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BLEEDING AND THROMBOEMBOLIC EVENTS IN PATIENTS WITH HEARTMATE II: ARE THESE RELATED TO THE DEVICE SPEED AND PROTHROMBIN TIME?

ACC Poster Contributions

Ernest N. Morial Convention Center, Hall F

Monday, April 04, 2011, 9:30 a.m.-10:45 a.m.

Session Title: Cardiac Transplantation/Assist Devices -- Basic and Clinical

Abstract Category: 23. Cardiac Transplantation/Assist Devices--Basic and Clinical

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Background: Bleeding and thrombosis are known complications in heart failure patients with the HeartMate II (HMII) left ventricular assist device. The objective of this study was to assess these complications in a consecutive series.

Methods: Retrospective analysis was done of 34 patients with NYHA class III or IV heart failure who underwent HMII implantation. Bleeding and thromboembolic events (TE) were analyzed for one year after implantation or until an end point was reached defined by heart transplantation, device explanation or death. Mean age of the population was 52.9+/- 11.2 years and 80% of the patients were male. Goal INR was 2-3. Severity of bleeding was assessed using the GUSTO classification.

Results: All patients received aspirin and warfarin. There were 20 bleeding events in 13 patients (38%); 7 (35%) were severe, 5 (25%) moderate and 8 (40%) mild. Bleeding caused death in 3 (8.8%) and 4 (11.8%) required major surgical interventions. Bleeding etiology was: epistaxis 6 (33%), gastrointestinal bleeding 5 (25%), intracranial hemorrhage 4 (20%); vaginal bleed, pericardial tamponade, hemothorax, leg hematoma and tongue bleed all occurred once each. Average time to first bleeding event was 75.4+/- 82 days and 65% of the total events occurred in the first 3 months. Most events (11 or 55%) occurred at INR 2-3, 4 (20%) at INR<2 and 5 (25%) at INR>3. There were no significant differences between the means of INR and HMII speeds in bleeding and non bleeding patients (2.37+/- 0.33 vs. 2.2+/- 0.33; p = 0.1 and 9118 +/-412 vs. 9108+/-365 rpm; p =0.8). There were 7 TE in 5 patients (14.7%); 5 (71.4%) events were ischemic stroke; ischemic bowel and HMII thrombus occurred once each. No events occurred at INR>3, 3 (42.8%) at INR 2-3 and 4 (53.2%) at INR<2. Average time to first TE was 161.8+/- 210 days. There were no significant differences between means of INR and HMII speeds in these subjects compared to those without a TE event (2.47 +/- 0.46 vs. 2.13 +/- 0.31; p = 0.1 and 8886 +/- 268 vs. 9090 +/- 409 rpm; p = 0.1).

Conclusion: HMII with anticoagulation carries a high risk of bleeding and TE that does not appear to be related to the INR or HMII speeds.