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Original Article

ORBIT versus HAS-BLED Scores in Predicting Major Bleeding in Patients with Atrial Fibrillation Receiving Oral Anticoagulants

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Abstract

Background: Atrial fibrillation (AF) is marked by irregular and often rapid heartbeats and is closely tied to various cardiovascular diseases. This study set out to examine and compare bleeding events in AF patients receiving oral anticoagulants at Sohag University Hospital, using bleeding risk scores such as HAS-BLED (which assesses hypertension, abnormal renal/liver function, stroke and bleeding history, and labile INR) alongside the ORBIT registry for better-informed treatment choices.

Methods: A total of 100 patients with valvular heart disease or heart valve replacement, who were receiving anticoagulants for non-valvular atrial fibrillation (AF) and had a CHA2DS2-VASc score of 2 or higher, participated in this prospective observational comparative study. The goal of the study was to assess bleeding events using the HAS-BLED and ORBIT bleeding risk scores in patients treated with either warfarin or NOACs.

Results: A moderate risk of bleeding was prevalent among most patients, as reflected by median ORBIT and HAS-BLED scores of 3 (range 2-3). Both scores effectively predicted major bleeding ($P < 0.001$), with area under the curve values of 0.734 for ORBIT and 0.845 for HAS-BLED. At a cutoff of >2, ORBIT demonstrated sensitivity of 64.79%, specificity of 72.41%, positive predictive value of 85.2%, and negative predictive value of 45.7%, while HAS-BLED showed 69.01% sensitivity, 79.31% specificity, 89.1% positive predictive value, and 51.1% negative predictive value.

Conclusions: In patients with atrial fibrillation (AF) treated with direct oral anticoagulants, both the HAS-BLED and ORBIT bleeding risk scores show moderate predictive power for bleeding. However, the HAS-BLED score excels over the ORBIT score when predicting significant bleeding, with better sensitivity and specificity.

Keywords: ORBITScore, HAS-BLED Score, Major Bleeding, Atrial Fibrillation, Anticoagulants

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Introduction:

Atrial fibrillation (AF) is a prevalent arrhythmia characterized by irregular and often rapid heartbeats, frequently linked to cardiovascular diseases such as heart failure, coronary artery disease, valvular heart disease, diabetes, thyrotoxicosis, and hypertension. Projections indicate that by 2050, the US will see 6–12 million AF cases, with 17.9 million cases expected in Europe by 2060, solidifying AF as the most common arrhythmia globally. AF substantially increases the risk of ischemic stroke and exacerbates economic and public health challenges, given its high rates of morbidity and mortality.[1,2]

Stroke prevention is the primary goal in managing AF, as the condition increases stroke risk by five times. Oral anticoagulants (OACs), including non-vitamin K oral anticoagulants (NOACs) and vitamin K antagonists like warfarin, are essential for this purpose. Balancing the risk of bleeding complications with the prevention of thromboembolic events is critical to ensuring the best patient outcomes. [3]

The increased bleeding risk in patients receiving anticoagulants, driven by a range of clinical characteristics, has led to the development of several bleeding risk scores in recent years. The "HEMORRH2AGE," "HAS-BLED," and "ATRIA" scores have been frequently applied in clinical practice until recently.[4]

The HAS-BLED score, a practical and efficient tool, can be utilized in clinical settings to assess major bleeding risk in patients both with and without atrial fibrillation (AF), including those with venous thromboembolism, acute coronary syndrome, or undergoing percutaneous coronary interventions or bridging therapy. [5, 6]

A five-factor bleeding risk score was also developed by the ORBIT-AF registry for bedside use, which includes anti-platelet therapy, low hemoglobin/HCT levels, a history of bleeding, elderly age, and renal insufficiency. [7, 8]

This study sought to estimate and compare the rate of bleeding events in AF patients treated with oral anticoagulants by using the HAS-BLED and ORBIT bleeding risk scores at Sohag University Hospital.

Patients and Methods:

In this prospective, comparative, and observantional study, 100 patients, both male and female, aged 18 or older, with valvular heart disease or heart valve replacement who were receiving anticoagulants, were included. A CHA2DS2-VASc score of 2 or higher indicated non-valvular atrial fibrillation in these patients, who were being treated with NOACs or warfarin. The study, conducted from October 2023 to May 2024, was approved by the Sohag University Hospitals' Ethical Committee, and all patients provided informed written consent.

