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## ORBIT Bleeding Risk Score for Atrial Fibrillation

The ORBIT score predicts bleeding risk in patients who are taking anticoagulants for atrial fibrillation.

### Points & Pearls

- The derivation and validation studies for the ORBIT score (older, reduced hemoglobin, bleeding history, insufficient kidney function, treatment with anti-platelets) defined *major bleeding* as fatal bleeding, symptomatic bleeding in a critical organ, or bleeding with a hemoglobin drop requiring transfusion of  $\geq 2$  units of blood (O'Brien 2015).
- The ORBIT score does not consider the choice of anticoagulant.
- Unlike the HAS-BLED score (hypertension, abnormal liver/renal function, stroke history, bleeding predisposition, labile international normalized ratio, elderly, drug/alcohol usage), the ORBIT score was derived in a patient population that included patients who received vitamin K antagonists (eg, warfarin) as well as patients who received direct oral anticoagulants.
- Unlike the HAS-BLED score, the ORBIT score does not consider the time in therapeutic range, as there is no reliable or readily available objective measure for therapeutic range of the direct oral anticoagulants.

### Critical Actions

Risk assessment is multifactorial for both stroke risk and bleeding risk.

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### Why to Use

The ORBIT score is not superior to the HAS-BLED score (see the "Evidence Appraisal" section), but it was derived more recently and has been validated in the era of direct oral anticoagulants, so it may be more useful. The ORBIT score can be used in conjunction with the CHA<sub>2</sub>DS<sub>2</sub>-VASc score to risk stratify patients for clinically significant bleeding and help guide decisions about anticoagulation for stroke prevention.

### When to Use

The ORBIT score is used for patients with atrial fibrillation for whom treatment with oral anticoagulants is being considered.

### Next Steps

The presence of risk factors that are not included in the ORBIT score may influence the clinician's decisions regarding anticoagulation in patients with atrial fibrillation. Patient preferences and values should also inform these decisions, in the context of the risks and benefits of taking oral anticoagulants for stroke prevention.

### Evidence Appraisal

Stroke prevention is part of the management plan for patients with atrial fibrillation. The CHADS<sub>2</sub> or CHA<sub>2</sub>DS<sub>2</sub>-VASc scores are often used to calculate stroke risk in patients with atrial fibrillation. Drug therapies for stroke prevention can include anti-platelet therapy (eg, aspirin) or anticoagulation, depending on the risk for stroke; however, anticoagulation also creates bleeding risk. Other bleeding

risk scores include HAS-BLED, ATRIA, and others; among these scores, HAS-BLED is best validated and likely the most used.

O'Brien et al (2015) derived and validated the ORBIT score as a way to assess bleeding risk in patients with atrial fibrillation. Derivation was based on data from ORBIT-AF, a prospective registry of patients with atrial fibrillation from 176 sites in the United States. Of the 10,132 patients in the registry, 7411 were analyzed (2721 patients were excluded because they were not on oral anticoagulants or because there were no follow-up data available). *Major bleeding* was defined as fatal bleeding, symptomatic bleeding in a critical organ, or bleeding with a hemoglobin drop requiring transfusion of  $\geq 2$  units of blood. The simplified 5-item ORBIT score was based on the 5 predictors with the strongest association with major bleeding.

The authors also validated the ORBIT score with data from the ROCKET-AF trial, a cohort of patients receiving either once-daily rivaroxaban or a vitamin K antagonist. The validation study showed that the ORBIT score had better discrimination than ATRIA or HAS-BLED (C statistic = 0.67, 0.66, and 0.64, respectively).

Subsequent studies in different patient populations did not show the ORBIT score to be superior to the other scores. Senoo et al (2016) studied 2293 patients in the AMADEUS trial and found that the HAS-BLED score performed better than the ORBIT score for predicting major bleeding (C statistic = 0.65 and 0.61, respectively;  $P = .001$ ). Esteve-Pastor et al (2016) found that the ORBIT score was not superior to the HAS-BLED score in predicting major bleeding in 406 patients who underwent electrocardioversion (C statistic = 0.82 and 0.77, respectively;  $P = .08$ ), or in 1276 patients with persistent atrial fibrillation who were in the FANTASIA registry (C statistic = 0.70 and 0.63, respectively;  $P = .12$ ). Wang et al (2017) conducted a meta-analysis that showed the HAS-BLED score to be superior to the ORBIT score in predicting major bleeding in 8079 patients with anticoagulated, nonvalvular atrial fibrillation patients from the United States, Britain, Spain, and the Netherlands.

The same studies also showed that the ORBIT score places more patients in the low-risk category than the HAS-BLED score, potentially underpredicting the major bleeding risk for these patients (Senoo 2016, Esteve-Pastor 2016, Wang 2017). This raises the concern that some at-risk patients may not be identified by the ORBIT score. Lip et al (2018) suggest that the HAS-BLED score has higher sensitivity but lower specificity for major bleeding risk as compared to the ORBIT score. As a result, care must be taken when clinically applying the results of either score.

