



AMERICAN JOURNAL OF PHARMTECH RESEARCH

Study of Drug Use Evaluation and Bleeding Risk of Anticoagulants by Has-Bled In Geriatrics

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ABSTRACT

Anticoagulant therapy being the most conventional form of therapeutic intervention is the cornerstone for the treatment and prevention of various ailments including Atrial Fibrillation (AF), Acute Coronary Syndrome (ACS), Venous Thromboembolism (VTE) and patients undertaking cardiac procedures¹. Bleeding is the principal complication of anticoagulants even though used within its therapeutic limit. An innovative tool HAS-BLED score come up with the assessment of bleeding risk among patients under anticoagulant therapy supporting the physicians in a better clinical decision making^{2,3}. The objective is to evaluate drug use and bleeding risk of anticoagulant drugs using HAS-BLED Score among geriatric patients. A prospective observational study was conducted in a tertiary care hospital among hundred patients for a period of six months. It was found that 61% were males and 49% were females. Most of the patients were from the age group of 65-70 (53%), 71-75 (31%) and least less than 75 (16%). The most commonly prescribed dosage form was parenteral (79%) and drug was heparin (52%). The bleeding risk of twenty patients taking warfarin was assessed using HAS- BLED Score, the risk categories shows greater than or equal to 3 (60%) high risk and score between 1-2 (40%) moderate risk. Drug use pattern of anticoagulants needs uninterrupted and repeated surveillance not only to discern therapeutic efficacy but also to scrutinize potential adverse drug reaction. From the HAS-BLED score distribution of patients taking warfarin conveys the need to monitor the parameters especially INR before and after initiation of anticoagulant therapy.

Keywords: Drug Use Evaluation, Anticoagulant Therapy, HAS-BLED Score, Atrial Fibrillation, Bleeding Risk, Warfarin

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Received 12 June 2021, Accepted 20 July 2021

Please cite this article as: Abraham CA *et al.*, Study of Drug Use Evaluation and Bleeding Risk of Anticoagulants by Has-Bled In Geriatrics. American Journal of PharmTech Research 2021.

INTRODUCTION

Anti-coagulation therapy and geriatric population:

Geriatric people represents a population of patients with a higher thromboembolic and haemorrhagic risk. Physicians had a widespread propensity to underuse anticoagulants among elderly patients possibly because of both under evaluation of thromboembolic risk and over assessment of bleeding risk. Thromboembolic risk represents a significant problem in patients with Atrial Fibrillation⁴. The incidence of burden among patients with Atrial Fibrillation and related thrombosis increases progressively with age. In US emergency department it has been reported that more than sixty five thousand patients are treated for warfarin related haemorrhage per annum. Due to this high incidence of bleeding, along with narrow therapeutic drugs and the requirement for continuous monitoring led to development of novel anticoagulants without such strict monitoring⁵. The principal test for monitoring the patients under anti coagulation therapy is INR (International Normalized Ratio). It is obtained from Prothrombin time, which is estimated as the ratio of PT of patients to PT of control.

$$\text{INR} = \text{Patient PT} / \text{Control PT}$$

The patients who are under anticoagulation therapy the estimated range of INR is 2.0-3.0 and monitored every 2-3 weeks⁶.

Drug Utilization Evaluation (DUE):

Drug Utilization Review (DUR) also known as Drug Utilization Evaluation (DUE) is defined as an authorized, structured, ongoing review of health care practitioners prescribing, pharmacist dispensing and patient utilization of drugs. DUEs are developed to study and promote the appropriate drug use and prescribing model, issue feedback of outcomes to other relevant groups^[7]. DUEs are broadly classified as Prospective, Retrospective and Concurrent. DUEs are the source of enhancing the quality of patient care, improving clinical outcomes and reducing the overall healthcare costs. The process of DUE involves 11 steps: 1. Identify the drug/therapeutic area 2. Study Design 3. Define standards and criteria 4. Design the data entry form 5. Data accumulation 6. Evaluate the results 7. Provide feedback 8. Develop and apply the results 9. Re-evaluate to ascertain the drug use has improved 10. Re-assess and revise the DUE process 11. Feedback of results⁸.

Significance of DUE- Identifies opportunities to enhance the quality of life and to promote appropriate drug utilization and minimize the overall healthcare costs.

