

Processed fat cells show potential as treatment for refractory ischemia patients

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Patients treated with processed autologous adipose-derived regenerative cells (ADRCs) injected into the heart muscle demonstrated symptomatic improvement and a trend towards lower rates of heart failure hospitalizations and angina, despite no improvement in left ventricle ejection fraction (LVEF) or ventricular volumes. The ATHENA trial results were presented today as a late-breaking clinical trial at the Society for Cardiovascular Angiography and Interventions (SCAI) 2016 Scientific Sessions in Orlando, Fla.

ADRCs are a combination of cell types, such as <u>adult stem cells</u>, <u>vascular endothelial cells</u>, and vascular <u>smooth muscle cells</u>. Preclinical data indicates that these cells promote blood vessel growth, modulate inflammation and reduce cell death. These cells can be used in a variety of tissue types, including bone, cartilage, fat, skeletal muscle, smooth muscle and cardiac muscle.

"ADRCs consist of multiple <u>cell types</u> with multiple potential benefits," said Timothy D. Henry, MD, MSCAI, director, division of cardiology at the Cedars-Sinai Heart Institute and the study's lead investigator. "Based on the results seen with ADRCs in the PRECISE trial, we designed ATHENA to look at these cells as a possible treatment option for people with refractory chronic myocardial ischemia."

The phase 2 program was comprised of two prospective, randomized double-blind, placebo-controlled, parallel group trials (ATHENA and ATHENA II). The patients (average age 65 years) in each group (17



ADRCs, 14 placebo) were on the maximally tolerated medical management with an EF score of 20-45 percent. EF, the amount of blood pumped out of the ventricles with each contraction, can be an early indicator of heart failure if the score is 35 percent or below. The baseline average EF score for both groups was 31.6 percent. The patients were also CCS angina class II-IV and/or NYHA class II-III, had ongoing ischemia and multi-vessel cardiovascular disease, but were not candidates for revascularization.

Using standard liposuction, a small volume of the patient's fat tissue (

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