpatients aged ≥18 years were monitored for ADRs. Causality was assessed using the Naranjo Scale and WHO-UMC criteria; severity was evaluated using the Hartwig Scale.
Results: A total of 50 ADRs were reported, with hematological (36%), gastrointestinal (24%), and cardiovascular (16%) systems most affected. Anticoagulants, antiplatelets, diuretics, RAAS inhibitors, and SGLT2 inhibitors were commonly implicated. Most ADRs were moderate (50%), with 62% categorized as probable. No fatalities occurred; 66% of patients recovered fully.
Conclusions: ADRs are common among cardiology inpatients, with polypharmacy and comorbidities as key risk factors. Regular pharmacovigilance, patient monitoring, and individualized therapy are essential to minimize ADR-related complications.

Keywords: Drug utilization, Adverse drug reactions, Cardiology, Pharmacovigilance, Naranjo scale, WHO causality, Hartwig severity scale, Patient safety

INTRODUCTION

Cardiovascular diseases (CVDs) are the foremost cause of mortality worldwide, accounting for nearly 17.9 million deaths annually, which translates to approximately 32% of all global deaths.[1] The burden of CVDs is steadily rising in low- and middle-income countries, including India, driven by rapid urbanization, sedentary lifestyles, dietary changes, obesity, tobacco use, and the increasing prevalence of hypertension, diabetes, and metabolic syndrome.[2] According to the Indian Council of Medical Research (ICMR), India faces an alarming rise in cardiovascular morbidity and mortality, with CVDs contributing to over a quarter of all deaths in the country.[3] Management of cardiovascular diseases is highly dependent on pharmacotherapy. The drug regimens often involve multiple medications, including antiplatelet agents, anticoagulants, diuretics, beta-blockers, ACE inhibitors, ARBs, statins, and newer agents such as sodium-glucose co-transporter-2 (SGLT2) inhibitors and angiotensin receptor-neprilysin inhibitors (ARNIs). While these medications have revolutionized the treatment of conditions such as ischemic heart disease, heart failure, arrhythmias, and hypertension, they are also associated with an increased risk of adverse drug reactions (ADRs), particularly when used in combination or in vulnerable patient populations.[4] Adverse drug reactions (ADRs) are defined by the World Health Organization (WHO) as "a response to a drug which is noxious, unintended, and occurs at doses normally used for prophylaxis, diagnosis,

or therapy."[5] ADRs are a significant concern in the cardiology setting due to factors such as polypharmacy, narrow therapeutic indices of certain cardiovascular drugs, complex drug-drug interactions, and the presence of comorbidities like renal dysfunction, diabetes, and hepatic impairment.[6] The incidence of ADRs varies across healthcare settings, but studies consistently report a higher frequency of ADRs among hospitalized cardiac patients.[7] Common ADRs in cardiology include bleeding complications with anticoagulants, gastrointestinal disturbances with antiplatelet therapy, electrolyte imbalances with diuretics, hypotension or bradycardia with beta-blockers, and renal complications with newer agents such as SGLT2 inhibitors.[8] Given the serious implications of ADRs, timely detection, assessment, and intervention are critical for improving patient outcomes.

Pharmacovigilance, the science and activities related to detecting, assessing, understanding, and preventing ADRs, plays a crucial role in ensuring medication safety.[9] Despite its global recognition, pharmacovigilance practices in India are still evolving. The Pharmacovigilance Programme of India (PvPI), initiated by the Ministry of Health and Family Welfare in 2010, has made significant strides in promoting ADR reporting, yet underreporting, lack of awareness, and inadequate monitoring remain major challenges.[10]

Standardized tools are essential for the systematic evaluation of ADRs. The Naranjo adverse drug reaction probability scale, developed in 1981, is one of the most widely used tools for determining the likelihood of a causal relationship between a drug and an adverse event. It classifies ADRs as definite, probable, possible, or doubtful based on a structured scoring system.[11] The Hartwig and Siegel severity assessment scale categorizes ADRs into mild, moderate, and severe, based on clinical outcomes and the level of intervention required.[12] The WHO-Uppsala monitoring centre (WHO-UMC) Causality Assessment Scale provides another framework for assessing the relationship between drug administration and adverse events, classifying ADRs as certain, probable, possible, unlikely, conditional/unclassified, or unassessable/unclassifiable.[13]

