Meta Analysis

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A prospective observational study to assess the cardiac risk factors and treatment patterns in established heart diseases

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1. Introduction

<u>ABSTRACT</u>

The study aimed to assess established and non-established risk factors and drug therapy problems in the cardiology department and perform a Prospective Observational Study. The study was conducted for a period of 6 months from September 2019 to February 2020 in 200 patients with established heart diseases attending a tertiary care hospital in the cardiology department. A patient interview was conducted using an evaluation form. Among 100 patients with established cardiovascular diseases that were engaged in this study, a high number of patients were males and the majority of the patients were in the age group 'Between' 41-60 years. This study shows smoking and alcohol consumption is the most common risk factors in males, hypertension was the mainly 'established' risk factor for cardiovascular disease followed by Angina and Myocardial infarction. Among non-established risk factors, CKD was the main risk factor in cardiovascular disease followed by cardiovascular accidents. ACE Inhibitors and BB are the drugs mainly used in cardiovascular diseases followed by statins and diuretics. This study throws light on the statistical evidence among the age group and gender risk factors, and drug utilization. In the course of this study use of drug pattern was as follows: Anticoagulants are used in (29%) patients, ACE in (22.5%) patients, Antiplatelets in (68%) patients, diuretic in (34%) patients, Statins in (57%) patients, BB in (67.5%) patients, PPI in (22%) patients, CCB in (19.5%) patients, Nitrates (26.5%) patients, OHA (25%) patients. Similar findings in other studies (Blessy Rachel Thomas) (26) on drug therapy usage were found. There is a need to assess both nonestablished and established risk factors among patients with established heart diseases as in this study, CKD and HTN were the most common peril and counsel patients about their risk factors and social habits and lifestyle changes. There is a need for a clinical pharmacist to counsel about lifestyle changes and assess drug therapy utilization patterns in cardiac patients.

Cardiovascular diseases (CVDs) are a group of disorders of the heart and blood vessels.

They include Hypertension, Coronary heart disease, Myocardial Infarction, Dyslipidemia, Arrhythmia, Congestive cardiac failure, Deep vein thrombosis and pulmonary embolism[1].

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In recent years, the dominance of chronic diseases as major contributors to total global mortality has emerged and has been previously described in detail elsewhere[2].

Bv 2005, the total number of cardiovascular disease (CVD) deaths (mainly coronary heart disease, stroke, and rheumatic heart disease) had increased globally to 17.5 million from 14.4 million in 1990. Of these, 7.6 million were attributed to coronary heart disease and 5.7 million to stroke[3, 4]. More than 80 percent of the deaths occurred in lowand middle-income countries. The World Health Organization (WHO) estimates there will be about 20 million CVD deaths in 2015, accounting for 30 percent of all deaths worldwide. The projected trends in CVD mortality and the expected shifts from infectious to chronic diseases over the next few decades [5, 6].

The poorest people in low- and middleincome countries are most affected. At the household level, evidence is emerging that CVDs and other non-communicable diseases contribute to poverty due to catastrophic health spending and high out-of-pocket expenditure. At the macro-economic level, CVDs place a heavy burden on the economies of low- and middle-income countries[7, 8].

By 2030, researchers project that noncommunicable diseases will account for more than three-quarters of deaths worldwide; CVD alone will be responsible for more deaths in low-income countries than infectious diseases (including HIV/AIDS, tuberculosis, and malaria), maternal and perinatal conditions, and nutritional disorders combined. Thus, CVD is today the largest single contributor to global mortality and will continue to dominate mortality trends[5, 6, 9].

Globally, there is an uneven distribution of age-adjusted CVD mortality that is being mapped. The lowest age-adjusted mortality rates are in advanced industrialized countries and parts of Latin America, whereas the highest rates today are found in Eastern Europe and a number of low- and middleincome countries[10, 11]. For example, agestandardized mortality rates for CVD are in excess of 500 per 100,000 in Russia and Egypt; between 400 and 450 for South Africa, India and Saudi Arabia; and around 300 for Brazil and China. This is in contrast to rates of between 100 and 200 per 100,000 for Australia, Japan, France, and the United States. Overall, age-adjusted CVD death rates are today higher in major low- and middle-income countries than in developed countries [5, 6, 9-11].