Has-bleed score:

HAS-BLED is a scoring system discovered to evaluate 1-year risk of major bleeding in patients under anticoagulant therapy with atrial fibrillation. It was initially conducted by Euro Heart Survey in 2010 with data collected from 3978 patients. It is based on 7 parameters with a score between 0 and 9. HAS-BLED is the abbreviated form of the following: 1.Hypertension 2.Abnormal renal and liver function 3.Stroke 4.Bleeding 5.Labile INR 6.Elderly 7.Drugs or alcohol⁹. HAS-BLED has been well verified and proved to outweigh other risk scores in foreseeing therapeutically significant bleeding. Bleeding risk assessment using HAS-BLED was much simpler and showed greater precision. HAS-BLED score of ≥ 3 indicated the need for frequent monitoring, review and follow-up, hence an increased HAS- BLED score permits the clinicians to be alert about the patients at potential bleeding risk^[10].

| | Clinical Characteristics | Points Awarded |
|----------|---------------------------------------|----------------|
| H | Hypertension (> 160 mmHg) | 1 |
| A | Abnormal Liver/ Renal Function | 1 OR 2 |
| S | Stroke | 1 |
| B | Bleeding History Or Predisposition | 1 |
| L | International normalized labile ratio | 1 |
| E | Elderly > 65 yrs | 1 |
| D | Drug /alcohol concomitantly | 1 OR 2 |

MATERIALS AND METHOD:

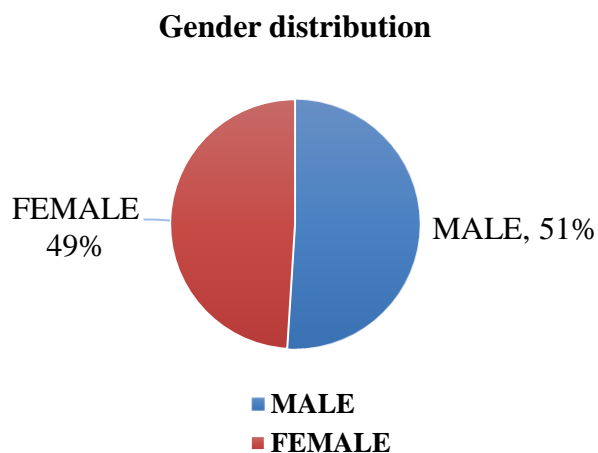
A Prospective observational study was conducted in general medicine and cardiology department of St. James Hospital, Chalakudy, Kerala over a period of six months after getting Institutional Human Ethics Committee Clearance (IHEC/SJCP/A-19/2019-2020). The patients were recruited based on listed criteria:

Inclusion Criteria: 1. Patients of age 65 or above 2. Patients on anticoagulant therapy.

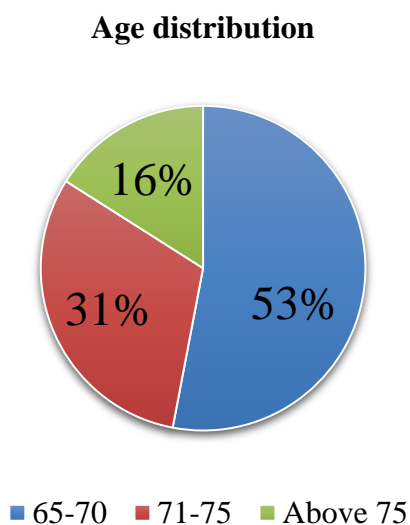
Exclusion Criteria: 1. Patients who are not willing to participate in the study. Patient case report were collected, reviewed and analyzed based on gender, age, admitted department, social history, comorbid and co-prescribed drugs, dosage form, class of anticoagulant used, anticoagulant prescribed, brands of anticoagulant, patients based on HAS-BLED score and its percentage distribution. Out of prescribed anticoagulants, warfarin was analyzed for its bleeding risk using HAS-BLED Score. The patients and their caretakers were verbally counselled on relevance of anticoagulant therapy and need of continuous monitoring of bleeding risk.

RESULTS AND DISCUSSION

From the study we have seen that majority of patients with anti-coagulant treatment participated in the study were Male i.e. 51% and 49 % females.

