ANTIPLATELET PRESCRIPTION PATTERN AND SAFETY PROFILE AMONG CARDIOVASCULAR PATIENTS IN A RURAL TERTIARY CARE TEACHING HOSPITAL

Marrela balaram[1]
MBBS, Dr pinnamaneni sidhartha institute of medical sciences and research foundation.

SAI SANDEEP DUDEKONDA[2]
DR dudekonda Sai Sandeep PGY1, General surgery, DUTTA MEGHE medical college.

Gajawada Pragna[3]
Doctor of Medicine, Kazakh National Medical University.

Yamini Saraswathi Gurram[4]
MBBS, Dr pinnamaneni sidhartha institute of medical sciences and research foundation.

Alekhya Golagabathula[5]
MBBS, National Medical College and Teaching Hospital.

Dr Sirisha Annavarapu[6]
Assistant professor, Department of Pharmacology, Dr pinnamaneni sidhartha institute of medical sciences and research foundation.

ABSTRACT: -

This research aims to determine the pattern of prescription and safety outcome of utilise antiplatelet agents in cardiovascular patients at Tertiary care education hospital in rural area involving two hundred and thirty patients. Employing an observational and prospective fashion, the objective of the current study was to evaluate the demographic features of the participants, the clinical diagnosis, comorbidities about the specifics of the antiplatelet therapy. The patient cohort was predominantly male (56. 53%) and of age 51-64 years (70%), who had significantly high comorbidity of ischemic heart disease (80. 87%), coexisting with hypertension and diabetes at some time (33. 91%). From them Aspirin was the most agreed antiplatelet agent (94. 79%); the rest demographic distribution for clopidogrel (64. 35%); ticagrelor (13. 05%); prasugrel (6. 96%). Dual antiplatelet therapy with special reference to aspirin and clopidogrel (70. 86%) was relatively more frequent where this prescription was associated with bleeding tendencies in 3.47% of the patients.

The study noted full compliance with hospital formulary prescription, as observed in the second research question of 100% while lower formulary prescription was noted to be 75. 65% in preference to brand-name medications as noted in the last research question. According to available guidelines, preference should be given to generics, while in the case of antiplatelet drugs generics accounted only for 14 percent. In summary, the study observed a slightly elevated prevalence rate of adverse drug reaction at 3.47%, of which majority were bleeding disorders attributed to the use of dual antiplatelet agents.

This observational and prospective study design was conducted in a rural area and it is important because it provides real-time data regarding prescribers' behaviour and drug safety in communities that suffer from a lack of access to healthcare. The rural background makes a focus on accessibility

to the healthcare system and elevated levels of CVD risk factors important to address via healthcare interventions. Thus, as a result of identifying the prescription practices for rural patients, the current study aims to advance the understanding and implementation of data-driven practices to improve cardiovascular care for rural populations.

Observational and prospective study was conducted as the prescription pattern and safety outcome of the agents such as antiplatelet were wanted to be studied in real-time in a rural health care setting. Since data is collected longitudinally, it becomes easier to evaluate prescriber's behaviours, taking into account the interacting details of the clinical prescriptions and how they affect patients. In the case of hypertension as well as other health issues other such real-world data are imperative for understanding the present and optimizing treatments, as well as cardiovascular care approaches for otherwise overlooked rural communities.

INTRODUCTION

Pathologies affecting the cardiovascular system (CVS) include heart disease and other related conditions. Heart conditions such as angina, myocardial infarction, CAD, rheumatic heart disease, cardiomyopathy, arrhythmia, congenital heart defects, aortic aneurysms, peripheral artery disease, valvular heart disease, venous thrombosis, and congenital heart defects are all types of cardiovascular illness.

The leading cause of death on a global scale is cardiovascular disease.[1] cardiovascular disease (CVD) was responsible for 17.3 million fatalities in 2013, up from 12.3 million in 1990 (25.8% of all deaths).[2] Stroke and coronary artery disease accounted for 80% of men's and 75% of women's cardiovascular disease mortality[1]. Cardiovascular disease affects 11% of US individuals aged 20–40, 37% of those aged 40–60, 71% of those aged 60–80, and 85% of those aged 80 and more.[3] The median age of death from coronary artery disease in industrialised nations is about 80, whereas in poor nations it is about 68.[4] Men often have disease access seven to ten years before women do.[5] Additionally, by 2030, cardiovascular disorders are projected to impact more than 23 million individuals. Despite only accounting for 20% of the global population, the South Asian subcontinent is expected to bear 60% of the global burden of cardiovascular disease. Environmental and genetic variables may work together to cause this.

