Purpose: Prior studies demonstrated significant outcome disparities in patients undergoing left ventricular assist device (LVAD) implantation 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 patients 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 (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. 21%) (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 = 0.28, p = 0.21), driveline infection (p = 0.9, p = 0.92), GI bleed (p = 0.48, p = 0.45), or pump thrombosis (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.

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 ≥3 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 implants 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 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%.

Pump thrombosis occurred in 54 patients (0.07 events per patient year, EPPY). Cumulative incidence rate for pump thrombosis was 10.6% and 13.8% after 1 and 2 years. Driveline infections were reported in 64 patients (0.08 EPPY). Cumulative incidence rate for driveline infections was 8.3% and 12.5% resp. Major bleeding events were seen in 74 patients (0.09 EPPY), resulting in 1- and 2-year cumulative incidence rate of 13.6% and 14.7%.

Finally, cerebral events (hemorrhagic or ischemic strokes) occurred in 89 (0.11 EPPY) patients, with a cumulative incidence rate of 12.7% and 15.2%.

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

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of 20.5% and 21.8%. Finally, cerebral events (hemorrhagic or ischemic strokes) occurred in 137 patients with 1- and 2-year cumulative incidences of 10.6 and 13.8%.

**Conclusion:** The HeartWare HVAD has found broad acceptance during recent years, offers great versatility in implant strategies and shows an acceptably low complication profile.

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**Temporal Analysis of Outcomes During Long-Term Mechanical Circulatory Support: An Initial Report From the Mechanical Circulatory Support Research Network**

S. Malata,1 N.A. Haglund,2 M.E. Davis,3 M.R. Danter,1 M. Xu,4 S.M. Dunlay,5 J. Cowger,6 P. Shah,7 K.D. Aaronson,9 F.D. Pagani,9 J.M. Stulak,10 1Cardiac Surgery, Vanderbilt Univ Med Ctr, Nashville, TN; 2Cardiovascular Medicine, Vanderbilt Univ Med Ctr, Nashville, TN; 3Vanderbilt Univ Med Ctr, Nashville, TN; 4Biostatistics, Vanderbilt Univ Med Ctr, Nashville, TN; 5Cardiovascular Medicine, Mayo Clinic, Rochester, MN; 6Cardiovascular Medicine, St Vincent Heart, Indianapolis, IN; 7Cardiovascular Medicine, Inova Fairfax, Falls Church, VA; 8Cardiovascular Medicine, University of Michigan, Ann Arbor, MI; 9Cardiac Surgery, University of Michigan, Ann Arbor, MI; 10Cardiac Surgery, Mayo Clinic, Rochester, MN.

**Purpose:** Device indications and practice management have changed for placement of continuous-flow left ventricular assist device (CF-LVAD). We sought to perform a multicenter analysis evaluating temporal variations in outcomes after CF-LVAD implantation.

**Methods:** We retrospectively collected data from our multicenter research network. Three time intervals were defined to reflect changes in CF-LVAD technology (Period 1: 2004 to 02/2009; Period 2: 03/2009 to 12/2012; and Period 3: 12/2012 to 2014). Kaplan-Meier curves were used to compare survival and freedom from first adverse events between time periods.

**Results:** 1,064 patients (HearMate II (HMII)=835, HeartWare (HVAD)=229) underwent CF-LVAD implantation between March 2009 and October 2014. Median age at implant was 59 years, and 850 patients (80%) were males. Median follow-up was 0.96 years, and was 100% complete. Device utilization was different between periods (Period 1: HMI=134, 100%; Period 2: HMII=480, 88% vs HV=63, 12%; Period 3: HMII=221, 57% vs HV=166, 43%, p<0.001). While patients in Period 1 were more likely to be reoperations, Period 2 had an increase use of preoperative intraaortic balloon pump. Despite group differences, survival was comparable between time periods. Multivariable analysis adjusting for device type, time periods, age, gender, heart failure etiology and INTERMACS category revealed later periods (2 and 3 vs 1) where at increased risk of gastrointestinal bleeding (GIB, HR=1.52 and 1.99, p<0.001) and pump thrombus (PT, HR=2.45 and 2.67, p=0.04), while risk of neurological events, driveline infection, and mortality was comparable.

**Conclusion:** Despite significant differences in device types, indications, and patient characteristics, post-implant survival is comparable across time intervals. Most contemporary cohort seems to be at increased risk of GIB and PT. Recent practice variability in anticoagulation management may explain these later results.