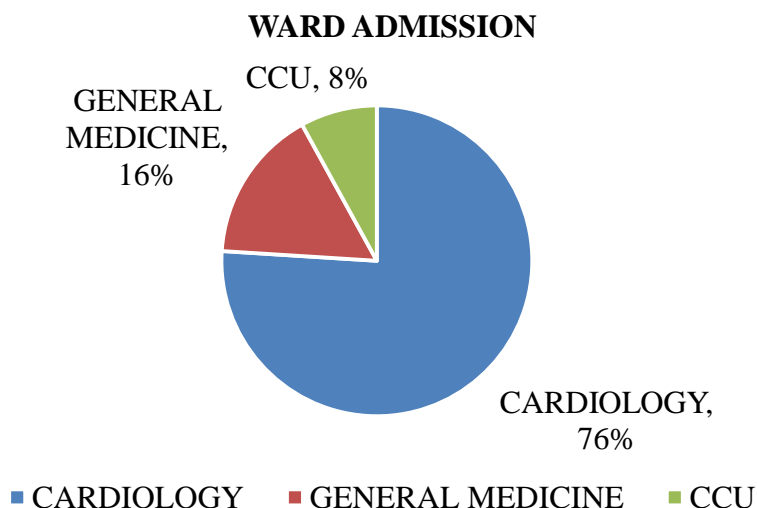
Distribution Based On Gender N=100

Based on patient's age group it was divided in to 3 categories, among 100 patients selected, the highest percentage i.e. 53% was in group of 65 to 70 years and lowest percent i.e. 16% was in group of above 75 years.

Distribution Based On Age N=100

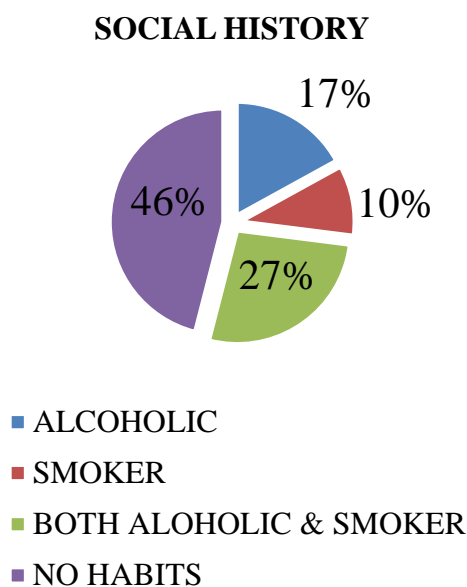
Based on various departments it was concluded that CCU had 76% of patients admitted with highest number of anti-coagulant use and least was seen in general medicine department with 8% admission.

Distribution Based On Admitted Departments N=100



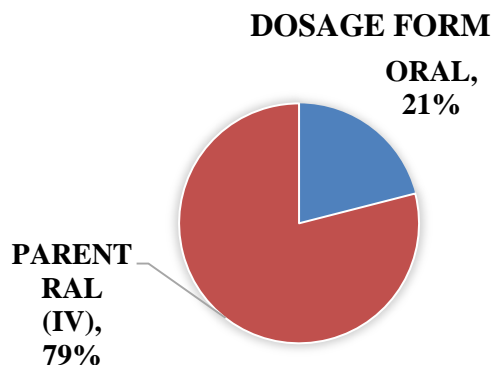
Based on social history majority of the patients i.e. 46% had no social history, 27% were both alcoholics and smokers and 17% were alcoholics alone 10% have social history of smoking.

Distribution Based On Social History N=100



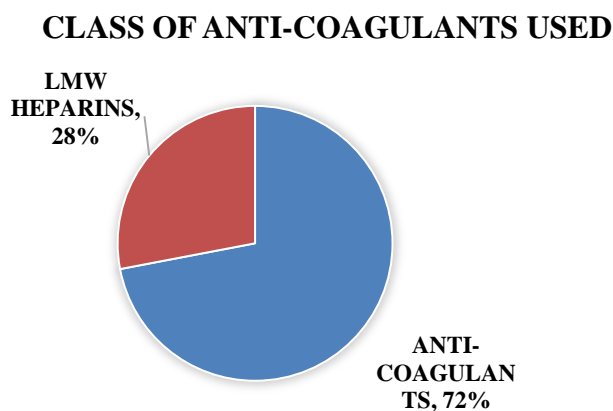
Based on the dosage forms prescribed for anti-coagulants it was found that majority of the drugs given were parenteral with 79% and Oral administration was 21%.