Exclusions from the study included patients on anticoagulants without AF, pregnant women diagnosed with AF, and individuals with AF treated with non-oral anticoagulants.

Before the study began and throughout the 6-month follow-up, each patient underwent a complete history review, clinical examination, and lab tests like CBC, liver and kidney function tests, INR, and aPTT. Other tests, including HbA1C, thyroid function tests, and lipid profiles, were also conducted.

The occurrence of major bleeding events, includeing spontaneous epistaxis, gum bleeding, hematemesis, rectal bleeding, intracranial hemorrhage, and internal bleeding, was monitored during the entire 6-month follow-up period.

In order to evaluate which score better predicts bleeding events in AF patients receiving oral anticoagulants, bleeding incidents were assessed using both the HAS-BLED and ORBIT scores, and the findings were compared for all cases.

Statistical analysis

SPSS v26 was an appropriate choice for statistical analysis, enabling effective data manipulation. The Shapiro-Wilks test and histograms ensured proper normality assessment, and data were summarized using mean ± SD for parametric data and median with IQR for non-parametric data. The ROC curve was used to evaluate diagnostic performance, offering key insights into sensitivity, specificity, PPV, and NPV, crucial for assessing the accuracy of the tools.

Results:

This table lists the study patients' demographic information and comorbidities. (Table1)

Table 1: Demographic data and comorbidities of the studied patients

		N=100
Age (years)		52.4 ± 10.83
Sex	Male	42(42.0%)
	Female	58(58.0%)
Comorbidities	HTN	51(51.0%)
	Antiplatelet treatment	58(58.0%)
	History of stroke	38(38.0%)
	History of bleeding	71(71.0%)
	Incidenc of major bleeding	11(11.0%)

Data are presented as mean ± SD or frequency (%). HTN: hypertension.

CBC, liver function tests, lipid profile, glucose, HbA1C and INR were enumerated in this table. **Table 2**

Table 2: CBC, liver function tests, lipid profile, glucose, HbA1C and INR of the studied patients

		N=100
CBC	**WBC (103/ul)**	8.9±2.89
	RBC (106/ul)	4.4±0.77
	HGB (g/dl)	11.9±2.07
	HCT (%)	36.2±5.82
	MCV (fl)	82.6±6.15
	MCH (pg)	27.2±2.42
	MCHC (g/dl)	32.9±1.46
	PLT (103/ul)	269.7±88.58
Liver function tests	**ALT (u/l)**	20.8 ± 11.56
	AST (u/l)	21.7 ± 11
	ALB (g/dl)	3.8 ± 0.84
	T. Bilirubin (mg/dl)	0.5 ± 0.53
	D.Bilirubin (mg/dl)	0.2 ± 0.46
	IN. Bilirubin (mg/dl)	0.3 ± 0.19
Lipid profile	**Cholesterol (md/dl)**	150.8±54.37
	Triglyceride (mg/dl)	144.9±89.52
	HDLC (mg/dl)	38.2±11.23
	VLDL (mg/dl)	29±17.9
	Cholesterol (md/dl)	150.8±54.37
Kidney function tests	**Creatinine (mg/dl)**	1.5±0.99
	urea (mg/dl)	52±30.9
Glucose (mg/dl)		202.4±132.34
HA1C (%)		7.1±2.28
INR		3.8±1.61

The data are displayed as mean ± SD, with WBC (white blood cell)and RBC (red blood cell) HCT stands for hematocrit, HGB for hemoglobin, Mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), mean corpuscular hemoglobin concentration (MCHC), platelet count (PLT), alanine aminotransferase (ALT), aspartate aminotransferase (AST), ALB: albumin, t. bilirubin: total bilirubin, D. Bilirubin: direct, I. Bilirubin: indirect, VLDL: very low-density lipoprotein, HDLC: high-density lipoprotein cholesterol, INR stands for International Normalized Ratio, and HbA1c for hemoglobin.

