



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

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MEDAMACS 1-YEAR STUDY RESULTS ON ADVANCED HEART FAILURE INDICATE CLINICIANS SHOULD EXPAND VAD THERAPY TO THOSE PREVIOUSLY THOUGHT AS 'TOO HEALTHY'

SAN DIEGO (April 8, 2017) – Today researchers presented findings of the Medical Arm of Mechanically Assisted Circulatory Support (MedaMACS) study, a multi-center, U.S.-based study, which analyzed patients with advanced heart failure (INTERMACS profiles 4-7) in an effort to better understand their disease trajectory. As presented at the 37th Annual International Society for Heart and Lung Transplantation (ISHLT) Meeting and Scientific Sessions, the results suggested that patients with advanced heart failure enrolled in the study are at a very high risk for poor outcomes on medical therapy. The MedaMACS study enrolled a total of 161 patients across 11 left ventricular assist device (LVAD)/transplant centers across the United States. Researchers noted that the study population represents an under-studied group of patients with advanced heart failure. INTERMACS (IM) profiles of patients at enrollment were; Profile 4 (12%), Profile 5 (32%), Profile 6 (49%) and Profile 7 (7%). INTERMACS is a North American interagency registry tracking patients who receive mechanical circulatory support device therapy to treat advanced heart failure. Patients in profiles 5-7 are less sick and not typically considered for LVAD therapy.

Year one results revealed patients in the MedaMACS Registry, only 53% of patients were alive and had not required transplant or placement of an LVAD. These findings push the envelope of what was previously believed, as about 80 percent of patients in the MedaMACS study were generally thought to be “too good/healthy” for an LVAD, according to lead researcher Amrut Ambardekar, MD, Medical Director Cardiac Transplant Program at the University of Colorado.

Advanced heart failure affects about 10 percent of the more than 6 million Americans living with heart failure. Doctors consider the condition advanced when patient's become sicker despite conventional heart failure therapies.

About the MedaMACS Study

The study also compared the outcomes of the MedaMACS patients with 1,753 patients from the INTERMACS registry who were implanted with an LVAD prior to needing inotropes. The authors found no difference in survival for patients between the two groups as a whole, but there was a trend for improved survival with an LVAD versus among those patients who were IM profile 4.

“The MedaMACS one-year study results give us the first detailed look at patients who are INTERMACS profiles 4-7,” said ISHLT 37th Annual Meeting and Scientific Sessions Program Chair and Board Member Jeffrey Teuteberg, MD.

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"These patients have typically been considered too well for LVAD therapy, so the data from MedaMACS will be critical as we try to determine if there are groups of these patients who may derive benefit from early implantation."

Study Results

Results imply the morbidity in this population was high with over half requiring hospitalization, and many required multiple hospitalizations for heart failure. The overall MedaMACS primary endpoint event rate after a mean of 1 year of follow up was very high: 24% mortality, 11% required VAD implantation, 12% required a heart transplant, and only 53% were alive on medical therapy. The secondary endpoint rate is also high: 14% required intravenous inotrope treatment, and 57% required re-hospitalization with an average of 1.7 re-hospitalizations. Quality of Life (QoL) scores increased slightly for medical therapy patients (from 56 at baseline to 65 at one year). However, there was a larger increase in QoL scores among INTERMACS profiles 4-7 patients receiving VAD therapy.

In proportion of patients alive with a good QoL at one year is higher among LVAD therapy patients in the INTERMACS registry, compared to the medical therapy patients in MedaMACS registry

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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