To prevent thromboembolic illnesses, doctors provide antiplatelet medications, which block platelet function. These medications influence platelet function at various stages and act in different places. Their acts complement each other when taken collectively. Aspirin and other thromboxane synthesis inhibitors, P2Y12 receptor blockers (e.g., Clopidogrel, Prasugrel, and Ticagrelor), and GPIIb/IIIa antagonists (e.g., Abciximab) are antiplatelet medications. Preventing intravascular thrombosis and embolisation with a low risk of haemorrhage is the goal of employing antiplatelet medicines. The thrombotic variables of the patient determine the dosage of antiplatelet medicine. Aspirin with clopidogrel is the usual regimen for patients with coronary artery disease or risk factors for stroke. Indications such as ACS, stent insertion, vessel grafting, potent inhibition of platelet activity, maintenance of vascular recanalization, etc., require this. Dual antiplatelet therapy, which involves taking two antiplatelet drugs with different mechanisms of action, makes this feasible.[6]

The ability of healthcare providers to differentiate between different medication options and choose the ones that will benefit their patients the most is reflected in their prescribing patterns.[7] Writing a prescription is both an art and a science because it conveys the doctor's order to the patient. To provide medical care reasonably and cost-effectively, the research of prescribing patterns aims to

monitor, analyse, and suggest changes to prescribing procedures.

The field of pharmacoepidemiology that studies drug use sheds light on the nature, extent, and factors that influence drug exposure. With an emphasis on the medical, social, and economic ramifications that followed, the World Health Organisation (WHO) defined drug utilisation in 1997 as the distribution, prescription, marketing, and use of medications in society.[8] Drug marketing and promotion, illiteracy, poverty, the use of various health care systems, the sale of prescription drugs without a prescription, competition in the pharmaceutical and medical markets, and the lack of independent, unbiased drug information are some of the major factors that impact a treating clinician's drug usage in India. Underuse, overuse, or abuse of medications can prevent the full advantages of pharmacological therapy from reaching patients. Medical complications, antibiotic resistance, side effects, and patient deaths could all rise as a result of careless medication use.[9] Therefore, modern research on drug use has evolved into a probable means to be utilised in the assessment of health systems. Drug utilisation studies have been known since the early 1960s, but their significance has grown since then due to factors such as the increased marketing of new drugs, significant differences in drug prescribing and usage patterns, growing worries about delayed adverse events and increasing worries about drug prices. One of the most important things that prescription pattern studies do is help the healthcare system figure out how to prescribe, administer, and use pharmaceuticals reasonably and cost-effectively.[10] The available data concerning antiplatelet drug usage is not sufficient to make a clear conclusion concerning rational therapeutics. Particularly there is an increasing need to fill the knowledge gap concerning prescribing patterns of antiplatelet agents in cardiovascular diseases. Hence, the purpose of this research was to examine the antiplatelet medication prescription trend among cardiology patients at the present institution.

REVIEW OF LITERATURE

Rishitha Reddy P *et al*., (2021) conducted a prospective study on the pattern of antiplatelet agent drug utilisation in a tertiary care hospital in southern India. Hospitalised patients in the cardiology, general medicine, and neurology departments had 160 prescriptions examined. The data was collected from 160 patients, with a female representation of 51.87% and a male representation of 48.125%. People in their 50s and 70s made up the largest age group for individuals diagnosed with IHD and stroke. The patients' most common co-morbidities were hypertension (61.88%), diabetes (34.38%), hypothyroidism (5%), and epilepsy (3.75%). Aspirin (97.5% usage) and clopidogrel (82.5%) were determined to have different patterns of antiplatelet drug utilisation. More patients were on DAPT than on monotherapy (19% vs. 81%). Smokers made up 38.75% of the patients with social habits, drinkers 31.25%, and those who smoked and drank together 22%.[11]