The median (IQR) of ORBIT score was 3(2-3). The median (IQR) of HAS-BLED score was 3(2-3). **Table 3**

Table 3: ORBIT score and HAS-BLED of the studied patients

	N=100
ORBIT score	3(2–3)
HAS-BLED score	3(2–3)

The median is used to display the data (IQR). The HAS-BLED risk factor scoring system is based on bleeding history, hypertension, abnormal renal/liver function, stroke, and labile INR. ORBIT Score is an acronym for the Outcomes Registry for Better Informed Treatment.

ORBIT and HAS-BLED score respectively can significantly predict major bleedig (P <0.001 and AUC = 0.734 and 0.845) at cut-off >2 with 64.79% and 69.01% sensitivity, 72.41% and 79.31% specificity, 85.2% and 89.1% PPV and 45.7% and 51.1% NPV

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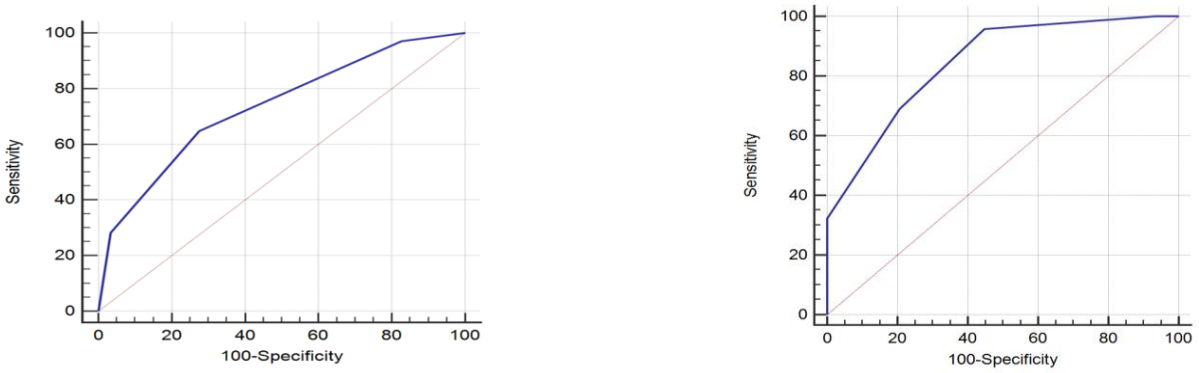

(A) **(B)**

Figure 1: ROC curves for (A) outcomes registry for better informed treatment score and (B) HAS-BLED score for major bleeding prediction.

Discussion

The mainstays of managing AF to avoid stroke, thromboembolic events, and death are oral anticoagulants (OAC). One main drawback of OAC treatment is bleeding. [9]

Regarding the results, WBC ranged from 4.26 to 17.13 10^3/ul with a mean value (±SD) 8.9 (± 2.89) 10^3/ul. RBC ranged from 2.72 to 6.28 10^3/ul with a mean value (±SD) 4.4 (± 0.77) 10^3/ul. HGB ranged from 8.1 to 16.2 g/dl with a mean value (±SD) 11.9 (± 2.07) g/dl. HCT ranged from 23.4 to 47.6% with a mean value (±SD) 36.2(± 5.82) %.MCV ranged from 63.8 to 100 fl with a mean value (±SD) 82.6(± 6.15) fl. MCH ranged from 19.8 to 32.7 pg with a mean value (±SD) 27.2(± 2.42) pg. MCHC ranged from 29.1 to 36.3 g/dl with a mean value (±SD) 32.9(± 1.46) g/dl. PLT ranged from 150 to 628 10^3/ul with a mean value (±SD) 269.7(± 88.58) 10^3/ul. O'Brien et al. [10]

stated that in 7411 AF patients took DOACs, showed significantly abnormal hemoglobin/ Hct which increased significantly in patients with major bleeding risks.

