# Drug Utilization and Evaluation of Anticoagulant and Anti-Platelet Drugs and Assessing Their Safety in Preventing Cardiovascular Diseases

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**Keywords:** Anticoagulants, Antiplatelets, Cardiovascular diseases, Bleeding risk assessment

**ABSTRACT**

**Aim:** The study aimed to analyse the utilization pattern of anti-coagulant and antiplatelet drugs in preventing cardiovascular diseases and also the bleeding risk was assessed in the study population. **Methods:** A prospective observational design was used for this study. The data were collected during regular ward rounds. The utilization pattern of antiplatelets and anticoagulants and possible drug-drug interactions were studied. Bleeding risk scores of individual patients were calculated using HAS- BLED score and the patients with a higher risk for bleeding were identified. **Results:** Out of 110 patients 86 (78.18%) were male and 24 (21.81%) were female. Antiplatelet drugs like Aspirin were prescribed in 53 (88.3%) patients, clopidogrel in 30(27.27%) and Ticagrelor in 27 (24.55%) patients. Parenteral anticoagulants like Heparin were prescribed in 49 (55.06%) patients, Enoxaparin in 30(33.70%) patients. Oral anticoagulants like Acenocoumarol were prescribed in 4(4.49%) patients, Dabigatran in 4 (4.49%) and Warfarin in 2 (2.26%) patients. HAS- BLED score was used to assess bleeding risk in anticoagulant users and a high risk was found in 29 (32.58%) patients. Drug -drug interactions were also assessed for each prescription. **Conclusion:** Drug utilization pattern of anticoagulant& antiplatelet drugs shows that Aspirin, Clopidogrel, Heparin and Enoxaparin are the frequently used drugs in cardiovascular disease prevention. The timely detection of bleeding risk using HAS- BLED score can help in preventing morbidity and mortality.

**INTRODUCTION:**

Cardiovascular diseases (CVDs) are one amongst the leading causes of death worldwide. India is having the highest burdens of CVD[1]. Coronary heart disease prevalence rates in India are estimated over the past several decades and have ranged from 1.6% to 7.4% in rural populations and from 1% to 13.2% in urban populations [2, 3].Management of CVD includes behaviour modification (i.e., diet, weight reduction, physical activity, smoking cessation) to interrupt atherosclerotic processes, also risk factor management, including blood pressure control, treatment with lipid-lowering agents, antiplatelet therapy, surgery or percutaneous revascularization whenever necessary. CVD management also helps in assessment of health outcomes, making interventions for appropriate use of clinical guidelines, improving patient compliance and thereby improve the quality of life (QOL) of the patients [4, 5].

Anticoagulant drugs are indicated primarily for thrombotic event prevention in many CVDs, including stroke prevention in atrial fibrillation, treatment and secondary prevention of Acute Coronary Syndrome (ACS)[6]. Antiplatelet agents are the fundamental therapeutic option for both primary and secondary prevention therapies of ischemic events resulting from coronary atherosclerotic disease. Dual antiplatelet therapy (DAPT) usually, aspirin with clopidogrel is having a central role in the treatment of ACS and after coronary stent deployment[7]. Despite the higher efficacy of Oral anticoagulants & DAPT, their adverse bleeding complications poses a challenge in achieving the therapeutic outcome in CVD prevention[8].The use of accurate bleeding risk assessment tools based on patient's individual risk factors can contribute in clinical decision making for prescribing an anticoagulant drug based on the individual's risk- benefit ratio.[9]

Potentially inappropriate medications (PIM) may pose more risks than benefits to patients and is a major factor contributing to the likelihood of serious adverse drug reactions, negative health outcomes, increased risk of morbidity and mortality, and increased health care costs[10].Detection of irrational use of drugs, making interventions to improve drug use and quality of life is a part of drug utilization review. It also investigates the therapeutic efficacy, cost effectiveness and minimizing adverse effects and ensures safe and effective use of drug[11].Alongside, optimization of the therapy and the management of bleeding complications can help in minimizing the risk of antiplatelet & anticoagulant therapy and magnifies its benefits[9,12]. Individualization of the therapy based on the patient's age, comorbidities and other relevant risk factors must be taken into account by the pharmacist. Monitoring the

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parameters especially platelet count for antiplatelet therapy before and after initiation of therapy in order to prevent bleeding risk is crucial. This helps in making interventions during bleeding manifestations in high-risk patients when their use cannot be avoidable. Study on drug prescribing pattern provides a framework for continuous prescription audit in a hospital in-patient setting. This can help prescribers in improving patient care by rationalizing the prescribing practices.