A better understanding of drug utilization patterns is equally critical for optimizing prescribing practices and preventing irrational drug use. Drug utilization research (DUR) examines the marketing, distribution, prescription, and use of medications in a society, with a focus on medical, social, and economic outcomes.[14] This is especially relevant in cardiology, where overuse, underuse, or misuse of medications can significantly affect patient safety and healthcare costs. Numerous studies have highlighted the high prevalence of ADRs among cardiac patients, especially in elderly populations with multiple comorbidities.[15] Elderly individuals often exhibit altered pharmacokinetics and pharmacodynamics, leading to increased susceptibility to ADRs, particularly when exposed to polypharmacy.[16] Despite these findings, there remains a paucity of systematic research on drug utilization patterns and ADR monitoring within the cardiology departments of tertiary care hospitals in India. The present study was undertaken to fill this gap by evaluating drug utilization, assessing the incidence and characteristics of ADRs, and applying standardized tools for causality and severity assessment among inpatients in the Cardiology Department of a tertiary care hospital. The findings from this study are expected to contribute to improving pharmacovigilance practices, enhancing patient safety, guiding rational prescribing, and informing targeted interventions for high-risk cardiac populations.

METHODS

Study design and setting

This was a prospective, observational, and descriptive study conducted over a period of 3 months (April 2025-June 2025) in the Department of Cardiology at Owaisi Hospital and Research Centre, Hyderabad, Telangana, India. The study aimed to evaluate drug utilization patterns and monitor adverse drug reactions (ADRs) among inpatients admitted to the cardiology department.

Study population

The study included hospitalized patients diagnosed with cardiovascular diseases, with or without comorbid conditions, who were receiving pharmacological therapy in the cardiology department.

Inclusion criteria

The study included male and female patients aged 18 years and above who were admitted to the cardiology department and receiving at least one medication for cardiovascular disease or associated comorbidities. Both newly admitted and existing patients at the time of study initiation were considered eligible, provided they were conscious, coherent, and willing to give informed consent.

Exclusion criteria

Patients were excluded if they were under 18 years of age, presented with cases of intentional or accidental poisoning or therapeutic failures, had a history of drug abuse or noncompliance, or were pregnant or lactating. Additionally, patients who were unwilling or unable to comprehend the questionnaire or provide the necessary information were also excluded from the study.

Sample size

A total of 50 patients meeting the inclusion criteria were enrolled in the study.

Adverse drug reaction monitoring

Suspected ADRs were identified and recorded systematically. To ensure standardized evaluation, the following tools were used. Naranjo ADR probability scale

for causality assessment, classifying ADRs as definite, probable, possible, or doubtful. WHO-UMC causality assessment scale to further validate the likelihood of drug-event relationship. Hartwig and Siegel Severity Assessment scale to categorize ADRs as mild, moderate, or severe based on clinical outcomes and the intervention required. The nature, type, severity, and suspected drugs responsible for the ADRs were documented for each case.

Statistical analysis

Data were compiled using Microsoft Excel and analyzed using descriptive statistics. Continuous variables were expressed as means and percentages. Categorical variables, such as gender distribution, types of ADRs, and severity grading, were expressed in percentages. The association between patient characteristics, comorbidities, and ADR occurrence was assessed to identify potential risk factors. Results were presented in tables and graphical formats where appropriate.

RESULTS

A total of 50 patients admitted to the cardiology department were included. The majority were male (54%), and most patients (48%) were aged between 46–60 years. Hypertension (86%) and diabetes mellitus (56%) were the most common comorbidities (Table 1). A total of 50 adverse drug reactions (ADRs) were identified during the study period. Drug-wise distribution of ADRs in study population is depicted in Table 2. The hematological system (36%) was most affected, followed by gastrointestinal (24%) and cardiovascular (16%) systems (Table 3) (Figure 1). The severity of ADRs, assessed using the Hartwig scale, showed that 50% were moderate, 34% mild, and 16% severe. Causality assessment revealed 62% probable, 28% possible, and 10% certain ADRs based on Naranjo (Figure 2) and WHO-UMC scales. Management outcomes indicated that 66% of patients recovered fully, 20% remained under observation, and 14% required drug discontinuation or dose adjustment. No fatalities were reported.

