



# ISHLT

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

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## **Older heart-failure patients ineligible for transplants fare well on novel pump, opening door to new treatment option**

- *Study shows heart pump can extend longevity – and reduced adverse events for older patients who are ineligible for heart transplantation*
- *Researchers suggest changing strategy and abandoning patient classifications*
- *Findings presented at 39<sup>th</sup> Annual Meeting and Scientific Sessions of ISHLT*

ORLANDO, Fla, April 3, 2019 – A common heart pump has traditionally been seen as only a short-term option for heart-failure patients but new research shows it may provide a similar quality of support as a permanent treatment in patients ineligible for transplantation. The study, part of the MOMENTUM3 trial, is the largest of its kind and was presented today at the International Society for Heart and Lung Transplantation’s 39<sup>th</sup> Annual Meeting in Orlando, Fla.

Investigators led by Daniel Goldstein, MD, Montefiore Medical Center, Bronx, New York, analyzed two groups of heart-pump recipients: those who received the pump as short-term therapy, meaning it would serve as a bridge to a transplant or candidacy towards a transplant; and those who received the pump as long-term or permanent therapy because their age and other co-morbid conditions deemed them ineligible for a transplant. Traditionally, these pumps, known as Left Ventricular Devices or LVADs, were not seen as a broadly applicable and viable long-term option for older patients because physicians felt their age would make them more prone to adverse outcomes such as clotting, strokes and bleeding. An LVAD is a surgically implanted, battery-powered pump that helps a failing heart’s left ventricle pump adequate levels of blood to the body.

“These findings are significant because we now know that older patients can take full advantage of a growing treatment for heart failure,” said Goldstein. “It’s exciting to know that this population won’t be deprived of the benefits of this successful treatment.”

The work is part of a broader study known as the MOMENTUM3 trial, a randomized controlled trial of the newer HeartMate 3 (HM3) pump versus the HeartMate II (HMII) pump in patients with advanced heart failure – regardless of whether the device was used as a bridge to transplantation (BTT) or a destination therapy (DT). The study looked at 1,028 heart-failure patients and its final report was recently published in the *New England Journal of Medicine*.

In this analysis, researchers found:

- The benefits noted between the short term group (n=396) and the destination therapy or permanent implant group (n=624) were the same.
- The Hazard Ratio for the primary end point, which was survival at two years free of a disabling stroke or need to replace the pump, were identical at a Hazard Ratio of 0.62 (95 percent CI 0.40-0.94) versus 0.61 (95 percent CI 0.46-0.81), each with a P <0.0001.
- The overall survival of the destination therapy patients was 77 percent at two years.
- For every 100 destination therapy patients implanted with the new pump, 110 hemocompatibility related adverse events of pump thrombosis, stroke or bleeding are prevented over two years.

### **Rethinking LVAD Labels**

Researchers suggest their findings support the elimination of labeling pump recipients as either:

- Bridge-to-transplant patients, those waiting for a transplant
- Bridge-to-candidacy patients, those waiting to be deemed a transplant candidate
- Destination patients, those who receive the LVAD pump because conventional medications have stopped working

“The labels are arbitrary and, in fact, may impact a patient’s treatment plan,” said Goldstein. “We need to abolish them from consideration.”

What’s more, abandoning labels would remove the need to conduct separate trails for patients with the same clinical problem.

The study found that patients move in and out of categories frequently. For example, patients labeled as “bridge-to-transplant” received a transplant 50 percent of the time within two years. Meanwhile, 13.5 percent of patients deemed “ineligible” for transplant ended up getting a transplant, meaning that their organs improved so much on support that they became eligible to receive a heart. In the grey zone category of “bridge to candidacy,” 35 percent of patients ended up receiving a transplant.

Because of this, the investigators argue that the present use of these arbitrary designations should be abandoned in favor of one pre-implant strategy: to improve the survival and the quality of life of patients with advanced heart failure while reducing the burden of complications with left ventricular assist systems.

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](http://www.isHLT.org).