

Artificial hearts may help patients survive until transplant

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The largest single-center study of patients implanted with a total artificial heart finds the device may help patients in severe heart failure survive until they can receive a heart transplant, according to research to be presented at the American College of Cardiology's 63rd Annual Scientific Session.

Researchers studied 22 patients implanted with total artificial hearts at Cedars-Sinai Heart Institute in 2012 and 2013 to look at the primary endpoints of death and incidence of stroke at 60 days. They found that five patients had died, four had successfully undergone heart transplants and 13 were alive and waiting for donor hearts. Eight of these patients were discharged home with the artificial hearts to await transplant. Three patients had strokes, one of whom was alive and waiting for a transplant. No patients had artificial heart -associated infections.

All patients in the study had end-stage cardiomyopathy – heart disease in which the heart muscle becomes thick, enlarged or rigid – and were in end-stage heart failure prior to implantation.

"We were pleased to see how well many of these patients did," said Swaminatha Gurudevan, M.D., cardiologist at Cedars-Sinai Heart Institute, and lead investigator of the study. "Given how sick these patients were, we expected to see higher mortality rates."

Most of the deaths that occurred were among patients who were sickest before their procedure, he said.

Patients were separated into three categories based on how sick they were before receiving the artificial heart. The sickest patients were in critical cardiogenic shock, a serious condition in which the heart is unable to pump enough blood for the body's needs that has a nearly 100 percent

mortality rate when untreated. Of the 10 patients in this category, six were alive at 60 days. One had received a <u>heart transplant</u>, and five were awaiting transplant – one from home.

In the middle category of patients, in progressive decline despite medications, eight of nine had survived at 60 days. Two of these patients received heart transplants, and the other six were awaiting transplant – five of them at home.

"This is very impressive, as the mortality rate among this group is usually at least 50 percent," Gurudevan said.

In the third category, patients' health was stable prior to receiving their artificial heart. All three patients in this category were alive and at home at 60 days – one of them post-transplant.

The total artificial heart is a device that is used to replace the ventricles for patients in end-stage heart failure. In end-stage heart failure, patients' heart function has become so poor that their only option is a heart transplant. The artificial heart attaches to the patient's upper heart chambers (the atria), and blood flows between the chambers through mechanical valves.

While a number of artificial hearts have been in development since the 1950s, only one type currently has FDA approval. Patients in the study received the Syncardia total artificial heart, which pumps up to 9.5 liters of blood per minute through the ventricles and has tubes that run from the device to a power source outside the body that patients can carry in a backpack.

"Before, patients had to stay in the hospital while they waited for a new heart," Gurudevan said. "With the artificial heart, some can wait at home and continue to conduct many of their regular activities."

He added that this helps patients maintain muscle



tone, strength and conditioning. "When patients are lying in a hospital bed for a month, it's harder on their bodies to have major surgery," he said. "Heart transplants are usually done on an emergent basis, so it's good for people to keep up their strength and be ready in order to have the best possible outcome."

About 5,000 heart transplants occur each year around the world, though it is estimated that 50,000 people are candidates for transplant. Use of the total artificial heart is still rare, as the implantation surgery is long and complex, and the number of certified health care facilities capable of artificial heart implantation is still relatively small. In addition, the artificial heart carries its own set of risks, including blood clots, bleeding, infections and device malfunctions.

Gurudevan recommends additional research to examine the use of the total artificial heart as a permanent solution for patients, rather than simply a bridge to transplant. In order to do this, he said, patients need an easier way to recharge the external battery or have a backup power option to decrease the risk of device failure.

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