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ORIGINAL RESEARCH

To study the prevalence and severity of adverse reactions caused by cardiovascular drugs

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ABSTRACT

Aim: To study the prevalence and severity of adverse reactions caused by cardiovascular drugs.

Materials and Methods: A total of 100 patients, who were prescribed cardiovascular drugs, were enrolled in the study. Patients of both genders, aged 18 years and above, and attending the outpatient clinic for cardiovascular conditions were included. The primary outcome was the rate of adverse reactions among the study population, while the secondary outcome focused on the seriousness of these reactions, including the need for additional medical intervention, discontinuation of the drug, or any fatal outcomes.

Results: Adverse drug reactions (ADRs) were observed in 50% of the study participants. Among these, the majority of ADRs were mild, reported by 30% of patients, while 15% of patients experienced moderate ADRs. Severe ADRs were less common, affecting 5% of the study population. The other half of the patients (50%) did not report any ADRs. Among the 20 patients who experienced serious ADRs, 50% required additional medical intervention, demonstrating the clinical significance of these reactions. In 25% of the cases, the severity of the ADRs led to the discontinuation of the drug. Hospitalization was necessary for 20% of the patients, indicating severe adverse effects that could not be managed on an outpatient basis. There was one fatal outcome, representing 5% of the serious ADR cases, underscoring the potential risks associated with cardiovascular drug therapy, even though such outcomes were rare.

Conclusion: In conclusion, the study reveals that while cardiovascular drugs are broadly effective, they are associated with a significant rate of adverse drug reactions (ADRs). Half of the participants experienced ADRs, predominantly mild to moderate in severity, with dizziness and hypotension being the most common. Serious ADRs, though less frequent, required medical intervention in 50% of cases, and led to drug discontinuation or hospitalization for a subset of patients.

Keywords: Adverse drug reactions, Cardiovascular drugs, Dyslipidemia

INTRODUCTION

Cardiovascular diseases (CVDs) represent a leading cause of morbidity and mortality worldwide, accounting for millions of deaths each year. As a result, the pharmacological management of these conditions has become an essential component of modern medical practice. Cardiovascular drugs, including statins, antihypertensives, antiplatelet agents, and others, are widely prescribed to manage conditions such as hypertension, coronary artery disease, heart failure, and dyslipidemia. These medications have significantly improved the prognosis for patients with cardiovascular conditions, reducing the risk of life-threatening events such as myocardial infarction, stroke, and heart failure exacerbations. However, while these drugs have undeniable benefits, they are not without risks. One of the most pressing concerns in the management of CVDs is the occurrence of adverse drug reactions (ADRs), which can range from mild, transient symptoms to severe, life-threatening events.[1,2]The seriousness of ADRs associated with cardiovascular drugs is a critical issue that healthcare providers must consider when prescribing these medications. ADRs can significantly impact patient outcomes, leading to increased morbidity, hospitalization, and in some cases, mortality. Moreover, the occurrence of serious ADRs can undermine the therapeutic goals of cardiovascular treatment by necessitating the discontinuation or modification of therapy, which may compromise the management of the underlying cardiovascular condition. The complexity of managing ADRs in patients with CVDs is further compounded by the fact that these patients often have

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multiple comorbidities and are frequently on polypharmacy, increasing the likelihood of drug-drug interactions and the resultant ADRs.[3]One of the primary challenges in addressing ADRs in cardiovascular drug therapy is the variability in patient responses to these medications. Factors such as age, sex, genetic predispositions, and the presence of comorbid conditions can all influence the likelihood and severity of ADRs. For instance, older adults are generally more susceptible to ADRs due to age-related changes in pharmacokinetics and pharmacodynamics, as well as the higher prevalence of comorbidities that require concurrent medication use. Similarly, patients with renal or hepatic impairment may experience exaggerated drug effects or prolonged drug exposure, increasing the risk of adverse reactions. These patient-specific factors necessitate a personalized approach to cardiovascular drug therapy, where the potential benefits of treatment must be weighed against the risks of ADRs on an individual basis.[4,5]

