Assessment of Adverse Drug Reactions and Medication-Associated Risk Factors in Patients with Five Different Cardiovascular Diseases: A Pharmacovigilance Study

Rani Kumari[1] and Komal Sharma[2]

[1]*Research Scholar, Faculty of Pharmacy, Bhupal Noble's University, Udaipur, Rajasthan*

[2]*Professor, Department of Pharmacology, Faculty of Pharmacy, Bhupal Noble's University, Udaipur, Rajasthan*

Corresponding Author: Rani Kumari, Email ID: 25ranijha@gmail.com; Orcid Id: 0009-0007-3702-7951

Research Guide: Dr. Komal Sharma, Email ID: komalsharmagautam@yahoo.com; Orcid Id:0000-0002-1189-9555

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Abstract

Background: One of the main causes of morbidity and mortality in worldwide countries is cardiovascular disease (CVD). Pharmacological therapy is essential for managing CVDs; however, polypharmacy and long-term use of medications may raise the risk of adverse drug reactions (ADRs). To improve patient safety and identify medication-related risks, pharmacovigilance is essential.

Objective: In this study, patients with five different cardiovascular disease were Angina pectoris CHF, Myocardial infarction, Atherosclerosis and Coronary artery diseases were evaluated for adverse drug reactions and medication-associated risk factors.

Methods: Over a period of a year, from January 10, 2024, to January 10, 2025, a prospective observational study was conducted at Mulana Azad Medical College, Delhi, a tertiary care teaching hospital. Patients with cardiovascular disease had their ADR reports collected and evaluated. Clinical characteristics, severity, prescribed medications, demographic details, and associated risk factors were analyzed. The WHO–Uppsala Monitoring Center (UMC) method was used to assess causality. Statistical methods were used to analyze the data.

Results: After validation, 950 (86.36%) of the 1100 ADR reports that were evaluated were accepted, while 150 (13.63%) were rejected. Compared to females (40.31%), men represented the majority of reported ADRs (59.57%). 40% of patients had atherosclerosis, 15.79% had myocardial infarction, 10% had congestive heart failure, 6.63% had angina pectoris, and 8.10% had coronary artery disease. It was found as hypertension was the most common risk factor for all cardiovascular diseases. Antihypertensive, antiplatelet, lipid-lowering, and other cardiovascular therapies were among the frequently prescribed drugs; amlodipine was one of the most commonly used medications.

Conclusion: The study highlights the significant pharmacovigilance is in monitoring adverse drug reactions (ADRs) associated with cardiovascular medications. To minimize drug-related risks, improve therapeutic outcomes, and improve patient safety among patients with cardiovascular disease, rational prescribing, continuous medication monitoring, and regular ADR reporting are essential.

Keywords: Adverse Drug Reactions, Pharmacovigilance, Cardiovascular Diseases, Medication Safety and Amlodipine**.**

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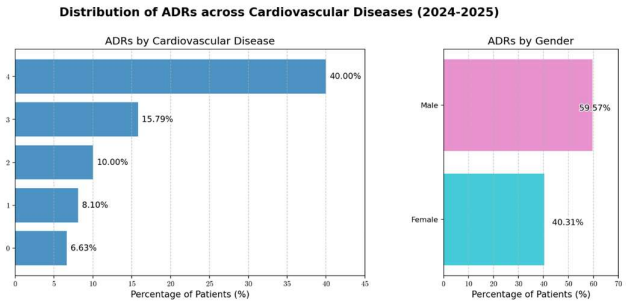
Graphical Abstract



INTRODUCTION

Cardiovascular diseases (CVDs) including coronary artery diseases, Congestive heart failure, rheumatic heart disease, cerebrovascular disease (stroke) and other disorders that affect the heart and blood vessels. These diseases remain to be

considered the global leading cause of death and are caused by structural and functional abnormalities in the cardiovascular system [1]. The World Health Organization estimates about 19.8 million people died from cardiovascular diseases in 2022 which is almost 3percent of all fatalities world-wide with heart attacks and strokes accounting for nearly 85% of those deaths. More than three quarters of these deaths take place among low- and middle-income nations highlighting a serious inequality in global health. Many modifiable risk factors for cardiovascular diseases are associated with environmental exposures and lifestyle decisions, such as unhealthy [2].

Many risk factors for cardiovascular disease can be changed and are linked to environmental exposures and lifestyle habits. These involve unhealthy eating habits that are high in fat, sugar and salt, physical inactivity, tobacco use, excessive alcohol consumption and air pollution. These conditions frequently result in intermediate physiological changes that significantly increase the risk of heart attacks, strokes, heart failure and other related adverse effects [3]. These changes include higher blood pressure, elevated blood glucose, high blood lipids, overweight and obesity. Importantly, early detection and management of these risk factors through lifestyle changes and medical therapy can substantially reduce the disease burden and premature mortality. Chronic demographic changes such as population ageing, urbanization and persistent socioeconomic determinants like poverty and stress further contribute to the rising burden of CVD worldwide [4].

The cornerstone of treatment cardiovascular disease is pharmacological management which includes antihypertensive, antiplatelet drugs, anticoagulants, lipid-lowering medications, antiarrhythmic and heart failure therapy. Long-term use of these drugs is often associated with adverse drug reactions which can range from moderate and normal to severe and possibly fatal with the fact that they significantly lower morbidity and mortality. Patients with comorbid diseases such diabetes mellitus, chronic renal disease, chronic obstructive lung disease and hepatic dysfunction are even more at risk for adverse drug reactions. Therefore, monitoring and assessing adverse drug reactions (ADRs) related to cardiovascular medications is crucial for improving patient safety and therapeutic outcomes [5].