Rajesh Hadia *et al.*, (2021) examined the overall pattern of antiplatelet medication use among patients with cardiovascular disease in a tertiary care hospital through cross-sectional observational research. Out of 150 patients enrolled, men made up 79% (N=119) and women 21% (N=31). The majority of patients are between the age bracket of 51 to 60. Nearly half of all patients with inferior wall myocardial infarction (N=65, or 43.3% of the total) are on highly recommended antiplatelet medications. The results showed that alcohol was the second most common risk factor, at 26.7% (N=40) after smoking at 54.7% (N=82). Of the patients surveyed, 60.7% (N=91) did not have any co-morbidities, while 31.3% (N=47) did have a co-occurring heart disease. Combination therapy with both aspirin and clopidogrel accounted for 51.2% of all antiplatelet prescriptions (N=82), while monotherapy of aspirin accounted for 28.8% (N=43).[12]

Emil G Rajesh et al., (2020) conducted a prospective observational study in a tertiary care teaching hospital to examine the prescribing pattern of antiplatelet drugs in patients with cardiovascular disease. Out of 236 case sheets involving cardiovascular disease patients, 160 (or 68% of the total) were men and 76 (or 32% of the total) were women. Cardiovascular disease patients were found to be 2% in the 30–40 age group, 11% in the 41–50 age group, 28% in the 51–60 age group, 61–70 age group, 71–70 age group, and 9% in the >80 age group. An astounding 84% of anti-platelet drugs were actually used. Aspirin was given to most of the patients.[13]

MATERIAL & METHODS

Methodology: [14,15] Type of study: an observational, prospective, analytical study Study population: Department of Cardiology

Sample Size: 230

Inclusion criteria:

1. Patients of age between 18 and 65 years of either gender.
2. Patients who are on antiplatelet agents in the cardiology department Exclusion criteria:
    a. Patients of less than 18 years and more than 65 years of age.
    b. Pregnant & lactating women.
    c. Patients who are not prescribed antiplatelet agents in the cardiology department
    d. Patients who are not willing to participate in the study

Data collection procedure:

A pre-designed case report form is used to collect data in a way that does not interfere with their treatment. Information on the patient's demographics, such as their age, sex, present diagnosis, co-morbidities, and antiplatelet therapy (whether it's a single medicine, like aspirin or clopidogrel, or a mix of drugs).

Data instruments:

Data will be collected and tabulated as per the following parameters.

1. Demographic data: Age, Sex
2. Clinical diagnosis: Unstable angina, Post Coronary angiography, myocardial infarction, Ischaemic diseases
3. Co-morbidities: Hypertension, Diabetes Mellitus, Asthma, Dyslipidaemia, Chronic kidney disease
4. Class of the drug: COX inhibitor, P2Y12 inhibitors, GPIIb/IIIa inhibitors
5. Individual drug of the class: Aspirin, Clopidogrel, Prasugrel, Ticagrelor, Abciximab
6. Monotherapy/ Dual therapy/Fixed drug combinations
7. Generic / branded name written in the prescription
8. Average number of antiplatelet agents per prescription
9. Adverse drug reactions: Bronchospasm, bleeding tendencies, diarrhea

Confidentiality and ethical considerations:

The confidentiality of the study will be maintained by not revealing their names and the result will be used only for the research purpose for the future benefit of society. Physician confidentiality will also be maintained. Informed consent will be obtained from the participant

before the study.

Data management/ Statistics:

Statistical analysis will be done using Microsoft excel. The percentage-wise or frequency distribution of various parameters employed in the study will be analyzed.

Ethical Committee approval: The study was started after Institutional Ethics Committee approval.

OBSERVATION AND RESULTS

A tertiary care teaching hospital's cardiology department was the setting for the present investigation. We analysed the demographic profile, medication prescription pattern, and safety profile of antiplatelet medicines in 230 cases that had prescriptions. The following are the findings of this medical audit-study that was observational, prospective, non-interventional, and published online.

Demographic profile of patients

a. Gender distribution in study population

In our study involving 230 patients in total, 130 (56.53%) were males and 100 (43.47%) were females. The male : female ratio was 1.3:1 **[Table 1 and Figure 1]**.