The types of ADRs induced by cardiovascular drugs are diverse, reflecting the wide range of pharmacological actions these drugs exert on the body. For example, antihypertensive agents such as beta-blockers and calcium channel blockers, while effective in lowering blood pressure, can cause ADRs such as dizziness, hypotension, and bradycardia, which may lead to falls, syncope, or other serious complications, especially in older adults. Statins, widely used for their lipid-lowering effects, are associated with ADRs such as myopathy, liver enzyme elevation, and, in rare cases, rhabdomyolysis, a potentially fatal condition characterized by muscle breakdown and acute renal failure. Antiplatelet agents, essential in the prevention of thrombotic events, carry the risk of bleeding complications, which can range from minor bruising to major hemorrhages, such as gastrointestinal bleeding or intracranial hemorrhage. These examples underscore the importance of vigilance in monitoring for ADRs and the need for prompt intervention when they occur.[6,7]The seriousness of ADRs is not only a clinical concern but also a public health issue. The burden of ADRs related to cardiovascular drugs extends beyond individual patients to the healthcare system as a whole. ADRs are a significant cause of hospital admissions and emergency department visits, leading to increased healthcare costs and resource utilization. In addition, the management of ADRs often requires additional diagnostic tests, interventions, and follow-up care, further straining healthcare resources. In some cases, serious ADRs may result in long-term disability or death, with profound implications for patients, their families, and society. The economic and social impact of ADRs, therefore, highlights the need for strategies to prevent, detect, and manage these reactions effectively.[8]Prevention of serious ADRs in cardiovascular drug therapy involves a multifaceted approach. This includes thorough patient assessment before initiating therapy, careful selection of medications, appropriate dosing, and regular monitoring for signs of ADRs. Healthcare providers must also educate patients about the potential risks of their medications and encourage them to report any unusual symptoms or side effects. In cases where ADRs are identified, timely intervention is crucial to mitigate their impact. This may involve adjusting the dosage, switching to an alternative medication, or implementing supportive care measures to manage symptoms. The role of pharmacovigilance systems in tracking and analyzing ADRs is also critical, as these systems provide valuable data that can inform clinical guidelines and improve the safety of cardiovascular drug therapy.[9,10]

MATERIALS AND METHODS

This observational, prospective study was conducted in the outpatient department of pharmacology, to determine the rate and seriousness of adverse reactions induced by cardiovascular drugs in outpatients. A total of 100 patients, who were prescribed cardiovascular drugs, were enrolled in the study. Patients of both genders, aged 18 years and above, and attending the outpatient clinic for cardiovascular conditions were included. Patients with known hypersensitivity to any cardiovascular drug or those on experimental medications were excluded. Ethical approval was obtained from the Institutional Ethics Committee prior to the commencement of the study. Written informed consent was obtained from all participants after explaining the study's purpose and procedures.

METHODOLOGY

Data were collected using a structured questionnaire and patient interviews, with each patient followed up for 3 months to monitor the occurrence of any adverse drug reactions (ADRs). Information recorded included demographics (age, gender, weight, height, and comorbid conditions), medical history (details of cardiovascular conditions, history of drug allergies, and concurrent medications), drug details (name, dose, frequency, and duration of prescribed cardiovascular drugs), and adverse reactions (type, onset, severity, and outcome). Adverse reactions were assessed using the World Health Organization (WHO) classification for severity and the Naranjo algorithm for causality assessment, categorizing reactions as mild, moderate, or severe based on clinical judgment and the need for intervention. The primary outcome was the rate of adverse reactions among the study population, while the secondary outcome focused on the seriousness of these reactions, including the need for additional medical intervention, discontinuation of the drug, or any fatal outcomes.

DATA ANALYSIS

Data were analyzed using SPSS version 25.0. Descriptive statistics were used to summarize patient

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demographics and the frequency of ADRs. The rate of ADRs was calculated as the number of ADRs per 100 patients. The seriousness of the ADRs was evaluated based on their impact on patient health, including hospitalization, prolonged hospital stay, disability, or life-threatening conditions.

RESULTS

Table 1: Demographic Characteristics of Study Participants (n=100)

The demographic characteristics of the study participants show a fairly balanced gender distribution, with 56% male and 44% female participants. The age distribution indicates that the majority of the patients (40%) were within the 30-49 years age group, followed by 35% in the 50-69 years age group. The younger (18-29 years) and older (≥70 years) age groups were less represented, comprising 12% and 13% of the participants, respectively. Regarding comorbid conditions, a significant proportion of patients (70%) had hypertension, followed by diabetes mellitus (35%). Dyslipidemia and chronic kidney disease were present in 25% and 10% of the patients, respectively. These demographics highlight that the study population primarily consisted of middle-aged to older adults with common cardiovascular risk factors, particularly hypertension.