Heart disease, a heart attack, and stroke are typical cardiovascular diseases (CVDs) that affect the heart and blood arteries. Over the past few decades, cardiovascular diseases (CVDs) have overtaken infectious diseases as India's leading cause of mortality. About 31% of the deaths in the country are triggered by cardiovascular disorders, according to the Sample Registration System (SRS) Report on Causes of Death, 2021–2023. This indicates that heart-related issues contribute to about one in three deaths in India [6].

Adults 30 years of age and above have the highest burden of cardiovascular disease, and the risk increases with age. Gender inequalities are further evident in national data, with men being marginally more impacted than women. According to the Economic Survey 2026, cardiovascular disorders were responsible for 29.1% of female deaths and 32.4% of male deaths between 2021 and 2023. This shows that heart disease is a serious health issue among people of both genders [7].

The rising incidence of CVD in India is caused by modifiable risk factors. These include unhealthy diets high in fat, sugar and salt, inactivity, tobacco use, excessive alcohol use, obesity, high blood pressure, diabetes and raised cholesterol. Air pollution, stress, fast urbanization all increase the risk of heart disease. Many people receive treatment either late or go wrong, which increases a chance of complications and death [8].

Although these medicines provide significant therapeutic benefits, prolonged use and polypharmacy may lead to adverse drug reactions (ADRs), drug interactions, and medication-related complications. Pharmacovigilance is essential for evaluating drug safety and identifying preventable medication-related risks.[10,11].

Myocardial infarction, atherosclerosis, congestive heart failure, angina pectoris, and coronary artery disease represent major cardiovascular conditions associated with multiple risk factors and extensive medication use. [12,13].

According to the Economic Survey 2026, cardiovascular diseases contributed to around 32.4 percent of male deaths and 29.1 percent of female deaths, showing a significant gendered impact [9].

The present study was conducted to assess ADR-related concerns and medication-associated risk factors among patients with five different cardiovascular diseases.

MATERIALS AND METHODS

Study Methodology

A prospective observational study was conducted by reviewing adverse drug reaction (ADR) reports from a Mulana Azad Medical College, a tertiary care teaching hospital located in Delhi.

Study Design

A prospective observational study was conducted to analyze adverse drug reactions (ADRs) in cardiovascular patients.

Study Site

The study was conducted in a government tertiary care teaching hospital Mulana Azad Medical College located in Delhi.

Study Duration

The study included ADR reports collected over a period of one years from 10th Jan 2024-10th Jan

2025

Study Population

The study population consisted of adverse drug reaction (ADR) reports from patients with cardiovascular diseases that were reported to the pharmacovigilance centre during the study period.

Inclusion Criteria

- ADR reporting forms with complete and relevant patient information.
- All patients diagnosed with cardiovascular diseases
- Patients aged 18 years and above.

Exclusion Criteria:

- Patients undiagnosed with cardiovascular diseases will not be considered
- Pregnant and lactating women were excluded from the study.
- Patient below 18 years of age.
- Patients with psychiatric disorders were not included in the study.

Data Collection Procedure

Out of a total study population of 1100 patients with cardiovascular diseases, 950 suspected ADR reports were received between 10th Jan 2024 and 10th Jan 2025. These reports were evaluated and analyzed for the incidence and patterns of ADRs.

Data on demographic characteristics, including age and sex as well as details of prescribed medications (generic name, dose, frequency, strength, and dates of initiation and discontinuation) were collected and assessed. ADRs were further evaluated with respect to the description of the adverse event, time of onset and resolution and seriousness.

In accordance with the CDSCO ADR reporting form, all data was collected in a structured format. The WHO–Uppsala Monitoring Centre (UMC) global introspection method was used to assess causality.

Statistical Analysis:

Data were entered and analyzed using statistical software (e.g Microsoft Excel etc). Incidence and prevalence of ADRs were calculated and associations with demographic variables and drug classes were analyzed.

Ethical Considerations:

After obtaining Institutional Review Board (IRB) approval, the study was conducted. Patient confidentiality and anonymity were strictly maintained throughout the study.

RESULTS:

A total of 1100 was reported ADR forms from Mulana Azad medical college, a tertiary care hospital was analyzed. Out of these, 950 ADRs (86.36%) were accepted meaning they were validated or confirmed as true ADR cases after evaluation. The remaining 150 ADRs (13.63%) were not accepted indicating they were either incomplete, duplicated or did not meet the criteria to be classified as ADRs.

Table 1. Total number of reported and accepted ADRs in the study population.

ADRs	Number	Percent
Reported	1100	100.00
Accepted	950	86.36
Not Accepted	150	13.63

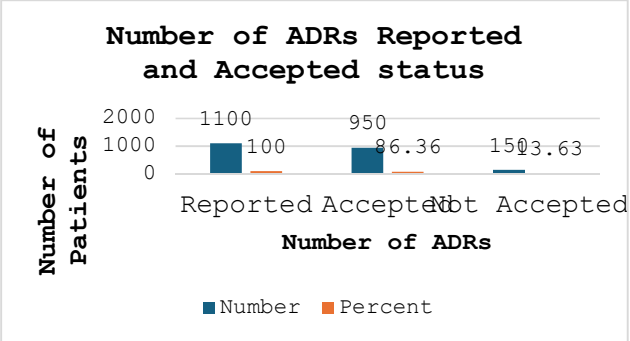


Fig 1. Among 1,100 reported ADRs, 86.36% (950) were accepted while 13.63% (150) were not accepted. The high acceptance rate suggests effective and reliable ADR reporting practices.