Added to that, these results are in accordance with Esteve-Pastor et al,[11]

declared that in 1433 patient with AF took anticoagulants, mean Hb level was 14.1 ± 1.6 g/dl. Concerning liver function test, ALT ranged from 4 to 76 u/l with a mean value (±SD) 20.8(± 11.56) (u/l). AST ranged from 6 to 67 u/l with a mean value (±SD) 21.7 ± 11 u/l. alkaline phosphatase ranged from 1.6 to 5.5 g/dl with a mean value (±SD) 3.8(± 0.84) g/dl. Total Bilirubin ranged from 0.14 to 4.72 mg/dl with a mean value (±SD) 0.5(± 0.53) mg/dl. Direct Bilirubin ranged from 0.02 to 4.52 mg/dl with a mean value (±SD) 0.2(± 0.46) mg/dl. Indirect Bilirubin ranged from 0.06 to 1.29 mg/dl with a mean value (±SD) 0.3(± 0.19) mg/dl. In the same line of our results, Proietti et al.[12]

showed that in 3018 AF patients took oral anticoagulants, there was liver disease in 49 (1.6%) patients. Our study reports that Creatinine ranged from 0.5 to 6.2 mg/dl with a mean value (±SD) 1.5(± 0.99) mg/dl. Urea ranged from 16 to 136 mg/dl with a mean value (±SD) 52(± 30.9) mg/dl. Wattanaruengchai et al. [13]

ascertained our outcomes as they found that in 961 AF patients took DOACs, renal functions (eGFR) were 64.71 ± 18.77 mL/min/1.73m^2. Added to that, these findings are supported by Esteve-Pastor et al. [11]

demonstrated that in 1433 patients with AF, mean creatinine clearance was 74.9 ± 21.7 ml/ min.

Our study concludes that the median(IQR) of ORBIT score was 3(2-3). ORBIT score can significantly predict major bleeding (P <0.001 and AUC = 0.734) at cut-off >2 with 64.79% sensitivity, 72.41% specificity, 85.2% PPV and 45.7% NPV. These results are in the same line of

Wattanaruengchai et al,[13] who found that in 961 AF patients took DOACs, ORBIT score was 2.37 ± 1.71 and showed sensitivity for prediction major bleeding 70.6%, NPV 94.4%, and PPV 5.6%. In line with Esteve-Pastor et al., (11) who found that the ORBIT score has a sensitivity of 0.724 and specificity of 0.707 for predicting major bleeding in AF patients on OAC, our results differ from those of Wattanaruengchai et al. (13)

In their study of 961 AF patients on DOACs, the ORBIT score showed a specificity of 56.4%. This was attributed to the higher incidence of bleeding among Asian patients, who typically experience more bleeding events than individuals from other ethnic groups.

Concerning our results, The median (IQR) of HAS-BLED score was 3(2-3). HAS-BLED score can significantly predict major bleeding (P <0.001 and AUC = 0.845) at cut-off >2 with 69.01% sensitivity, 79.31% specificity, 89.1% PPV and 51.1% NPV. Lane & Lip al. (14)

agreed to our outcomes as they noticed that HAS-BLED was sensitive in predicting major bleeding [0.53 (0.52–0.54) in AF patients.

Supporting the findings of Esteve-Pastor et al. (11), this study confirms that the HAS-BLED score, a discrete variable with integer values, has a sensitivity of 0.862 and an ideal cutoff of 2 for assessing the risk of major bleeding in AF patients receiving DOACs. Esteve-Pastor et al. (11) found that the HAS-BLED score had a specificity of 0.543 for predicting major bleeding in AF patients. For high-risk patients, bleeding risk assessment tools with higher sensitivity should be used, whereas low-risk individuals should be evaluated with instruments that offer greater specificity. (15)

In our study, the HAS-BLED score was found to be marginally more sensitive and specific than the ORBIT score. Additionally, Esteve-Pastor et al. (11) noted that the HAS-BLED score had better calibration, particularly in patients more prone to bleeding.

The study's limitations include a small sample size, a single-center design, and a heavy reliance on accurate documentation of risk factors. The presence of missing event data may have introduced bias, while the labile INR factor in the HAS-BLED score could have skewed the model's performance, leading to inaccurate predictions of bleeding risk.

Conclusions:

While both the HAS-BLED and ORBIT bleeding risk scores provide moderate accuracy in predicting major bleeding in AF patients on direct oral anticoagulants (DOACs), the HAS-BLED score proves more effective. It shows greater sensitivity (69.01% vs. 64.79%), specificity (79.31% vs. 72.41%), positive predictive value (PPV) (89.1% vs. 85.2%), and negative predictive value (NPV) (51.1% vs. 45.7%), making it a more reliable tool for clinicians assessing bleeding risks in AF patients treated with oral anticoagulants.

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