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PROSPECTIVE OBSERVATIONAL STUDY ON DRUG UTILIZATION REVIEW FOR CARDIOVASCULAR DISEASES IN TERTIARY CARE TEACHING HOSPITAL

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Abstract:

Background: *CVD remains the most non-communicable reasons for death and its prevalence is increasing nowadays. DUR plays an important role in helping the health care systems understand, clarify and improve the prescribing pattern, medication use.*

Aims And Objectives: *The objectives of this study are to observe types of Cardiovascular Diseases (CVD) and find out its prevalence, to review risk factors and co-morbidities contributing to worsening of CVD among the patients. This study aims to analyse the prescribing patterns of CVD drugs, track drug-drug interactions and any Adverse Drug Reactions (ADR) as well as to determine patient's compatibility to medication adherence.*

Methodology: *A prospective observational study was carried out at tertiary care teaching hospital over the course of six months. Study included patients with age above 18 years of either sex or any co-morbidity; patients with symptoms possibly related to CVD and receiving continuous care. Patients with coagulation disorders with bleeding manifestations, malignancies, congenital diseases, COVID -19, pregnant and nursing mothers, uncooperative and unconscious patients and who reported using indigenous medications were excluded.*

Results: *A total of 118 cases were collected, consisting of 60 females (50.84%) and 58 males (49.15%). Patients in the age group of 51-60 years (26.27%) were most afflicted. The two most prevalent diseases in the study were CVA (31.35%) and CAD (20.33%). The most universal risk factors and co-morbidities were hypertension (70.33%) and diabetes mellitus (38.13%). Alcohol (33%) and smoking abuse (16.94%) were the next prevailing factors. Statins (71.18%), anti-platelets (70.33%) and diuretics (57.62%) were commonly prescribed drugs. Possible drug-drug interactions were listed. Drugs prescribed from NLEM and in generic at lower rates, and polypharmacy was evident which led to injection and antibiotic overuse, according to standard values of WHO indicators. Majority of patients were medium (50.84%) to low (39.83%) adherent to medications. Using Naranjo scale, ADRs were assessed.*

Conclusion: *CVD is on rise in patients owing primarily to lifestyle habits, followed by risk factor contribution and low compliance to medications. DUR using WHO indicators aided in observing the prescribing trends of drugs, polypharmacy which ultimately led to high probability of drug interactions, ADR and drug misuse.*

Keywords: Cardiovascular diseases, Drug utilisation review, polypharmacy.

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INTRODUCTION:

Cardiovascular disease (CVD) has become the leading cause of death in the developing countries. This epidemic has the potential to inflict a significant social and economic burden on nations with limited resources, given that CVD primarily affects those in their most productive years of employment.[1] Estimates indicate that 17.9 million people worldwide suffer from cardiovascular diseases each year. CVDs refer to an array of heart and blood vessel ailments that include coronary heart disease, cerebrovascular disease, rheumatic heart disease, and others.[2] The etiological risk factors that contribute to the development of cardiovascular diseases (CVDs) are well-known and comprise obesity, smoking, diabetes, hypertension, hyperlipidemia, and physical inactivity. Collectively, they account for almost 90% of the risks of CVD in all epidemiological analyses. Despite the high death rate associated with CVDs, the global epidemic of these diseases can be considerably curbed by identifying and carefully preventing the underlying risk factors.[3] Drug therapies are essential for the treatment of CVDs and if not used appropriately, they may have unfavorable effects. The treatment of CVDs continues to be complicated in clinical practice because of intricate medication regimens, a large variety of drugs available, various comorbidities, polypharmacy, advanced age, and a lack of adherence to evidence-based guidelines.[4] Furthermore, using multiple drugs raises the risk of unwanted drug reactions and interactions in addition to cost and complicated regimens.[5]

Irrational use of medicines is a major concern on a global scale. According to WHO estimates, half of patients do not take their medications as recommended and over half of all medications are improperly sold, administered, or prescribed.[6] There are multiple aspects that influence rational prescribing such as; the medical state of patients, beliefs, values and prescribing practices of physicians, the working atmosphere within the health system, the medication supply system and regulation.[7] The key components for the rational use of medications include a proper diagnosis, an accurate prescription, proper dispensing, suitable packaging, and effective patient counseling.[5]