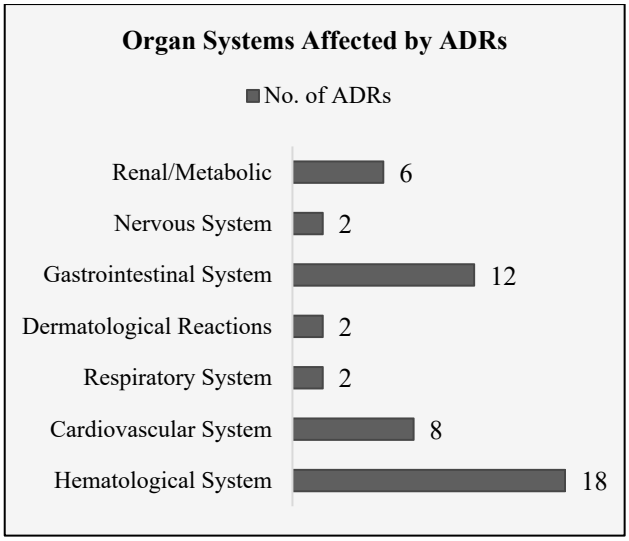

Figure 1: System-wise distribution of adverse drug reactions.

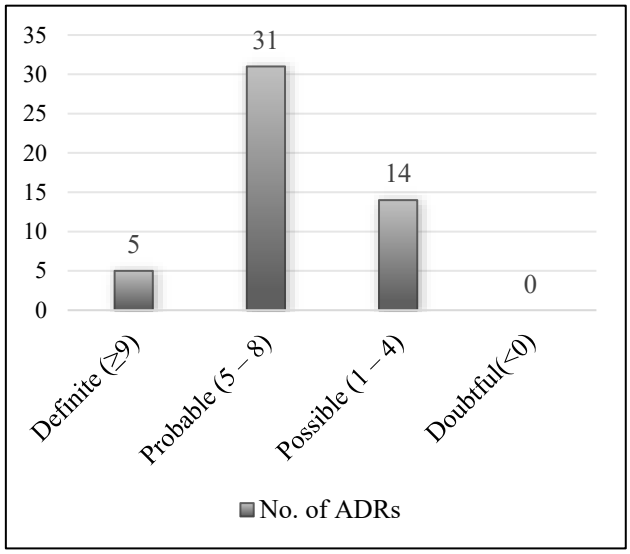

Figure 2: Naranjo's causality assessment of reported ADRs.

Table 1: Demographic and clinical characteristics (n=50).

Variable	Frequency	%
Gender		
Male	27	54
Female	23	46
Age distribution (in years)		
46–60	24	48
61–75	16	32
>75	10	20
Comorbidities		
Hypertension	43	86
Diabetes mellitus	28	56
Coronary artery disease	10	20
Hypothyroidism	7	14
Seizure disorders	5	10

Table 2: Drug-wise distribution of ADRs in study population.

Generic name	No. of ADRs	%	Type of reaction
Heparin sodium	14	28	Bleeding (gums, puncture site, hematuria, itching)
Ticagrelor	2	4	Increased creatinine levels, Dyspnoea
Clopidogrel	1	2	nosebleed
Furosemide	3	6	Hypokalemia, headache, dizziness
Enalapril	2	4	Dry cough, Hypotension
Metoprolol succinate	2	4	Severe nausea, constipation, first-degree atrioventricular block
Amiodarone	3	6	Bradycardia, pancytopenia, prolonged QT interval on ECG
Ivabradine	1	2	Palpitations
Ranolazine	1	2	orthostatic hypotension
Telmisartan	1	2	Hyperkalemia
Spironolactone	1	2	Thrombocytopenia
Nitro-glycerine	2	4	Headache, Hypotension
Norepinephrine	2	4	Drowsiness, Bradycardia
Aspirin	4	8	Abdominal pain, dyspepsia, nose bleed, gastrointestinal ulcer
Dapagliflozin	4	8	pyelonephritis, Nausea, Nasopharyngitis, increased serum creatinine
Empagliflozin	5	10	Increased thirst, nausea, urticaria, constipation, acute pancreatitis
Digoxin	2	4	ventricular tachycardia, anorexia

Table 3: ADR profile summary (n=50 ADRs).

Parameter	Frequency	%
System affected		
Hematological	18	36
Gastrointestinal	12	24
Cardiovascular	8	16
Renal/metabolic	6	12
Respiratory, dermatological, nervous system	6 (combined)	12
Severity of ADRs		
Mild	17	34
Moderate	25	50
Severe	8	16
Causality (Naranjo/WHO-UMC)		
Naranjo score category		
Certain	5	10
Probable	31	62
Possible	14	28
Doubtful	0	0
WHO causality category		
Certain	5	10
Probable	31	62
Possible	14	28
Unlikely	0	0
Conditional/unclassified	0	0
Unassessable/unclassifiable	0	0

