Importance of HAS-Bled Score in Patients on Warfarin Therapy for Atrial Fibrillation

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**ABSTRACT**

**Introduction:** Bleeding is a significant complication when patients are on anticoagulant therapy. The risk of bleeding overall when anticoagulant therapy is used is 3.8%. A number of risk factors are associated with increased bleeding when patients are on anticoagulants. A practical risk score HAS-BLED score was developed to estimate 1-year risk for major bleeding in patients with atrial fibrillation. This study aimed to understand to assess the relevance of HAS-BLED score in predicting bleeding in patients coming to AJ institute of medical sciences.

**Material and methods:** We conducted a case control study in patients on Warfarin therapy for Atrial fibrillation who presented with major bleeding manifestations between September 2017-2018 in a tertiary care center in AJ Institute Of Medical Sciences in South India. Patients or their medical power of attorneys provided written informed consent. A total no of 100 patients were enrolled based on the inclusion criteria patients aged more than 18 years. They were grouped into cases who had bleeding and controls who did not have bleeding. HAS BLED score was calculated. The data was entered in Microsoft Excel and was analysed with SPSS

**Results:** Total of 100 patients (50cases and 50controls) were studied. On analysing the HAS-BLED score the P value showed significant difference between the case and control groups. The sensitivity was 80% and specificity was 68%. The positive and negative predictive value of HAS-BLED values were 71.4% and 77.27% respectively.

**Conclusion:** Our study emphasises the need for making better use of HAS-BLED score in predicting bleeding and the need for monitoring the INR regularly and educating patients on Warfarin therapy about frequent monitoring, the risks of bleeding and to seek early medical attention on developing bleeding.

**Keywords:** Has-Bled Score, Warfarin Therapy, Atrial Fibrillation

**INTRODUCTION**

The prevalence of atrial fibrillation (AF), which is already the most common sustained cardiac arrhythmia, is constantly rising even after adjusting for age and presence of structural heart disease¹. AF increases the risk of stroke six fold and is associated with two fold increase in mortality which remains above 1.5fold even after adjusting for co-morbidity predominantly caused by cerebrovascular events, progressive ventricular dysfunction and increased coronary mortality.² The adverse hemodynamic effects of AF are well described and relate not only to loss of atrial contraction, but also the accompanying rapidity and irregularity of ventricular contraction.³ The possibility of occurrence of thromboembolic event with atrial fibrillation is high. Several studies, such as the Framingham study showed the probability of thromboembolism in patients with atrial fibrillation (AF) rhythm is 17.5-fold higher than in general population, without arrhythmia.¹,²,⁴ Thus anti thrombotic prevention becomes mandatory for this group of patients. The prevalence of atrial fibrillation increase with age, hence increasing numbers of elderly patients are candidates for and could benefit from the use of anticoagulants. The quantification of bleeding risk and identification of modifiable factors are crucial for management decisions. The present study aimed at analysing possible risk factors associated to the oral anticoagulation therapy that could contribute to the hemorrhagic event in Dakshina Kannada population and test the validity of HAS- BLED score in this population.⁴,⁵

HAS-BLED score provides a practical tool to assess the individual risk of bleeding in AF patients potentially supporting clinical decision making regarding anti thrombotic therapy. HAS-BLED is an easy to use tool wherein it helps to assess the risk of major bleeding. The acronym HAS-BLED represents each of the bleeding risk factors and assigns 1point for the presence of each of the following: Hypertension(SBP >160 mmhg); Abnormal Renal and/or liver functions; Previous Stroke; Bleeding history or predisposition; Labile INR; Elderly and concomitant drugs and/or alcohol excess. The score ranges from 0-9 with score >or equal to 3 indicates high risk of bleeding.

HAS-BLED should not be used exclude the patients from oral anticoagulant therapy, it allows clinicians to identify bleeding risk factors and to correct those that are modifiable.

**MATERIAL AND METHODS**

We conducted a Case Control study in patients with Atrial...
Fibrillation on Warfarin therapy for at least one year, age more than 18 years, in medical intensive care unit in AJ INSTITUTE OF MEDICAL SCIENCE a tertiary care hospital in South India from SEPTEMBER 2017-2018. Informed consent was taken for the study. A total no of 100 patients with clinical diagnosis of Atrial Fibrillation during the study period fulfilling the following inclusion criteria

**Inclusion criteria:** All Patients with atrial fibrillation on Warfarin therapy for at least 1 year

**Exclusion criteria:** Known case of bleeding disorders and coagulation disorders. Pregnant females.

The study group was subjected to detailed interview regarding their age, addictions, co-morbidities, history of prior bleeding and any drug intake. Previous INR recordings were looked into. Relevant lab investigations were done for all patients.