The development of drug usage as research area enabled to study drug use in a scientific manner. Drug utilization studies have proven to be an effective tool for assessing the standard of the healthcare system. The ultimate goal of drug utilization research is to determine the best possible quality of drug therapy by the identification, documentation, analysis, and monitoring of drug utilization issues and their effects. Drug use research promotes the rational prescribing of medications, advances our understanding of how drugs are currently used in society, and investigates whether a specific intervention has an impact on drug use by the general public by analyzing drug use patterns.[8] Evaluation also tends to focus on medications that are expensive, have a high side effect profile, or require complex dose schedules.[9] In an effort to promote proper therapeutic decision-making and favorable patient outcomes, it includes a thorough examination of a patient's prescription and medical history before, during, and after dispensing.[8]

In order to improve the quality of life of patients, the aim of this study was to assess the trend in drug prescribing and to observe rational prescribing using WHO prescribing indicators for cardiovascular diseases in the inpatient department of a tertiary care teaching hospital.

METHODOLGY:

STUDY DESIGN

A hospital based Prospective Observational study.

LOCATION OF STUDY

The study was carried out in Department of General Medicine, Osmania General Hospital, a Tertiary Care Teaching Hospital.

STUDY PERIOD

The study was carried out for the period of 6 months.

STUDY POPULATION

A sample size of 100 or more patients with complaints related to cardiovascular diseases.

SELECTION CRITERIA

(1) Inclusion criteria

- Patients of either sex (male or female).
- Patients above 18 years of age.
- Patients with typical and atypical symptoms suspicious for CVD and on-going pharmacological management for CVD.
- Patients with any co-morbidity.

Exclusion criteria

- Pregnant women and lactating mothers.
- Patients who reported to have consumed indigenous (Ayurveda and homeopathy) medicines.
- Unconscious and non-cooperative patients.
- Covid-19 patients and terminally ill cancer patients.

Congenital diseases and coagulation disorder patients with bleeding manifestations

1. RESULTS AND OBSERVATIONS

Our study, carried out at Osmania General Hospital, a tertiary care teaching hospital, provides an insight into the goals of observational research on cardiovascular diseases, especially about their prevalence and prescribing practices for cardiovascular medications.

The data collected on patient profile form for CVDs during the study period was analysed according to various objectives.

During the study period of six months, at Department of General Medicine, Osmania General Hospital, Hyderabad, a total of 118 cases of CVDs were documented and the results were concluded.

2. AGE AND SEX DISTRIBUTION OF CVDs

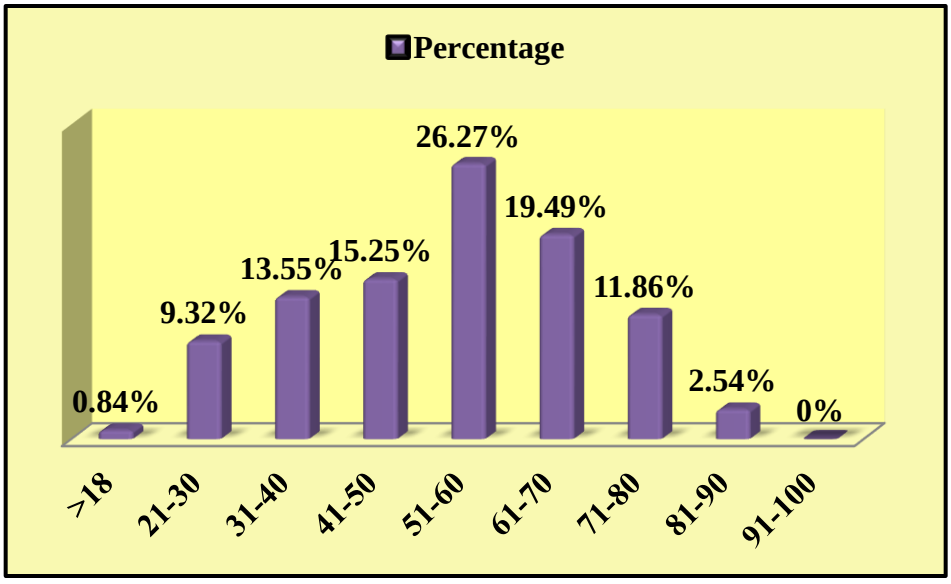
In the overall subjects encountered, 60 females (50.84%) and 58 males (49.15%) were observed to be afflicted with CVDs. The details of sex distribution pattern are shown in the Table 1 (a) and Figure 3 (a).

