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## Heart failure: 'Temporary' pumps could become a permanent treatment

**A new, more reliable type of device greatly boosts survival rate, researchers find. Tens of thousands in the U.S. could benefit, though the costs to the healthcare system could be huge.**

By Thomas H. Maugh II

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Mechanical pumps originally designed to supplement the pumping action of a failing heart and keep the patient alive until a transplant could be found have taken a major step toward becoming a permanent treatment -- a development that could expand their use to tens of thousands of patients in the United States alone.

Results presented Tuesday at the Orlando, Fla., meeting of the American Heart Assn. showed that a new type of device more than doubled the two-year survival rate among heart failure patients. The key was the development of a smaller, quieter, more reliable pump that is less likely to break down and need replacement, an outcome that requires the patient to undergo a second major surgery.

The pumps are called left ventricular assist devices, or LVADs. They are not meant to replace the entire heart, only to assist in the pumping of the left ventricle, which pushes blood out through the aorta to the body.

Researchers originally thought that LVADs had to mimic the action of the heart, pushing out blood in a series of pulses that were timed to coincide with pulses from the heart itself. That required complex machinery to produce the pulses and sophisticated electronics to synchronize them with the heart.

Such devices had a high propensity to fail.

But more recently, researchers have concluded that a simple, continuously operating pump can work just as well, if not better. Such pumps typically have only one moving part -- the impeller -- and don't need to be synchronized with the heart, so their reliability is much greater. They are also much smaller, typically about one-seventh the size of older models.

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The findings presented Tuesday involved one such device, manufactured by Thoratec Corp. of Pleasanton, Calif., and called the HeartMate II. The device is currently approved by the Food and Drug Administration only as a temporary bridge to a transplant.

"We had a sense that these smaller devices were going to have better long-term outcomes, and this trial proves it," Dr. Alfred A. Bove, president of the American College of Cardiology, said in an e-mailed statement. He was not involved in the research. "These devices have come a long way in five years. I expect that technology will continue to move things forward and they will be even better five years from now."

The need is great. About 150,000 Americans have advanced heart failure that could be treated with a transplant, but only about 2,100 donor hearts are available per year.

The big issue in the future may not be the availability of the devices but the financial strain they will put on the healthcare system. The Thoratec pump costs about \$80,000 and the surgery to implant it \$45,000. With thousands of patients needing the device, the tab could mount quickly.

In the new trial, headed by researchers from Duke University Medical Center and the University of Louisville, 200 heart failure patients between the ages of 26 and 81 were enrolled at 38 sites around the United States. All had failed medical therapy for their condition and were considered too sick for a transplant. About two-thirds of the patients received the HeartMate II, and the rest received an older version that pumps in pulses.

The team reported in Orlando and in an article published online in the New England Journal of Medicine that patients who received the new pump lived longer and had a higher quality of life than those who got the older one.

One year after the original surgery, 68% of those with the new pump were still alive, compared with 55% of those who received the older pump. But at two years, the results were much more dramatic: 58% of those who received the HeartMate II were still alive, compared with 24% of those who got the old pump.

Similar patients who receive only medical therapy typically survive about six months, and fewer than 10% survive two years.

One reason for the better survival rate is the reliability of the new device. About a third of the older pumps failed during the experiment and had to be replaced, compared with 10% of the new ones.

The devices also improved quality of life. The patients with the continuous-flow LVADs could walk twice as far as those with a pulsatile-flow device, the researchers found.

Thoratec is not the only one attempting to capture this market. A similar device developed by HeartWare International Inc. of Australia has been shown to keep as many as 80% of patients alive for two years in smaller clinical trials.

In an editorial accompanying the new report, Dr. James C. Fang of University Hospitals Case Medical Center in Cleveland said, "The first priority would be to make sure patients and physicians are aware that ventricular assist therapy is available, effective and safe for well-selected patients.

"Second, we should not delay referral until surgical morbidity and mortality become prohibitive. . . . The optimal time for referral is most likely before the development of major complications from heart failure."

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