TABLE: 1. Gender Distribution of patients

S.N0	Gender	Frequency	Percentage
1	Female	100	43.47%
2	Male	130	56.53%

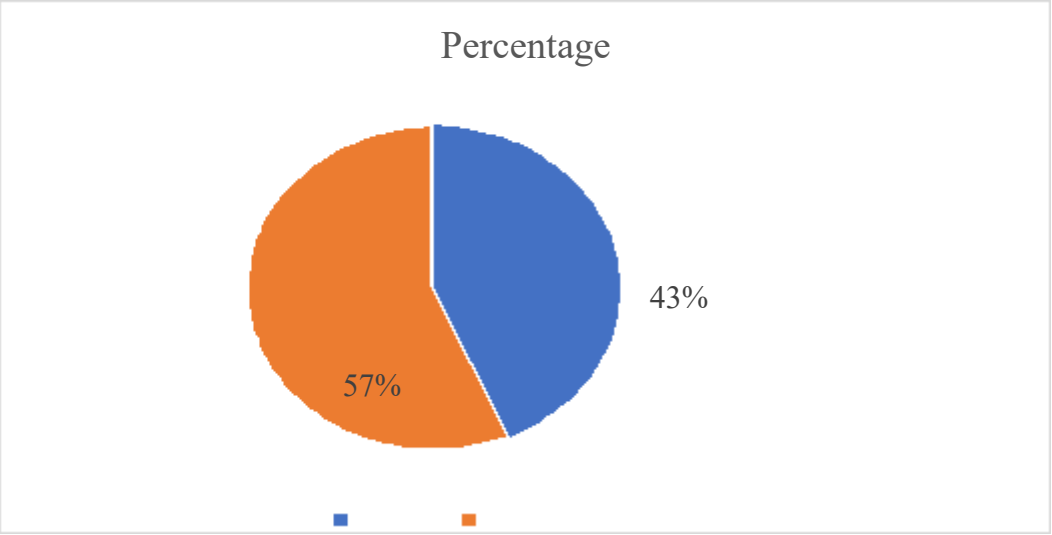

FIGURE:1. Gender Distribution of Patients

b. Age distribution in study population

The average age of the people under study was 52.43 years with a standard deviation of 9.38. The patients were categorised into three age groups: 1] 18–35 years old - 2] Thirty-six-40 years 3] 50–65 years old. The 51–65 age group was the most hit, accounting for 161,70%.

(Table 2) Table 2: Gender and age wise distribution

Gender	Age group					
	18-35		36-50		51-65	
	Number	Frequency	Number	Frequency	Number	Frequency
Male	13	5.65%	27	11.74%	90	39.13%
Female	9	3.91%	20	8.69%	71	30.87%

B. CARDIOVASCULAR DISEASE DATA:

Table 3 and Figure 2 show that out of all the prescriptions that were analysed, 186 were for ischemic heart disease, whereas 23 were for dilated cardiomyopathy.

Table 3 : Distribution of patients based on diagnosis

S.NO	Indication	No of Patients	Percentage
1.	Ischemic Heart Disease	186	80.87%
2.	Dilated Cardiomyopathy	23	10%
3.	Heart Failure	13	5.66%
4.	Rheumatic Heart Disease	8	3.48%