The patient's suffering from CVD was highest in the age range of 51-60 years (26.27%) followed by 61-70 years (19.49%) and 41-50 years (15.25%) (Observed range was 18-99 years of age). Table 1 (b) and Figure 3 (b) shows the age distribution pattern analysed during the study.

TABLE 1 : DEMOGRAPHIC PROFILE OF PATIENTS

Demographic profile	No. of patients	Percentage (%)
Female	60	50.84%
Male	58	49.15%

FIGURE 1 (a): AGE DISTRIBUTION PATTERN



2.PREVALANCE STUDY ON CARDIOVASCULAR DISEASES

In our prevalence survey, Cerebrovascular accidents (31.35%) and Coronary artery disease (20.33%) were the two CVDs that were more frequently found. When opposed to 6 patients with haemorrhagic stroke (5.08%), ischemic stroke (26.27%) was most frequent, in about 31 patients within CVAs. In CAD, 10 individuals presented with unstable angina (8.47%) which signals underlying heart disease. In case of myocardial infarction, 10 patients were diagnosed with NSTEMI (8.47%) indicating partial obstruction in major arteries or block in minor arteries and only 4 patients accounted for STEMI (3.38%) in which there is complete blockage of main arteries. The prevalence study

was further followed by heart failures (18.64%), venous thromboembolism (9.32%), cardiomyopathies (8.47%), hypertensive emergencies and urgencies (6.77%), arrhythmias (3.38%) and rheumatic heart disease(169%)

