

### Prediction of major bleeding in patients receiving DOACs for venous thromboembolism: a prospective cohort study

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**Background:** The accuracy of currently available bleeding scores in patients on treatment with direct oral anticoagulants (DOACs) for venous thromboembolism (VTE) is undefined.

**Purpose:** In a prospective cohort of patients with VTE treated with DOACs, we evaluated the accuracy of the ATRIA, HAS-BLED, Kujjer, ORBIT, RIETE and VTE-BLEED risk scores in predicting major bleeding (according to ISTH definition).

**Methods:** The accuracy of different scores to correctly classify subjects into a defined risk category was assessed by the c-statistic.

**Results:** Overall, 1141 patients were evaluated and 1034 included in the study. The index event was pulmonary embolism in 509 patients (49.2%) and proximal deep vein thrombosis in the remaining patients (50.8%). During the 12-month study period, 26 major bleedings occurred in 25 patients

(2.8% patient-year): 14 major bleedings occurred in the first 6 months of treatment and 12 from 6 to 12 months in the 654 patients remained on treatment.

In the 12-month study period, the VTE-BLEED score showed the best predictive value for bleeding complications (c-statistics 0.674, 95% CI 0.593–0.755). The lowest incidence of major bleeding (0.3%) was observed in the low risk category of VTE-BLEED which includes 38% of patients. The highest incidence of major bleeding (7.1%) was observed in the high-risk category of ORBIT which includes 10.9% of patients.

**Conclusions:** The VTE-BLEED score had the best accuracy in predicting major bleeding during treatment with DOACs for VTE. Whether the VTE-BLEED score can be used for decision making on anticoagulation should be tested in a management study.