

Updated Review of HAS-BLED Score for Major Bleeding Risk

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Abstract

The HAS-BLED Score for Major bleeding risk estimates 1-year risk of major bleeding for patients with atrial fibrillation on anticoagulation as a part of shared decision-making.

I. HOW TO USE

When to Use

- Consider using the HAS-BLED Score as a reference tool to assist in the shared decision-making discussion regarding anticoagulation in patients with atrial fibrillation.
- Consider using the HAS-BLED Score instead of, or in conjunction with, other bleeding risk scores such as HEMORR₂HAGES and ATRIA to determine risk of major bleeding in a patient with atrial fibrillation.
- Consider comparing the risk for major bleeding as calculated by the HAS-BLED Score to the risk for thromboembolic events by the CHA₂DS₂-VASc to determine if the benefit of anticoagulation outweighs the risk.

Pearls / Pitfalls

The HAS-BLED Score was developed as a practical risk score to estimate the 1-year risk for major bleeding in patients with atrial fibrillation.

Study included 3456 ambulatory and hospitalized patients with AF and one-year follow-up status regarding major bleeding, and without mitral valve stenosis or valvular surgery.

- Patients were followed up at one year to determine survival and major adverse cardiovascular events, such as major bleeding.

- Major bleeding was defined as intracranial hemorrhage, bleeding requiring hospitalization, bleeding with hemoglobin decrease >2 g/L, or bleeding requiring transfusion
- Researchers performed univariable analysis to find potential bleeding risk factors associated with major bleeding at 1 year follow-up
- Developed HAS-BLED score based on results of their analysis as well as known significant risk factors for major bleeding
- Results showed that the annual bleeding rate increased with increasing scores

Points to keep in mind:

- Despite its popularity, neither the European nor the American guidelines recommend any specific risk score for predicting bleeding events in patients with AF
- The derivation study was based on a cohort in which only around 2/3 were on any antithrombotic therapy. The score has since been validated extensively.
- Clinical factors that contribute to stroke risk and support anticoagulation in patients with atrial fibrillation are frequently risk factors for bleeding as well.
- There may be superior predictive scores for bleeding events in patients taking direct oral anticoagulants, e.g. the DOAC score.
- Use this score with caution in patients with conditions that are associated with elevated bleeding

risks, including but not limited to chronic kidney disease and cancer – this score has been shown to perform poorly in both of these conditions.

Why Use

The HAS-BLED Score can assist in the shared decision-making discussion regarding anticoagulation in patients with atrial fibrillation.

II. NEXT STEPS

Critical Actions

Patient specific risks and benefits of anticoagulation must be carefully weighed in all patients who are potential candidates for long-term anticoagulation therapy.

III. EVIDENCE

Evidence Appraisal

The HAS-BLED Score was developed in 2010 as a practical risk score to estimate the 1-year risk of major bleeding in patients with atrial fibrillation (AF). [The original study](#) used data from the prospective Euro Heart Survey on AF, and included 3456 ambulatory and hospitalized patients with AF and one-year follow-up status regarding major bleeding, and without mitral valve stenosis or valvular surgery. These patients were identified from both academic and non-academic hospitals in 35 member countries of the European Society for Cardiology (ESC).

Major bleeding was defined as intracranial hemorrhage, bleeding requiring hospitalization, bleeding with hemoglobin decrease >2 g/L, or bleeding requiring transfusion. The authors performed univariable logistic regression to identify potential risk predictors ($p < 0.10$), which were then included in a multivariable logistic model and underwent variable selection by stepwise regression. Importantly, the authors noted the short follow-up period and the resultant scarcity of events, and thus added three risk factors consistently demonstrated to predict major bleeding in the then-contemporary literature (stroke, alcohol use, systolic blood pressure >160 mmHg) to the selected variables. The resultant score, HAS-BLED, thus included nine risk factors with one point each. In the derivation study, HAS-BLED achieved a c-statistic of 0.72 in the overall cohort, with c-statistics ranging between 0.69 (in those with oral anticoagulant alone) and 0.91 (in those with antiplatelet therapy alone) in various subgroups stratified by the type of antithrombotic therapy at baseline.