**REVIEW OF LITERATURE:**

**Ratul.,** *et al.* **(2020)** studied the Usage pattern and rationality of Antiplatelet, Anticoagulant, and Fibrinolytic use in the Cardiac Care Unit of a tertiary care teaching hospital. The magnitude of use of antiplatelet agents, anticoagulants and fibrinolytics was assessed and rationality of such use was evaluated on a case-to-case basis. The study concluded in most of the patients studied, antiplatelets, fibrinolytics and anticoagulant were used rationally and in all the patients[13].

**Vijay.,** *et al.* **(2015)** conducted a study on Anticoagulant Utilization Evaluation in a Tertiary Care Teaching Hospital. The prospective observational study evaluated the prescribing pattern of anticoagulants for various cardiovascular conditions, identified the drug interactions and adverse drug events occurred during the treatment. The study highlighted the importance of following the guidelines for appropriate use of anticoagulants[14].

**Jyothi K.,** *et al.* **(2015)**[54]performed a retrospective drug utilization study of antiplatelet drugs in patients with ischemic heart disease. Total of 250 samples were included in the study. 221 patients were prescribed with antiplatelet drugs. The most commonly used antiplatelet drugs were aspirin and clopidogrel. The dual antiplatelet drugs (both aspirin and clopidogrel) are more prescribed than single antiplatelet drug (either aspirin or clopidogrel. Thus, this study emphasizes the collective use of these agents reduce long term risk of CVD and mortality by as much as 75%[15].

**OBJECTIVES:**

✓ To study the utilization pattern of Anticoagulant and Antiplatelet drugs.

✓ To assess the appropriateness of Anticoagulant and Antiplatelet drugs prescribed.

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✓ To evaluate the safety of Anticoagulant and Antiplatelet drugs in preventing CVD.

✓ To assess the bleeding risk among the study population using the bleeding risk score.

✓ To identify the risk factors associated with bleeding.

✓ To identify the possible Drug-Drug interaction in the prescriptions.

✓ To monitor and prevent the Adverse Drug Reactions.

## MATERIALS AND METHODS:

**Study design and Subjects:** A prospective observational study was conducted at a 1000 bedded multi- speciality hospital for a period of 6 months. The study population was chosen from all the patients admitted to the cardiology ward based on the inclusion and exclusion criteria. The study was approved by the Institutional Ethics Committee(SRH/EC/2021/0501/CR/10) and a written consent was obtained from all the patients involved in the study.

**Inclusion criteria** include all in patients who are≥ 18years of age, alert and cooperative, having a risk of CVD and who are suffering from CVD and are prescribed with at least one anticoagulant or anti-platelet drug.

**Exclusion criteria** include critically ill patients, those who are not willing to participate and if the data are insufficient in patient's records.

**Data collection & Analysis:**

**Data collected includes**

➢ Sociodemographic details: age, gender, past medical history, past medication history

➢ Clinical details: diagnosis and comorbid conditions.

➢ Drug therapy includes all the drugs prescribed with its dose, dosage regimen, route of administration, duration of treatment.

➢ The drug – drug interactions were recognized using the standard drug data base Micromedex.

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➢ The ADRs were recorded on the 'Suspected Adverse Drug Reaction Reporting Form Version 1.2', and then reported using the Vigiflow software. Causality assessment of ADRs was assessed using the WHO and Naranjo scale of probability.

➢ The rationality of the prescribed antiplatelets were analyzed using the following guidelines - 2016 European Guidelines on cardiovascular disease prevention in clinical practice, 2017 ESC focused update on dual antiplatelet therapy in coronary artery disease developed in collaboration with EACTS.

➢ Bleeding risk assessment was carried out among the study population who are treated with anticoagulant drugs. Using HAS-BLED score the study population was categorized into 3 risk categories as low risk, moderate risk and high risk.

**Statistical analysis:**

The data collected were analyzed statistically using descriptive statistics and the results were depicted in the form of tables, graphs and percentages.

**RESULTS AND DISSCUSION**

A total number of 110 patients who has satisfied the inclusion criteria were enrolled in the study after obtaining their consent.