Distribution Based On Dosage Form N=100



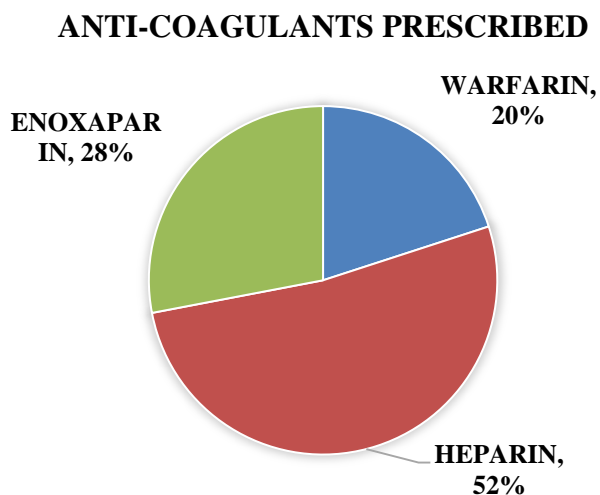
Based on the class of anticoagulants used it is clear that majority of the drugs fall under anti-coagulant class with 72%, 28% fall under the class of low molecular weight heparins.

Distribution Based on Class of Anti-Coagulants used N=100



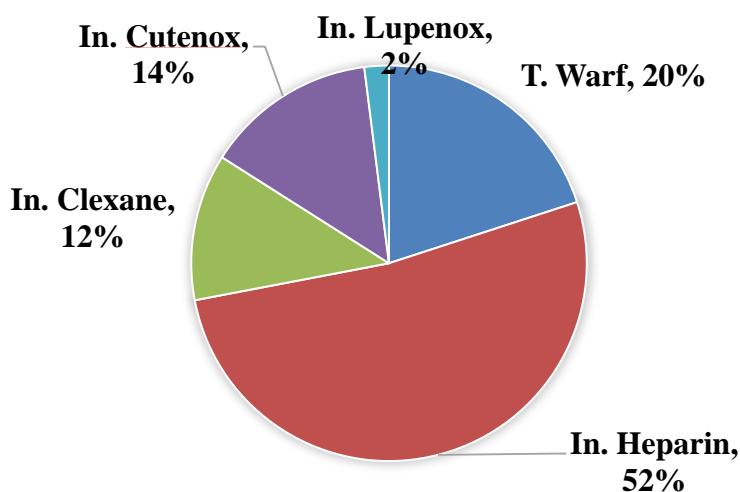
In the study, highest number of anti-coagulant prescribed was heparins found to be 52%, Enoxaparin found to be 28%, Least prescribed was Warfarin with 20%.

Distribution Based On Anti-Coagulants Prescribed N=100



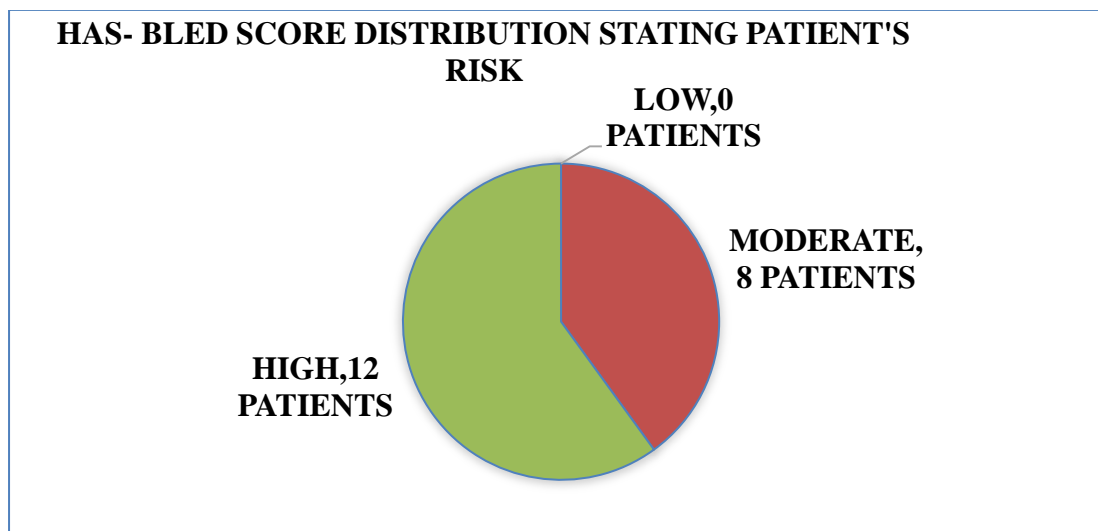
From the study we can clearly conclude that the most commonly prescribed anti-coagulant was found to be Injection Heparin with 52%, least prescribed brand was Injection Lupenox with 2% usage.

