

New Hope for Broken Hearts

The Lancet Publishes Research on First-of-its-Kind Stem Cell Treatment That Re-grows Healthy Heart Muscle in Heart Attack Patients

Cedars-Sinai Heart Institute clinical trial underscores promise that stem cells may reverse heart attack damage

LOS ANGELES (FEB. 13, 2012) Results from a [Cedars-Sinai Heart Institute](#) clinical trial show that treating heart attack patients with an infusion of their own heart-derived cells [helps damaged hearts re-grow healthy muscle](#). Patients who underwent the stem cell procedure demonstrated a significant reduction in the size of the scar left on the heart muscle by a heart attack. Patients also experienced a sizable increase in healthy heart muscle following the experimental stem cell treatments.

One year after receiving the stem cell treatment, scar size was reduced from 24 percent to 12 percent of the heart in patients treated with cells (an average drop of about 50 percent). Patients in the control group, who did not receive stem cells, did not experience a reduction in their heart attack scars.

The study appears online at www.thelancet.com and will be in a future issue of the journal's print edition.

"While the primary goal of our study was to verify safety, we also looked for evidence that the treatment might dissolve scar and regrow lost heart muscle," said [Eduardo Marbán, MD, PhD](#), the director of the Cedars-Sinai Heart Institute who invented the procedures and technology involved in the study. "This has never been accomplished before, despite a decade of cell therapy trials for patients with heart attacks. Now we have done it. The effects are substantial, and surprisingly larger in humans than they were in animal tests."

"These results signal an approaching paradigm shift in the care of heart attack patients," said [Shlomo Melmed, MD](#), dean of the Cedars-Sinai medical faculty and the Helene A. and Philip E. Hixon Chair in Investigative Medicine. "In the past, all we could do was to try to minimize heart damage by promptly opening up an occluded artery. Now, this study shows there is a regenerative therapy that may actually reverse the damage caused by a heart attack."

The clinical trial, named CADUCEUS (CARDiosphere-Derived aUTologous stem CELls to Reverse ventricUlar dySfunction), was part of a Phase I investigative study approved by the U.S. Food and Drug Administration and supported by the National Heart, Lung, and Blood Institute.

As an initial part of the study, in 2009, Marbán and his team completed [the world's first procedure in which a patient's own heart tissue was used to grow specialized heart stem cells](#). The specialized cells were then injected back into the patient's heart in an effort to repair and re-grow healthy muscle in a heart that had been injured by a heart attack. The 25 patients -- average age of 53 -- who participated in this completed study experienced heart attacks that left them with damaged heart muscle. Each patient underwent extensive imaging scans so doctors could pinpoint the exact location and severity of the scars wrought by the heart attack. Patients were treated at Cedars-Sinai Heart Institute and at Johns Hopkins Hospital in Baltimore.

Eight patients served as controls in the study, receiving conventional medical care for heart attack survivors, including prescription medicine, exercise recommendations and dietary advice.

The other 17 patients who were randomized to receive the stem cells underwent a minimally invasive biopsy, under local anesthesia. Using a catheter inserted through a vein in the patient's neck, doctors removed small pieces of heart tissue, about half the size of a raisin. The biopsied heart tissue was then taken to Marbán's specialized lab at Cedars-Sinai, using methods he invented to culture and multiply the cells.

In the third and final step, the now-multiplied heart-derived cells – approximately 12 million to 25 million – were reintroduced into the patient’s coronary arteries during a second, minimally invasive [catheter] procedure.

Patients who received stem cell treatment experienced an average of 50 percent reduction in their heart attack scars 12 months after infusion while patients who received standard medical management did not experience shrinkage in the damaged tissue.

“This discovery challenges the conventional wisdom that, once established, scar is permanent and that, once lost, healthy heart muscle cannot be restored,” said Marbán, The Mark S. Siegel Family Professor.

The process to grow cardiac-derived stem cells involved in the study was developed earlier by Marbán when he was on the faculty of Johns Hopkins University. The university has filed for a patent on that intellectual property and has licensed it to a company in which Dr. Marbán has a financial interest. No funds from that company were used to support the clinical study. All funding was derived from the National Institutes of Health and Cedars-Sinai Medical Center.

About the Cedars-Sinai Heart Institute

The Cedars-Sinai Heart Institute is internationally recognized for outstanding heart care built on decades of innovation and leading-edge research. From cardiac imaging and advanced diagnostics to surgical repair of complex heart problems to the training of the heart specialists of tomorrow and research that is deepening medical knowledge and practice, the Cedars-Sinai Heart Institute is known around the world for excellence and innovations.