**Age categorization:**

Based on the age, the study population was categorized into 4 groups ranging from age 18 years to >70 years**.** The maximum number of patients were in the age group of 51 to 70 years 64 (58.19%) patients, followed by the age group of 31 to 50 years 34 (30.90%) patients. 10 (9.09%) patients were in the age group of above 70 years. The least number of patients 2 (1.82%) was there in the age group 18 to 30 years. Elderly is at greater risk of developing cardiovascular disease. Although the process of aging cannot be changed, leading a generally healthy lifestyle is recommended to help reduce the likelihood of developing cardiovascular conditions. Similar studies conducted by Gaur A., et al. (2019)[16]andSolanki N., et al. (2019)[17]shown that risk of CVD increases with age.

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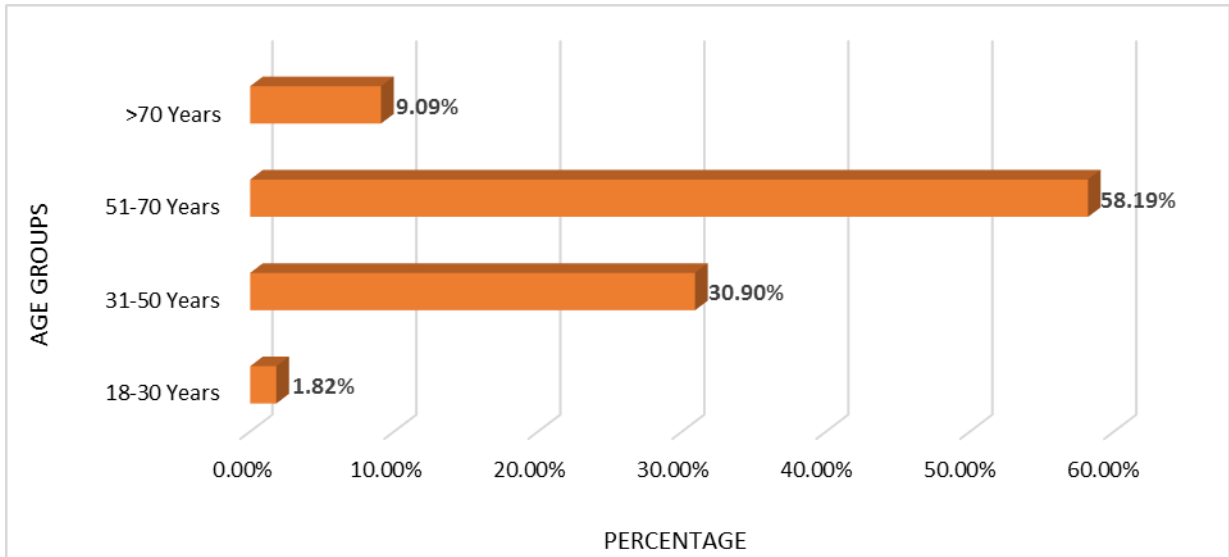
**Fig No. 1 AGE CATEGORIZATION**

**Laboratory investigations:**

Various laboratory investigations performed among the study population revealed that Plasma lipid profile, INR, aPTT values Prothrombin Time were commonly performed in CVD patients.
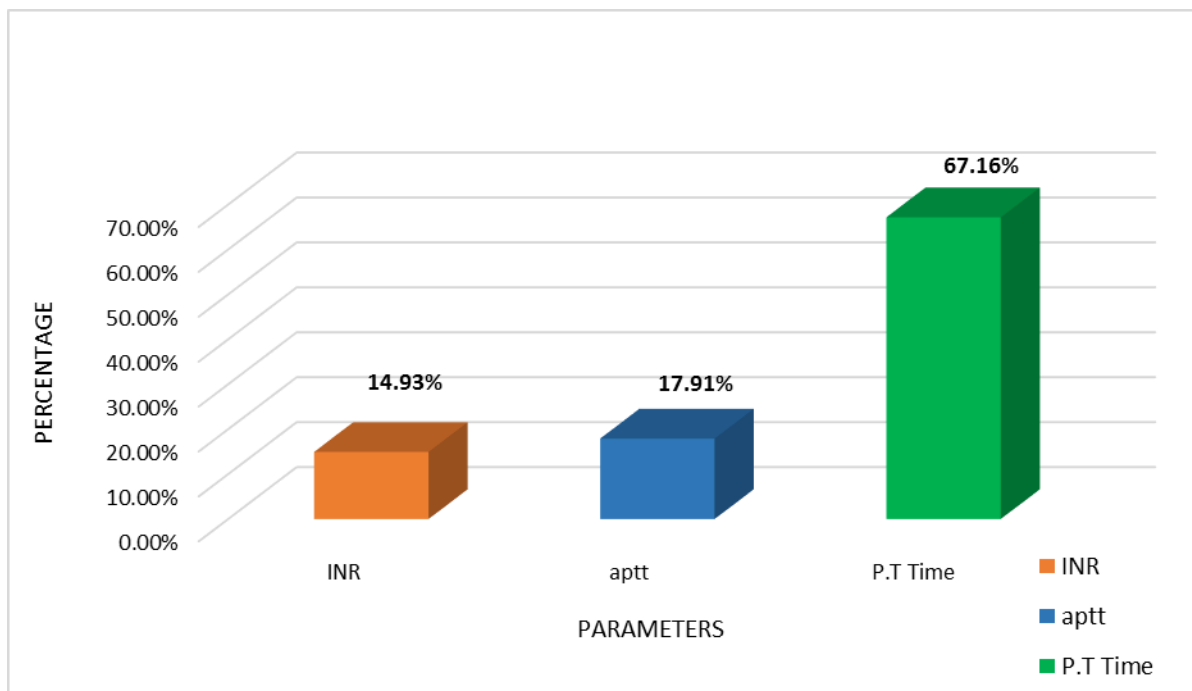


