



ISHLT

A Society that Includes Basic Science, the Failing Heart, & Advanced Lung Disease

Media Contact: Nancy Mays
Phone: +1 (913) 568.3605
Email: nk.mays@ishlt.org

HeartMate 3 heart pump reduces burden of bleeding and stroke rates, eliminates pump thrombosis

Largest study of its kind shows newer pump far superior to predecessor; Results presented at #ISHLT2019

ORLANDO, Fla– April 4, 2019 – Patients with a newer version of a common heart pump experienced a reduced aggregate burden of bleeding and stroke rates – and no pump thrombosis requiring surgical exchange, compared to patients with the predecessor device. The MOMENTUM3 study was a randomized controlled trial of the new HeartMate 3 (HM3) pump versus the HeartMate II (HMII) pump and included a patient cohort of 1028, the largest such trial of its kind.

The study showed that the HM3 pump is more hemocompatible, a term that encompasses the interface of the device with the blood elements that pass through its pathway. In this analysis that specifically examined the net burden of such events occurring after the first 30 days to account for the early surgical risk, the investigators demonstrated markedly lower rates of bleeding, particularly gastro-intestinal bleeding. The newer device reduced stroke rates of all types and any severity, and eliminated the need for a pump replacement due to clotting within the device.

“This study proved that the newer engineering of the HM3 worked and did what it was designed to do – reduce hemocompatibility related adverse events across the board,” said Nir Uriel MD, University of Chicago Medicine, Chicago, Ill. “All of the adverse effects were improved – without creating any additional adverse events.”

The heart pumps, known as Left Ventricular Assist Devices (LVAD), are used for patients with end-stage heart failure. Battery-operated, they function by helping the heart’s left ventricle pump blood to the rest of the body.

The 1,028 patients participating in the study were followed for at least two years. Among the key findings:

- Lower stroke rates. Patients with HM3 were half as likely to have a stroke than those with HMII. Ischemic strokes, hemorrhagic strokes and disabling strokes were all decreased with the HM3 pump
- The Hemocompatibility Related Adverse Event (HRAE) end point was reached in 45 percent in the HM3 and 32 percent in the HII group (Hazard Ratio 0.70, 95% CI 0.59 to 0.82, P<0.0001).
- The total burden of HRAE as calculated by the Hemocompatibility Score was Halved in the HM3 versus the HM II (1.1 versus 2.1, P <0.0001)

The MOMENTUM3 study included all-comers, which means researchers evaluated the device regardless of whether the patient needed a short-term support option while awaiting transplantation or a long-term support option for those who are not candidates for cardiac transplantation.

The HeartMate 3 LVAD is CE Mark approved and FDA approved for short-term (bridge-to-transplant) use in the United States. The HeartMate 3 LVAD is limited by federal law to investigational use in the United States for long-term (destination therapy) support.

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About ISHLT

The International Society for Heart and Lung Transplantation is a not-for-profit, multidisciplinary professional organization dedicated to improving the care of patients with advanced heart or lung disease through transplantation, mechanical support and innovative therapies. With more than 3,800 members in more than 45 countries, ISHLT is the world's largest organization dedicated to the research, education and advocacy of end-stage heart and lung disease. ISHLT members represent more than 15 different professional disciplines. For more information, visit www.isHLT.org.