Clinical Investigations

HAS-BLED and CHA_2DS_2-VASc Scores as Predictors of Bleeding and Thrombotic Risk After Continuous-Flow Ventricular Assist Device Implantation

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ABSTRACT

Background: HAS-BLED and CHA_2DS_2-VASc scores predict bleeding in patients on anticoagulation and thromboembolic (TE) risk in patients with atrial fibrillation, respectively. We hypothesized that these scores would be predictive of bleeding and TE complications following continuous-flow ventricular assist device (CF-VAD) implantation.

Methods and Results: Baseline HAS-BLED and CHA_2DS_2-VASc scores were retrospectively determined for 173 consecutive patients who underwent HeartMate II CF-VAD implantation at a single center from 2005 to 2011. Forty-three patients had bleeding (24.9%) and 22 had TE (12.7%) events over a 290 patient-year follow-up period. The mean ± SD HAS-BLED scores were 2.7 ± 1.0 and 1.9 ± 1.1 ($P < .0001$) in patients with and without bleeding, respectively. The CHA_2DS_2-VASc scores were 3.6 ± 1.4 and 2.9 ± 1.5 ($P = .03$) in patients with and without TE events, respectively. A HAS-BLED score of ≥3 was associated with a significantly higher risk of bleeding events compared with a score of <3 (42% vs 15%, respectively; hazard ratio [HR] 3.40, 95% confidence interval [CI] 1.82−6.32; $P < .001$). A CHA_2DS_2-VASc score of ≥3 was associated with a higher risk of TE events compared with a score of <3 (18% vs 4%, respectively; HR 4.02, 95% CI 1.19−13.6; $P = .025$).

Conclusions: Baseline HAS-BLED and CHA_2DS_2-VASc scores of ≥3 conferred significantly higher risks of bleeding and TE, respectively, following HeartMate II implantation. (*J Cardiac Fail 2014;20:800−807*)

Key Words: Ventricular assist devices, heart failure, hemorrhage, clotting, risk factors.

The use of continuous-flow ventricular assist devices (CF-VADs) has increased in patients with end-stage heart failure. Although the risk-benefit profile of CF-VADs continues to evolve, thromboembolic (TE) and bleeding events persist despite progress toward improved devices, a better understanding of the pathophysiology of these complications, and efforts to individualize patient management.[1] Although patient characteristics at the time of implantation would be expected to influence future adverse events, current practice is characterized by starting with a ''one-size-fits-all'' strategy, reserving adjustment of anticoagulation therapy for those in whom a complication has occurred.[2] Estimating the risks of thrombotic and hemorrhagic events is not unique to patients receiving mechanical circulatory support, and it is conceivable that tools developed and validated in other, much larger, populations may retain utility in the CF-VAD population. There is significant precedent for using previously validated scores in novel populations (eg, Model for End-Stage Liver Disease score to estimate prognosis after left ventricular assist device

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(LVAD),[3] APACHE II score to select LVAD candidates[4]), and therefore we applied this concept in the present analysis. The HAS-BLED (hypertension, abnormal renal/liver function, stroke, bleeding history or predisposition, labile international normalized ratio, elderly, drugs/alcohol concomitantly) score predicts bleeding events in patients on oral anticoagulation therapy, and the CHA_2DS_2-VASc (congestive heart failure, hypertension, ≥75 years, diabetes, stroke/transient ischemic attack or thromboembolism, vascular disease, elderly, sex) score predicts TE events in patients with atrial fibrillation.[5−8] The aim of the present study was to evaluate the predictive ability of these 2 scoring tools when applied to patients undergoing CF-VAD implantation. If predictive, these scores might then be used to guide anticoagulation management decisions and reduce the risk of complications.