Direct etiologists of CVD, as seen in some patients are patient atrial fibrillation resulting in ischemic stroke, and rheumatic fever causing valvular heart disease. In others, assessing risk factors for atherosclerosis is most important as it is a common attribute in the pathophysiology of CVD. Specifically, physical inactivity, intake of high-calorie, saturated fat, and sugars are associated with the development of atherosclerosis and others like metabolic syndrome, diabetes mellitus, and hypertension that are highly prevalent in people with CVD [12, 13].

The most important behavioral risk factors for heart disease and stroke are unhealthy diets, physical inactivity, tobacco use and harmful use of alcohol. The effects of behavioral risk factors may show up in individuals with raised blood pressure, raised blood glucose, raised blood lipids, and overweight and obesity. These "intermediate risk factors" can be measured in primary care facilities and indicate an increased risk of heart attack, stroke, heart failure and other complications[14, 15].

Cardiovascular diseases are diagnosed using an array of laboratory tests and imaging studies. The primary part of diagnosis is the medical and family histories of the patient, risk factors, physical examination and coordination of these findings with the results from tests and procedures [16-18]. Some of common tests used to diagnose the cardiovascular diseases include Blood Tests. Laboratory tests are used to detect the risk factors for heart diseases. These include the detection of the fats, cholesterol, and lipid components of blood including LDL, HDL, and triglycerides. Blood sugar and glycosylated haemoglobin are measured for the detection of diabetes. C-reactive protein (CRP) and other protein markers like Apolipoprotein A1 and B are used to detect inflammation that may lead to heart diseases. During a heart attack, heart muscle cells die and release proteins into the bloodstream. High levels of these proteins are a sign of a recent heart attack. One of the markers of heart attack is the Cardiac Troponin-T. Other biomarkers include fibrinogen and PAI-1, high levels of homocysteine, elevated asymmetric dimethylarginine, and elevated brain natriuretic peptide (also known as B-type) (BNP)[<u>19</u>, <u>20</u>].

KG/ECG(Electrocardiogram),Echocardiogr aphy, Coronary Angiography and Cardiac Catheterization, Chest X-Ray, Electron-Beam Computed Tomography or EBCT, and Cardiac MRI[<u>21</u>, <u>22</u>]. If not properly controlled, diabetes can lead to heart disease and heart damage, including heart attacks. Control diabetes through a healthy diet, exercise, maintaining a healthy weight, and medication as prescribed by your doctor[<u>23</u>, <u>24</u>].

some researches, а significant In correlation was shown between the seasonal increase in saturated fat and the increase in BMI (r= 0.37), total cholesterol and LDL cholesterol. Seasonal change in dietary cholesterol intake was significantly and positively correlated with serum total cholesterol (r= 0.24) and LDL cholesterol (r= 0.24). Blood pressure was not associated with nutritional intake variables. Dietary intake in summer and winter is different as well as blood pressure, BMI and serum cholesterol. The seasonal increase in fat and cholesterol intake at winter time is associated with changes in BMI and serum cholesterol [25-<u>27</u>].

Comparatively, cardiovascular diseases are showing an escalated trend nowadays due to lifestyle changes and social habits. Among chronic illnesses, cardiovascular disorders are more common in the world. Over 80% of cardiovascular fatalities are seen in underdeveloped and developing countries, most of these deaths are due to modifiable risk factors. In established cardiovascular disease there is a greater need to assess the prescription pattern and educate the patient about their condition, modified risk factors, and lifestyle adaptations that help them to their symptoms, manage prevent complications, and have a better therapeutic and pharmacoeconomic outcome[<u>28</u>, <u>29</u>]. This study aimed to assess established and nonestablished risk factors and drug therapy problems in the cardiology department and perform a Prospective Observational Study.

2. Material and methods

2.1. study design

• The study is a prospective Observational study.

2.2 source of data and materials

- Patient consent form
- Patient Data Entry Form
- Framingham Risk Score Scale

2.3 inclusion criteria

- Patients with established cardiovascular diseases of the cardiology department.
- The patient who has undergone major surgeries on heart.
- The patient who is willing to give their consent.

2.4 exclusion criteria

- Pediatric Patients.
- Patients with autoimmune Cardiovascular Diseases.
- Pregnant women.

