Stem cell therapy shows potential for difficult-to-treat RA patient population

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A study using a stem cell therapy to treat challenging refractory angina (RA) patients demonstrated promising results, including improved exercise time, reduced angina and reduced mortality. The RENEW 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.

RA, also known as chronic symptomatic coronary artery disease, impacts an increasing number of people. Due to inadequate blood supply from severe blockages, many experience ongoing chest pain, shortness of breath, fatigue and have limited treatment options.

RENEW was designed to determine the effectiveness of granulocyte-colony stimulating factor (G-CSF) mobilized CD34+ stem cells (CD34+) to treat RA patients. G-CSF triggers the bone marrow to produce white blood cells and stem cells and release them into the bloodstream. CD34+ are a specific type of stem cells that have been shown to increase blood flow in pre-clinical models.

"Clinicians are seeing more RA patients because people are living longer," said Timothy D. Henry, MD, MSCAI, director, division of cardiology at the Cedars-Sinai Heart Institute and the study's co-principal investigator. "Unfortunately, despite better medical care, these people are still confronting ongoing symptoms that affect their daily lives."

The patients had class III or IV angina on maximally tolerated medical management, had at least seven episodes of chest pain per week, were not candidates for revascularization and whose treadmill exercise time was between 3-10 minutes. Patients were randomized into three groups: 28 to open-label standard of care (SOC), 27 to blinded placebo injections, (PL) and 57 received treatment with CD34+ cells. The researchers assessed treadmill exercise time and angina frequency at three, six and 12 months and major adverse cardiac events (MACE) for up to two years.

Exercise time for cell-treated patients increased by more than two minutes at three months (122 seconds), six months (142 seconds) and 12 months (124 seconds). This group also experienced a 40 percent decrease (relative risk 0.57) of angina at six months when compared to the PL group.

At two years, the CD34+ cell group saw lower rates of mortality (3.7 percent) when compared with PL (10 percent) and SOC (7.1 percent). Further, the study found higher rates of MACE after two years for SOC (68 percent) patients vs. CD34+ cell (46 percent) and PL (43 percent) patients.

"Cell therapy appears to be a promising approach for these patients who have few options," said Dr. Henry. "Our results were consistent with phase 2 results from the ACT34 trial."

While the investigators aim was to include 444 RA patients, final results are based on 112, because the trial was prematurely terminated by the sponsor due to financial considerations. "It is unfortunate the early termination of this study precludes a full evaluation of the efficacy of this therapy for these patients with very few options," said Tom Povsic, MD, FSCAI, co-principal investigator, associate professor at the Duke Clinical Research Institute (DCRI) and an interventional cardiologist at

Duke University School of Medicine. "Studies like RENEW are critical to developing reliable and effective cellular therapies for heart patients, and continued funding is essential to advancing the work that this study began. We need to find a way to bring these therapies to patients as quickly and safely as possible."

This study was accepted for publication by *JACC: Cardiovascular Interventions*.

Provided by Society for Cardiovascular Angiography and Interventions