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Variability Across Implanting Centers in Short and Long-Term Mortality and Adverse Events in Patients on HeartMate 3 Support: A Momentum 3 Secondary Analysis

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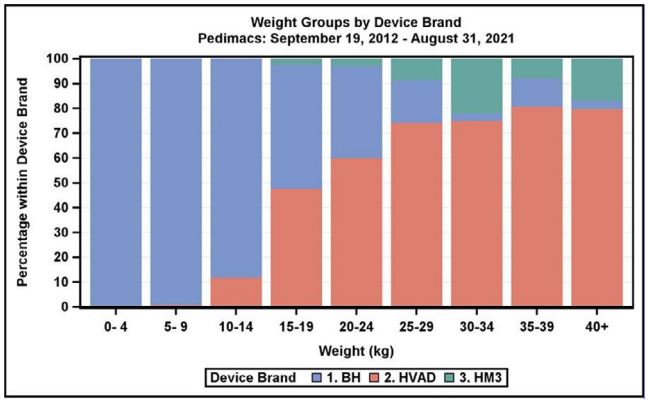

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Variability Across Implanting Centers in Short and Long-Term Mortality and Adverse Events in Patients on HeartMate 3 Support: A Momentum 3 Secondary Analysis

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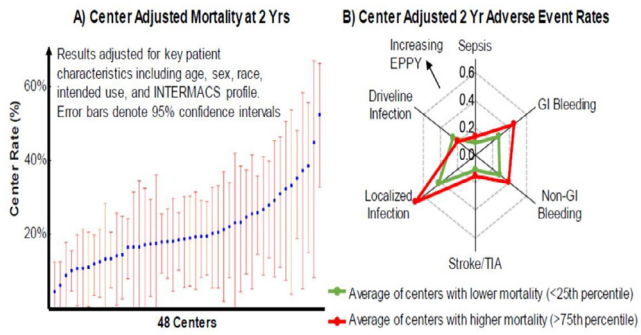
Purpose: We aimed to characterize center-specific variability in HeartMate 3 (HM3) patient survival within the MOMENTUM 3 studies and to examine the correlation between implanting center survival and major adverse events (AEs).

Methods: Center HM3 implant volume during the MOMENTUM 3 pivotal (n=515) and continued access protocol (n=1685) trials were tallied. Centers implanting ≤16 HM3 patients (25th percentile) were excluded. De-identified center variability in mortality was assessed at 90 days and 2 years using direct adjusted survival while accounting for key baseline risk factors. The 90-day frequency and 2-year rates of stroke, bleeding, and infection were compared across centers and correlations between survival and event rate variability were assessed.

Results: Among 48 centers, 1957 HM3 patients were included in this analysis with site implants ranging between 17 to 103 patients. Patient cohorts differed across the sites by age (average 52-68 years), sex (60-95% male), destination therapy intent (25-100%), and %INTERMACS profile 1-2 (2-81%). At 90 days, center adjusted median mortality was 6.5%, nadiring at ≤3.2% (25th percentile) and peaking at ≥10.5% (75th percentile). Median 2-year center adjusted mortality was 18.6%, nadiring at ≤14.0% and peaking at ≥25.2% (figure A). AEs were also highly variable across centers; centers with low mortality tended to have lower AE rates at 2 years (figure B).

Conclusion: Patient characteristics and outcomes were highly variable across MOMENTUM 3 centers despite trial preoperative inclusion/exclusion criteria. Many centers had exemplary risk-adjusted HM3 patient outcomes. Studies are needed to improve our understanding of top performing centers' best practices as they relate to HM3 care in the pre, interoperative, and chronic support stages in an effort to further improve HM3 LVAD-associated clinical outcomes.



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Sex-Based Outcomes After Implantation of a Fully Magnetically Levitated Left Ventricular Assist Device

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Purpose: Left ventricular assist devices (LVAD) remain underutilized in females and therefore poorly studied in relation to biological sex. Whether outcomes vary by sex after implantation of a fully magnetically levitated LVAD implantation remains uncertain.

Methods: In this analysis, MOMENTUM 3 study data was utilized (pivotal randomized clinical trial and continued access protocol) and adjusted for age (>65 years), body mass index (>30 kg/m^2), race, ischemic cardiomyopathy, INTERMACS profile (>2), history of stroke or diabetes, bilirubin, albumin, and estimated GFR. Survival free of disabling stroke or reoperation to replace or remove a malfunctioning device at 2 years was compared by sex (primary endpoint). Overall survival, major adverse events (calculated as events per 100 patient-years), and quality of life (QOL) using EQ-5D-5L visual analogue scale (VAS) scores were also compared.

Results: Of 2,200 HeartMate 3^{TM} LVAD patients, 448 (20.4%) were female and 1,752 (79.6%) were male. Relative to males, females implanted with HeartMate 3 were younger, more likely to be a Black person and have a non-ischemic cardiomyopathy. There was no difference in the primary endpoint (female: 81.0% vs. male: 77.4%; HR 0.98 [0.76-1.25], p=0.84). Overall survival at 2 years was similar (female 83.9% vs. male: 81.8%; HR 1.08 [0.82-1.41], p=0.60 (Figure 1A). Females were at higher risk of adverse events, driven by stroke (8.3 vs. 6.4; p=0.011), bleeding (77.4 vs. 66.1; p<0.001), and infection (85.7 vs. 72.0; p=0.011), however, males had more arrhythmia (32.4 vs 27.2; p=0.042) (Figure 1B). QOL measurement gains were similar.

Conclusion: Females have similar survival as males in this contemporary LVAD cohort, although major adverse events are increased including stroke, bleeding, and infection. Further work is needed to understand disparity by sex in device implantation, mechanisms of adverse events, and response to medical management.