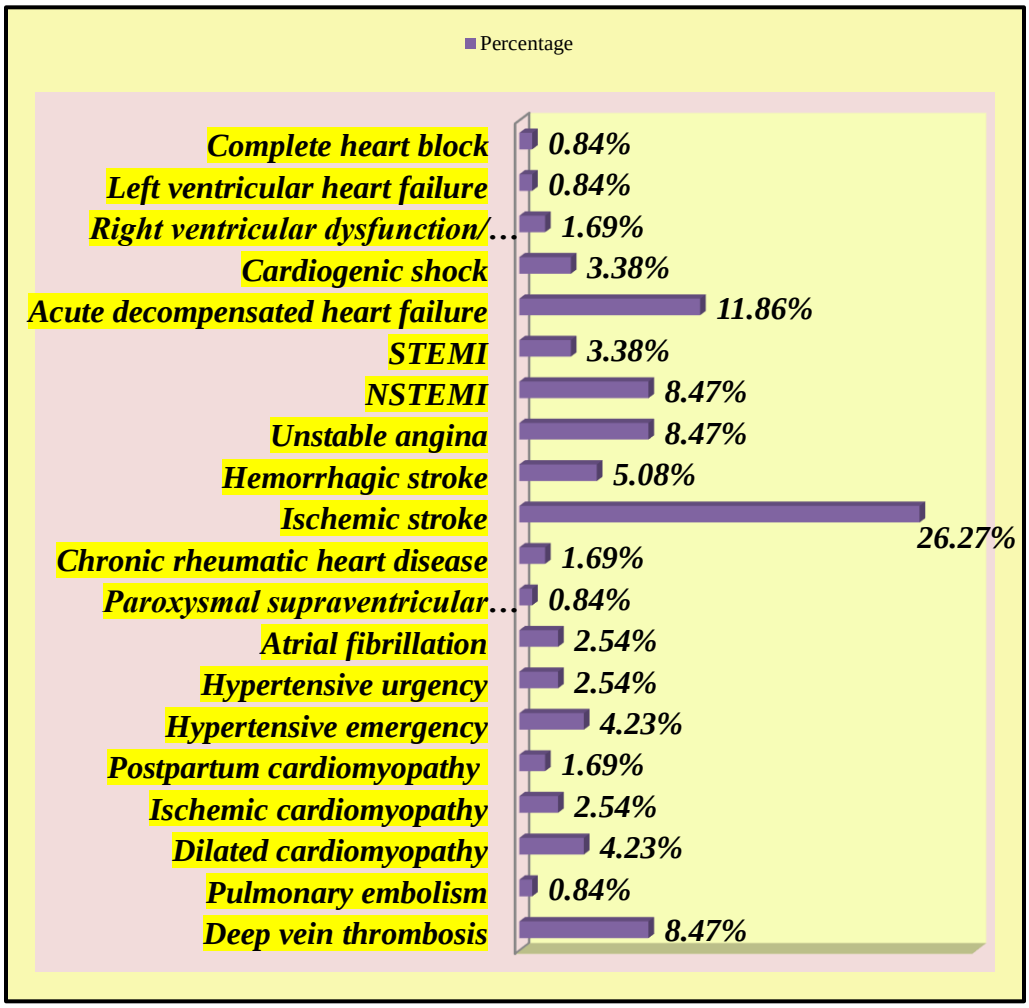


Figure 2 PREVALENCE PATTERN OF CARDIOVASULAR DISEASES

3. VARIOUS RISK FACTORS ENCOUNTERED

The most frequent risk factor observed were a cardiovascular disease, hypertension (70.33%) and a non-cardiovascular disease, Diabetes Mellitus (38.83%). Addictions such as alcohol consumption (33%) and smoking abuse (26.27%) were the next prevailing factors observed followed by chewing tobacco (16.94%) which is a form of smokeless tobacco. Around 18 patients were found to have mental illnesses, primarily stress (15.25%). Abnormalities in lipid profile i.e. dyslipidemia (12.71%) is also a leading cause. Only one patient was found to be obese (0.84%). All the above factors increase the patient's risk of CVD or exacerbation of pre-existing CVD