Table 2. Gender-wise distribution of the study population

GENDER	Reported		Accepted	
	Number	Percent	Number	Percent

Male	656	59.63	566	59.57
Female	444	40.36	384	40.31
Total	1100	100	950	100

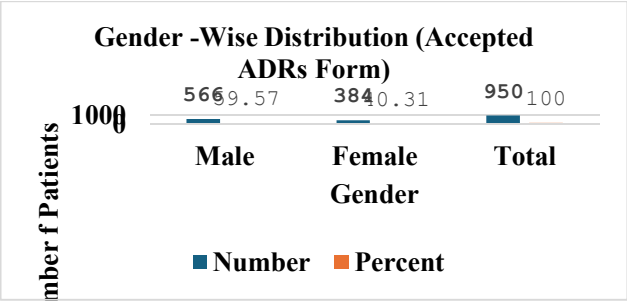


Fig 2. Out of 1,100 reported ADRs, males accounted for 59.63% and females for 40.36%. Similarly, among 950 accepted ADRs, 59.57% were males and 40.31% were females, showing a higher occurrence of reported and accepted ADRs among male patients.

Table 3. Distribution of MI in Population

MI Status	Number of Participants
MI Present	150
MI Absent	800
Total	950

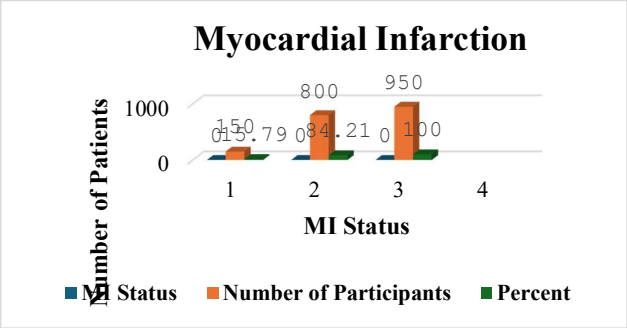


Fig 3. Among the 950 participants, Myocardial Infarction was present in 150 (15.79%) participants and absent in 800 (84.21%) participants. The results indicate that the majority of participants did not have Myocardial Infarction.

Table 4. Severity-wise distribution of Myocardial Infarction Cases (among MI Present n=150)

Severity of MI	Number of Cases	Percentage (%)
Mild	55	36.67
Moderate	65	43.33
Severe	30	20.00
Total	**150**	**100**

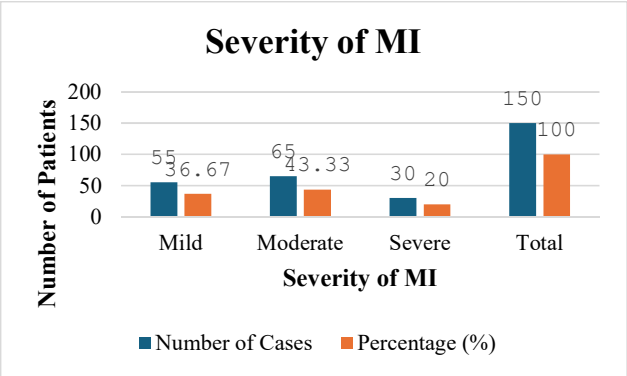


Fig 4. Among 150 MI cases, moderate severity was most common (43.33%), followed by mild cases (36.67%), while severe cases accounted for 20.00%. This indicates that most patients experienced moderately severe myocardial infarction.

Table 5 Risk Factor-wise Distribution Among MI Patients (n=150)

Risk Factor	Present (n)	Percentage (%)
Hypertension	63	42.00
Diabetes Mellitus	30	20.00
Dyslipidemia	15	10.00
Smoking/Tobacco Use	17	11.33
Obesity	10	6.67
Family History of Cardiac Disease	10	6.67
Physical Inactivity	5	3.33
Total	150	100

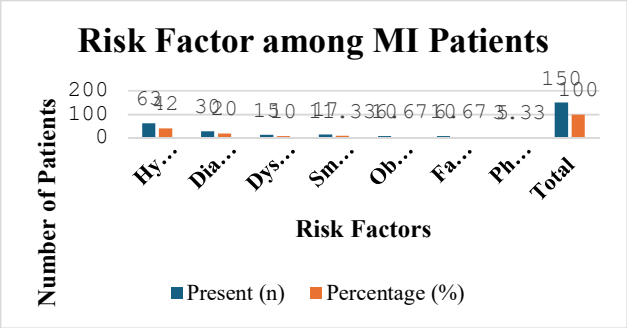


Fig 5. Among 150 MI patients, hypertension was the most common risk factor (42.00%), followed by diabetes mellitus (20.00%). Smoking/tobacco use (11.33%), dyslipidemia (10.00%), obesity (6.67%), family history of cardiac disease (6.67%), and physical inactivity (3.33%) were also identified. Hypertension emerged as the major contributing risk factor for MI.

