MedicalXpress

New heart failure pump works well in those awaiting transplants

November 17 2010, By Shantell Kirkendoll

An experimental pump implanted to assist the heart in patients with advanced heart failure waiting for a heart transplant works as well as approved devices, according to late-breaking clinical trial results presented at the American Heart Association's Scientific Sessions 2010.

In the non-randomized Evaluation of the HeartWare HVAD Left Ventricular Assist Device System for the Treatment of Advanced Heart Failure (ADVANCE) study, researchers found that the HeartWare left ventricular assist device (HVAD) met its primary endpoint, producing outcomes comparable to already approved bridge-to-transplant pumps.

Among HVAD patients, 92 percent survived for 180 days with the pump, received a transplant or had recovered enough to have the device removed – all considered successful treatment. Similarly, 90 percent of control patients waiting for heart transplants on approved pumps were treated successfully. Nearly one year (360 days) after implantation, 91 percent of HVAD patients and 86 percent of controls had survived, a difference that was not statistically significant.

From March 2009 to February 2010, investigators enrolled 140 patients from the United Network for Organ Sharing's heart-transplant waiting list to receive an HVAD at one of 30 centers. Their average age was 53 years, 72 percent were male and most (82 percent) had suffered from heart failure for at least a year.

The control group included 499 comparable patients from a nationwide

listing of all heart failure patients who received commercially available left ventricular assist pumps during the same period. Researchers compared survival and success rates between the HVAD and control patients 180 and 360 days after implantation. They also evaluated the HVAD patients' functional capacity and quality of life, as well as adverse effects of the HVAD pump.

HVAD patients were able to walk 113 meters, about 371 feet, farther in six minutes than at baseline when tested three months after surgery, and had very large improvements on two heart failure-specific and two generalized quality of life measures.

"With this success rate, doctors and patients should have increased comfort with a ventricular-assist device as a bridge to transplant," said Keith Aaronson, M.D., M.S., lead author of the study and associate professor of internal medicine and medical director of the Heart Transplant and Mechanical Circulatory Support Programs at the University of Michigan Cardiovascular Center. "These patients don't just survive to a transplant, they feel better and can be much more active."

Two types of these surgically implanted devices are approved for use. First generation devices are known as pulsatile-flow because they pause between pumps to fill with blood, creating a pulsing rhythm similar to the heart's beat. The newer, more durable, continuous-flow pumps continually propel blood outwards and, therefore, flow is less pulsatile.

"The results of ventricular assist device therapy have improved dramatically in recent years with the advent of continuous-flow pumps," Aaronson said. "The commercially available continuous-flow pump is an excellent pump, but all would agree that there is room for improvement."

The HVAD is also a continuous-flow pump, but is smaller in size. This allows part of it to be implanted directly into the heart's main pumping

chamber, the left ventricle, with the remainder of the device positioned within the space surrounding the heart. In contrast, other continuous-flow devices are placed in the abdomen within a surgically created pocket.

Another key difference is that the HVAD, a centrifugal device, propels blood outward from the center of a spinning disc, which is suspended only by magnetics and the blood itself. In comparison to axial devices that propel blood in the direction of flow, centrifugal flow devices may provide greater pulsatility, which is proposed to reduce the incidence of internal bleeding often associated with continuous-flow devices. It may also reduce arrhythmias.

Researchers didn't compare complication rates in this study. However, Aaronson noted that bleeding and infection rates in this study were lower than have been found in studies investigating other ventricular assist devices. He said only a head-to-head comparison can confirm whether these differences are valid and significant.

Provided by University of Michigan