Methods

The University of Minnesota Medical Center left ventricular assist device (LVAD) database was retrospectively analyzed after Institutional Review Board approval was obtained. We identified 173 consecutive patients who received a HeartMate II (HMII; Thoratec, Pleasanton, California) CF-VAD from June 20, 2005, to October 15, 2011. Details of the device have been previously described.[9] We reviewed each patient's electronic health record to obtain information on baseline characteristics, clinical data, laboratory data, bleeding events, and TE events. We excluded surgery-related complications, including mediastinal bleeding, any stroke or bleeding event that occurred within 48 hours of initial implantation, and complications from any subsequent surgery. We defined a bleeding event as any occurrence of systemic bleeding that required hospital admission or blood transfusion at any time during admission outside the 48-hour immediate postoperative period. Hemorrhagic conversion from ischemic stroke was not considered to be a bleeding event. Iatrogenic bleeding, such as that from tissue plasminogen activator (tPA; n = 1) or high-intensity intravenous heparin (n = 1), was excluded. TE events included ischemic stroke, transient ischemic attack (TIA), systemic embolus, or pump thrombosis. Pump thrombosis was defined as a thrombus found during pump exchange, echocardiographic appearance of a thrombus, or diagnosis of pump thrombosis based on clinical suspicion alone if reported in the hospital discharge summary. Baseline HAS-BLED and CHA_2DS_2-VASc scores were retrospectively determined for all 173 patients from the medical history at the time of implantation.

HAS-BLED Score Calculation

Laboratory data, patient data, and patient history before LVAD implantation were reviewed. HAS-BLED scores were calculated with the use of the original scoring system[8] with previous aspirin use defined as use for >1 month: current systolic blood pressure of >160 mm Hg (uncontrolled hypertension; 1 point); abnormal renal function (dialysis, transplantation, or serum creatinine of >2.6 mg/dL) and/or abnormal liver function (cirrhosis, bilirubin >2× normal, aspartate transaminase/alanine transaminase/alkaline phosphatase >3× normal) (1 point for abnormal renal function plus 1 point for abnormal liver function; maximum of 2 points); previous ischemic stroke, TIA, or embolic event (1 point); bleeding diathesis (previous significant bleeding event or anemia; 1 point); labile international normalized ratio (INR) (ie, therapeutic time <60% of the time; the INR therapeutic range depended on the previous indication; only outpatient INR and the first INR of an admission were used; 1 point); age >65 years (elderly; 1 point); and drug use (antiplatelet agents or nonsteroidal antiinflammatory drugs [NSAIDs]) and/or alcohol consumption (≥8 units of alcohol consumption per week) (1 point for drugs plus 1 point for excess alcohol consumption; maximum of 2 points). The maximum HAS-BLED score is 9.

CHA_2DS_2-VASc Score Calculation

Laboratory data, patient data, and patient history before CF-VAD implantation were reviewed. CHA_2DS_2-VASc scores were calculated with the use of the original scoring system[5,7]: congestive heart failure (1 point); history of hypertension (1 point); age ≥75 years (2 points) and age >65 to <75 years (1 point); diabetes mellitus (1 point); history of stroke, TIA, or embolic event (2 points); vascular disease (coronary heart disease, peripheral artery disease, or complex aortic plaque; 1 point); and female sex (1 point). The maximum CHA_2DS_2-VASc score is 9.

Statistical Analysis

Continuous variables were compared with the use of paired *t* tests and dichotomous variables with the use of Pearson χ^2 test. Follow-up began at the time of HMII implantation, and patients were censored at the time of death, explantation, heart transplantation, or the end of data collection on October 15, 2012, whichever came first. A time-to-first-event analysis was performed with the use of Cox proportional hazards regression. Univariable hazard ratios were obtained for the HAS-BLED and CHA_2DS_2-VASc scores and their individual components. The proportional hazards assumption was checked with the use of Schoenfeld residuals and was not violated. Kaplan-Meier survival curves were obtained for bleeding and TE events. A 2-sided *P* value of <.05 was considered to be statistically significant. All analyses were performed with the use of Stata 12 (Statacorp, College Station, Texas).

Data Collection and Follow-up After Device Implantation

After device implantation, all patients were on warfarin as well as ≥81 mg aspirin (2 patients were on dipyridamole instead of aspirin owing to a history of anaphylaxis with aspirin). At our institution, the goal INR has been 1.5−2.5 since 2006, although since 2011 our routine goal has been narrower (2−2.5). After discharge from the index hospitalization, patients returned for follow-up, device review, and assessment of their general status. All patients received standard heart failure therapy as tolerated, and all underwent a standardized postoperative rehabilitation program.

Results

A total of 173 patients received an HMII CF-LVAD from June 20, 2005 to October 15, 2011. Total follow-up period was 290 patient-years, and median follow-up was 1.26 years (interquartile range [IQR] 0.57−2.30 y). The mean age of the implanted patients was 55 years (range 14−82 y). The mean Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) profile before implant for the entire cohort was 3.9 ± 1.7. Patients who had a