Distribution Based On Anti-Coagulants of Various Brands Used N=100



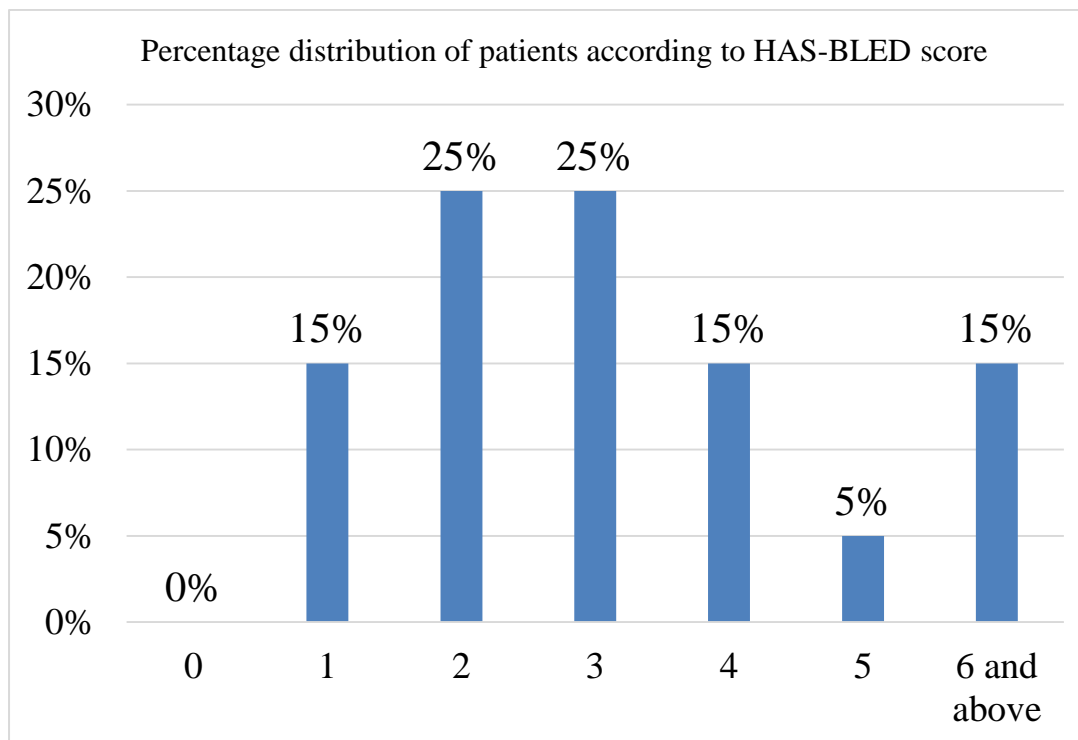
With the sample size n=20 of warfarin taking patients the bleeding risk was assessed using HAS-BLED Score, and hence patients were divided into three risk categories and was found that 12 patients with high risk, 8 patients with moderate risk category.

Distribution Based On Has Bled Score (n=20)



Majority of the patients fall under high bleeding risk with score of ≥ 3 , 40% of patients with moderate risk category of score between 1-2.

Percentage distribution of patients according to HAS-BLED score (n) = 20



CONCLUSION

Drug use pattern of anticoagulants needs uninterrupted and repeated surveillance not only to discern therapeutic efficacy but also to scrutinize potential adverse drug reaction. From this analysis we understood about the requirement of the bleeding risk tools & also the need of continuous evaluation of patients taking Anticoagulants. From the HAS-BLED score distribution of patients taking warfarin conveys the need to monitor the parameters especially INR before and after initiation of anticoagulant therapy.

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