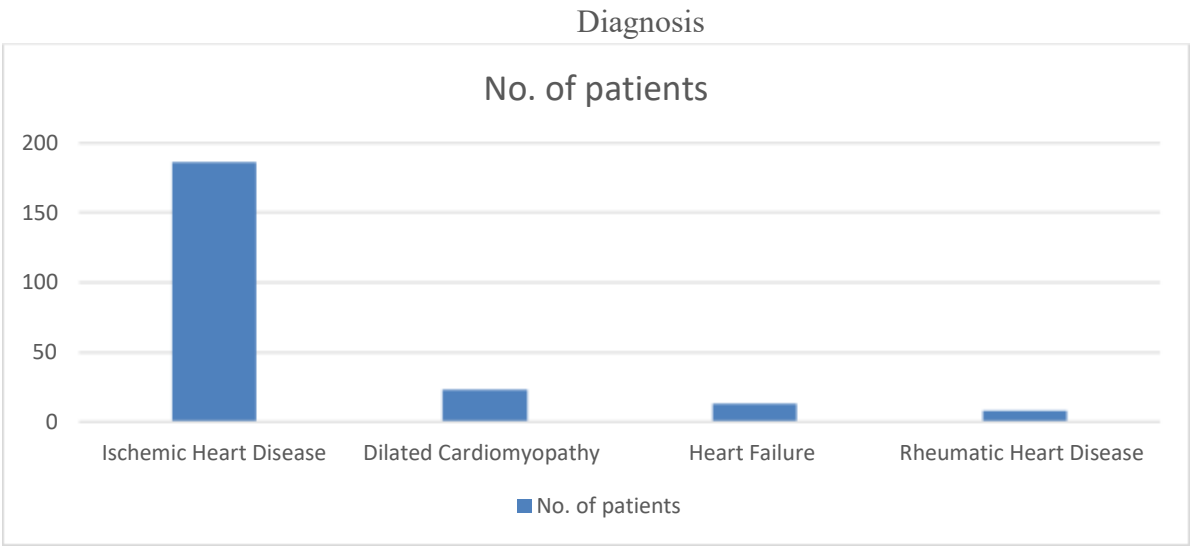

Fig 2: Distribution of patients based on diagnosis

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C. COMORBIDITIES DATA:

Table 4 and Figure 3 highlight the co morbidities in the prescription analysed. Hypertension with Diabetes being the most common co morbidities, around 21 prescriptions had no clear data concerning coexisting disease conditions.

Table 4: Incidence of co-morbid diseases.

S.NO	Comorbidity	Number	Percentage
1.	HTN+DM	78	33.91%
2.	DM	50	21.73 %
3.	HTN	28	12.17%
4.	Morbid Obesity	11	4.78%
5.	Renal Disorders	13	5.6%
6.	Thyroid	14	6.08%
7.	COPD	15	6.5%
8.	Nil	21	9.13%

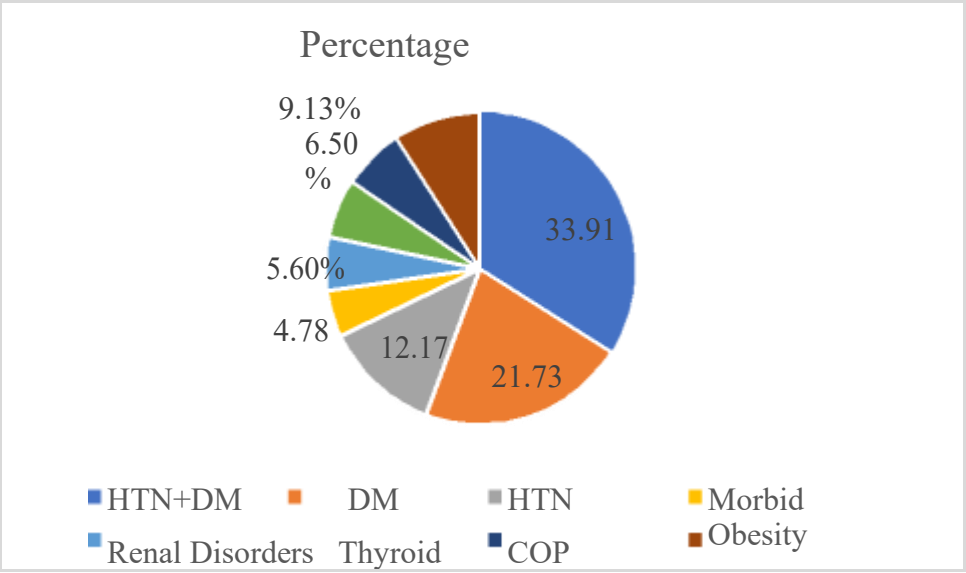

Figure3:Pie diagram showing Incidence of co morbidities

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D. PRESCRIPTION DRUGS DATA :

Note: Antiplatelet medications were administered orally in all of the prescriptions recorded.

1. Frequency of administration of individual antiplatelet drugs:

Thromboxane inhibitors such as aspirin were provided to 94.79% of patients, whereas P2Y12 inhibitors were given to 84%. None of the patients analysed received GPIIb/IIIa prescriptions. Aspirin was the most commonly used antiplatelet agent (n=218), followed by Clopidogrel (n=148), Ticagrelor (30), and Prasugrel (16). Table 5 illustrates the most frequently prescribed class of antiplatelet medication, whereas Table 6 and Figure 4 show the frequency of antiplatelet drugs.

