Cell therapy treatment for cardiac patients with microvascular dysfunction provides enhanced quality

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Trial results presented today revealed a promising therapy for patients experiencing angina due to coronary microvascular dysfunction (CMD). The results of the study were presented today as feature clinical research during the SCAI 2020 Scientific Sessions Virtual Conference.

CMD is heart disease that causes the small blood vessels feeding the heart muscle to not work as normal. CMD results in ischemia, angina and adverse outcomes in patients with non-obstructive coronary artery disease (NOCAD), with a high predilection for women. Patients experience significant impairment in their quality of life, and no specific therapy for CMD exists. CD34+ cell therapy augments microvasculature in preclinical models and improves symptoms, exercise tolerance and mortality in refractory angina obstructive coronary artery disease patients.

CD34+ stem cells are a naturally occurring endothelial progenitor cell shown in pre-clinical models to improve microvascular angiogenesis in ischemic tissues. Clinical studies in refractory angina, critical limb ischemia, and dilated cardiomyopathy have shown therapeutic benefit, including reduction in angina, improvement in exercise time, a reduction in amputation and mortality.

Researchers conducted a two-center NHLBI-sponsored (R44HL135889)1 trial of autologous CD34+ cell therapy (CLBS16-P01)

(NCT03508609) in 20 NOCAD patients with persistent angina and invasive coronary flow reserve (CFR) ≤2.5. Measures included angina frequency, CCS Class, Seattle Angina Questionnaire (SAQ), modified Bruce exercise treadmill test (ETT), and labs. Subjects received GCSF 5mcg/kg/day for 5 days before leukapheresis, followed by manufacturing to select the CD34+ cells. Cells were administered via a single infusion to the LAD coronary artery. Six-month assessment included invasive CFR, angina frequency, CCS, SAQ, and ETT.

CFR significantly increased from 2.08+/-0.3 at baseline to 2.68+/-0.8 at 6 months after a single infusion of CD34+ cells (p=0.0045) and study investigators reported that there were no cell-related adverse events. "This was a proof of concept trial to evaluate the safety and efficacy of CD34+ stem cells administered via intracoronary infusion for CMD patients with abnormal coronary flow reserve