**Fig No.2 LABORATORY INVESTIGATIONS**

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**Utilization pattern of antiplatelet drugs:**

The utilization pattern of antiplatelet drugs reveals that single antiplatelet drug was prescribed in 35 (31.81%) patients, Dual antiplatelet drugs (DAPT) were prescribed in 71 (64.54%) patients, Triple antiplatelet drugs were prescribed in 4 (3.63%) patients. Our results correlate with the study conducted by Reddy R., et al. (2021)[18] which reported that Dual Antiplatelet Therapy (DAPT) was superior to monotherapy in preventing cardiovascular diseases. The prescribing pattern reveals that Aspirin was prescribed in 53 (48.18%) patients, clopidogrel was prescribed in 30 (27.27%) patients, Ticagrelor was prescribed in 27 (24.55%) patients.

Our study correlates with the study conducted by Thomas BR., et al. (2017)[19]which reported that aspirin is the most preferred antiplatelet for prevention of CVD.
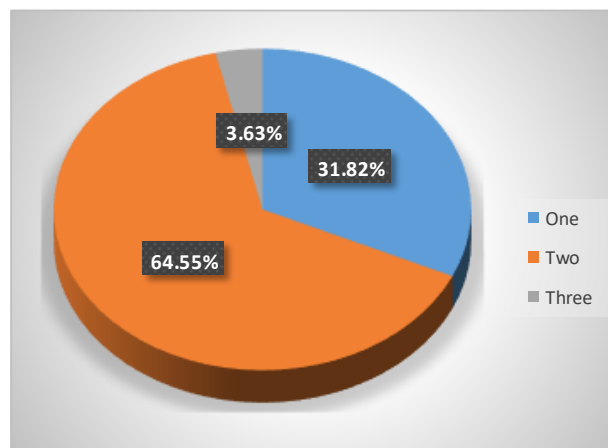
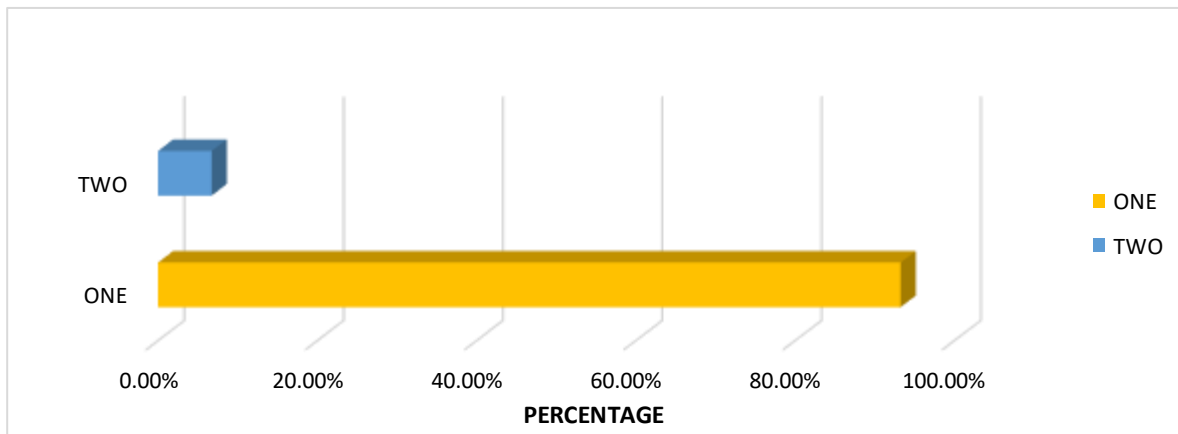