Many external validations of the HAS-BLED score have been published. These include [a seminal study published in 2011](#) using data from the SPORTIF III and V clinical trials (which evaluated ximelagatran, a thrombin

inhibitor, as anticoagulant in patients with AF) which outperformed 4 other contemporary predictive scores for major bleeding with a modest c-statistic. Perhaps more importantly, this validation study was also the first to define the risk categories of HAS-BLED, as these were not mentioned in the original derivation study. A large number of studies have since been published, which both validated HAS-BLED and often compared it against other similar predictive scores. A [2020 network meta-analysis of 18 studies](#) found HAS-BLED to be the most balanced predictive score for major bleeding in terms of sensitivity and specificity, compared to other contemporary scores including the ABC-bleeding score, ATRIA, European score, GARFIELD-AF, HAS-BLED, HEMORR2HAGES, ORBIT, Shireman, and mOBRI. A [2021 meta-analysis of 39 studies](#) further estimated a c-statistic of 0.63 for major bleeding in anticoagulated patients, with almost identical performances in those using vitamin K antagonists and those using direct oral anticoagulants (DOAC). However, the same meta-analysis did not quantitatively evaluate the calibration of HAS-BLED, as was done by [an earlier 2015 meta-analysis](#) which found significant under-prediction of bleeding events in those with HAS-BLED-defined moderate bleeding risk, but acceptable calibration in those with HAS-BLED-defined low or high bleeding risk. This was despite the fact that only around 2/3 of the derivation cohort were on at least one antithrombotic therapy.

The simplicity of the HAS-BLED score and the extensive external validations have led to widespread clinical adoption, with the [2020 ESC guidelines](#) specifically recommending HAS-BLED for the assessment of bleeding risk in patients with AF. However, the more recent [2024 ESC guidelines](#) and the [2023 ACC/AHA/ACCP/HRS guidelines](#) both did not recommend a specific predictive score for major bleeding, citing uncertainties over accuracy and potential harms of not anticoagulating appropriately. The American guideline also mentioned the inclusion of multiple common risk factors for both bleeding and stroke in HAS-BLED as being unconvincing to balancing the risks of these events in patients with AF.

Such reservation at least partly stemmed from the fact that HAS-BLED was derived when DOAC were only starting to become available, which casts doubt on the predictive accuracy of HAS-BLED in truly contemporary cohorts with DOAC use. A [recent meta-analysis](#) found it to be inferior to the DOAC score in patients with AF using DOAC. Even when others found HAS-BLED to be comparable or superior in performance to other scores, such as by [Chichareon et al in 2023](#), its discriminatory performance has remained mediocre since its original derivation. Additionally, the definition of estimated risk of major bleeding cited in most studies came from much earlier work, and was not aligned with most modern definitions of major bleeding. It is not clear whether these remain valid or translatable to modern

clinical practice, with recent studies (e.g. [Chichareon et al 2023](#), [Mei et al 2024](#)) showing conflicting results. Furthermore, studies have shown HAS-BLED (and other common risk scores for bleeding events) to have poor performance in patients with specific risk-modifying conditions, such as [chronic kidney disease](#) and [cancer](#), calling into question the score's utility in these patients.

Lastly, and perhaps most importantly, even though clinicians are advised to balance the risks of bleeding and thromboembolism in patients with AF when considering anticoagulation, the real-life implications of these events may not be equivalent. Without more granular data on the mortality and quality-of-life implications of these events (and thus different categories of HAS-BLED score), the HAS-BLED score should continue to be a metric of reference for clinicians to consider when discussing the risks and benefits of anticoagulation in patients with AF, and it may not be prudent for clinicians to directly compare bleeding and thromboembolic risks in a simplistically numeric manner without discussion with patients.

Formula

Addition of the selected points:

Variable	Points
Hypertension	1
Renal disease (dialysis, transplant, Cr >2.26 mg/dL or 200 µmol/L)	1
Liver disease (cirrhosis or bilirubin >2x normal with AST/ALT/AP >3x normal)	1
Stroke history	1
Prior major bleeding or predisposition to bleeding	1
Labile INR (unstable/high INRs, time in therapeutic range <60%)	1
Elderly (age >65)	1
Medication usage predisposing to bleeding (aspirin, clopidogrel, NSAIDs)	1
Alcohol usage (≥8 drinks/week)	1

Note: HAS-BLED is an acronym for Hypertension, Abnormal liver/renal function, Stroke history, Bleeding predisposition, Labile INR, Elderly, Drug/alcohol usage.

Facts & Figures

HAS-BLED Score	Risk group	Risk of major bleeding**	Bleeds per 100 patient-years***	Recommendation
0	Low	0.9%	1.13	Anticoagulation should be considered
1		3.4%	1.02	
2	Moderate	4.1%	1.88	Anticoagulation can be considered
3	High	5.8%	3.72	Alternatives to anticoagulation should be considered
4		8.9%	8.70	
5		9.1%	12.50	
>5*	Very high	-	-	

*Scores greater than 5 were too rare to determine risk, but are likely over 10%.

**Risk figures from [Lip 2011](#).

***Risk figures from [Pisters 2010](#).

Literature

Original/Primary

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