2.5 method of data collection

- Data Collection Form
- Patient questionnaire/interview
- Framingham Risk Score Scale

2.6 STUDY PROCEDURE

This is a prospective observational study where patient's eligible is enrolled in to the study after obtaining consent. The data collection form will be prepared and used. This form mainly contains the demographic details of the patient and the medication chart. The study will be conducted at SVS Medical College hospital. All information relevant to the study will be collected at the time of admission till the date of discharge and the data will be analyzed using suitable methods for statistical analysis.

2.7 Does the study require any investigation or intervention to be conducted on patients?

• No

2.8 Has ethical clearance been obtained from your institution in case of the above?

• The ethical committee clearance will be obtained from the Institutional Ethical Committee of SVS Medical College Hospital before initiating the study.

2.9. Duration of the study

• The study will be conducted for a period of 6 months

2.9.1. Place of study

• The study will be conducted at SVS Medical College & Hospital.

2.10. Plan of work

- 2. 10. 1. Screening of all patients visiting with Cardiac heart diseases
- 2. 10. 2. Enrolling of patients for study after taking their consent
- 2. 10. 3. Demographic details and other details will be recorded by using the patient data collection form
- 2. 10. 4. Patient will be interviewed for the comorbidities and complications of the disease.
- 2. 10. 5. Previously used and currently using drugs of various classes will be analyzed for the assessment treatment regimen
- 2. 10. 6. Patient will be interviewed specifically for fulfillment of the purpose of the objectives of this study
- 2. 10. 7. After the collection of data statistical analysis will be done

- 2. 10. 8. Results will be interpreted after analysis of data
- 2. 10. 9. Finally result will be concluded and the impression will be highlighted.

3. Results

The prospective observational study was conducted at SVS medical college and hospital. A total of 100 patients were observed.

3.1. Prevalence of CVD in different age groups

According to the obtained data, CVD is highly prevalent 'between' 41-50 years age group i.e., 42 patients followed by 71-80 years age group i.e., 28 patients and least prevalent in 51-70 years of age i.e., 15 patients (Figure 1). According to the obtained data, it is observed that CVD is highly prevalent in Males with 71% and least in Females with 28%.

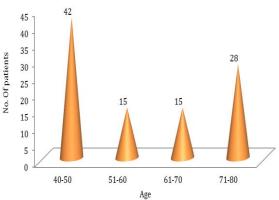


Fig. 1. Bar graph showing the prevalence of cvd in different age groups.

3. 2. Prevalence of various diseases in CVD

During this study, we found that patients with Hypertension were seen more frequently followed by Angina pectoris, Myocardial infarction and Dyslipidemia (Table 1).

Table 1.	Various diseases in CVD		
Disease	No. of patients	Percentage	
Hypertension	37	51%	
Angina Pectoris	17	24%	
Myocardial Infarction	13	18%	

05

07%

Dyslipidemia

3. 3. Comorbidities in cardiovascular disease

During this study, we found that patients are having major comorbidity of Hypertension with Thyroid and the least was Dyslipidemia with Angina (Figure 2).

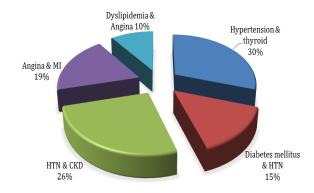


Fig. 2. Pie chart showing the prevalence of comorbidities in CVD

3. 4. Distribution of CVD patients based on social habits

3.4.1. Distribution based on smoking

In this study, we have found that Smokers are at high risk of cardiac diseases at about 65%.

3.4.2. Distribution based on alcohol

A higher number of heart diseases in this study were found in Alcoholic patients with 68%.

3. 5. Commonly prescribed drugs in CVD

According to the obtained data, CVD is mostly treated with Statins apart from PPI as it is used only to reduce the gastric acid secretion in the stomach, later followed by ACE Inhibitors, Diuretics, CCB, Beta-blockers and Anticoagulants. Among these, the least prescribed drugs were Beta Blockers and Anti-coagulants (Table 3).

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Adjuvant therapy	Drugs prescribed to no. Ofpatients	Percentage
Anticoagulants	08	08%
ACE Inhibitors	15	15%
Diuretics	12	12%
Beta blockers	08	08%
Statins	18	18%
CCB	10	10%
PPI	23	23%

3. 5. 1. Anticoagulant treatment in CVD

In this study the most frequently used drug was found to be Enoxaparin Sodium with 62.5% and the least used drug was Heparin with 12.5% besides Warfarin with 35% (Figure 3).