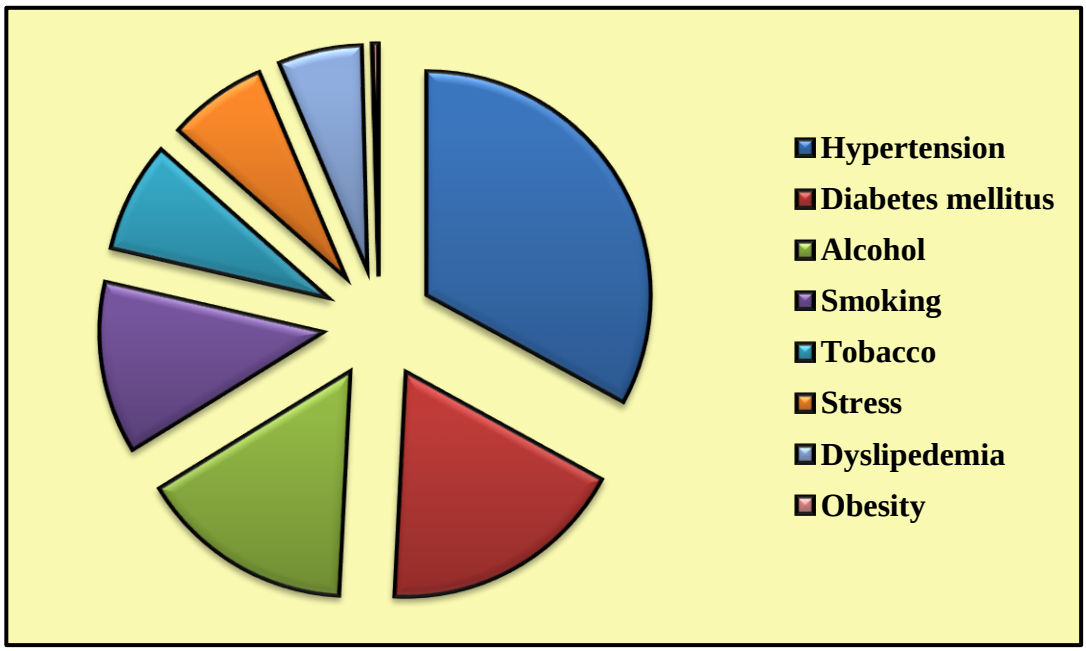


FIGURE 3: VARIOUS RISK FACTORS

4. PRESCRIBING PATTERN OF CARDIOVASCULAR DRUGS

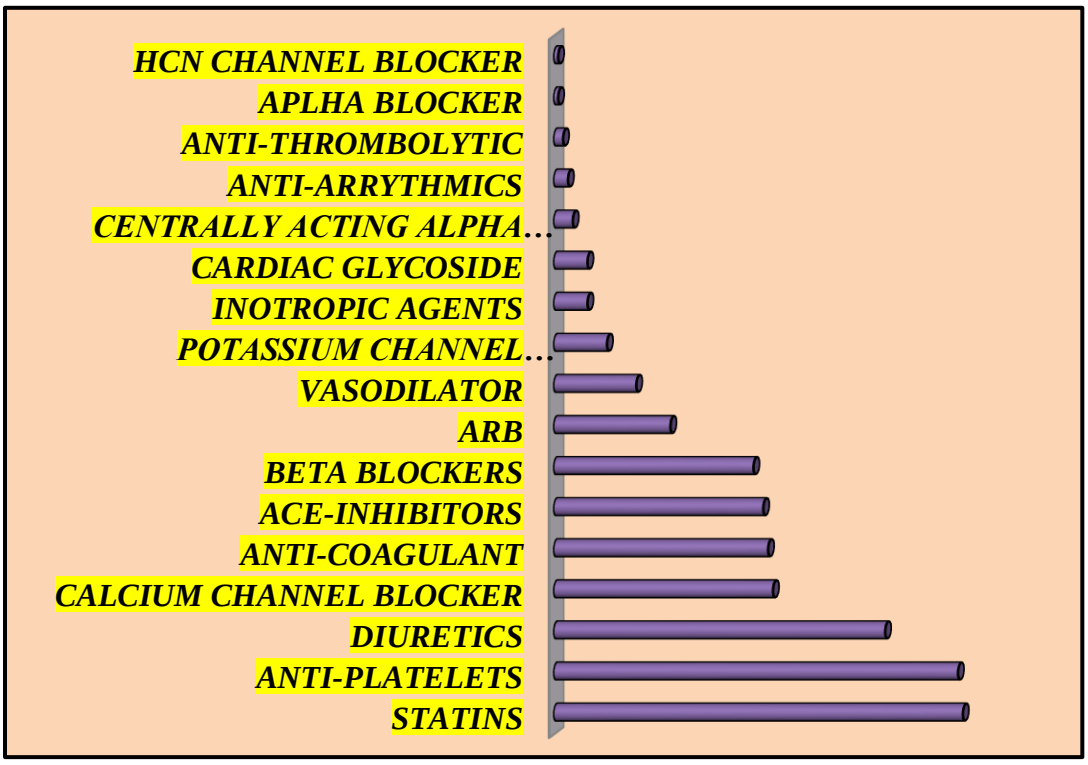


FIG 4:PRESCRIBING PATTERN OF CARDIOVASCULAR DRUGS

5. EVALUATION OF WHO PRESCRIBING INDICATORS

TABLE NO:2 EVALUATION OF WHO PRESCRIBING INDICATORS

Prescribing indicators	Results	Standard values
Average number of drugs prescribed per encounter	14.37	1.6-1.8
Percentage of drugs prescribed by generic names	31.36%	100
Percentage of encounters with an antibiotic prescribed	60.16%	20.0-26.8
Percentage of encounters with an injection prescribed	83%	13.4-24.1
Percentage of drugs prescribed from Essential drug list	54.65%	100

6. ASSESSMENT OF ADHERENCE TO MEDICATION

Determination of how well the patients were adhered to medications was done using MMAS-8 score scale. Percentage of patients who were highly compliant accounted for only about 9.32%. Majority of patients admit medium (50.84%) to low (39.83%) adherence to the medications prescribed. Considerable reasons for poor compliance were forgetfulness, financial instability and lack of information on utilization of drugs, its route, and dosage regimen.

