Research team launches trial of upgraded heart pump device

February 26 2016, by Tracie White

Researchers at the Stanford University School of Medicine have launched their portion of a multicenter clinical trial that is evaluating a new version of a mechanical heart pump designed with remote-monitoring capabilities.

As part of that trial, the Stanford team implanted the device Jan. 21 in a patient with heart failure. That patient was the first person on the West Coast to receive it.

The pump is an upgraded version of a left ventricular assist device, or LVAD, which has been used in the United States since 1984, when a Stanford patient was the first person nationwide to have such a device implanted. The LVAD is used to restore blood flow when the left ventricle fails to pump enough blood to sustain life. Most often, the pumps serve as a bridge to keep patients alive while they wait for a donor heart.

The new version, called the HeartAssist 5, is being evaluated for safety and efficacy. The randomized trial is being conducted at 15-20 sites. The plan is for 192 patients with severe heart failure to participate. Half will be implanted with the new version of the device, and the other half with the regular version. The trial is restricted to patients on the heart transplant list.

Stanford plans to recruit 20 heart failure patients for the study. Ten will receive the new device.

Several features of the experimental device have the potential to improve patient outcomes, said Richard Ha, MD, a clinical assistant professor of cardiovascular medicine who is the principal investigator for Stanford's portion of the trial.

"This would be the first device that we could potentially monitor from a distance," said Ha, who also is a heart and lung transplant surgeon at Stanford Health Care and surgical director of the ventricular assist device program. Built-in wireless monitors are designed to alert clinicians 24/7 if blood-flow problems develop.

The remote-monitoring capabilities could also help patients who live far away from cardiologists with LVAD expertise. "Patients would not have to come here as often for visits," Ha said. Currently, patients are required to make frequent checkup visits in the six months following surgery.

In addition, the new device has a smaller motor, designed to help reduce blood clotting, and a sensor to measure blood-flow speed, Ha said.

Dipanjan Banerjee, MD, medical director of the mechanical circulatory support program at Stanford, also sees potential advantages of the new device. "The device has an ultrasound probe incorporated that directly measures blood flow generated by the device, as opposed to other LVADs, which estimate flow," said Banerjee. "More accurate measurements of flow may allow us to fine-tune the device speed to match the patient's needs."

The trial is expected to run through 2017. It is sponsored by the Houston-based ReliantHeart Inc., which makes the device.

More information: For more information about the trial, contact Kokil Bakshi at kbakshi@stanford.edu