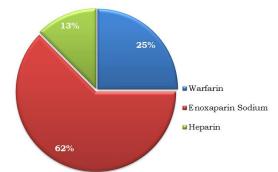


Fig. 3. Pie chart showin ganticoagulant treatment in $\ensuremath{\mathsf{CVD}}$

3. 5. 2. Ace inhibitor therapy prescribed to CVD patients

Among 100 patients the most frequently used drug was found to be Captopril with 53.4% followed by Enalapril with 26.6% and Lisinopril with 20% (Table 4).

Table 4. Prevalence of ace inhitor therapy	

Ace inhibitor therapy	Drugs prescribed to no. Of patients	Percentage
Captopril	08	53.4%
Enalapril	04	26.6%
Lisinopril	03	20%

3.5.3. Diuretics therapy used in treating CVD

Among 100 prescriptions prescribed to patients the most commonly prescribed drug was Furosemide.

3. 5. 4. Beta-blockers therapy given to CVD patients

The most commonly used drug in this study was found to be Metoprolol with 62.5% and the least commonly used drug was found to be Carvedilol with 12.5% (Figure 4).

3. 5. 5. Statins therapy in specified CVD patients

According to this study Among 100 prescriptions, the most commonly prescribed drug was Rosuvastatin.

Atenolol

5

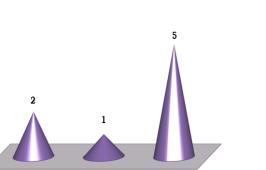
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3

2

1

0



Metoprolol

DRUGS PRESCRIBED TO NO. OF PATIENTS

Carvedilol

Fig. 4. Column chart showing beta-blockers therapy given to cvd patients

3. 5. 6. Calcium channel blocker therapy is given for CVD patients

Among 100 patients the most commonly used drug was found to be Nefidipine with 60% and the least commonly used drug was found to be Amlodipine with 10% and the other was Cilidipine with 30% (Figure 5).

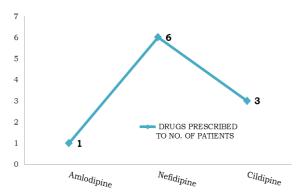


Fig. 5. Calcium channel blocker therapy given for CVD patients

5. 6. 7. Proton pump inhibitor therapy in the study group

The most frequently prescribed drug in this study was found to be Pantoprazole with 52.2% followed by Rabeprazole with 30.4% and Esmoprazole with 17.4% (Table 5).

Table 5. Prevalence of proton pump inhibitor

 therapy

s prescribed to b. Of patients percentage
F
12 52.2%
07 30.4%
04 17.4%

4. Discussion

The study population of 100 subjects comprised 72 males and 28 females. Data collection was based on a review of medical files and interview and risk assessment for 6 months. In this study, it was observed that the maximum number of patients were in the middle age group 41-60 years followed by the age group 61-80 years such as in another study maximum in the middle age group. In the course of this study use of the drug, the pattern was as follows: Anticoagulants are used in (08%) of patients, ACE in (15%) patients, diuretic in (12%) of patients, Statins in (18%) of patients, BB in (08%) patients, PPI in (23%) patients, CCB in (10%) patients. Similar findings in other studies [30, 31] in drug therapy usage were found.

Conducted a prospective cohort study comprising a population of 8698 men and women aged 35–65 years who were recruited the Mashhad Stroke and from Heart Atherosclerotic Disorder (MASHAD) study. Socioeconomic and demographic status, anthropometric laboratorv parameters, evaluations, lifestyle factors, and medical history through were gathered а comprehensive questionnaire and laboratory and clinical assessment for all participants[32].

