Treating heart attack with fat-derived stem cells may be safe in humans

EurekAlert

Fat cells — liposuctioned from a patient's belly — can safely boost heart function after a heart attack, according to a first-of-its-kind study presented at the American Heart Association's Scientific Sessions 2010.

"The study suggests that these cells can be safely obtained and infused inside the hearts of patients following an acute heart attack," said Eric (HJ) Duckers, M.D., Ph.D., lead author of the small study and head of Molecular Cardiology Laboratory at the Thoraxcenter, Erasmus University Medical Center in Rotterdam, Netherlands.

The treatment reduced the amount of damaged heart tissue, increased blood flow in the heart and improved the heart's pumping ability. These changes were not statistically significant, but the fat-derived stem cells worked as expected, Duckers said.

Duckers and colleagues recruited 11 men and three women for the prospective, double-blind, placebo-controlled APOLLO study (A Randomized Clinical Trial of AdiPOse-Derived Stem ceLLs in the Treatment of Patients With ST-Elevation myOcardial Infarction). They randomized the 14 patients — 10 received stem cells and four got a placebo infusion. All patients had suffered a severe heart attack and had a catheter procedure to evaluate their heart damage within two to 12 hours of symptom onset.

With the patients' consent, researchers liposuctioned 200-250 cubic centimeters of fat from the abdomen of each, using a system called Celution 800 device (Cytori Tx). From the fat cells, they isolated 20 million regenerative stem cells, which took nine to 10 minutes to infuse.

With the Celution device, physicians can isolate and sometimes infuse stems cells into the heart while the original catheter is still in place. APOLLO participants received cells within 24 hours after their catheterization.

At six months follow-up, researchers found encouraging results in the treatment group:

- Those receiving stem cells showed a 3.5-fold improvement in heart perfusion. The treatment arm also had a 5.7 percent increase in the amount of blood ejected by the left ventricle versus those receiving placebo.
- The average size of heart muscle damage dropped from 31.6 percent to 15.4 percent in the treatment group. For the placebo arm, the average area of damage remained the same as when the patients enrolled in the study —

i.e. 24.7 percent.
- The infused stem cells did not interfere with blood flow in the heart.
- Stem cell therapy was not associated with ventricular arrhythmias, which are potentially fatal erratic heartbeats.
- Two patients experienced adverse events from the liposuction procedure. Both formed a hematoma, an area of swelling filled with blood.

Although the APOLLO patients were white Europeans from the Netherlands (13) and Spain (one), "findings in the European Union population should be directly applicable to the United States population," Duckers said. "But, it's unclear whether the results would apply to non-Caucasians."

APOLLO's major limitation is its small size, and therefore its low statistical power to detect differences. This may be why researchers didn't find a significant difference between the treatment and placebo groups.

Duckers and his colleagues have initiated a phase II-III clinical trial called ADVANCE that will enroll up to 375 patients at 35 medical centers in the European Union. It will focus on acute heart attack patients with a left ventricle ejection fraction less than 45 percent. Forty percent of patients will receive 20 million stem cells; another 40 percent will get 30 million stem cells; and 20 percent will make up the placebo group.

"The primary efficacy endpoint of ADVANCE will be absolute improvement in infarct size at six months follow-up," Duckers said. "Several studies have shown that this is an excellent and more consistent predictor of survival and major adverse events (than other endpoints) in patients after an acute heart attack."

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