Implant of the HeartMate 3 Left Ventricular Assist Device using Techniques Other Than Full Median Sternotomy – Primary Findings of the Multi-center HeartMate 3 SWIFT Clinical Trial

Objectives: The HeartMate 3 (HM3) left ventricular assist device (LVAD) provides substantial improvement in short and long-term morbidity and mortality in patients with advanced heart failure. In the prospective multicenter SWIFT trial, we compared clinical outcomes of non-sternotomy techniques for implantation of the HM3 LVAD with a standard full sternotomy.

Methods: We conducted a non-inferiority trial in patients eligible for HM3 implantation with surgical techniques other than full median sternotomy (left thoracotomy with upper right mini-thoracotomy or hemi-sternotomy). The composite primary endpoint was survival free of disabling stroke (modified Rankin Scale >3), device malfunction requiring an operation to replace or remove the device, or conversion of the surgical approach to standard full sternotomy at 6-months post-implant. The primary end point was compared to a propensity-matched cohort derived from the MOMENTUM 3 Continued Access Protocol (CAP), with >80% power to evaluate for non-inferiority in a 1:2 ratio for total success (defined as elective transplants or freedom from primary endpoint event). The secondary endpoint was the length of stay defined as days from implant to initial hospital discharge, powered for superiority.

Results: The trial was conducted at 23 centers and enrolled 102 patients between November 2020 and July 2022 with follow-up concluded in December 2022. In the SWIFT group total success occurred in 85% (85/100) of the patients versus 86.2% (175/203) in the control group at 6-months and the non-inferiority criterion was met (absolute between-group difference, 1.2%; Farrington Manning CI: -5.3%, 7.7%, P<0.001). Right heart failure occurred in 22(21.6%) of SWIFT patients and 58(28.4%) controls group patients (p=0.26). No differences were observed for length of stay, blood product utilization, adverse events, functional status, and quality of life measurements between the two groups.

Conclusion: Implantation of the HM3 LVAD using techniques other than sternotomy is non-inferior to implantation via full sternotomy. This study establishes non-sternotomy implantation techniques as a second standard for surgical implantation of the HeartMate 3 LVAD. (Funded by Abbott; NCT04548128)

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