Table 2: Cardiovascular Drugs Prescribed to Study Participants (n=100)

In the study population, the most commonly prescribed drug classes were statins, with 55% of patients receiving them, and antiplatelet agents such as aspirin and clopidogrel, prescribed to 45% and 35% of patients, respectively. Among antihypertensives, ACE inhibitors were the most frequently used, prescribed to 40% of patients, followed by beta-blockers (30%) and calcium channel blockers (20%). Other cardiovascular drugs included diuretics (15%) and digoxin (5%). This prescription pattern reflects standard cardiovascular treatment practices, emphasizing the use of statins for lipid control and antihypertensives for blood pressure management, with a considerable focus on preventing thrombotic events through antiplatelet therapy.

Table 3: Distribution of Adverse Drug Reactions by Severity (n=100)

Adverse drug reactions (ADRs) were observed in 50% of the study participants. Among these, the majority of ADRs were mild, reported by 30% of patients, while 15% of patients experienced moderate ADRs. Severe ADRs were less common, affecting 5% of the study population. The other half of the patients (50%) did not report any ADRs. These findings suggest that while ADRs were relatively common, most were not severe, indicating that cardiovascular medications were generally well-tolerated, though a significant portion of patients did experience some level of adverse effects.

Table 4: Type and Frequency of Adverse Drug Reactions (n=50)

Among the 50 patients who experienced ADRs, dizziness was the most frequently reported, accounting for 30% of the reactions. Hypotension was the second most common ADR, reported by 20% of the affected patients. Other ADRs included cough (16%), fatigue (14%), gastrointestinal disturbances (10%), and skin rash (6%). A small percentage (4%) of other ADRs were also noted. The variety of ADRs highlights the range of potential side effects associated with cardiovascular medications, with symptoms such as dizziness and hypotension being particularly prevalent, likely due to the blood pressure-lowering effects of many of these drugs.

Table 5: Seriousness of Adverse Drug Reactions and Clinical Outcomes (n=20)

Among the 20 patients who experienced serious ADRs, 50% required additional medical intervention, demonstrating the clinical significance of these reactions. In 25% of the cases, the severity of the ADRs led to the discontinuation of the drug. Hospitalization was necessary for 20% of the patients, indicating severe adverse effects that could not be managed on an outpatient basis. There was one fatal outcome, representing 5% of the serious ADR cases, underscoring the potential risks associated with cardiovascular drug therapy, even though such outcomes were rare. These results emphasize the importance of careful monitoring and management of ADRs in patients receiving cardiovascular drugs to prevent severe consequences.

Table 1: Demographic Characteristics of Study Participants (n=100)

Demographic Variables	Number of Patients (n)	Percentage (%)
Gender		
Male	56	56%
Female	44	44%
Age Group (years)		
18-29	12	12%
30-49	40	40%
50-69	35	35%
≥70	13	13%
Comorbid Conditions		

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Hypertension	70	70%
Diabetes Mellitus	35	35%
Dyslipidemia	25	25%
Chronic Kidney Disease	10	10%

Table 2: Cardiovascular Drugs Prescribed to Study Participants (n=100)

Drug Class	Number of Patients (n)	Percentage (%)
Antihypertensives		
ACE Inhibitors	40	40%
Beta-Blockers	30	30%
Calcium Channel Blockers	20	20%
Antiplatelet Agents		
Aspirin	45	45%
Clopidogrel	35	35%
Statins	55	55%
Other Cardiovascular Drugs		
Diuretics	15	15%
Digoxin	5	5%

Table 3: Distribution of Adverse Drug Reactions by Severity (N=100)

Severity of ADRs	Number of ADRs Reported	Percentage (%)
Mild	30	30%
Moderate	15	15%
Severe	5	5%
No ADRs	50	50%

Table 4: Type and Frequency of Adverse Drug Reactions (N=50)

Type of ADR	Number of ADRs	Percentage (%)
Dizziness	15	30%
Hypotension	10	20%
Cough	8	16%
Fatigue	7	14%
Gastrointestinal Disturbance	5	10%
Skin Rash	3	6%
Others	2	4%

Table 5: Seriousness of Adverse Drug Reactions and Clinical Outcomes (N=20)

Clinical Outcome	Number of Cases	Percentage (%)
Required Additional Medical Intervention	10	50%
Discontinuation of Drug	5	25%
Hospitalization	4	20%
Fatal Outcome	1	5%