Cox regression model and 95% confidence interval (CI) were used to evaluate the association of dyslipidemia and its components with CVD incidence. After 6 years of follow-up, 233 cases of CVD (including 119 cases of unstable angina [US], 74 cases of stable angina [SA], and 40 cases of myocardial infarction [MI]) were identified in the study population. However, after adjusting for confounding factors (age, body mass index [BMI], family history of CVD, smoking status [non-smoker, ex-smoker and current smoker], lipid-lowering drug treatment. antihypertensive drug treatment, hypertension, healthy eating index [HEI], total energy intake, and presence of diabetes mellitus), a significant direct association only remained between TC and MI risk in men (HR: 2.71; 95%CI: 1.12-6.57; P-value< 0.05)[32]. In the present study, TC baseline level was significantly associated with the risk of MI among men

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Conducted a study is Chronic kidney disease (CKD) is associated with accelerated cardiovascular disease (CVD) risk and a higher CVD event rate. Substantial data from prospective cohort studies support the concept that dialysis patients as well as those with advanced stage (stages 3-5) CKD are associated with an increased risk for all-cause and cardiovascular mortality. The risk for coronary artery disease (CAD) increases exponentially with declining kidney function, i.e., stage 3 or higher CKD. Indeed, CVD accounts for more than 50 % of deaths in patients with CKD. CKD patients are more likely to die of CVD than to progress to endstage kidney disease. This increase in CV risk is commonly attributed to the co-existence of numerous traditional and nontraditional risk factors for the development of CVD that frequently accompany reduced kidney function. Therefore, CKD itself is now considered an independent CVD risk factor a coronary artery disease (CAD) and equivalent to all-cause mortality. All patients at risk for CAD should be evaluated for kidney disease. Treatments used for the management of established CAD might have similar benefits for patients with concomitant CKD[33]. In this studv cigarette smoking and alcohol consumption were found to be higher in male patients. In this study, 9 male and 3 female patients with already established CVD's were with CKD showing CKD itself as one of the risk factors for CV co-morbidities. As in other studies, Andreas Kuznik1 in their study shows CKD have a high prevalence of CV-related Comorbidities. Department of Pharmacy Practice. Ivothishmathi Institute of Pharmaceutical Sciences.

Limitations and recommendations will be as follow:

- The time period of this study was limited due to which we could not enroll more no of cases.
- As the study was very time-consuming we could not conduct this study in a large population.
- This study can be further followed to study different types of cardiac diseases along with their treatment patterns.

- One can also study the adverse drug effects and drug interactions of the prescribed treatment in the patients.
- Go for day-to-day progress on the use of medication and Observe the change in symptoms after medication use.
- The population included in this study belongs to one origin. Involvement of different origins may have some impact on the present findings.

5. Conclusion

In this study, having assessed these two factors in terms of age, gender, social history, and concurrent use of drug therapy we have arrived at the following conclusion. In cardiovascular disease risk, factors and drug therapy are crucial. Among 100 patients with established cardiovascular diseases that were engaged in this study, a high number of patients were males and the majority of the patients were in the age group 'Between' 41-60 years. In this study hypertension was the mainly 'established' risk factor for cardiovascular disease followed by Angina, Myocardial infarction. Among non-established risk factors, CKD was the main risk factor in cardiovascular disease followed bv cardiovascular accidents. This study shows smoking and alcohol consumption is the most common risk factors in males.

This study shows ACE Inhibitors and BB are the drugs mainly used in cardiovascular diseases followed by statins and diuretics. This study throws light on the statistical evidence among the age group and gender risk factors, and drug utilization. These findings fortify many such earlier findings from well-established studies leading to an increasing need for initiating studies that limit their objectives to assess risk factors and drug patterns in established heart disease. In the course of this study use of the drug, the pattern was as follows: anticoagulants are used in (08%) of patients, ACE in (15%) patients, diuretic in (12%) of patients, Statins in (18%) of patients, BB in (08%) patients, PPI in (23%) patients, CCB in (10%) patients.

This study has accentuated the importance of analyzing risk factors and drug utilization in cardiovascular diseases thereby reducing the burden of heart diseases and improving the quality of life.

Abbreviation

CAD: Coronary Artery Disease CI: Confidence Interval CRP: C-Reactive Protein CVDs: Cardiovascular Diseases MI: Myocardial Infarction SA: Stable Angina US: Unstable Angina WHO: World Health Organization

Conflict of Interest

The authors hereby declare that they have no conflict of interest.

Author's contributions

All authors equally participated in designing experiment analysis and interpretation of data. All authors read and approved the final manuscript.

Consent for publications

All authors have read and approved the final manuscript for publication.

Availability of data and material

The authors have embedded all data in the manuscript.

Ethics approval and consent to participate

The authors did not use human or animals in the research

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