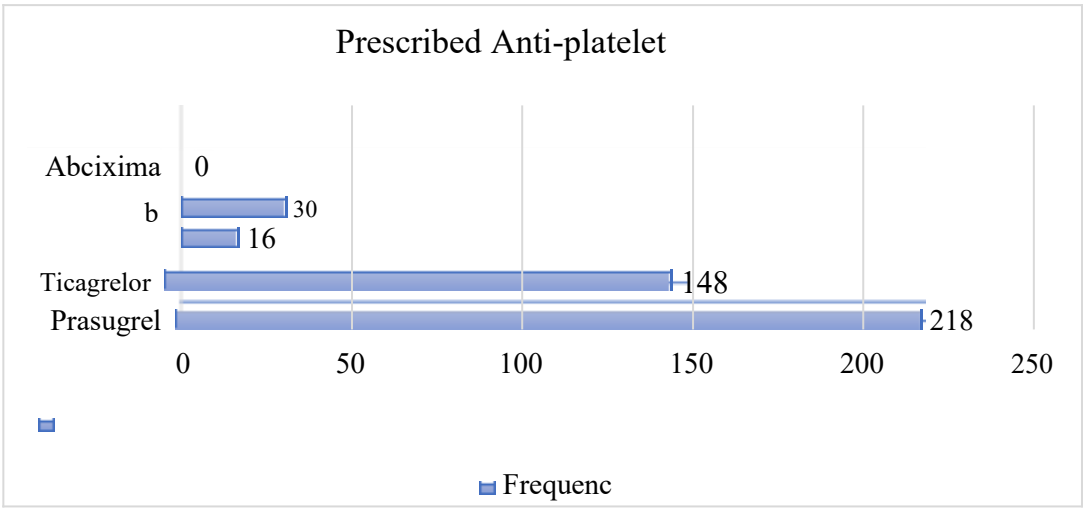
Table 5 : Prescribing frequency of antiplatelet drug classes

Class	Number of prescription	Percentage
Thromboxane inhibitors	218	94.79%
P2Y12 receptor inhibitors	194	84.34%
GPIIb/IIIa antagonists	0	0

Table 6 : Prescribing frequency of individual antiplatelet drug

S.NO	Antiplatelet agent	Frequency	Percentage
1.	Aspirin	218	94.79%
2.	Clopidogrel	148	64.35%
3.	Ticagrelor	30	13.05%
4.	Prasugrel	16	6.96%
5.	Abciximab	0	0

Fig 4 : Bar diagram showing frequency of individual antiplatelet drug



	Aspirin	Clopidogrel	Prasugrel	Ticagrelor	Abciximab
Frequency	218	148	16	30	0

2. Pattern of number of antiplatelet drugs prescribed:

The average number of antiplatelet medications provided per prescription was 1.3 ± 0.43 (mean + SD). Table 7 and Figure 5 demonstrate our study's trend of antiplatelet medication prescriptions. 56 (24.34%) patients underwent monotherapy, whereas 174 (75.66%) received polytherapy. Out of 174 patients getting polytherapy, 163 (70.86%) were on a two-drug combination, while 11 (4.78%) were on fixed drug combinations with hypolipidemic medications.

Table 7 : Prescribing pattern of number of antiplatelet drugs

S.NO	Type of Drug Therapy	Frequency	Percentage
1.	Dual	163	70.86%
2.	Mono	56	24.34%
3.	FDC with statin	11	4.78%