Table 6: Medicine associated with MI

Medicine	Number of Patients (n=150)	Percentage (%)
Aspirin	10	6.67
Atorvastatin	37	24.67
Metoprolol	10	6.67
Amlodipine	75	50
Enalapril	10	6.67
Warfarin	02	1.33
Nitro-glycerine	02	1.33
Other Medicines	04	2.67
Total	**150**	**100**

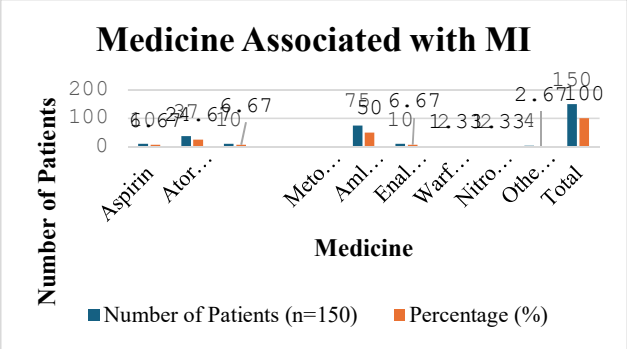


Fig 6. Among 150 MI patients, Amlodipine was the most commonly prescribed drug (50.00%), followed by Atorvastatin (24.67%). Aspirin, Metoprolol, and Enalapril each accounted for 6.67%, while Warfarin and Nitroglycerine were least prescribed (1.33% each).

Table 7 Distribution of Atherosclerosis in Population

Atherosclerosis Status	Number of Participants
Atherosclerosis Present	380
Atherosclerosis Absent	570
Total	950

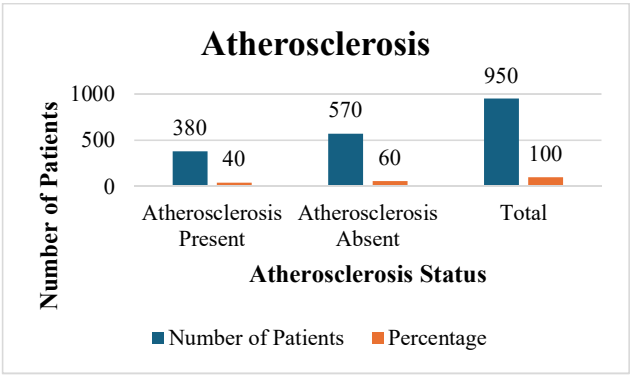


Fig 7. Out of 950 participants, atherosclerosis was present in 380 (40.00%) participants and absent in 570 (60.00%) participants indicating that the majority of participants did not have atherosclerosis.

Table 8. Severity-wise distribution of atherosclerosis cases (among atherosclerosis present n=380)

Severity of Atherosclerosis	Number of Cases	Percentage (%)
Mild	186	48.31
Moderate	157	41.31
Severe	42	11.05
Total	380	**100**

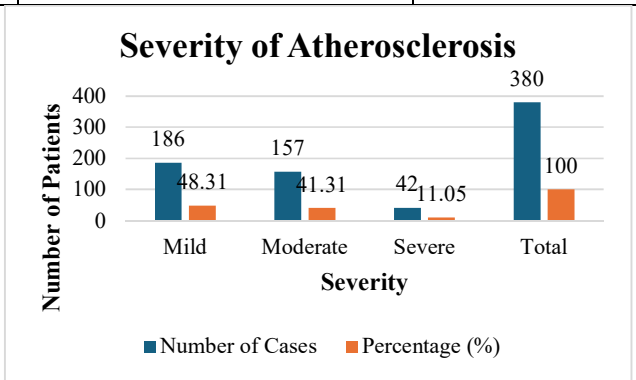


Fig 8 Among 380 cases of atherosclerosis, mild severity was most common (48.31%), followed by moderate severity (41.31%), while severe cases accounted for 11.05%. These findings suggest that most patients had mild to moderate atherosclerotic disease.

Table 9. Risk Factor-wise distribution among atherosclerosis Patients (n=380)

Risk Factor	Present (n)	Percentage (%)
Hypertension	103	27.10
High LDL level	72	18.94
Excessive alcohol consumption	62	16.31
Smoking/Tobacco Use	44	11.57
Obesity	40	10.52
Family History of Cardiac Disease	27	7.10
Physical Inactivity	20	5.26
Chronic kidney diseases	12	3.15
Total	**380**	**100**

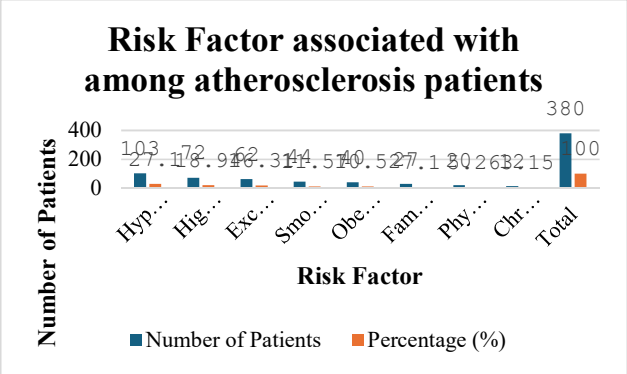


Fig 9. Among the 380 patients, hypertension was the most common risk factor, observed in 103 patients (27.10%) followed by high LDL level in 72 patients (18.94%). Excessive alcohol consumption (16.31%) and smoking/tobacco use (11.57%) were also important contributing factors. Obesity was present in 40 patients (10.52%) while family history of cardiac disease (7.10%), physical inactivity (5.26%) and chronic kidney disease (3.15%) were reported less frequently. Overall, the findings indicate that hypertension, lipid abnormalities and lifestyle-related factors were the major risk factors among the study population.

