

New heart pump could benefit thousands

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(PhysOrg.com) -- Although they have neither a pulse nor a measurable blood pressure, people with advanced heart failure lived longer and felt better when implanted with a new small pump that circulates their blood, according to UW Health heart experts whose patients took part in a recent clinical trial.

And now that the U.S. <u>Food and Drug Administration</u> has approved the device, known as the HeartMate II, to be used in patients with severe heart failure as a "destination" treatment, those benefits should be available to a much larger group of patients.

"The trial data are a very convincing demonstration of the superiority of this technology over the existing technology," said cardiologist and heart failure expert Dr. Nancy Sweitzer. "For properly selected patients, dying from heart failure, we have found that these devices can result in a return to good quality life and activities that provide pleasure and fulfillment. This new technology carries the possibility that this improvement can last for years."

The study, published in the <u>New England Journal of Medicine</u>, took place at 38 medical centers, including University of Wisconsin Hospital and Clinics. It compared 134 patients using the HeartMate II device with 66 who received an older, much larger implanted pump called the HeartMate XVE.

Patients in the trial had severe heart failure, which often means they have less than a year to live. But after two years, 47 percent of the



people with the new pump met the goal of two years without a stroke or a device failure, compared with 11 percent of those with the older pump.

Beyond the numbers, ventricular assist devices (VADs), as they are known, add precious time to patient's lives. Since May 2008, the pump was approved for use as a "bridge" therapy to keep patients alive until they could receive heart transplants. The new FDA decision broadens the group of eligible patients to include those heart-failure patients who do not qualify for heart transplants due to their age or underlying medical conditions.

The FDA decision could open the therapy to thousands of patients every year. About 2,100 patients a year receive transplanted hearts in the U.S., but physicians estimate that another 60,000 to 150,000 have advanced heart failure. There are many brands of pumps on the market and all work by augmenting the natural function of the left ventricle, which pumps oxygenated blood through the body. In heart failure, the left ventricle is not strong enough to pump the blood efficiently.

The earlier model was the size of a CD case, and an inch thick, so it had to be implanted in the abdomen. The newer pump, also made by Thoratec, is one-eighth that size, about the size of a C battery, so it can be implanted into the chest.

"Since the Heartmate II is much smaller than previously used devices, we can use it in much smaller patients, such as younger patients or female patients," said Dr. Takushi Kohmoto, a UW Health cardiothoracic surgeon who participated in the national trial. "The incision is smaller, and the device is more easy to implant, and to remove, if necessary."

Another improvement is that it lasts much longer. The original device used a diaphragm-style pump and pig valves, which wore out with use.



The newer version has an impeller pump modeled on one in the space shuttle and doesn't need valves because the blood can move in only one direction.

"All of the pumps on the market give patients a major improvement in quality of life," Sweitzer said. "But this one is much easier to live with."

An interesting sidelight is that because the blood moves continually, pushed by a propeller-like pump, patients with the newer device don't have a pulse or a <u>blood pressure</u>. Dr. Sweitzer said her staff has fielded worried calls from dentists and other health providers because they couldn't find a patient's blood pressure.

"We assure them that they're fine even though they don't have a blood pressure," she said.

Provided by University of Wisconsin-Madison

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