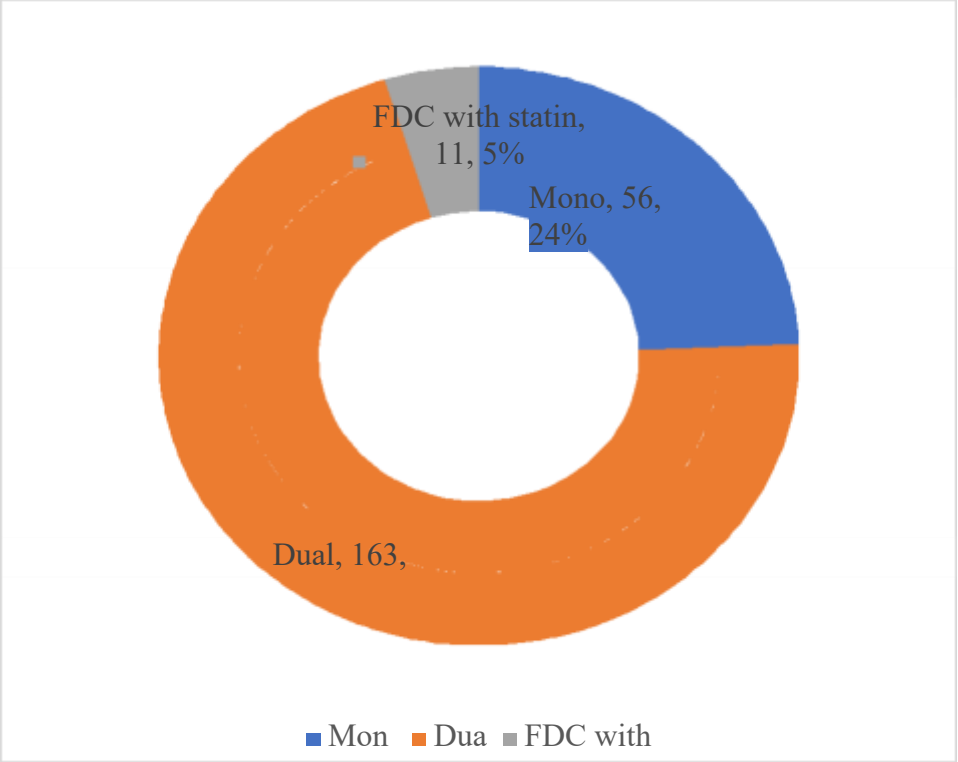


Fig 5 : Pie diagram showing prescribing pattern of number of antiplatelet drugs

E. PRESCRIPTION ANALYSIS DATA :

In our study, 230 cases were analyzed, which contains a total number of 1334 drugs out of which 393 drugs were anti-platelet drugs. The average number of medications used per patient is 5.80, with an average of 1.7 antiplatelet drugs. 56 prescriptions were written in generic names, whereas 174 were issued in brand names.

Table 8 : Table showing prescription analysis

S.NO.	Parameter	Number
1	Total no. of case sheets analyzed	230
2	Total number of drugs prescribed	1334
3	The average number of drugs prescribed	5.80
4	Total number of antiplatelet drugs prescribed	393
5	Average no. of antiplatelet drugs per patient	1.7
6	Total no. of anti-platelet drugs prescribed orally	393
7	Total no. of single antiplatelet drug prescribed	56
8	Total no. of antiplatelet drugs prescribed injectables	0
9	Antiplatelet drugs prescribed in generic name	56
10	Antiplatelet drugs prescribed in brand name	174

Table 9: Table showing assessment of WHO prescribing parameters

S.NO.	PARAMETERS	NUMBER
1	Average no. of antiplatelet drugs per prescription	1.7
2	Percentage of antiplatelet drugs prescribed by generic name	14%
3	Percentage of encounters with an antiplatelet drug prescribed	89%
4	Percentage of encounters with an antiplatelet injection	0
5	Percentage of drugs prescribed from the hospital formulary	100%

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E. SAFETY PROFILE ANALYSIS :

Of the 230 patients, 8 patients (3.47%) who were on dual antiplatelet therapy complained of developing petechiae (red patches) during the study period suggesting of increased bleeding tendency.

DISCUSSION :

Cardiovascular diseases are a leading cause of death globally. This study examines the patterns of antiplatelet drug use and safety among cardiovascular patients in rural tertiary care teaching hospitals. Antiplatelet therapy is essential in treating cardiovascular diseases as it helps prevent platelet clumping, lowering the chances of heart attacks and strokes. Although many studies are present there is always a knowledge gap that leads to many researches. The usage of antiplatelets for prevention of various cardiovascular diseases has been increased over the years which not improved the outcomes but lead to misuse regarding the duration of use and reduced review of medications mostly in the tertiary level.This is mainly due to less education, poverty,less medical supervision among people in rural areas.The main aim of this study is to conduct a research survey in a tertiary care centre.

The research involved 230 patients, with a higher number of male patients (N=130) compared to female patients (N=100). The majority of patients fell within the 51-65 age group (70%), consistent with previous studies in the same age range. The study identified ischaemic heart disease as the most common diagnosis (n=186) among the prescriptions analysed, followed by dilated cardiomyopathy (n=23), often linked to uncontrolled hypertension. A separate study by Rajesh Hadia et al. (2021) found that the majority of patients had experienced Myocardial infarction (IWMI-43.3%, AWMI-30%), with a smaller percentage experiencing Unstable Angina (6.7%), mirroring the findings of this study.