Table 10: Medicine associated with atherosclerosis

Medicine	Number of Patients (n=380)	Percentage (%)
Corticosteroids	45	11.8
Antipsychotics	30	7.9
Antihypertensive drugs	85	22.4
Antidiabetic drugs	70	18.4
Dyslipidemia	65	17.1
NSAIDs	25	6.6
Immunosuppressants	15	3.9
Other cardiovascular medicines	45	11.8
Total	**380**	**100**

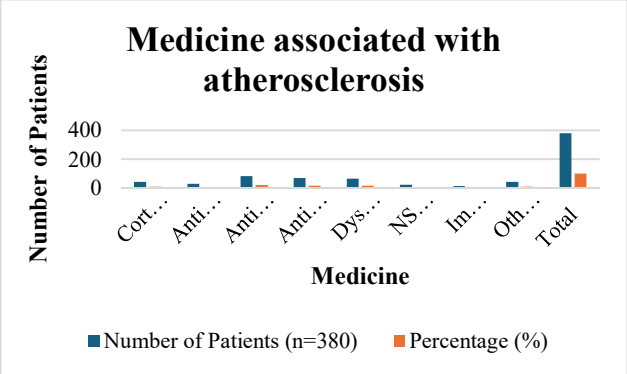


Fig 10 Among the 380 patients, hypertension was the most common risk factor (27.10%), followed by high LDL level (18.94%) and excessive alcohol consumption (16.31%). Smoking/tobacco use (11.57%) and obesity (10.52%) were also notable contributing factors. Family history of cardiac disease (7.10%), physical inactivity (5.26%) and chronic kidney disease (3.15%) were less frequently observed. Overall, modifiable risk factors such as hypertension, lipid abnormalities, alcohol use, and tobacco consumption were the major contributors to cardiovascular risk in the study population.

Table 11. Distribution of CHF in Population

CHF Status	Number of Participants
CHF Present	95
CHF Absent	855
Total	950

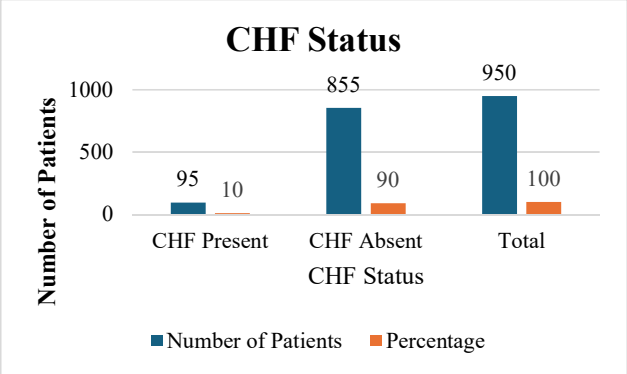


Fig 11. Among the total 950 participants, 95 patients (10%) had congestive heart failure (CHF) present, whereas 855 patients (90%) were CHF absent. The findings indicate that CHF was observed in a smaller proportion of the study population, while the majority of patients did not show CHF involvement.

Table 12. Severity-wise Distribution of CHF Cases (among CHF Present n=95)

Severity of CHF	Number of Cases	Percentage (%)
Mild	38	40.00
Moderate	34	35.79
Severe	23	24.21
Total	95	100

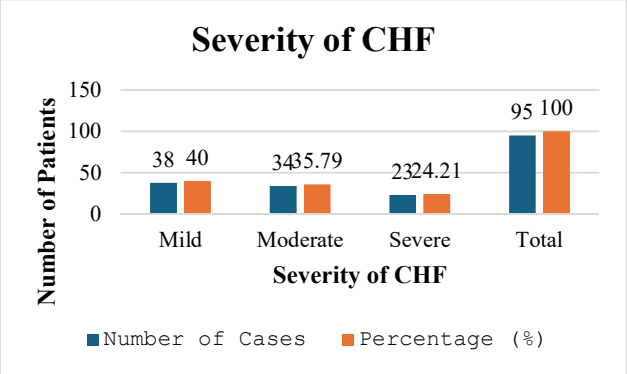


Fig .12 Among the 95 CHF patients, the majority had mild severity of CHF (38 cases, 40.00%), followed by moderate CHF (34 cases, 35.79%). Severe CHF was observed in 23 patients (24.21%). The findings indicate that most CHF cases were in the mild to moderate category, while a smaller proportion of patients had severe CHF.

