ABSTRACTS

1

HeartWare HVAD for the Treatment of Patients With Advanced Heart Failure Ineligible for Cardiac Transplantation: Results of the ENDURANCE Destination Therapy Trial

F.D. Pisani,1 C.A. Milano,2 A.J. Tatooles,3 G. Bhat,4 M.S. Slaughter,4 E.J. Birks,5 S.W. Boyce,5 S.S. Najjar,5 V. Jeevanandam,5 A.S. Anderson,5 I.D. Gregoric,5 R.M. Delgado,8 K. Leadley,10 K.D. Aaronson,1 J.G. Rogers,2 1University of Michigan, Ann Arbor; MI; 2Duke University School of Medicine, Durham, NC; 3Advocate Christ Medical Center, Oak Lawn, IL; 4University of Louisville, Louisville, KY; 5MedStar Heart Institute, Washington, DC; 6University of Chicago Medicine, Chicago, IL; 7Northwestern Memorial Hospital, Chicago, IL; 8Surgical Associates of Texas, Houston, TX; 9Texas Heart Institute, Houston, TX; 10HeartWare, Framingham, MA.

Purpose: Mechanically assisted circulation with the HeartMate II (HMII, Thoratec)® axial flow left ventricular assist device (LVAD) has been established as a viable option for the treatment of advanced heart failure in patients ineligible for heart transplantation. The HeartWare® centrifugal flow ventricular assist device system (HVAD) is currently approved for bridge to transplant in the US. The purpose of this study, which was sponsored by HeartWare®, was to compare the safety and effectiveness of the HVAD to HMII in patients with advanced heart failure ineligible for heart transplantation.

Methods: ENDURANCE was a prospective, multicenter evaluation of 450 patients with NYHA Class III-IV symptoms randomized 2:1 to HVAD or HMII. Patients were adults with an ejection fraction ≤25% despite treatment with optimal medical therapy for ≥45 days or treatment with intravenous inotropes for ≥14 days or an intra-aortic balloon pump for ≥7 days. Exclusion criteria included significant end-organ dysfunction, recent myocardial infarction or stroke, coagulopathy, or an anticipated need for a right ventricular assist device. The primary endpoint was stroke free survival at two years defined as alive on the originally implanted device, transplanted or explanted for recovery without a disabling stroke (modified Rankin score >4). Treatment failure was defined as subject death, stroke with a residual modified Rankin score >4, or device malfunction or failure requiring exchange, explantation, or urgent transplantation within the first two years of support. ENDURANCE was designed and powered to demonstrate non-inferiority of the HVAD.

Results: Protocol-driven 24 month follow-up has recently been completed in 450 patients and the data is currently being locked and analyzed. Primary endpoint data will be presented in a late-breaking clinical trial session. Overall success at two years was 73%, while only 22% of patients were transplanted in the initial study period of February 2009 and November 2012 (see Figure).

Conclusion: Real world use of the HVAD Pump continues to support the excellent outcomes on the device, and due to the low rate of transplantation, successful long term support is observed in a significant cohort of patients receiving the device. Final data on the total patients who remained on support beyond 2 years will be available at the time of presentation.

2

Long Term Support of Patients Receiving an LVAD for Advanced Heart Failure: A Subgroup Analysis of the Registry to Evaluate the HeartWare® Left Ventricular Assist System (The REVOLVE Registry)

I.D. Schmitto1,1 C.A. Milano,2 D. Zimpfer,2 A.E. Fiane,3 R. Larbalestier,4 S. Tsui,5 P. Jansz,6 A. Simon,7 S. Schueler,8 M. Struebe8,9 Hannover Medical School, Hannover, Germany; 2Medical University of Vienna, Vienna, Austria; 3Oslo University Hospital, Oslo, Norway; 4Royal Perth Hospital, Perth, Australia; 5Papworth Hospital NHS Foundation Trust, Cambridge, United Kingdom; 6St Vincent’s Clinic, Sydney, Australia; 7Royal Brompton and Harefield Hospital, London, United Kingdom; 8Freeman Hospital, Newcastle upon Tyne, United Kingdom; 9University Heart Center Leipzig, Leipzig, Germany.

