Donated hearts may beat much longer

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The "heart in a box" device uses a combination of fluid dynamics, software, and preservative solutions to keep a heart beating. Credit: ISNS

New technology increases the length of time that a human heart can remain viable for transplant after removal from a donor for transplantation.

A clinical trial already underway in the United States is evaluating the new technology, called the Organ Care System, which aims to keeps donated hearts viable for hours longer than currently possible. Manufactured by Andover, Mass.-based TransMedics, Inc., the device uses a combination of fluid dynamics, software, and preservative solutions to keep a heart beating while avoiding ischemia, or a reduction of blood supply to it, when traveling to the heart recipient.

"Because the device completely prevents ischemia during transport, the organ maintains normal energy stores, so that organs transplanted using the device will be in better condition at the time of transplant," said Dr. Bruce Rosengard, surgical director of cardiac transplantation at Massachusetts General Hospital in Boston. Rosengard has transplanted human hearts using the approach in both the United States and Europe.

In the traditional approach to transplantation, surgeons replace the blood in a donated heart with salt solution and then put it in an ice chest. They must transplant the heart within three or four hours before it deteriorates too much.

With the new "heart-in-a-box" system, "we kind of suspend time," explained Tamer Khayal, TransMedics' vice president of clinical development. "We have to keep the heart cold for about 15 minutes before it gets into the system. Then the system doesn't care if we wait one hour or eight hours before transplantation, because the heart's physiology is being constantly supported and monitored."

The system "will permit recovering organs from a greater distance," said Rosengard. "This platform is going to become a game changer in manipulating the technology of a transplanted organ."

Surgeons in Europe have used the beating heart transplant system to maintain a donated heart in good condition for over eight hours.

That time interval could allow a heart taken from a body on the west coast to be flown to the east coast for transplantation.

Rosengard performed the third European operation in 2006 at Papworth Hospital in Cambridge, England. "The patient did extraordinarily well," said Rosengard.

To prepare for the procedure, his team tested the technology on two human hearts that, because of abnormalities, were unsuitable for transplantation.

For the 138 European transplants conducted so far, the 30-day survival rate exceeds 97 percent. That's well above the 80 percent rate typical for the continent's heart transplants.

Determining the 30-day survival rates of patients who receive the beating hearts is the goal of the U.S.-based clinical trial.

Led by UCLA's Heart Transplant Program and carried out in nine other hospitals, the trial is scheduled to include 128 patients. Each has a 50 percent chance of receiving a heart from the new device or from cold storage. The trial, which has completed almost half the target number of transplants so far, should be complete by the end of 2012.

If approved by the Food and Drug Administration, the technology promises to increase significantly the number of donated hearts that surgeons can transplant.

At present, about 70 percent of donated hearts are not accepted for transplantation. The reason: "Surgeons want the best possible heart they can get for their patients," said Khayal. "So if they have any doubts about a donated heart, it's safer for them to say no."

By maintaining donated hearts in a more natural state, the technology can potentially remove some of those doubts.

The device has advantages beyond increasing the time a donated heart stays viable.

"Its use in Europe is proving to be highly sensitive in identifying hearts

with underlying pathology, such as cocaine scarring, that makes them unsuitable," Khayal noted. That's because surgeons can use the extra time the system gives them to undertake detailed examination of donated hearts for possible rejection factors.

On the other hand, the technology could allow surgeons to transplant hearts that they regard as physiologically unusable today.

They could "buff up" hearts that might be slightly damaged by brain death, said Bartley Griffith, head of cardiac surgery and cardiac transplantation at the University of Maryland School of Medicine, who is not involved in the clinical trial.

"It would allow you potentially to resuscitate those hearts," Rosengard added. "You can also use the machine to resuscitate hearts that have stopped beating."

That possibility is coming closer. Pittsburgh transplant surgeon Ayyaz Ali has already resuscitated non-beating animal hearts in this way.

Rosengard foresees the promise of treating more severely damaged hearts as part of the resuscitation process.

"Drug therapy, cellular therapy, and gene therapy all become possible," he said.

The new technology also has potential for other organs. "Over 20 cases of transplanted lungs have been completed, with excellent and exciting results," said Neal Beswick, TransMedics' vice president of global marketing. "And working prototypes have been developed for both liver and kidney systems."

Source: Inside Science News Service