Table 13. Risk Factor-wise Distribution among CHF Patients (n=95)

Risk Factor	Present (n)	Percentage (%)
Hypertension	35	36.84
Coronary artery diseases	15	15.79
Drug related factors	10	10.52
Diabetes Mellitus	10	10.52
Cardiotoxic drugs	07	7.37
Smoking/Tobacco Use	07	7.37
Obesity	07	7.37
Family History of Cardiac Disease	02	2.11
Physical Inactivity	02	2.11
Total	95	100

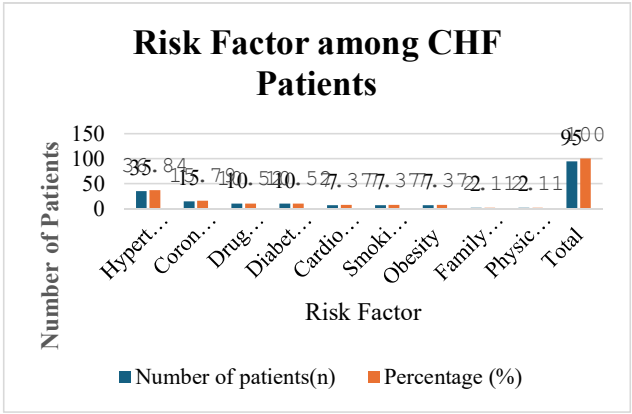


Fig 13. Among the 95 CHF patients, hypertension was the most common risk factor (36.84%), followed by coronary artery disease (15.79%). Drug-related factors and diabetes mellitus contributed 10.52% each, while cardiotoxic drugs, smoking/tobacco use, and obesity were observed in 7.37% each. Family history and physical inactivity were less common (2.11% each). Overall, hypertension was the major contributing risk factor for CHF.

Table 14: Medicine associated with CHF

Medicine/Class	Number of Patients (n=95)	Percentage (%)
Pioglitazone	18	18.95
NSAIDs	15	15.79

Calcium Channel Blockers	14	14.73
Antidiabetic agents	12	12.63
Corticosteroids	10	10.52
Beta blockers	09	9.48
ACE inhibitors/ARBs	08	8.42
Others	09	9.48
Total	95	100

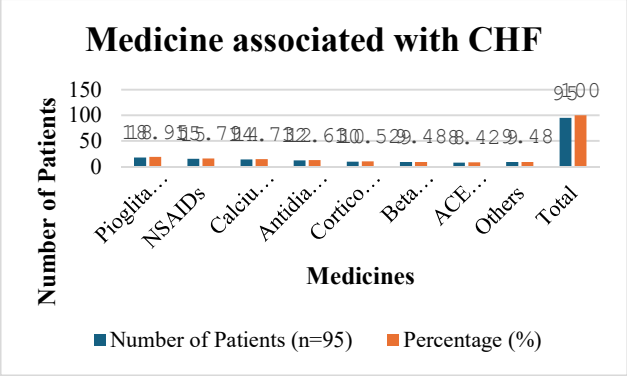


Fig 14 Among the 95 CHF patients, Pioglitazone was the most commonly associated medication (18.95%), followed by NSAIDs (15.79%) and Calcium Channel Blockers (14.73%). Antidiabetic agents (12.63%) and corticosteroids (10.52%) were also observed. Beta blockers and other medicines contributed 9.48% each, while ACE inhibitors/ARBs accounted for 8.42%. Overall, Pioglitazone and NSAIDs were the most frequently observed drug-related factors among CHF patients.

Table 15. Distribution on the basis of Angina Pectoris Status

Angina Pectoris Status	**Number of Participants**
Angina Present	63
Angina Absent	887
Total	950

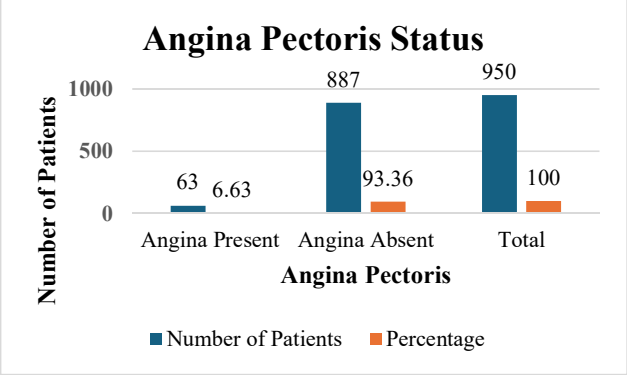


Fig. 15 Among the 950 participants, 63 patients had angina pectoris present, while 887 patients did not have angina. This indicates that angina was observed in a smaller proportion of the study population, whereas the majority of patients were free from angina symptoms.

Table 16. Severity-wise distribution of Angina Pectoris Cases (among angina pectoris present n=63)

Severity of Angina Pectoris	**Number of Cases**	**Percentage (%)**
Mild	41	65.07
Moderate	15	23.90
Severe	07	11.11
Total	63	**100**

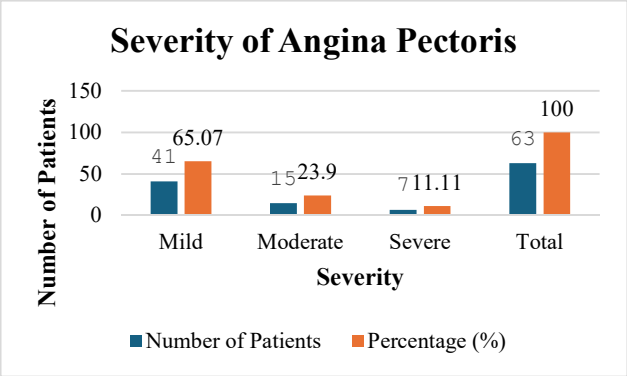


Fig 16. Among the 63 patients with angina pectoris, mild severity was most common (41 cases, 65.07%), followed by moderate severity (15 cases, 23.90%). Severe angina was observed in 7 patients (11.11%). The findings indicate that the majority of patients had mild angina symptoms, while only a smaller proportion experienced severe angina.

