

Patient's lifesaving donor heart arrives 'warm and beating' inside experimental device

August 30 2011

(Medical Xpress) -- When Rob Evans' new donor heart arrived at Ronald Reagan UCLA Medical Center, the organ wasn't frozen on ice inside a cooler, as is typical. Instead, it was delivered in an experimental device that kept it warm and beating with oxygen and nutrient-rich blood during its journey from Northern California.

The special delivery was part of an ongoing national, multi-center phase 2 clinical study of an experimental organ-preservation system that allows donor hearts to continue functioning in a near-physiologic state outside the body during transport. The trial is being led by principal investigator Dr. Abbas Ardehali, surgical director of the heart and lung transplantation program at UCLA.

Evans, 61, the CEO of a nonprofit in Arizona, had been waiting nearly four years for a new heart. When asked if he was interested in enrolling in the research study, he said he thought the concept of a "warm, beating heart" sounded like common sense. His transplant surgery took place in June.

The Organ Care System (OCS), developed by a medical device company called TransMedics, works this way: After a heart is removed from a donor's body, it is placed in a high-tech OCS device and is immediately revived to a beating state, perfused with <u>oxygen</u> and nutrient-rich blood, and maintained at an appropriate temperature. The device also features



monitors that display how the heart is functioning during transport.

According to Ardehali, the technology could also improve <u>donor-heart</u> function and could potentially help transplant teams better assess donor hearts — including identifying possible rejection factors that could complicate tissue-matching — since the organs can be tested in the device, over a longer period of time.

In addition, it could help expand the donor pool by allowing donor hearts to be safely transported across longer distances, he said.

UCLA's Heart Transplant Program is leading the nationwide study, which started in 2009. The randomized trial will enroll a total of 128 patients — half whose donor hearts will be transported the traditional way, and half who will receive hearts in the device. To date, UCLA has enrolled nine patients in the phase 2 trial. Columbia University and the Cleveland Clinic are also enrolling patients, and more centers are being added.

"There are not enough donor hearts to help all the patients who are waiting," Ardehali said. "If we can find ways to improve upon our limited supply of hearts, then more lives will be saved."

With his new, strong heart beating inside his chest, Evans says he is thankful to the donor family for his gift of life and that he is ready to get back to the things he loves, including riding horses, playing with his grandson, and his work. But first, he jokes, he plans on tackling his wife's "to do" list of chores.

The OCS clinical trial, called the "Prospective, Randomized, Multicenter Safety and Effectiveness Evaluation of the Organ Care System Device for Cardiac Use" (PROCEED II), is fully designed and sponsored by TransMedics.



Ardehali has no financial ties to disclose.

Provided by University of California Los Angeles

Citation: Patient's lifesaving donor heart arrives 'warm and beating' inside experimental device (2011, August 30) retrieved 2 May 2024 from https://medicalxpress.com/news/2011-08-patient-lifesaving-donor-heart-experimental.html

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