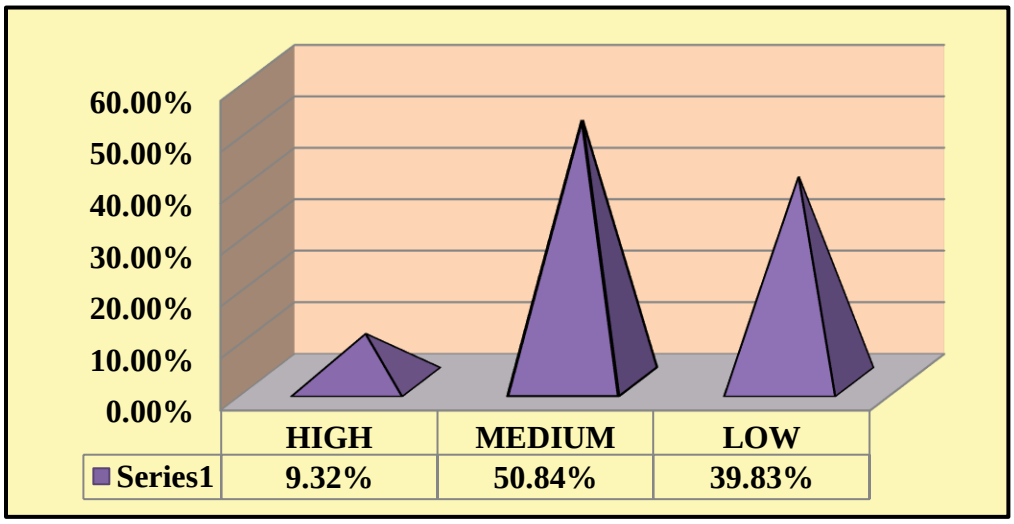


FIG 5: DISTRIBUTION OF MEDICATION ADHERENCE

7. POSSIBLE DRUG - DRUG INTERACTIONS IN PRESCRIPTIONS.

Out of 118 cases, probable drug -drug interactions observed were pharmacodynamic in action. The drug combinations with the highest incidence of drug- drug interactions were reported to be aspirin+clopidogrel in 53 patients (44.91%), atorvastatin+pantoprazole in 47 patients (39.83%) and clopidogrel+pantoprazole in 43 patients (36.44%)

8.ASSESSMENT OF ADR ENCOUNTERED

The Naranjo scale was used to measure the adverse drug reactions observed during the study period. Table depicts the reactions observed with offending drug causing ADR and corrective action taken to prevent the ADR. Table 11 gives an overview to types of ADR encountered

TABLE 3: ADR OBSERVED DURING STUDY PERIOD

S.no	Adverse drug reaction	Causative Drug	Treatment (or) alternative	Naranjo scale score
1.	Aspirin induced hematochezia	Tablet Aspirin	Inj tranexa 500mg	7-Probable
3.	Metoprolol induced bradycardia	Tablet Metoprolol	Hold Metoprolol tablet.	8-Probable
5.	UGI Bleed	Tablet Acitrom	Stop Acitrom tablet & add apixaban tablet.	5-Probable
6.	Enam induced hyperbilirubinemia (Tbil-1.91 & Dbil-1.02)	Tablet Enam	Hold Enam tablet.	3-Possible
7.	Aspirin induced gastritis	Tablet Aspirin	Hold Aspirin tablet & add inj tranexa.	3-Possible

DISCUSSION:

Cardiovascular diseases are among the main causes for significant mortality rates across the globe. They are the prominent reasons for continuing hospital visits and long term hospitalisation, especially among elderly individuals to a large extent. Lifestyle pattern adopted by the population remains to be the most reliable cause for developing CVDs at various ages. Due to multiple risk factors and assorted co-morbidities, CVD emerges in an array of clinical characteristics and drug responses. Utilization of drugs investigations have proven to be an effective technique for combating inappropriate drug use and irrationality of drug patterns, along with maintenance of good quality of life.

A Prospective, Observational study was carried out for a time span of 6 months recording 118 cases which were keenly reviewed and analysed. Of the 118 cases, 58 (49.15%) were males and 60 (50.84%) were females indicating female preponderance, which was nearly complimentary to the study reported in literature review by Raval N et al (2020)[12] in which female dominance with 55.88 % was reported. Unlike in the study of M Rangapriya et al (2021)[10], Veeramani V et al (2020)[11], Fardan M et al (2019)[14], Kumaraswamy M et al (2019) and Joe Sindhuri.N et al (2018)[15] which revealed male preponderance

In our study, highest percentage of CVDs were recorded in the age group of 51-60 years with a total of 31 patients (26.27%) which were correlating to the studies outlined by Veeramani V et al (2020)[11] and Vinodkumar M et al (2015)[17]. The following age group of 61-70 years was reported with adjoining 23 patients (19.49%) being prevalent. However studies by M Rangapriya et al. (2021)[10], Raval N et al (2020)[12], Naliganti C et al (2019)[13], Joe Sindhuri.N et al (2018)[15] and Kerkar SS et al (2017)[16] concluded that subjects in age group of 61-70 years were most affected. Considering results from studies mentioned, individuals falling under the age 50-70 years are known to be commonly afflicted.