Purpose: The REVOLVE Registry is an investigator-initiated registry established to collect post CE Mark clinical data on patients receiving the HeartWare® HVAD System in the European Union and Australia.

Methods: REVOLVE is a multi-center, prospective, single arm registry. Each patient is followed to device explant, transplantation or death. Data was collected on 254 commercial implants between February 2009 and March 2012 from nine centers in Europe (7) and Australia (2). We are now evaluating those patients who remained on support in order to summarize long term support and outcomes in this population. Summary statistics will be used to describe patient demographics, adverse events, length of support and outcomes.

Results: At the time of the initial analysis completed in November 2012, a total of 37 patients were on support for at least 2 years (range 730-1057 days), 26 of who were still alive on support. Another 126 patients who were supported for less than 2 years were still alive on support and could have potentially exceeded 2 years of support during this continued post hoc analysis period. Overall success at two years was 73%, while only 22% of patients were transplanted in the initial study period of February 2009 and November 2012 (see Figure).

Conclusion: This large, randomized clinical trial of the HVAD as mechanical circulatory support for patients ineligible for heart transplantation represents the initial clinical experience supporting this patient population.

3

A Multi-Institutional Outcome Analysis of Patients Undergoing Left Ventricular Assist Device Implantation Stratified By Sex and Race

L. Van Meeteren1, J.D. Schmitto,1 S. Maltais,2 S. Dunlay,3 N. Hogland,4 M.E. Davis,2 F.D. Pugoni,1 K.D. Aaronson,5 J. Cowger,7 P. Shah,8 J.M. Stubak,1 Cardiovascular Surgery, Mayo Clinic, Rochester, MN; 2Cardiac Surgery, Vanderbilt Heart and Vascular Institute, Nashville, TN; 3Cardiovascular Diseases, Mayo Clinic, Rochester, MN; 4Cardiovascular Diseases, Vanderbilt Heart and Vascular Institute, Nashville, TN; 5Cardiac Surgery, University of Michigan Health System,
Purpose: Prior studies demonstrated significant outcome disparities in pt undergoing left ventricular assist device (LVAD) implant when stratified by sex and race. Because very few data exist from large experiences, we reviewed the Mechanical Circulatory Support Research Network registry.

Methods: Between May 2004 and September 2014, 719 pt underwent LVAD implantation at our respective institutions. Median age was 57 years (range, 18-82) and there were 577 males (80%). Race included Caucasian (C) in 586 pt (82%), African-American (AA) in 112 (16%), and Other (O) in 21 (3%). Between sexes, significant preop differences included median age (male: 60 vs. female: 57), ischemic etiology (53% vs. 35%), mean INTERMACS profile (2.9 vs. 2.5), and creatinine (1.3 vs. 1.1) (all p < 0.001). Between races, significant preop differences included median age (C: 61 vs. AA: 51 vs. O: 61), ischemic etiology (55% vs. 24% vs. 40%), redo sternotomy (37% vs. 12% vs. 35%), left ventricular ejection fraction (15% vs. 15% vs. 35%), and creatinine (1.9 vs. 1.4 vs. 2.9) (all p < 0.001). Between sexes, significant preop differences included median age (male: 60 vs. female: 57), ischemic etiology (53% vs. 35%), mean INTERMACS profile (2.9 vs. 2.5), and creatinine (1.3 vs. 1.1) (all p < 0.001).