**Fig no: 3 NO. OF ANTIPLATELET DRUGS PRESCRIBED**
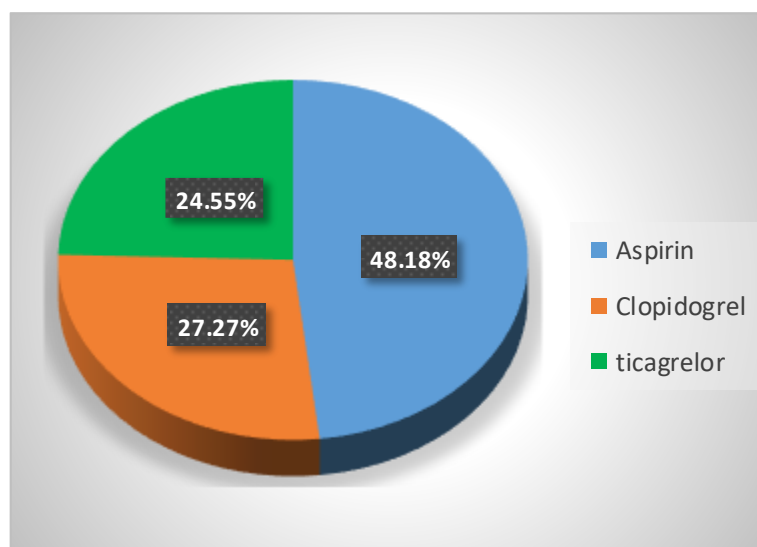


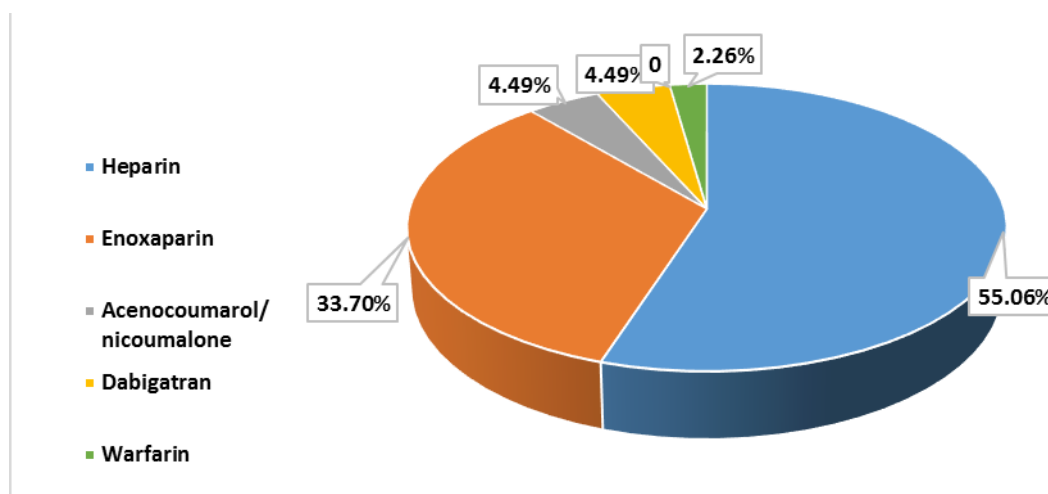**Fig No. 4 TYPES OF ANTI-PLATELET DRUGS**

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**Utilization pattern of anticoagulants**:

Number of anticoagulant drugs used by the study population was analyzed and observed. The study reveals that a total of 89 patients received anticoagulant drugs. Among them, single anticoagulant drug was prescribed for 83 (93.26%) patients, Dual anticoagulant drugs were prescribed for 6 (6.74%) patients. The types of Anticoagulant drugs prescribed were analyzed and observed for all 89 patients. The study reveals that parenteral anticoagulants like Heparin was prescribed in 49(55.06%) patients, Enoxaparin was prescribed in 30(33.70%) patients, oral anticoagulants like Acenocoumarol was prescribed in 4(4.49%) patients, Dabigatran was prescribed in 4 (4.49%) and Warfarin was prescribed in 2 (2.26%).

