Abstract: P4767

VTE-BLEED score predicts major bleeding in patients with atrial fibrillation

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Topic(s):
Oral Anticoagulation

Citation:

Background
Bleeding risk scores in atrial fibrillation (AF) are used to identify risk factors for bleeding but not to determine anticoagulant therapy since high bleeding risk strongly correlates to high risk of stroke. VTE-BLEED is a simple bleeding risk score (Klok FA Eur Respir J 2016) that predicts major bleeding (MB) in patients with venous thromboembolism, but has never been evaluated in AF.

Aims
To evaluate VTE-BLEED in AF and whether dabigatran dose reduction in VTE-BLEED high-risk patients would result in a lower incidence of MB and the composite endpoint of MB plus stroke/systemic embolism.

Methods
Assessment of VTE-BLEED in 18040 patients of the RE-LY trial (Connolly SJ NEJM 2009) that compared dabigatran (both 150mg BID and 110mg BID) to warfarin. The score was calibrated to fit the AF population. Hazard ratios (HR) were obtained for the VTE-BLEED high-risk patients randomized to dabigatran. The risk ratios for MB and the composite outcome of MB plus stroke/systemic embolism between dabigatran 150mg and 110mg were calculated for the VTE-BLEED high-risk group.

Results
The adapted VTE-BLEED score classified 4060 patients (22.5%) as high-risk. A high score indeed predicted MB in patients treated with dabigatran 150mg BID or 110mg BID, for HRs of 2.48 (95%CI 1.96-3.13) and 2.61 (95%CI 2.04-3.33), respectively. In VTE-BLEED high-risk patients, the risk ratio between the two dabigatran doses was 0.53 (95%CI 0.35-0.78) for MB and 0.55 (95%CI 0.38-0.79) for the composite outcome, both in favor of dabigatran 110mg BID (Figure 1). Compared to the current European label of dabigatran, application of VTE-BLEED to determine dabigatran dosing would result in a different dose for 21% of patients.

Conclusions
VTE-BLEED was validated for AF. Our data suggest that dabigatran dose reduction in VTE-BLEED bleed high-risk patients -in addition to targeting individual modifiable risk factors for bleeding- may lower the risk of MB and improve patient outcome. This finding could have important clinical implications but should be confirmed in future studies.
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