Analysed the risk factors and calculated the HAS BLED score in them.

Hypertension was defined as SBP >160mm Hg. Abnormal Renal function was defined as Serum Creatinine >2.3mg/dL. Abnormal Liver Function was defined as total bilirubin >2.6 (2* the UL) Or SGOT >114 (3*the UL) Or SGPT >123 (3*the UL). Anaemia was defined as haemoglobin <12 in females and < 13 in males.

Excess Alcohol intake was defined as >8 drinks/week. HAS-BLED score was calculated. Data entered in Microsoft Excel and analysed using SPSS software.

**RESULTS**

HAS-BLED score less than 3 is protective with respect to bleeding. P value was 0.000 showing highly significant difference in between the 2 groups.

**Age wise, gender-wise distribution**

all patients included in the study were above 18 years of age. Among the 100 patients, 55 were males 45 were females.

<table>
<thead>
<tr>
<th></th>
<th>Risk of Bleeding &gt;3</th>
<th>Not at risk &lt;3</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Present</strong></td>
<td>40</td>
<td>10</td>
<td>50</td>
</tr>
<tr>
<td><strong>Absent</strong></td>
<td>16</td>
<td>34</td>
<td>50</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>56</td>
<td>44</td>
<td>100</td>
</tr>
</tbody>
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*Table-1: Diagnostic test evaluation of HAS-BLED Score*

Mean age group of case were 65.06 and majority of cases were in the age group 81-90 years. Mean age group among controls was 60.2 (graph-1,2,3).

Association between HAS-BLED score and Bleeding P value 0.0000, less than 0.0001, there was highly significant difference in the two groups. An independent sample t Test was also done comparing the HAS BLED scores which showed P value of 0.0000 showing highly significant difference (graph-5, table-1).

**Sensitivity**

Here is the probability that a patient with bleeding would give a HAS-BLED score suggestive of high risk of bleeding.
Sensitivity = 40/50 * 100 i.e; 80%

Specificity
Here it is the probability of the control subject to give a HAS-BLED score less than 3 score suggestive of no risk of bleeding.
Specificity = 34/50*100 = 68%

Positive predictive value
Here it is the probability for an AF patient on Warfarin with a HAS-BLED score more than 3 to have bleeding
PPV = 40/56 * 100 = 71.4%

Negative predictive value
Here it is the probability for an AF patient on Warfarin with a HAS-BLED score less than 3 to not have bleeding
NPV = 34/44 * 100 = 77.27%

DISCUSSION
In our study 50 cases and 50 controls were included out of which 55 were females and 45 were males. 32 among cases and 23 among controls were females. Gender was not found to be a significant risk factor in our study. In a study done by S.Takach Lapner et al also the risk of major bleeding during the anti coagulant therapy appears to be the same in men and women.6

In our study majority of the bleeding manifestations occurred in the age groups 81 to 90 years but on statistical analysis age wasn’t found to be a risk factor but in the study conducted by Elaine M. Hylek et al age was a significant independent risk factor for haemorrhage (odds ratio; CI: 1:3 to 3:1).7

In another study done by Daniela Poli also >80yrs was associated with increased bleeding risk. In our study the maximum number of cases occurs during the first month of warfarin therapy. In the study conducted by Landelfeld et al the monthly risk of major bleeding decreased overtime from 3% during the first month if therapy to 0.3% per month after the first year of therapy.8

The sensitivity and specificity of HAS-BLED score from our study was 80% and 68% respectively. The positive and negative predictive value was 71.4% and 77.27% respectively. In the original validation in the Europe Heart survey the predictive accuracy of HAS-BLED score was compared against another bleeding risk score, Hemorrhages and revealed similar C statistics of 0.72 and 0.66 respectively, for the overall validation cohort. Overall HAS-BLED offers better prediction of bleeding compared with many other bleeding risk scores, although the predictive value varies depending upon the cohort.9

CONCLUSION
The sensitivity and specificity of HAS-BLED score from our study was 80% and 68% respectively. The positive and negative predictive value was 71.4% and 77.27% respectively. HAS-BLED has better accuracy at predicting the risk of major bleeding. Our present findings emphasise the need for monitoring the INR regularly and educating the people about the risk of bleeding and to seek early medical attention on developing bleeding.

REFERENCES
9. Landelfeld CS, Goldman OL, Major bleeding in outpatients treated with warfarin incidence and prediction by factors known at the start of outpatient therapy. The American journal of Medicine 1989;87:144-152.