## Use the Calculator Now

[Click here to access the ORBIT score on MDCalc.](#)

## Calculator Creator

Emily C. O'Brien, PhD

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## References

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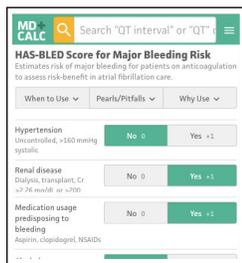
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# HAS-BLED Score for Major Bleeding Risk

The HAS-BLED score estimates the risk of major bleeding for patients on anticoagulation, in order to assess risks and benefits in the care of patients with atrial fibrillation.

## Points & Pearls

- For patients with atrial fibrillation, the clinical factors that contribute to stroke risk and support anticoagulation are frequently risk factors for bleeding as well. The HAS-BLED score (hypertension, abnormal liver/renal function, stroke history, bleeding predisposition, labile international normalized ratio [INR], elderly, drug/alcohol usage) was developed as a practical risk score to estimate the 1-year risk for major bleeding in patients with atrial fibrillation.
- The original HAS-BLED study provided risk percentages for given risk factors but did not stratify scores into low, medium, or high risk; subsequent studies have looked at risk stratification using the score (see the “Evidence Appraisal” section).
- The performance of the HAS-BLED score has been shown to be superior to the ATRIA and HEMORR<sub>2</sub>HAGES scores, and similar to the ORBIT score.
- Clinicians should consider comparing the risk for major bleeding as calculated by the HAS-BLED score to the risk for thromboembolic events by CHADS<sub>2</sub> or CHA<sub>2</sub>DS<sub>2</sub>-VASc scores to determine whether the benefit of anticoagulation outweighs the risk.

## Critical Actions

Risk assessment is multifactorial for both stroke risk and bleeding risk.

## Evidence Appraisal

The HAS-BLED score was developed by Pisters et al (2010) as a practical risk score to estimate the 1-year risk for major bleeding in patients with atrial fibrillation. The study included 5333 ambulatory and hospitalized patients with atrial fibrillation from both academic and nonacademic hospitals in 35 member countries of the Euro-

## Why to Use

The HAS-BLED score can be used to help guide the decision on whether to start anticoagulation in patients with atrial fibrillation.

## Next Steps

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

pean Society for Cardiology. Patients were followed up at 1 year for survival and major adverse cardiovascular events, such as major bleeding. (*Major bleeding* was defined as any bleeding that required hospitalization, caused a decrease in hemoglobin level of > 2 g/dL, or required blood transfusion, excluding hemorrhagic stroke.)

Researchers performed a retrospective univariate analysis to find potential bleeding risk factors when comparing the groups with and without major bleeding at the 1-year follow-up, and developed the score based on the results of their analysis as well as known significant risk factors for major bleeding. Results showed that the annual bleeding rate increased with increasing risk factors, with an overall major bleeding rate of 1.5%.

These findings were validated in a study by Lip et al (2011), who studied the score in 7329 patients with atrial fibrillation who participated in the SPORTIF clinical trial. They found a stepwise increase in rates of major bleeding with an increasing HAS-BLED score (*P* for the trend < .0001, *C* statistic = 0.50-0.67).

Apostolakis et al (2012) compared the HAS-BLED score with 2 alternative bleeding risk scores, HEMORR<sub>2</sub>HAGES and ATRIA, using data from the AMADEUS trial cohort. AMADEUS was a multicenter randomized open-label noninferiority study comparing fixed-dose idraparinux (a novel oral anticoagulant) with warfarin or acenocoumarol (vitamin K antagonists) in nonvalvular atrial fibrillation. They found that the HAS-BLED score performed best for the primary endpoint of any clinically relevant bleeding. Patients in the co-

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hort were already at low risk for stroke and major bleeding, which differs from many real-life scenarios.

Roldán et al (2013) conducted a study comparing the HAS-BLED score with the ATRIA score as both quantitative and dichotomized variables (ie, low-medium vs high risk) in 937 outpatients with atrial fibrillation on anticoagulation who had stable INR, and found that the HAS-BLED score more accurately predicted major bleeding. There were some criticisms of the study related to potential selection bias, as it excluded patients who were warfarin-naive and patients with unstable INR, and the study had limited applicability outside the clinic setting.

### Use the Calculator Now

[Click here to access the HAS-BLED score on MDCalc.](#)

### Calculator Creator

Ron Pisters, MD, PhD

[Click here to read more about Dr. Pisters.](#)

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DOI: <https://doi.org/10.1378/chest.12-0608>

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