Table 17. Risk Factor-wise distribution among Angina Pectoris patients (n=63)

Risk Factor	Present (n)	Percentage (%)
Hypertension	33	52.90
Coronary Artery Disease (CAD)	09	14.29
Myocardial Infarction History	04	6.34
Diabetes Mellitus	10	15.87
Dyslipidemia	03	4.76
Chronic Kidney Disease/Nephropathy	02	3.17
Congestive Heart Failure	01	1.59
Cardiac Arrhythmia	01	1.59
Total	63	100

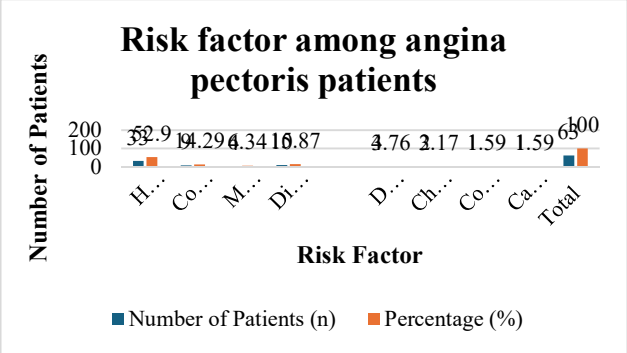


Fig 17. Among the 63 patients with angina pectoris, hypertension was the most common risk factor (52.90%), followed by diabetes mellitus (15.87%) and coronary artery disease (14.29%). A history of myocardial infarction was observed in 6.34% of patients, while dyslipidemia (4.76%) and chronic kidney disease/nephropathy (3.17%) were less common. Congestive heart

failure and cardiac arrhythmia were reported in 1.59% each. Overall, hypertension was the major contributing risk factor associated with angina pectoris.

Table 18: Medicine associated with Angina Pectoris

Medicine/Class	Number of Patients (n=95)	Percentage (%)
Amlodipine	30	18.95
Metoprolol	10	15.79
Atorvastatin	08	14.73
Nitro-glycerine	05	12.63
Losartan/Telmisartan/Olmesartan	04	10.52
Nicorandil	03	9.48
Clopidogrel	01	8.42
Others	01	9.48
Total	95	100

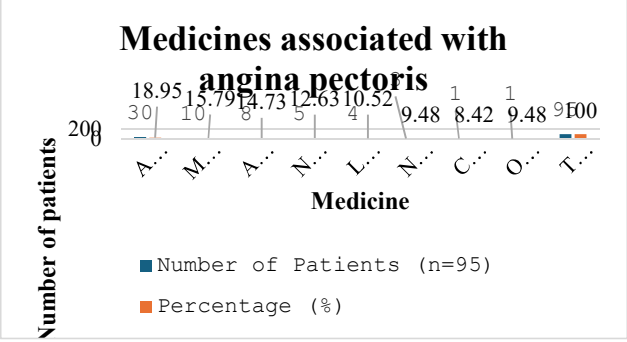


Fig 18. Among the 95 patients, Amlodipine was the most commonly used medicine (18.95%), followed by Metoprolol (15.79%) and Atorvastatin (14.73%). Nitro-glycerine (12.63%) was also frequently used for symptom management.

Losartan/Telmisartan/Olmesartan (10.52%) and Nicorandil (9.48%) were observed in some patients, while Clopidogrel (8.42%) and other medicines (9.48%) were less commonly prescribed.

Overall, Amlodipine, Metoprolol, and Atorvastatin were the most frequently used medications among the study population.

Table 19. Distribution on the basis of Coronary artery diseases Status

CAD Status	Number of Participants
CAD Present	77
CAD Absent	873
Total	950

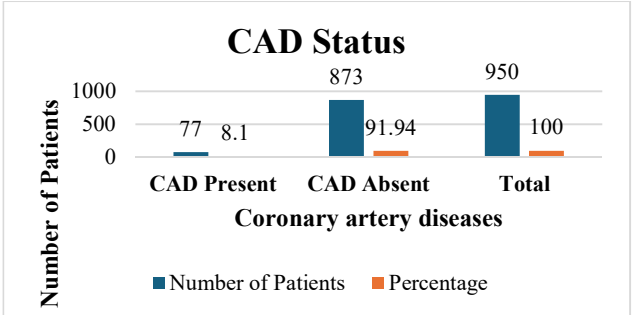


Fig 19. Among the 950 participants, 77 patients had coronary artery disease (CAD) present, whereas 873 patients did not have CAD. This indicates that CAD was observed in a smaller proportion of the study population, while the majority of participants were CAD-absent.

Table 20. Severity-wise Distribution of Coronary Artery Disease Cases (among Coronary artery diseases Present n=77)

Severity of CAD	Number of Cases	Percentage (%)
Mild	50	64.93
Moderate	20	25.97
Severe	07	9.09
Total	77	**100**

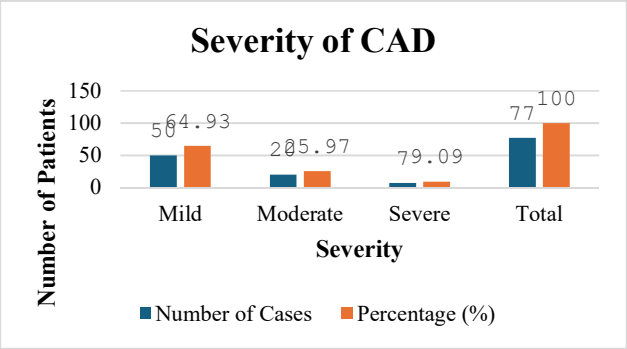


Fig 20 Among the 77 patients with coronary artery disease (CAD), mild CAD was most common (50 cases, 64.93%), followed by moderate CAD (20 cases, 25.97%). Severe CAD was observed in 7 patients (9.09%). The findings indicate that the majority of patients had mild CAD, while only a smaller proportion had severe disease.

