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.

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

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**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 (HeartMate II (HMI)=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: HMI=480, 88% vs HW=63, 12%; Period 3: HMI=221, 57% vs HW=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.

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

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**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%; HVAD, 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) 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 2013. Median age was the lowest in Bridge To Transplant (BTT) 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.
Long Term Outcomes in HeartMate II Patients Managed With Vitamin K Antagonists Without Antiplatelet Therapy - Results of the EU-TRACE Study

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Purpose: TRACE (Study of Reduced Anti-Coagulation/Anti-platelet Therapy in Patients with the HeartMate II LVAS) is a multi-center study of HeartMate II patients on reduced anti-thrombotic (RT) therapy. Herein, we present the results of an interim analysis of patients who have been followed up for at least 2 years post initiation of RT therapy.

Methods: RT therapy in the TRACE study was defined as HMII patients managed with: Warfarin (or other vitamin K antagonist (AVK)) only; Aspirin only; or no anticoagulation and no antiplatelet therapy. 101 HMII patients from 9 centers were enrolled in the European (EU) arm of the TRACE Study. All patients in the EU arm of the study were on AVK only and no anti-platelet therapy at the time of RT therapy initiation.

Results: 71 patients had reached at least 2 years on device support or outcome post RT initiation [RT Duration: 735[range: 28-2859] days] as of September 2014. Median age was 56 [24-72] years, 93% were male, 54% had an ischemic etiology, 23% received the device as destination therapy, and the median support duration at RT therapy initiation was 21 days. Outcomes at 2 years post RT initiation were as follows: 42% transplanted, 4% expired, 3% had ventricular recovery, and 51% were ongoing on device support. Types of AVK used were: 31% on Warfarin only, 35% PlaXidione only, 32% on Marcumur only, and 1% were on Acenocoumarol. At last follow-up (or at outcome), 67 (94%) patients were still on the single AVK, 3% were converted to full therapy (anticogulation+ antiplatelet therapy), 1% on antplatelet therapy only, and 1% were on no antithrombotic therapy. Median INR at follow-up was 2.31 [range: 0.73-5.2] which was higher than the median INRs of patients in the HMII clinical trial (median of 2.0). Only 4% of the INR measurements were below 1.5. Median LDH was 365 U/L [range: 66-3020]. At 2 years post initiation of RT therapy, freedom from bleeding, hemorrhagic stroke, ischemic stroke and pump thrombosis were respectively 86±5%, 96 ± 3%, 93 ± 3%, 93 ± 3%.

Conclusion: This preliminary analysis of the TRACE study suggests that patients may be safely managed on a single vitamin K antagonist (AVK) with a target INR greater than 2.0, without anti-platelet therapy. Further prospective studies are needed to confirm if these results are applicable to a larger patient population.

Chronic Management With Reduced Anti-Thrombotic Therapy in HeartMate II Patients With Persistent Bleeding - Results From the US-TRACE Study

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Purpose: Persistent bleeding in LVAD patients often requires a reduction in standard anti-thrombotic therapies of warfarin plus aspirin. To assess the long term safety of such approaches, TRACE (STudy of Reduced Anti-Coagulation/Anti-platelet Therapy in Patients with the HeartMate II LVAS) was initiated in the US and Europe.

Methods: The TRACE-US enrolled HMII outpatients who at enrollment or as of Jan 1, 2011 were on a reduced anti-thrombotic (RT) regimen: warfarin only (RT-w), aspirin only (RT-a), or no anticoagulant or antiplatelet therapy (RT-n). The indication for RT, subsequent anti-thrombotic changes, as well as any bleeding, stroke, or pump thrombosis after RT were documented. Patients were prospectively followed for up to 24 months post-enrollment. 100 outpatients on RT were enrolled in the TRACE-US Study from 9 sites. In this report we present adverse events in patients on RT for 2 years.

Results: As of September 2014, 75 patients had been on RT for at least 24 months (n=58) or reached an outcome (n=17). The median age was 65 years (36-80), 87% were male, 64% had ischemic etiology and 71% were DT. The primary reason for RT (79% of pts) was to control bleeding (GI or epistaxis). RT-w, RTa and RT-n, were used in 33%, 29%, and 37% of the patients. At enrollment the median INR of the RT-w group was 2.1 (IQR 1.7-2.5). The primary indication for RT therapy at the time of RT initiation was bleeding (GI or epistaxis) in 79% of pts, followed by pump failure in 9% of pts.

Among the 17 patients who reached an outcome, 3 expired, 13 were transplanted and 1 withdrew from the study. Within 2 years after initiating RT therapy, there were 5 ischemic (0.04 EPPY) and 0 hemorrhagic strokes, and 5 pump thrombosis events (EPPY 0.04). 47% of patients continued to have bleeding events within 2 years post-RT initiation. Freedom from ischemic stroke, hemorrhagic stroke, and pump thrombosis at two years were 93±3%, 100%, and 93±3%, respectively.

Conclusion: Results from the TRACE-US Study suggest that reducing anti-thrombotic therapies on a chronic basis to manage select patients with persistent non-surgical bleeding is safe; but bleeding events continue to occur in this relatively old and primarily DT patient population.