DISCUSSION

ADRs remain a significant concern in the management of cardiovascular diseases, especially given the complexity of drug regimens, frequent comorbidities, and polypharmacy in this patient population. The present study aimed to evaluate the drug utilization patterns and monitor ADRs in patients admitted to the cardiology department of a tertiary care hospital. In this study, 50 patients were monitored over a 3-month period, with a total of 50 ADRs reported. The incidence of ADRs was considerable, reflecting the global challenge of ensuring drug safety in high-risk populations, particularly in cardiology settings. Previous research has

shown that the prevalence of ADRs in hospitalized cardiac patients ranges from 10% to 30%, depending on study design and patient profiles.[17] The demographic analysis revealed a slight male predominance (54%), consistent with prior studies indicating higher hospital admission rates for cardiovascular diseases among males.[18] Additionally, the majority of ADRs were reported in patients aged 46–75 years, aligning with global data highlighting increased cardiovascular risk and susceptibility to ADRs in middle-aged and elderly individuals.[19] Comorbidities such as hypertension (86%) and diabetes mellitus (56%) were highly prevalent, both of which are well-established risk factors not only for cardiovascular morbidity but also for increased ADR susceptibility due to polypharmacy and altered pharmacokinetics.[20]

System-wise and drug-wise adverse drug reactions patterns

The hematological system was most frequently affected (36% of ADRs), primarily due to anticoagulants such as Heparin Sodium, which accounted for a significant proportion of bleeding complications, including gum bleeding, hematuria, and puncture site hemorrhage. These findings align with known safety concerns associated with anticoagulant therapy, particularly in hospitalized cardiac patients.[21]

Similarly, antiplatelet agents such as Ticagrelor, Clopidogrel, and Aspirin were responsible for ADRs ranging from gastrointestinal discomfort and bleeding to increased creatinine levels and dyspnea. These outcomes are consistent with established literature regarding the gastrointestinal and bleeding risks of these agents.[8] Diuretics, including furosemide and spironolactone, contributed to electrolyte imbalances such as hypokalemia and thrombocytopenia, a known class effect, especially in elderly and comorbid populations.[22]

Notably, newer therapeutic agents such as SGLT2 inhibitors (Dapagliflozin and Empagliflozin) were associated with dehydration, urinary tract infections, increased thirst, and, in some cases, acute pancreatitis. Recent studies have similarly reported renal and metabolic ADRs with these drugs, reinforcing the need for close monitoring, especially in diabetic and elderly populations.[23]

Severity and causality assessments

The severity assessment using the Hartwig scale revealed that 50% of ADRs were moderate, 34% mild, and 16% severe. The severe ADRs predominantly involved major bleeding, bradyarrhythmia's, and serious electrolyte disturbances, all of which necessitated intervention or drug withdrawal. Causality assessment using the Naranjo Scale and WHO-UMC criteria showed that 62% of ADRs were probable, 28% possible, and 10% certain. The predominance of probable ADRs reflects the challenges in establishing definitive causality in complex, polymedicated patients, a challenge similarly noted in global pharmacovigilance studies.[24]

Clinical implications

Encouragingly, most patients (66%) recovered completely with symptomatic management, while drug discontinuation or dose adjustment was required in 14% of cases. No fatalities were reported, suggesting that proactive monitoring, early detection, and timely interventions are effective in reducing ADR-related morbidity. The study emphasizes the critical need for routine pharmacovigilance activities in cardiology settings. Comprehensive patient assessment, particularly for high-risk groups such as the elderly and those with multiple comorbidities. Rational prescribing and close monitoring for drugs known to have narrow therapeutic indices or significant ADR potential. These findings are consistent with global recommendations advocating for enhanced ADR reporting systems, continuous education of healthcare providers, and patient counselling to improve drug safety outcomes.[25]

This study was limited by its small sample size (50 patients) and short duration (3 months), which may restrict the generalizability of results. Additionally, long-term ADRs and post-discharge events could not be captured. Despite these limitations, the findings provide valuable insights into drug safety patterns in the cardiology department of a tertiary care hospital.

CONCLUSION

This study underscores the substantial burden of adverse drug reactions in hospitalized cardiovascular patients, emphasizing the heightened vulnerability of elderly individuals and those with multiple comorbidities to drug-related complications. By systematically evaluating drug utilization and ADR patterns, the study highlights the critical role of pharmacovigilance in optimizing patient safety in cardiology settings. The identification of specific drug classes particularly anticoagulants, antiplatelets, diuretics, and SGLT2 inhibitors as common contributors to ADRs provides valuable insights for clinicians in tailoring safer, evidence-based therapeutic regimens. Overall, this research advances knowledge in the field by reinforcing the importance of proactive ADR monitoring and rational prescribing practices to mitigate risks and enhance clinical outcomes in cardiovascular care.

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

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