

Liver device helps man survive until transplant

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(07-01) 18:50 PDT -- Eddie Lopez, a 50-year-old San Francisco man with cirrhosis, went into liver failure in March, arrived at California Pacific Medical Center in a coma and was put on life support.

Lopez was too sick to qualify for a liver transplant, even if a donated organ became available, making his odds of survival limited at best. The odds could have been worse, but the San Francisco hospital he was in happened to be one of only seven institutions nationwide testing a new device designed to take over the functions of the body's liver for a few hours or several days - long enough to give the patient a chance to stabilize.

For decades, researchers have struggled to create an artificial liver that would mimic both the liver's ability to filter toxins as well as create vital chemicals necessary to live. Unlike people with kidney dysfunction, who can rely on a dialysis machine to keep them alive, patients in acute liver failure have fewer options because of the organ's complex nature.

The latest device to be tested is called the ELAD, for extracorporeal liver assist device. It is considered the first to have human liver cells, which are contained in cartridges that the patient's blood passes through to provide the liver's crucial tasks. A once-promising device that used pig liver cells failed to receive Food and Drug Administration approval.

Because California Pacific was involved in the clinical trial for ELAD, the hospital's doctors let Lopez's family decide whether Lopez should participate - an opportunity his family decided he would want even if he didn't survive because it could help others.

Less than a day after he was hooked up to the machine, his sister Dianna Lopez said she noticed his color improved and he became alert. After three days, he had to be removed from the machine because he developed an infection, but he eventually became well enough to return home.

On Saturday, about five weeks after he left the hospital, Lopez got the call he was waiting for: A donated liver had become available for him. He received a liver transplant Saturday night and was recovering at the hospital's intensive care unit Wednesday.

"We believe the ELAD really did some good for him and helped for him to be stable enough to get a transplant," Dianna Lopez said.

It did its job

Dr. Todd Frederick, the medical center's principal investigator for the trial, said in Lopez's case, the ELAD did exactly what it was designed to do.

The ELAD is not meant to replace the liver, he said.

"The goal for him was to support him through a critical period, get him out of hospital and allow him to do the things he

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needed to do to get listed for a transplant," he said.

Four patients at California Pacific were hooked up to the ELAD during the phase II trial, which ended in April. All had acute failure on top of chronic liver disease. Only two, including Lopez, survived to leave the hospital. The other survivor, who had kidney disease and other health issues, eventually died from pneumonia, Frederick said.

Participants in the trial had to stay on the machine at least three to 10 days, which is often long enough to allow patients to receive a liver transplant or return home to wait. In some cases, patients may recover enough for the liver to regenerate, avoiding a transplant.

About 28,000 Americans die each year of chronic liver disease, according to the U.S. Centers for Disease Control and Prevention. The cause is often the result of alcohol abuse or Hepatitis C. There also can be other medical reasons. A much smaller number - about 2,000 people a year - go into acute liver failure without an underlying disease, the leading cause being an inadvertent overdose of acetaminophen, or Tylenol.

But donated livers are in short supply. Nearly 16,000 people are on the liver transplant waiting list, but only about 6,500 got the operation last year. The procedure most recently gained media attention when Apple CEO Steve Jobs underwent such a transplant.

"It's great opportunity because it's a totally underserved market," said Terry Winters, chief executive of Vital Therapies Inc., the San Diego company that makes the ELAD. "Their only competition is transplant and there are not enough livers out there to meet the demand."

The device uses cells derived from a liver tumor because those cells, unlike normal liver cells, have the ability to replicate and maintain functionality, Winters said. He said the machine's filtering device prevents those cells from reentering the patient's body.

Financial struggles

The hope for the promising therapy may explain why the ELAD has survived while its business side has struggled. The original Texas company formed in 1991 to create a machine using human liver cells went into bankruptcy in 1995, reformed in San Diego and went bankrupt again in 2003. It was quickly revived under the latest incarnation.

Winters said the ELAD's concept has been sound - the previous company had trouble coming up with an effective clinical trial design - allowing Vital Therapies to raise \$40 million in venture capital funding. The company received the latest round of funding in 2007, \$28 million led by Versant Ventures in Palo Alto.

So far, the device has been tested on about 70 patients at the seven U.S. hospitals. Earlier trials included patients from China, bringing the total to 119 patients worldwide.

Winters said results of the trials have not yet been published, but the findings have demonstrated "statistically significant results bridging patients to transplant." The company is designing trials for the third phase of testing.

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<http://www.sfgate.com/cgi-bin/article.cgi?f=/c/a/2009/07/02/BUSL18E5UN.DTL>

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