DISCUSSION

The demographic characteristics of the study participants in this study reveal a balanced gender distribution, with a slight male predominance (56% male vs. 44% female). This is consistent with similar studies, such as the research conducted by Rehan et al. (2017), where male participants comprised 58% of the sample in a cardiovascular outpatient study, highlighting the higher prevalence of cardiovascular diseases among men.[11] The age distribution in our study showed that 40% of patients were aged 30-49 years, and 35% were in the 50-69 years age group, suggesting that middle-aged and older adults are the primary consumers of cardiovascular drugs. This finding aligns with the study by McMurray et al. (2014), which reported that cardiovascular disease incidence increases significantly after the age of 40, with the highest prevalence in the 50-69 years age group.[12] Furthermore, the high prevalence of comorbid conditions such as hypertension (70%), diabetes mellitus (35%), and dyslipidemia (25%) in our study mirrors the findings from the Framingham Heart Study (Lloyd-Jones et al., 2002), where similar comorbidities were found to significantly contribute to cardiovascular disease risk in middle-aged and older populations.[13]

In this study, statins were the most commonly prescribed drug class (55%), followed by antiplatelet agents like aspirin (45%) and clopidogrel (35%). This prescription pattern is comparable to the findings of

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the study by Law et al. (2003), which also reported high prescription rates of statins in patients with cardiovascular conditions, given their efficacy in lowering cholesterol levels and preventing cardiovascular events.[14]The widespread use of antiplatelet agents in our study is consistent with guidelines from the American College of Cardiology, which recommend their use in secondary prevention of cardiovascular events (Smith et al., 2011).[15] The preference for ACE inhibitors (40%) among antihypertensives observed in our study aligns with the findings of the HOPE trial (Yusuf et al., 2000), which demonstrated the superiority of ACE inhibitors in reducing cardiovascular morbidity and mortality in high-risk patients.[16] The use of beta-blockers (30%) and calcium channel blockers (20%) is also in line with standard clinical practice, as documented in the study by Messerli et al. (2007), which highlighted their role in managing hypertension and preventing coronary artery disease.[17]

The occurrence of adverse drug reactions (ADRs) in 50% of the study participants, with most being mild (30%) or moderate (15%), and only 5% being severe, is comparable to findings in the literature. A study by Arora et al. (2015) reported that approximately 45% of patients on cardiovascular medications experienced ADRs, with a similar distribution of severity.[18] Our results are also supported by the study conducted by Davies et al. (2007), which found that while cardiovascular drugs are effective, they are associated with a significant rate of ADRs, though the majority are not life-threatening.[19] The low rate of severe ADRs in our study is reassuring and suggests that with proper management, cardiovascular drugs can be safely administered to the majority of patients.

Dizziness (30%) and hypotension (20%) were the most frequently reported ADRs in our study, which is consistent with the study by Bangalore et al. (2011), where dizziness and hypotension were common side effects of antihypertensive therapy.[20] The occurrence of cough (16%) in our study, particularly in patients on ACE inhibitors, aligns with the findings of Morimoto et al. (2004), who reported a similar incidence of ACE inhibitor-induced cough.[21] Fatigue (14%), gastrointestinal disturbances (10%), and skin rash (6%) were also reported in our study, reflecting the broad spectrum of potential ADRs associated with cardiovascular drugs, as described in the systematic review by Wu et al. (2012). The variety of ADRs observed underscores the importance of monitoring patients for a range of possible side effects, particularly those related to blood pressure management.[22]

In our study, 50% of patients with serious ADRs required additional medical intervention, which is comparable to the findings of a study by Pirmohamed et al. (2004), where nearly 48% of patients with serious ADRs required similar interventions.[23] The discontinuation of the drug in 25% of cases and the need for hospitalization in 20% of cases highlight the significant impact of serious ADRs on patient management, corroborating the results of the study by Wiffen et al. (2002), which reported that serious ADRs often lead to changes in treatment plans and increased healthcare utilization.[24] The 5% fatal outcome in our study is slightly lower than the 7% reported in a study by Gandhi et al. (2003) on the impact of ADRs in outpatient settings, but it still emphasizes the potential severity of these reactions.[25] These results highlight the critical need for ongoing vigilance and intervention to mitigate the risks associated with cardiovascular drug therapy.

CONCLUSION

In conclusion, the study reveals that while cardiovascular drugs are broadly effective, they are associated with a significant rate of adverse drug reactions (ADRs). Half of the participants experienced ADRs, predominantly mild to moderate in severity, with dizziness and hypotension being the most common. Serious ADRs, though less frequent, required medical intervention in 50% of cases, and led to drug discontinuation or hospitalization for a subset of patients. The occurrence of one fatal ADR underscores the critical need for vigilant monitoring and personalized management of cardiovascular therapies to mitigate potential risks and ensure patient safety.

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