A survey on prevalence pattern of CVD among subjects affirms that Cerebrovascular accident (CVA) and Coronary artery disease (CAD) were the most prevalent diseases followed by Heart Failures (HF). An absolute count of 37 patients had CVA in which 31 patients (26.27%) accounted for ischemic stroke and 6 patients (5.08%) suffered from haemorrhagic stroke. In case of CAD 10 patients (8.47%) presented with Angina and 14 patients (11.86) were diagnosed with Myocardial infarction (MI). In terms of disease prevalence, our study did not match findings of other studies

In our analysis, Statins (71.84%) and Anti-platelets (70.33%) were the most frequently adopted class of drugs in prescribing practices. Among these classes, drugs particularly Atorvastatin, Aspirin and clopidogrel account as top 3 drugs in majority of prescriptions throughout the study showing its effectiveness in management of CVD. These results were similar to studies by M Rangapriya et al (2021)[10], Fardan M et al (2019)[14] and Joe Sindhuri.N et al (2018)[15]. Results are comparable to almost of the studies discussed in literature review

CONCLUSION:

The study has demonstrated that the incidence of cardiovascular diseases have increased among the general population. As a result, limiting CVDs has become crucial for preventing patients from unwanted development of CVD or any

complications. The study examined the individuals and revealed that female gender was the leading than males in terms of prevalence of CVDs thus concluding that both female and male genders are now at risk. Subjects aged between 51-60 years were particularly vulnerable to CVD at great extent. A comprehensive clinical pattern of CVDs ranging from Cerebrovascular Accidents (CVA), Coronary Artery Disease (CAD), Heart Failure, Venous Thromboembolisms (VTE), Cardiomyopathies, Hypertension, Arrhythmia's and Rheumatic heart disease was observed. Out of which CVA and CAD both were most common presentations with diagnosis of ischemic or haemorrhagic strokes, myocardial infarction or angina. The top two risk factors, as well as co-morbid conditions, remained hypertension and diabetes which lengthened the time for illness relief. Alcohol and smoking were next prevailing factors observed. The prescribing pattern showed that statins, anti-platelets and diuretics were the three most frequently opted medications exhibiting their effectiveness in early stages of CVD therapy. Addition of cardiovascular drugs increased drug to drug interactions. Upon interaction with patients, majority of them were medium to low adherent to their medications which was another evidence that recovery from CVD is being impeded. Using Naranjo scale, ADRs can be assessed and prevented by documenting, reviewing and informing the vigilance centres. In this study we have observed that prescribing drugs form NLEM and in generic were at low levels. In order to expedite the recovery of the admitted patients and further to minimize hospital acquired infections, injectable and antibiotics were used. Polypharmacy was detected, which concomitantly raise the chances of ADR, drug-drug interactions. This can be avoided by interaction and discussion with consultants about the alternative treatment and surveillance in patients specifically elderly by implementing criteria's like Beers criteria. The aim of the study was accomplished by evaluating all the objectives particularly about the CVD prevalence and prescribing practices concerned with cardiovascular medications. Adopting lifestyle modifications and with regular health check-ups, incidence of CVD can be curtailed

LIST OF ABBREVIATIONS
ADR- Adverse drug reaction
ACE- Angiotensin converting enzyme
ARB -Angiotensin receptor blockers
CVD- Cardiovascular disease
CAD -Coronary artery disease
CVA- Cerebrovascular accident
DUR -Drug utilization review
HCN -Hyperpolarization-activated cyclic nucleotide-gated
HF- Heart failure
MMAS -Morisky Medication Adherence scale
MI -Myocardial infarction
NLEM -National List of Essential Medicines
NSTEMI- Non ST elevated myocardial infraction
STEMI -ST elevated myocardial infraction
VTE -Venous thromboembolism
WHO -World Health Organization

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