Newer heart devices significantly improve survival, complication rate and quality of life

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A new generation of implanted devices that help a failing heart function properly is significantly more effective than the previous version, making these new devices an appropriate permanent therapy for many of the more than 5 million Americans who suffer from heart failure.

A research team led by a University of Louisville cardiac surgeon published data to support these conclusions in the November 17, 2009 Online First edition of the *New England Journal of Medicine*. The results were simultaneously presented in a press briefing at the annual meeting of the American Heart Association in Orlando, Fla.

"This study shows astounding improvements in survival, quality of life, reduced complications and device durability in patients who had the new device implanted," said Mark Slaughter, M.D., chief of thoracic and cardiovascular surgery at the University of Louisville and director of the heart transplant and mechanical assist device program at Jewish Hospital, lead enroller in the trial and lead author on the journal article. "This device should be considered for use in all patients who are eligible for this kind of treatment either while they await heart transplant or as a permanent therapy."

Two hundred patients at 38 centers nationwide were randomly assigned to receive either the newer, smaller continuous-flow left ventricular assist device (LVAD), or a larger, pulsatile-flow LVAD. The newer device creates a continuous flow of blood in and out of the failing heart, while the older device mimics the heart's function using a pulse action

with blood alternately sucked into the pump from the left ventricle then forced out into the aorta.

Fifty-eight percent of patients implanted with continuous-flow devices were alive two years after implantation, compared to just 24 percent of those with pulsatile flow devices. Nearly half of all patients who received a continuous-flow LVAD did not have a stroke or re-operation to repair or replace the device within two years of implantation, compared to just 11 percent of those with a pulsatile-flow device.

Patients with continuous flow LVADs also were half as likely to get an infection as their pulsatile-flow counterparts.

"We also looked at quality-of-life measures and found that patients with continuous flow LVADs could walk twice as far in six minutes, on average, than those with a pulsatile-flow device," Slaughter said. "Patients with continuous flow devices went from being unable to walk any distance at all without being short of breath to being able to walk the length of three football fields, on average. This is hugely significant for these patients."

This research was supported by Thoratec, the maker of both devices tested and the largest producer of cardiac mechanical assist devices in the United States. The devices are sometimes used while patients are awaiting heart transplants, though there is a demand for them to be used as a stand-alone therapy in certain patients with end-stage heart failure, Slaughter said. One reason for this is the number of patients who are eligible for heart transplantation is vastly larger than the amount of donor hearts available, he said.

LVAD support has been used as a treatment for advanced heart failure since the 1960s, experimentally, but it was not until the early twenty-first century that it became more widely used and began to be considered as a

permanent, or destination, therapy. Less than 10 percent of patients with advanced heart failure similar to the patients in this study survive for two years after diagnosis if they only receive medical therapy.

Approximately 5.7 million Americans suffer from heart failure, and 550,000 new cases are diagnosed each year. About 250,000 die from heart failure annually.

Source: University of Louisville Health Sciences Center