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Concomitant Valvular Procedures During LVAD Implantation and Outcomes: An Analysis of the MOMENTUM 3 Trial Portfolio

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Purpose: Although clinical trials inform on efficacy of left ventricular assist device (LVAD) therapy, individualized risk assessments for outcome prediction are important in guiding implementation of such treatment. In this analysis based on the MOMENTUM 3 trial portfolio (studies sponsored by Abbott), we seek to develop and validate patient-specific risk scores to facilitate the evaluation of candidates for HeartMate 3 (HM3) LVAD implantation.

Methods: The MOMENTUM 3 trial portfolio includes 2200 patients that underwent HM3 LVAD implantation in the pivotal trial and Continued Access Protocol (CAP) study, between 2014-2018. Patients were followed for 2 years, and the primary results were presented at ISHLT 2021 and published in *Eur J Heart Fail*. 2021;23:1392-1400. In this analysis, we shall randomly assign all enrolled patients implanted with the HM3 LVAD to a Derivation Cohort or an internal Validation Cohort. The Derivation Cohort will be used to develop multivariate regression models incorporating common, pre-implant patient parameters that are typically assessed when an informed decision is established. Calculation of the risk scores will be based on the parameter estimates of the final derived models. Receiver operating characteristic curve analysis will be used to evaluate the discriminatory ability of each risk score. The ability of the risk scores to predict outcomes after HM3 LVAD implantation will be tested independently in the Validation Cohort (results expected by February 2022). To avoid bias in the development of the scores, the Validation Cohort will only be analyzed after the risk models are derived. The risk scores will include estimates (and range of individual outcomes) for endpoints including short and long-term survival, hospitalization burden, quality of life, hemocompatibility and non-hemocompatibility related adverse events.

Endpoints: The scientific discovery and validation of personalized risk scores will inform clinicians on expectations of individualized outcomes through the clinical journey following HM3 LVAD implantation. Such risk scores and individualized estimates for outcomes will facilitate enhanced decision-making and guide communication among clinicians and patients when considering LVAD therapy in advanced heart failure.

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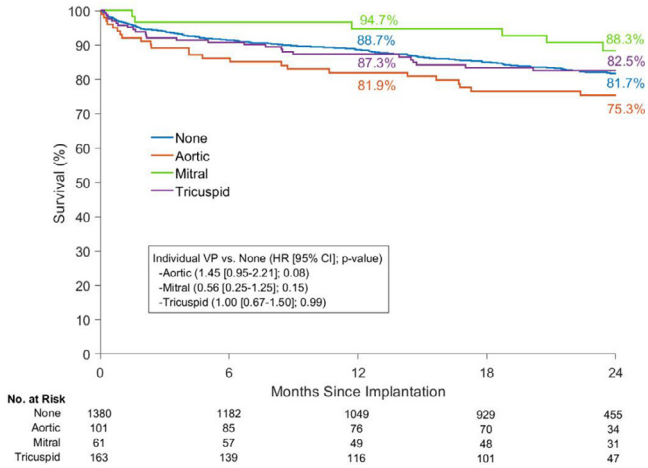
Purpose: Correction of valvular pathology is often undertaken in patients undergoing LVAD implantation but impact on outcomes is uncertain. We compared clinical outcomes with HeartMate 3 (HM3) LVAD implantation in those with concurrent valve procedures (VP) to those with an isolated LVAD implant within the MOMENTUM3 trial portfolio, including the Pivotal Trial (n=515, NCT02224755) and Continued Access Protocol/CAP (n=1685, NCT02892955).

Methods: The study included 2200 HM3 implanted patients. Among 820 concurrent procedures (including VP, CABG, RVAD, LAA closure), 466 (21.8%) were VPs (HM3+VP), including 81 aortic, 61 mitral, 163 tricuspid, and 85 patients with multiple VPs. Short and Long-term outcomes including peri-operative complications and healthcare resource use, major adverse events and survival were analyzed.

Results: Patients undergoing HM3+VP were older (63[54-70] vs. 62[52-68] yrs), with a sicker INTERMACS profile (1-2:41% vs.31%) and higher central venous pressure (11[8-16] vs. 9[6-14] mmHg) compared to HM3 alone (all $p<0.05$). The cardiopulmonary bypass time (124 [97-158] vs.76[59-96] mins); ICU (8.5 [5-16] vs. 7 [5-13]) and hospital length of stay (20 [15-30] vs. 18 [14-24] days) were longer in HM3+VP (all $p<0.0001$). A significantly higher incidence of stroke (4.9% vs. 2.4%), bleeding (33.9% vs. 23.8%) and right heart failure (41.5% vs. 29.6%) was noted in HM3+VP for 0-30 days post-implant (all $p<0.01$), but 30-day survival was similar between groups (96.7% vs. 96.1%). There was no difference in 2-year survival in HM3+VP vs HM3 alone patients (HR[95%CI]:0.93 [0.71-1.21];p=0.60). Analysis of individual VPs showed no significant differences in survival compared to HM3 alone (Figure).

Conclusion: Concurrent VPs are commonly performed during LVAD implantation, are associated with increased morbidity during the index hospitalization, but short and long-term survival are not impacted adversely when compared with those that undergo an isolated LVAD procedure.



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A Multi-Center Evaluation of Outflow Graft Obstruction with a Fully Magnetically Levitated Left Ventricular Assist Device

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