Results: There were no significant differences in overall survival at 1, 3 or 5 years when stratified by either sex or race (Figure 1). Similarly, there were no differences in freedom from stroke, driveline infection, gastrointestinal bleeding or pump thrombus when stratified by either sex or race (Figure 1). After controlling for differences in baseline characteristics with a multivariate analysis, neither sex nor race significantly affected survival (p = 0.09, p = 0.18, respectively), stroke (p = 0.28, p = 0.21), driveline infection (p = 0.9, p = 0.92), GI bleed (p = 0.48, p = 0.45), or pump thrombus (0.99, p = 0.8).

Conclusion: In this large multi-institutional analysis, while we detected significant differences in preop clinical characteristics, this did not translate into any meaningful differences in late survival or complications. These data greatly facilitate counseling of specific patient subsets prior to LVAD implantation in regards to outcomes.

Methods: We collected data from all HM II implantations performed at 4 European centers in 2006-2014. Analyses included patients’ demographics, operative strategies, adverse events according to Intermacs definitions, length of support and outcomes.

Results: Patients suffered from idiopathic dilated cardiomyopathy (CM) (49.5%, n = 237), ischemic CM (46.6%, n = 223), other CM (3.9%, n = 19). The percentage of patients in Intermacs class 1, 2, 3 and 4+ at implantation was 16.7%, 31.7%, 32.6% and 19%. Immediately before implantation 5.2% of patients had been supported with extracorporeal life assistance and one patient required hemodialysis.

In 9 patients (1.9%) the operation was carried out off-pump; 98% of the implantations were through a median sternotomy. The mean support period was 610 ± 592 days. Termination of LVAD support was due to transplantation in 87 patients (18.2%) after mean period of 582 ± 431 days and due to recovery of ventricular function allowing VAD explantation in 23 patients (4.8%) after mean 347 ± 234 days. Thirty-day, 1-year and 2-year survival rates were 87.2%, 68.2% and 61.9%.

Conclusion: The HM II LVAD has found broad acceptance during recent years and shows an acceptably low complication rate.

Purpose: Since 2006 the HeartWare HVAD has become one of the most frequently implanted ventricular assist devices (VAD) in Europe.

Methods: We collected data from all HVAD implantations performed at 4 European centers in 2006-2014. Analyses included patients’ demographics, operative strategies, adverse events according to Intermacs definitions, length of support and outcomes.

Results: In the study period 1,035 patients received implantation of one or two HVAD pumps. The majority of patients suffered from idiopathic dilated cardiomyopathy (CM) (46%, n = 480), ischemic CM (41%, n = 422), other CM (2%, n = 26) and myocarditis (2%, n = 18). The percentage of patients in Intermacs class 1, 2, 3 and 4+ at implantation was 23.2%, 37.9%, 30.2% and 8.7% respectively. Before implantation 15% of patients had been supported with extracorporeal life assistance and 3.0% required hemodialysis.

In 95% the HVAD was implanted as LVAD (n = 984), in 0.5% as RVAD (n = 5) and in 4.5% as BVAD (n = 46). 77 percent of the operations were carried out with heart-lung machine or on ECMO and 23% off-pump. Whereas 76.3% of the implantations were through a median sternotomy 7.6% used a lateral thoracotomy and 16% a minimally invasive incision. Among the implants in 2014 26% were minimally invasive.

Support periods lasted from 1 day to 5.2 years (mean 446 ± 442 days). Termination of VAD support was due to transplantation in 164 patients (15.9%) after a median of 427 ± 333 days and due to recovery allowing VAD explantation in 12 patients (1.2%) after 502 ± 302 days. Thirty-day, 1-year and 2-year survival rates were 86.6, 65.9 and 56.9%.

Pump thrombosis occurred in 99 patients. The cumulative incidence of pump thrombosis was 7.0% after 1 and 10.6% after 2 years. Driveline infections were reported in 145 patients. Cumulative incidence of driveline infections was 10.2% and 14.1% after 1 and 2 years.

Major bleeding events were seen in 306 patients, resulting in 1- and 2-year cumulative incidence of those events...