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**Preliminary Results From ITAMACS, the Italian Multi Center Registry for Mechanically Assisted Circulatory Support**

G. Feltrin,1 M. Frigerio,2 I. Martinelli,2 M. De Bonis,3 M. Rinaldi,4 M. Pilato,5 F. Musumeci,6 G. Faggian,7 U. Livì,8 M. Maccheroni,9 A. Iacovoni,10 A. Barbone,11 G. Di Giammarco,12 C. Maiello,13 G. Marinelli,14 F. Alamanii,15 G. Ambrosio,16 A. Grimaldi,17 G. Leonardo,18 F. Pagani,19 M. Massetti,20 L. Rizzato,21 G. Gerosa,22 A. Nanni Costa,23 1Veneto Region, Regional Centre for Transplant Coordination, Padova, Italy; 2De Gasperis Cardiocenter, Ospedale Niguarda Ca’ Granda, Milan, Italy; 3Cardiac Surgery, San Raffaele Vita-Salute University, Milan, Italy; 4Cardiac Surgery, University of Turin, Città della Salute e della Scienza, Turin, Italy; 5Department of Cardiothoracic Surgery, ISMETT Mediterranean Institution for Transplant and High Specialty Therapy, Palermo, Italy; 6Department of Cardiac Surgery, Azienda Ospedaliera San Camillo Forlanini, Roma, Italy; 7Division of Cardiac Surgery, University of Verona, Verona, Italy; 8Cardiothoracic Department, University Hospital of Udine, Udine, Italy; 9Cardiac, Thoracic and Vascular Department, Cardiac Surgery and Transplantation Unit, Siena, Italy; 10Cardiovascular Department, Ospedale Papa Giovanni XXIII, Bergamo, Italy; 11Cardiac Surgery Unit, Humanitas Research Hospital, Milan, Italy; 12Neuroscience, Imaging e Science Cliniche, Università “G. D’annunzio” Chieti, Chieti, Italy; 13Department of Cardiac Surgery, AORN Ospedali dei Colli, napoli, Italy; 14Department of Cardiothoracic and Vascular Surgery, Cardiac Surgery and Transplantation Unit, Bologna, Italy; 15Cardiovascular Surgery Cardiological Center Monzù, University of Milan, Milan, Italy; 16Cardiothoracic Department, University of Perugia School of Medicine, Perugia, Italy; 17Cardiac Surgery, University of Bari, Bari, Italy; 18Department of Cardiology, Azienda Ospedaliero Universitaria Policlinico - V. Emanuele”, Catania, Italy; 19Cardiac Surgery Department, IRCCS Foundation Policlinico San Matteo, Pavia, Italy; 20OUC Cardiochirurgia, Università Cattolica del Sacro Cuore, Rome, Italy; 21Istituto Superiore di Sanità, National Transplant Centre, Rome, Italy; 22Cardiac, Thoracic and Vascular Sciences, University of Padua Medical School, Padova, Italy; 23Superior Health Institute, National Transplant Centre, Rome, Italy.

**Purpose:** ITAMACS is a retrospective registry coordinated by the National Transplant Centre (CNT, an agency of the Italian Health Ministry), reporting on long-term left ventricular assist device (LVAD) or total artificial heart (TAH) implants performed in Italy. Data on adult patients (pts) from 2010 to 2013, and followed-up till July 2014 are shown.

**Methods:** Age, indication, INTERMACS (IM) profile, postoperative survival and heart transplant (HTx) rate were evaluated in 289 pts who received an LVAD, n=280 (INCOR, 8%; HeartAssist5, 2%; HeartMateII, 30%; HV AD, 34%; Jarvik 2000, 24%; CircuLite Synergy, 2%) or a TAH (N=9) at 20 Italian centers (median 13/center).

**Results:** Implants’ number increased over time, from 60 in 2010 to 91 in 2013. Median age was the lowest in Bridge To Transplant (BTT) pts (n=142: 55y), the highest in Destination Therapy pts (DT, n=104: 66.5y), and intermediate in Bridge To Candidacy (n=40: 58y) or Bridge To Decision pts (n=3: 64y). According to IM profiles, 23% of the pts were in class 1, 31% in 2, 30% in 3, 16% in 4. Classes 1 or 2 were prevalent in pts aged less than 50y (80%) and in BTT group (65%), while 63% of pts over 70y and 59% of DT group had 3 or 4 profile. 30-day mortality was 10% (29 pts). Excluding pts on an investigational device (CircuLite, 1-y survival was 64.8% (fig 1). In pts receiving commercially available LVADs (n=275), 1-year survival was correlated to indication (p=0.06) and IM profile (p=0.08) (fig 1). Only 43 pts (30% of BTT indication) had HTx, at a mean interval of 345±230 days.

**Conclusion:** ITAMACS shows an increasing use of assist devices. In keeping with international data, indication and IM class affect outcomes. The management of both HTx and LVAD/TAH registries by the same National Agency, a peculiar feature of Italian organization, will allow deeper insight into the interactions, role and outcome of these therapies, helping in steering future policies on organ and resource allocation. Prospective data collection, enriched dataset, and audits are warranted.