Our study results correlate with the study conducted by Raouf S., et al. (2021)[20]and reported that adherence to anticoagulant therapy plays an important role in the prevention of cardiovascular events and improve the outcomes.



**Fig no: 5 NO. OF ANTICOAGULANT DRUGS PRESCRIBED**



**Fig No. 6 TYPE OF ANTICOAGULANT DRUGS**

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**ASSESSMENT OF BLEEDING RISK:**

The antiplatelet and anticoagulant therapy has greater advantage in CVD prevention and thereby decreasing cardiovascular mortality and morbidity. They also increase the risk of bleeding. It is necessary to monitor bleeding risk of individual patient in order to titrate the dose and prevention of bleeding. In our study the assessment of bleeding risk was done using **HAS-BLED** risk score calculator.

HAS-BLED can be used for assessing major bleeding in anticoagulated patients with AF. The patients were classified into 3 groups based on HAS-BLED score. Patients with a score of **>/= 3** are categorized into **High** bleeding risk group. Patients with a score of **1 to 2** are categorized into **Moderate** bleeding risk group and those with a score of **0** are categorized into **Low-risk** group.

In our study total of 89 patients were treated with anticoagulants among them, risk score of **0** wasfound in15 (16.85%) patients, a score between **1 to 2** was found in 45 (50.56%) patients and score of **3 or more than 3** was found in 29 (32.58%) patients.

In the categorization of bleeding risk, high risk was found to be 29 (32.58%), moderate risk was found to be in 45 (50.56%) and low risk was found to be in 15 (16.85%) patients.

Similar studies conducted by Gallego P., et al (2012)[21]and Konishi H., et al (2015)[22] categorized the patients based on the HAS BLED score and reveals the increased risk of bleeding in high-risk category patients.

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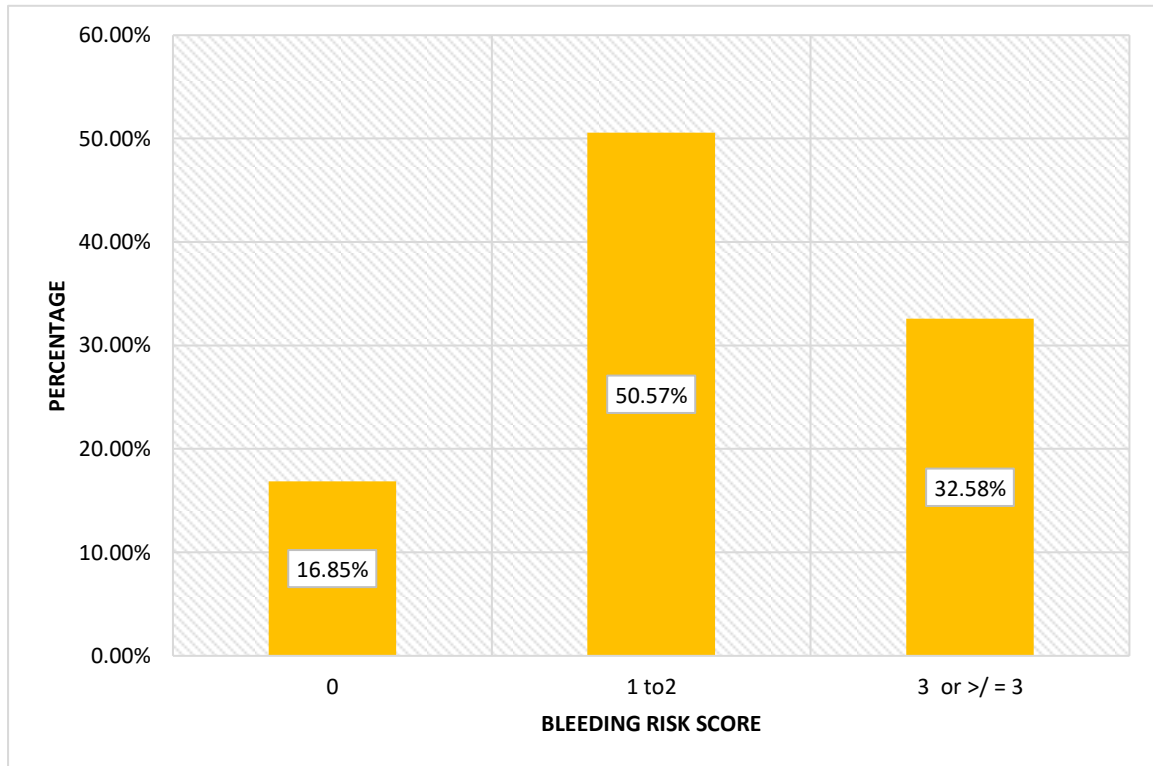
**Fig No. 7 ASSESSMENT OF BLEEDING RISK**
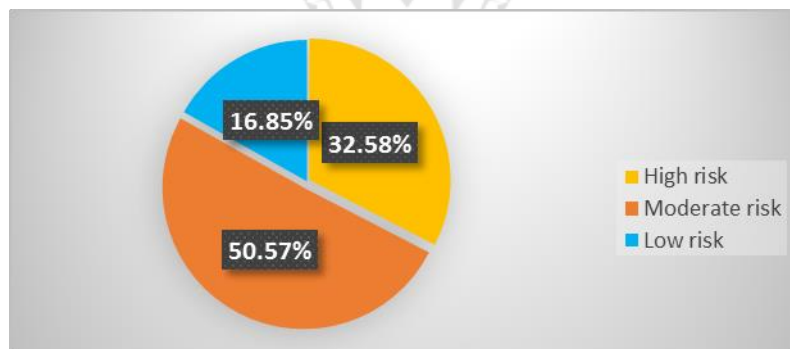


