

Letters

CHA₂DS₂-VASc Score for Predicting Stroke and Thromboembolism in Patients With AF and Biological Valve Prosthesis



Patients with valvular atrial fibrillation (AF), as defined in the 2012 European Society of Cardiology guidelines (those with a valvular prosthesis or rheumatic mitral disease) should receive anticoagulation regardless of the CHA₂DS₂-VASc score, with vitamin K antagonist being recommended (1-3). Whether thromboembolic risk related to bioprosthetic valve implantation differs from other forms of AF is not established with certainty. We evaluated the prognostic value of the CHA₂DS₂-VASc score for thromboembolic in AF patients with aortic or mitral bioprosthesis.

We included all AF patients seen in our institution between 2000 and 2010 (4) with nonvalvular AF, according to the European Society of Cardiology definition (e.g., those with neither rheumatic valve disease nor valvular prosthesis) (2), and, among patients with valvular AF, those with biological valve prosthesis. The CHA₂DS₂-VASc score, which has been validated in nonvalvular AF, was calculated for each patient (1). We calculated Harrell's C-statistic as a measure of model performance.

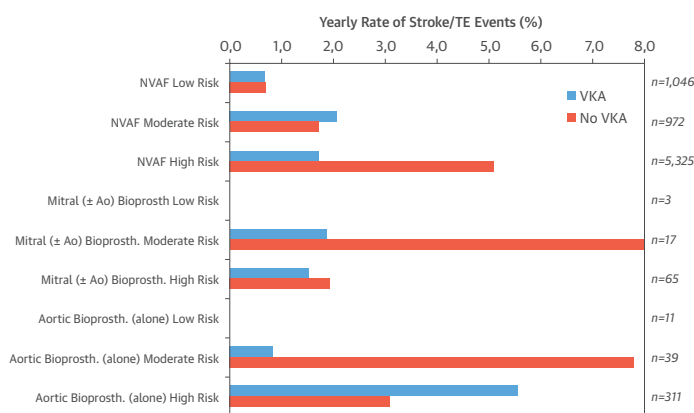
Among 8,602 AF patients, 8,053 patients (94%) had nonvalvular AF and 549 (6%) had a bioprosthesis. AF patients with a bioprosthesis had higher CHA₂DS₂-VASc score and were more often treated with oral anticoagulation. The follow-up was $876 \pm 1,048$ days and 681 thromboembolic events were recorded. The C-statistic for CHA₂DS₂-VASc score was higher in patients with nonvalvular AF than in patients with bioprostheses: 0.64 (95% confidence interval [CI]: 0.63 to 0.65) versus 0.55 (95% CI: 0.50 to 0.59; $p = 0.04$). However, the CHA₂DS₂-VASc score performed similarly in identifying low-risk patients in the 2 groups: 0.59 (95% CI: 0.58 to 0.60) versus 0.52 (95% CI: 0.47 to 0.56; $p = 0.11$). There was an increase

in the risk of thromboembolic events with increasing CHA₂DS₂-VASc score in all AF patients (Figure 1). Increasing age and CHA₂DS₂-VASc score were independently associated with an increased risk of thromboembolic events, whilst the presence of bioprosthesis was not.

Our population of AF patients is to date the largest series reporting outcomes in those with bioprosthesis. The CHA₂DS₂-VASc score should theoretically be used for patients with nonvalvular AF (2). Increasing age and CHA₂DS₂-VASc score were the main independent predictors of thromboembolic events in our study. The score was effective (although rather poor) to predict thromboembolic risk even in patients with bioprosthesis and performed similarly in identifying low-risk patients whether the patients had bioprosthesis. We confirm both the low thromboembolic risk for patients with a low risk score and a distinctly increased risk for higher scores in the case of nonvalvular AF. There was a less distinct increase in the incidence of adverse events in patients with aortic and/or mitral bioprostheses. This may indicate that important factors for risk prediction are not captured by the score. The presence of a bioprosthesis was not an independent predictive factor for thromboembolic events, suggesting that the presence of a bioprosthesis is not per se a thromboembolic risk factor.

A yearly rate of thromboembolic events $>1\%$ justifies anticoagulation for patients with nonvalvular AF (2). Patients with AF and a low theoretical thromboembolic risk score fitted with a bioprosthesis had a low annual rate of thromboembolic events even for those not treated with anticoagulation. These findings obtained in smaller subgroups of patients should be interpreted cautiously but may suggest that there is no increased risk with the valvular prosthesis in these AF patients who, in the absence of bioprosthesis, would be considered at low risk of thromboembolic events.

Overall, this real-world study lends support to the use of CHA₂DS₂-VASc score for the evaluation of AF patients with bioprostheses. The CHA₂DS₂-VASc score was predictive of thromboembolism in AF patients with a bioprosthesis and performed similarly in identifying low-risk patients whether patients had bioprosthesis or nonvalvular AF.

FIGURE 1 Yearly Rate of Thromboembolic Events in AF Patients

Low risk: CHA₂DS₂-VASc 0 in males, 1 in females; moderate: 1 in males, 2 in females; high: >1 in males, >2 in females. Ao = aortic; AF = atrial fibrillation; NVAF = nonvalvular atrial fibrillation; VKA = vitamin K antagonist.

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Effects of P-Selectin Antagonist Inclacumab in Patients Undergoing Coronary Artery Bypass Graft Surgery



SELECT-CABG Trial

Despite unprecedented advances over the last few decades, saphenous vein graft (SVG) failure remains a major concern following coronary artery bypass graft (CABG) surgery (1), and since contemporary treatment options are limited in these patients, there is an unmet need for novel therapeutic concepts. Early evidence to support the adhesion molecule P-selectin as a potential therapeutic target was provided by different animal models of vascular inflammation (2,3), as well as phase I clinical studies (4). The recent SELECT-ACS (Effects of the P-Selectin Antagonist Inclacumab on Myocardial Damage After Percutaneous Coronary Intervention for Non-ST-Segment Elevation Myocardial Infarction) trial then demonstrated the efficacy of inclacumab, a human monoclonal antibody directed against P-selectin, in reducing myocardial damage following percutaneous coronary intervention in patients presenting with acute coronary syndromes (5). The SELECT-CABG (Effects of P-Selectin Antagonist Inclacumab in Patients Undergoing Coronary Artery Bypass Graft Surgery) trial was therefore designed to assess the effects of inclacumab on SVG disease assessed by quantitative coronary angiography 1 year after CABG surgery.

Between December 2010 and May 2012, this prospective, randomized, multicenter, double-blind, placebo-controlled trial enrolled patients undergoing CABG surgery (with the use of ≥ 1 SVG) at 38 centers in Canada and the United States. Of 394 patients