
MEDICAL DEVICE DAILY™

THE DAILY MEDICAL TECHNOLOGY NEWSPAPER

WEDNESDAY, MARCH 4, 2009

VOL. 13, No. 41

Special Reprint PAGE 1 OF 2

Study reveals 37% of LVAD patients later need RVAD

By AMANDA PEDERSEN

Medical Device Daily Staff Writer

It probably goes without saying that if a heart failure patient is going to develop right ventricular (RV) failure after receiving a left ventricular assist device (LVAD), that patient should have received bi-ventricular support from the start. The problem is, predicting post-LVAD RV failure requiring mechanical support is anything but easy.

Data published in the December issue of the *Journal of Heart and Lung Transplantation (JHLT)* highlights this problem, as one article in the journal finds that RV dysfunction develops in 20% to 50% of LVAD patients and a second article finds that 37% of LVAD recipients later require a RV assist device (RVAD).

What happens is when the LVAD is implanted it begins to assist the left side, which powers up the body and moves blood back to the right atrium, and the right ventricle can't keep up with the assisted left ventricle, explained Roger Ford, CEO of **SynCardia Systems** (Tucson, Arizona), the company that makes the CardioWest temporary Total Artificial Heart.

"The mystery is how in the heck can you determine whether you have a poor function right and left side before you assist the left side? Nobody knows, some people think they know but nobody really knows," Ford told *Medical Device Daily*.

One article published in *JHLT* is from the **German Heart Institute Berlin**. It suggests that RV dysfunction develops in 20% to 50% of patients after LVAD implantation, leading to prolonged ICU stays and elevated mortality, according to the study authors. The article concludes that pre-operative evaluation of tricuspid incompetence and RV geometry may help to select patients who would benefit from biventricular support.

A second article, from the **Hospital of the University of Pennsylvania** (HUP; Philadelphia), found that of 266 LVAD recipients, 99 required a RV assist device (37%).

RV failure after LVAD placement is a "serious complication and is difficult to predict," according to the authors of the HUP article. "In the era of destination therapy and the total artificial heart, predicting post-LVAD RV failure requiring mechanical support is extremely important."

According to the HUP article, researchers reviewed patient characteristics, laboratory values and hemodynamic data from those 266 patients who underwent LVAD placement at the University of Pennsylvania from April 1995 to June 2007.

The researchers compared 36 parameters between LVAD and BiVAD patients to determine pre-operative risk factors for RVAD need. The study authors concluded that the most significant predictors for RVAD need were cardiac index, RV stroke work index, severe pre-operative RV dysfunction, creatinine, previous cardiac surgery and systolic blood pressure. Using these data, the researchers constructed an algorithm that can predict which LVAD patients will require RVAD with more than 80% sensitivity and specificity.

Both articles were presented at the 28th annual meeting of the **International Society for Heart and Lung Transplantation** (ISHLT; Addison, Texas) in April.

"The obvious point is, my goodness, 37% of people that got LVADs needed RVADs," Don Isaacs, director of communications for SynCardia, told *MDD*. "If they could determine whether that patient would need an RVAD or not . . . [then they could get a] more appropriate device, which for tiny patients would be a biventricular assist device and patients of any size would be a CardioWest total artificial heart."

SynCardia is in the process of developing a 50 cc version (compared to the 70 cc version) of its total artificial heart for smaller adults and adolescents. Ford said the development of the smaller device is on track to be completed by the third or fourth quarter of this year.

"Right ventricular failure in LVAD patients is tragic," said Jack Copeland, MD, chief of cardiothoracic surgery at **University Medical Center** (Tucson), who reports owning equity in SynCardia. "If it can be anticipated, the solution is bi-ventricular support from the start. If it becomes a crisis, in appropriate patients, the CardioWest temporary Total Artificial Heart (TAH-t) may be life-saving."

Originally designed as a permanent replacement heart, the CardioWest artificial heart is currently approved as a bridge to human heart transplant for patients dying from

©2009. Reprinted With Permission From Medical Device Daily,™ Atlanta, Georgia.

To subscribe, please call MEDICAL DEVICE DAILY™ Customer Service at (800) 688-2421; outside the U.S. and Canada, call (404) 262-5476.
Copyright © 2009 BioWorld®. Reproduction is strictly prohibited.

end stage biventricular failure. The device is the only FDA, Health Canada and CE mark approved total artificial heart in the world, the company notes.

“By replacing both sides of the dying heart, the CardioWest eliminates complications caused by failing ventricles, diseased valves, ventricle defects and electrical problems requiring a pacemaker and/or defibrillator,” Copeland said.

Although the CardioWest device is approved as a bridge-to-transplant device, Ford said there are some patients in Germany with a CardioWest artificial heart implanted who have decided to “avoid the hospital and have been on our device for three years now.”

Meanwhile, LVAD makers continue to release new and improved devices designed to support the left ventricle. Last year **Terumo Heart** (Ann Arbor, Michigan) received the go-ahead from FDA to start its U.S. trial of the DuraHeart Left Ventricular Assist System (LVAS) as a bridge-to-transplant device (*Medical Device Daily*, March 5, 2008).

Then, in August, the company reported that the first U.S. patient implanted with the DuraHeart had been discharged from the **University of Michigan Health System** (Ann Arbor) 15 days after receiving the device (*MDD*, Aug. 25, 2008).

Terumo says the hockey puck-sized DuraHeart LVAS uses a new type of magnetic levitation technology (Mag-Lev) designed to eliminate mechanical contact within the blood flow path thus minimizing the chance of mechanical failure. Mark White, marketing manager for Terumo Heart, told *MDD* at the time that the Mag-Lev technology is the core benefit of the DuraHeart, as it prevents a lot of the problems associated with other systems in which the impeller is suspended through pressure distribution.

That news came almost simultaneously with **HeartWare** (Farmingham, Massachusetts/Sydney, Australia) reporting that the first U.S. patient had received its LVAS at **Washington Hospital Center** (Washington), marking the start of its U.S. trial (*MDD*, Aug. 22, 2008). Similar to the DuraHeart, the impeller that spins inside the HeartWare LVAS pump is also suspended by magnetic forces. Although both pumps are much smaller than earlier generation devices, the HeartWare is actually small enough to fit directly adjacent to the heart in the pericardial space. Most other systems, including the DuraHeart, are implanted into a surgically-created pump pocket in the abdomen.

Other companies developing similar devices include **Ventricor** (Chatswood, Australia), **Abiomed** (Danvers, Massachusetts) and **Thoratec** (Pleasanton, California).

Last month Thoratec agreed to acquire HeartWare in a cash-stock deal valued at about \$282 million. The company said it would pay about 50% in cash and the rest would be paid in shares of its common stock (*MDD*, Feb. 17, 2009). Ford speculated that Thoratec was motivated to buy HeartWare because its device is small enough to fit directly in adjacent to the heart in the pericardial space, without the surgeon having to create a pump pocket in the abdomen.

“Thoratec had to get above the diaphragm to reserve their spot in the space because being above the diaphragm is where the surgeons want to go, it is a less invasive surgery . . . put the pump right in the pericardial space,” Ford said. ■