**Fig No. 8 CATEGORIZATION OF BLEEDING RISK**

**RATIONAL USE OF ANTIPLATELETS AND ANTICOAGULANTS:**

The rational use of antiplatelets and anticoagulants reduces the bleeding risk in CVD prevention.The rationality of prescriptions was analysed using the2016 European Guidelines on cardiovascular disease prevention in clinical practice, 2017 ESC focused update on dual antiplatelet therapy in coronary artery disease developed in collaboration with EACTS.The results reveal that all the prescriptions analysed were found to be rational according to the guidelines.

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**DRUG - DRUG INTERACTION:**

A Computerized drug interaction program (Micromedex drug database) was used to analyse the possible drug- drug interactions in the prescriptions. The prescription was analysed for drug -drug interaction was found to be 109(98.3%), prescription without drug-drug interaction 1 (1.7%) patients. A total of 110 interactions were identified which includes 60 Major interactions,29 moderate interactions and 11 minor interactions (TABLE NO:1) Similar interactions were reported in the study conducted by Thomas BR., et al. (2017)[19].
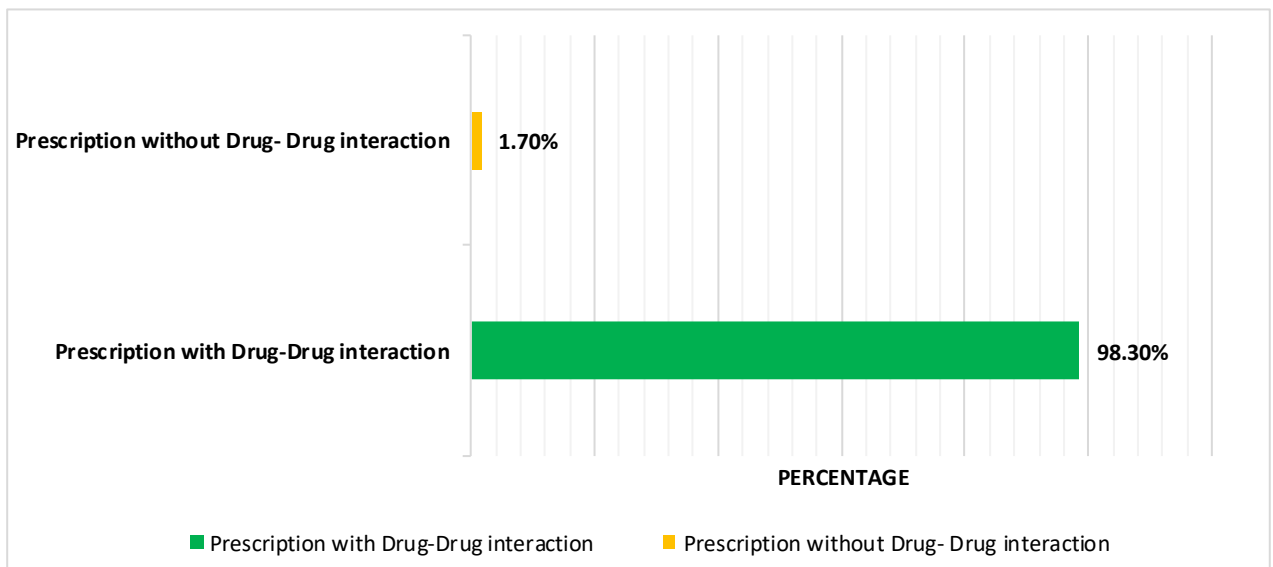


