

Stem cell therapy possibly helpful in heart failure patients

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A new study found that using a patient's own bone marrow cells may help repair damaged areas of the heart caused by heart failure, according to research presented today at the American College of Cardiology's 61st Annual Scientific Session. The Scientific Session, the premier cardiovascular medical meeting, brings cardiovascular professionals together to further advances in the field.

Millions of Americans suffer from <u>heart failure</u>, the weakening of the <u>heart muscle</u> and its inability to pump blood effectively throughout the body. If medications, surgery, or stents fail to control the disease, doctors often have few <u>treatment options</u> to offer.

This is the largest study to date to look at stem cell therapy, using a patient's own <u>stem cells</u>, to repair damaged areas of the heart in patients with chronic <u>ischemic heart disease</u> and left ventricular dysfunction. Researchers found that <u>left ventricular ejection fraction</u> (the percentage of blood leaving the heart's main pumping chamber) increased by a small but significant amount (2.7 percent) in patients who received stem cell therapy. The study also revealed that the improvement in ejection fraction correlated with the number of CD34+ and CD133+ cells in the <u>bone marrow</u> – information that will be helpful in evaluating and designing future therapies and trials.

"This is the kind of information we need in order to move forward with the clinical use of stem cell therapy," said Emerson Perin, MD, PhD, director of clinical research for cardiovascular medicine at the Texas



Heart Institute and the study's lead investigator.

This multi-center study was conducted by the Cardiovascular Cell Therapy Research Network and took place between April 2009 and 2011. At five sites, 92 patients were randomly selected to receive stem cell treatment or placebo. The patients, average age 63, all had chronic ischemic heart disease and an ejection fraction of less than 45 percent along with heart failure and/or angina, and were no longer candidates for revascularization.

"Studies such as these are able to be completed much faster because of the team approach of the network," said Sonia Skarlatos, PhD, deputy director of the division of cardiovascular sciences at the National, Heart, Lung and Blood Institute, and program director of the network.

Bone marrow was aspirated from the patients and processed to obtain just the mononuclear fraction of the marrow. In patients randomly selected to receive <u>stem cell therapy</u>, <u>doctors</u> inserted a catheter into the heart's left ventricle to inject a total of 3 ccs comprising 100 million stem cells into an average of 15 sites that showed damage on the electromechanical mapping image of the heart. Dr. Perin said the procedure is relatively quick and painless, involving only an overnight stay at the hospital.

The study used electromechanical mapping of the heart to measure the voltage in areas of the heart muscle and create a real-time image of the heart.

"With this mapping procedure, we have a roadmap to the heart muscle," said Dr. Perin. "We're very careful about where we inject the cells; electromechanical mapping allows us to target the cell injections to viable areas of the heart."



The study was designed to determine whether left ventricular end systolic volume and MVO2 changed in patients who received stem cell treatment. Researchers also wanted to see if nuclear scans of the heart showed a reversible change in perfusion defects in patients who had received the treatment. Dr. Perin said the original study endpoints showed no significant differences at baseline and six months later.

Patients' bone marrow cells were also sent to a biorepository, where studies were done to examine the phenotypes and functional characteristics of the bone marrow cells. Younger patients had a higher content of CD34+ and CD133+ cells in their bone marrow and had higher ejection fractions after stem cell treatment. Dr. Perin said these types of analyses are essential for autologous therapy because they will help identify which patients will most likely benefit from cell therapy. This information is also important in guiding the design of future trials.

"Developing a cell biorepository is a huge step forward for the future of autologous therapy because the composition and function of cells in the bone marrow may play a significant role in outcome," said Dr. Perin. "This trial provides a sound basis for further study of the relationship between bone marrow cell characteristics and clinical endpoints."

Provided by American College of Cardiology

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