



International Society for Heart & Lung Transplantation
www.isHLT.org

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ENDURANCE SUPPLEMENTAL ONE-YEAR HVAD RESULTS SHOW DECREASED RATE OF STROKE COMPARED TO ENDURANCE TRIAL

SAN DIEGO (April 5, 2017) – Today, during the opening plenary session of the 37TH Annual International Society for Heart and Lung Transplantation (ISHLT) Meeting & Scientific Sessions, researchers presented results of a much-anticipated late breaking trial. Results of the **HeartWare HVAD for the Treatment of Patients with Advanced Heart Failure Ineligible for Cardiac Transplantation: Results of the ENDURANCE Supplemental Destination Therapy Trial** confirms that an improved blood pressure management resulted in improved blood pressure control and a reduction in the incidence of strokes in patients supported with the HeartWare® centrifugal flow left ventricular assist device system (HVAD), compared to patients who received HVAD in the original ENDURANCE trial. Most importantly, the reduction in mean arterial blood pressure (MAP) reduced the stroke rate in patients receiving an HVAD by 24 percent in the ENDURANCE Supplemental trial compared to the ENDURANCE trial, which was presented two years ago at the ISHLT Annual Meeting in Nice, France.

The primary end point of the trial, the incidence of neurologic injury at 12 months compared to the control device, did not meet the non-inferiority criteria. However the secondary endpoint (survival at 12 months free from disabling stroke, death, device malfunction requiring exchange, removal of the device or urgent transplant) which was the primary endpoint of the ENDURANCE trial was found to be superior in the HVAD compared to control $p=0.035$.

“The results on the ENDURANCE Supplement show the importance of blood pressure control on reducing the incidence of neurological events in patients with left ventricular assist devices,” said ISHLT 37TH Annual Meeting and Scientific Sessions Program Chair and Board Member Jeffrey Teuteberg, MD. “Destination Therapy continues to be an excellent option for patients suffering from end-stage heart failure who are not candidates for transplantation. As we improve our understanding of how to manage patients after implantation, this will hopefully result in continued improvements in outcomes and reductions in adverse events.”

About ENDURANCE Supplemental

The ENDURANCE Supplemental trial was a prospective, multicenter evaluation of 465 patients with chronic Stage D or NYHA Class III-IV symptoms to either HVAD (N=308) or control device (N=157). Exclusion criteria included significant end-organ dysfunction, recent myocardial infarction or stroke, coagulopathy, or an anticipated need for a right ventricular assist device.

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The previous ENDURANCE Trial, while demonstrating non-inferiority of the HVAD compared to the control device (HeartMate II) in 445 end-stage heart failure patients ineligible for heart transplantation, revealed a higher than expected rate of stroke in the HVAD cohort.

Retrospective analysis of clinical trial data found that elevated MAP was the strongest independent risk factor for stroke. The ENDURANCE Supplement was designed to enroll patients under the same criteria as the original trial in order to prospectively evaluate the effectiveness of blood pressure management on patient outcomes.

Advanced heart failure affects about 10 percent of the more than 6 million Americans living with heart failure. Doctors consider the condition advanced when patients continue to decline despite conventional heart failure therapies. Destination therapy is long-term support with a left ventricular assist device for patients afflicted with advanced heart failure, but are ineligible for transplantation.

Today's Symposium Highlights

Symposium 1: Joint ISHLT/ICCAC: How to Make the VAD Patients Successful

The session is a collaborative effort between ISHLT and the International Consortium of Circulatory Assist Clinicians (ICCAC). The session was created to discuss frequently asked questions by mechanical circulatory support (MCS) teams around the globe regarding multidisciplinary program structure, practice guidelines, VAD education including simulation labs, cost-effectiveness and international aspects in care delivery from a program perspective, and with patients, families, and the staff caring for them.

SYMPOSIUM 5: Joint ISHLT/PHA Symposium: PH and Transplant: Where Do We Go From Here?

This session, a joint effort between ISHLT and the Pulmonary Hypertension Association (PHA) will address various aspects of lung transplantation in adult and pediatric patients with different forms of pulmonary hypertension (PH). Discussion topics include quality of life outcomes, oral versus intravenous therapies, pregnancy in PH and more.

Symposium 7: Joint ISHLT/ESCMID Symposium: Ongoing Challenges in Transplant Infectious Diseases

The session, a joint effort between ISHLT and the European Society of Clinical Microbiology and Infectious Disease (ESCMID), will provide important insight on relevant issues surrounding the management of infections in patients prior to and after thoracic organ transplant and patients on mechanical circulatory support.

About ISHLT

The International Society for Heart and Lung Transplantation (ISHLT) is a not-for-profit professional organization with more than 2,700 members from over 45 countries dedicated to improving the care of patients with advanced heart or lung disease through transplantation, mechanical support and innovative therapies via research, education and advocacy. For more information, visit www.isHLT.org.

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