Based on current observations, it was discovered that the average number of medications per prescription encounter was 7.28. This figure, although exceeding the WHO standard of less than 2, was deemed reasonable due to the majority being prescribed for cardiovascular emergencies. The situation does not meet the criteria for polypharmacy, as there is a necessity for empirical treatment of life-threatening conditions. The WHO strongly advocates for physicians to prescribe medications using generic names. Approximately 14% of drugs in this study were prescribed using generic names. All medications in this study were sourced from the hospital formulary.

Aspirin and Clopidogrel dual antiplatelet therapy was prescribed to the majority of patients (n=163). Aspirin was the most commonly prescribed drug in the cardiology department, either alone or in combination with clopidogrel, with 218 prescriptions (94.79%). Fixed-dose combinations of aspirin with statins were given to 11 patients. Clopidogrel followed as the second most prescribed drug, with 148 prescriptions. Dual antiplatelet therapy involving agents like Aspirin and Clopidogrel was evident in over 80% of the prescriptions.

ISSN: 0975-3583,0976-2833 VOL 16, ISSUE 5, 2025

In the analysed prescriptions, aspirin was prescribed for 94.79% of the patients, while P2Y12 inhibitors were prescribed for 84% of them. None of the patients were prescribed GPIIb/IIIa inhibitors. Among the antiplatelet agents, aspirin was the most commonly prescribed (n=218), followed by Clopidogrel (n=148), Ticagrelor (n=30), and Prasugrel (n=16).

Aspirin combined with Ticagrelor was the second most common dual therapy regimen in our hospital. These results are consistent with a study in Chennai, where dual therapy was favoured (80%) over monotherapy (20%). Aspirin held a significant share of the antiplatelet prescriptions due to its cost-effectiveness, efficacy, and availability in 75 mg and 150 mg doses. Aspirin topped the prescription because of less tendency to cause bleeding complications compared to other antiplatelet agents . Clopidogrel was frequently used as an antiplatelet agent in our study, particularly in patients with hypertension and coronary artery disease who were intolerant to or had contraindications for aspirin. Prasugrel had the lowest utilisation rate in our study, while Abciximab was not prescribed at all.

Though antiplatelet therapy is proven to reduce the risks of cardiovascular events especially in post-stroke patients, ischemic patients, mild embolic patients the adverse effects are not totally vanished.One of the most significant side effects of antiplatelet therapy is an increased risk of bleeding events due to inhibited platelet function. The severity of bleeding can vary from mild to severe and may include nosebleeds, easy bruising, gastrointestinal bleeding, and intracranial haemorrhage. More potent antiplatelet agents like ticagrelor and prasugrel carry a higher risk of bleeding compared to aspirin or clopidogrel. Thrombocytopenia (low platelet count) is a rare potential side effect associated with specific antiplatelet agents like clopidogrel.Some antiplatelet agents when combined with Aspirin can lead to acute kidney injury.

Aspirin is the most commonly prescribed drug among all the antiplatelet agents so adverse effects of Aspirin even though are less compared to other antiplatelet agents should not be totally ignored. Aspirin can irritate the stomach lining, potentially leading to gastrointestinal ulcers and bleeding. Symptoms may include abdominal pain, indigestion, or gastrointestinal bleeding. Other rare adverse effects of aspirin include allergic reactions like rash, itching, swelling, and dizziness.So prescription should always be patient specific which is totally lacking in the rural areas as per our study.

The study conducted showed that the dual therapy with aspirin and clopidogrel were prescribed more often there are people with CYP2C19 genetic polymorphisms associated with a slow bioactivation of clopidogrel, in these patients aspirin and clopidogrel dual therapy shown less effective results. This patients especially benefit from Aspirin and Ticagrelor dual therapy but Ticagrelor known to cause more hemorrhagic complications. So the prescription should also include disease duration, age, gender of the patient and their specific genetic hemorrhagic complications. Patients in tertiary care hospitals who had dual antiplatelet therapy experienced primarily petechiae as adverse drug reactions, which were observed in 8 prescriptions, indicating a higher tendency for bleeding. The majority of the recruited patients had low education levels and a poor economic status, resulting in inadequate responses regarding their adverse drug reactions. Dual antiplatelet therapy even though shows more effective results than

monotherapy the risks of bleeding are also increased especially with long-term use.So reviewing of medication is necessary for every 30 days as per previous researches which are lacking in the tertiary care centres. As the patients are from low economic and education status they are unable to notice the minor adverse reactions.

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