**Fig No. 9 DRUG - DRUG INTERACTIONS**

**TABLE NO:1 SEVERITY OF DRUG – DRUG INTERACTIONS**

**(n=110)**

| SEVERITY OF DRUG - DRUG INTERACTION | NO.OFPRESCRIPTIONS |
|---|---|
| Major | 60 |
| Moderate | 29 |
| Minor | 11 |

**ADVERSE DRUG REACTIONS:**

The antiplatelets and anticoagulants utilized for the prevention of CVD has the potential risk of bleeding. There were 12 suspected Adverse drug reactions in the study population. The

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most common ADRs seen are GI Ulcers and GI Bleeding in patients using aspirin, thrombocytopenia in patients using heparin, gum bleeding and nose bleeding in patients using ticagrelor (TABLE NO:2).

These findings correlate with the study conducted by Pramodh B., et al. (2017)[23] which report ADR found in study population due to utilization of antiplatelet drugs and anticoagulant drugs.

**TABLE NO: 2 SUSPECTED ADVERSE DRUG REACTIONS**

| S. NO | SUSPECTED ADVERSE DRUG REACTION | FREQUENCY | REACTION |
|-------|----------------------------------|-----------|----------|
| 1 | Aspirin | 6 | GI ulcer & GI bleeding |
| 2 | Ticagrelor | 4 | Gum bleeding & nose bleeding |
| 3 | Heparin | 2 | Thrombocytopenia |

**CONCLUSION:**

Increase in age, random changes in lifestyle, lack of physical activities, increased stress, work load, smoking habits have been the predominant factors in causing CVD. It is essential to prevent CVD with help of rational drug therapy. The present study gives an overview of pattern of antiplatelet and anticoagulants agents used in the prevention of CVD at a tertiary care hospital. Drug utilization pattern shows antiplatelet and anticoagulant agents are the widely used agents in CVD prevention in the cardiology department. Aspirin, clopidogrel, heparin and warfarin are the drug of choice irrespective of the side effects associated with its use. In spite of the efficacy of the antiplatelet and anticoagulant agents, the physicians must be concerned more about the bleeding risk in patients utilizing these agents. Individual risk stratification must be taken into account in order to prevent bleeding before initiating antiplatelet and anticoagulant agents, especially as dual or triple therapy. The irrational use of antiplatelet and anticoagulant agents can be avoided by reviewing the guidelines periodically and implementing the guidelines in a specific clinical setup. Drug-drug interaction is a major hurdle in management of CVD where multiple therapy is essential. Routine monitoring of

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drug interaction and effective strategies for the management of drug interaction may result in better outcome in CVD prevention. Adverse Drug Reactions monitoring and detection is very important in case of utilization of antiplatelet and anticoagulant agents because of their higher rate of inducing bleeding. The timely detection of bleeding will enable the prevention of morbidity and mortality in patients receiving antiplatelet and anticoagulant agents. The current study reveals clinical pharmacist has a major role in monitoring, identifying and preventing the bleeding risk associated with antiplatelet and anticoagulant drug use.

## FUTURE OUTLOOK:

➢ The current study can be conducted on a larger scale in different health sector where anticoagulant and antiplatelet drugs are used frequently, so that the number of adverse drug reactions and drug-drug interactions involved with these drugs can be explored further.

➢ The study can be extended to a large population, so that the study will be more effective and helps in providing a framework on individualizing therapy.

➢ Institutional guidelines and National guidelines can be developed to prescribe anticoagulant and antiplatelet drugs appropriately in Indian population.

➢ Cost effectiveness and cost benefit analysis of anticoagulant and antiplatelet agents can be done in order to reduce health care cost in CVD prevention.

## ACKNOWLEDGEMENT

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