Table 21. Risk Factor-wise distribution among coronary artery diseases (n=77)

Risk Factor	Present (n)	Percentage (%)
Hypertension	46	52.90
Diabetes Mellitus	10	14.29
Dyslipidemia	07	6.34
Smoking / Tobacco Use	03	15.87
Obesity	02	4.76
Physical Inactivity	02	1.59
Unhealthy diet	02	1.59
Total	77	100

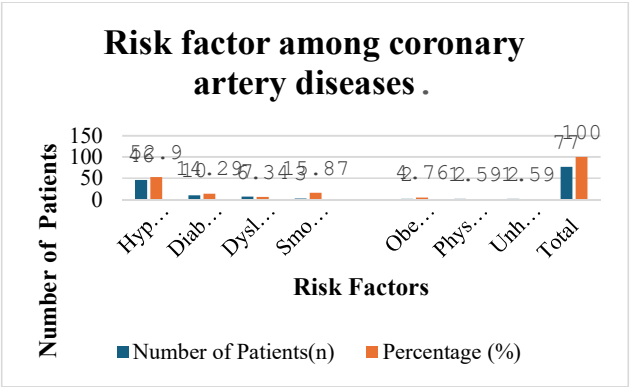


Fig 21. Among the 77 CAD patients, hypertension was the most common risk factor (52.90%), followed by diabetes mellitus (14.29%). Dyslipidemia was present in 6.34% of patients, while smoking/tobacco use accounted for 15.87%. Obesity (4.76%), physical inactivity (1.59%), and unhealthy diet (1.59%) were less frequently observed. Overall, hypertension was the major contributing risk factor associated with CAD in the study population.

Table 22: Medicine associated with angina pectoris

Medicine/Class	Number of Patients (n=77)	Percentage (%)

Amlodipine	37	48.05
Aspirin	10	12.98
Atorvastatin	10	12.98
Rosuvastatin	04	5.19
Perindopril	03	3.89
Calcium Supplements	10	12.98
Metformin Combination therapy	03	3.89
Total	77	100

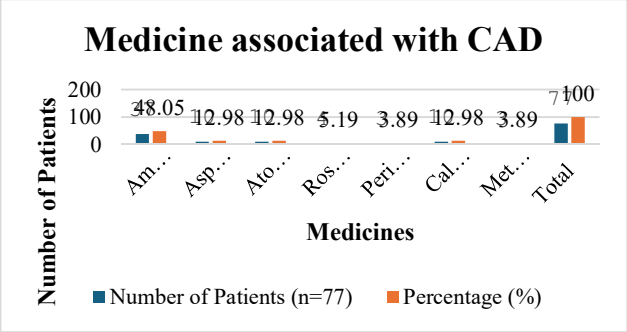


Fig 22 Among the 77 CAD patients, Amlodipine was the most commonly used medicine (48.05%), followed by Aspirin, Atorvastatin, and Calcium supplements (12.98% each). Rosuvastatin was used in 5.19% of patients, while Perindopril and Metformin combination therapy were used in 3.89% each. Overall, Amlodipine was the most frequently prescribed medication among CAD patients.

CONCLUSION:

The present study highlights the importance of pharmacovigilance in identifying and evaluating adverse drug reactions (ADRs) associated with cardiovascular medications. A total of 1100 ADR reports were analysed, out of which 950 (86.36%) were accepted after validation, indicating the effectiveness of ADR reporting and monitoring practices. Cardiovascular diseases such as myocardial infarction, atherosclerosis, congestive heart failure, angina pectoris and coronary artery disease were associated with multiple risk factors, with hypertension being one of the most commonly observed contributing factors. [1,13]

The study findings indicate that commonly prescribed cardiovascular medicines, including antihypertensive drugs, antiplatelet agents, lipid-lowering agents, and other cardiovascular therapies, provide significant therapeutic benefits but may also contribute to medication-related risks when used for prolonged durations or in combination with multiple drugs. Continuous monitoring, early detection and proper assessment of ADRs are essential to minimize preventable complications and improve patient safety. [10,11].

The results emphasize the need for effective pharmacovigilance programs, rational prescribing practices and regular medication review among cardiovascular patients, particularly those with multiple comorbidities. Implementation of appropriate monitoring strategies can help optimize treatment outcomes, reduce ADR-related morbidity and enhance the overall quality of cardiovascular care. [14, 15, 16]

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CONFLICTS OF INTEREST

Conflict of Motivation The authors declare no financial or various disputes of interest pertaining to this work.

DATA AVAILABILITY

The paper itself has data that backs up the study's conclusions. The related author will provide you the data if you ask for it.

Dispute Requiring Use of AI-Assisted Technology

There was no AI employed to write or edit the book, and AI techniques were not utilized to change the pictures.

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