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Conference Reports

IV stem cell infusion in HF patients brings improved health status, functional capacity, but not improved cardiac function

By Liz Meszaros

Rome, Italy, August 28, 2016—Intravenous mesenchymal stem cell infusion did not bring about significant improvements in cardiac structure or function in patients with chronic non-ischemic cardiomyopathy, according to results from this single-blind, placebo-controlled, crossover, multicenter, phase IIa study, which were presented here at the European Society of Cardiology Congress 2016. The treatment did, however, lead to improvements in both health status and functional capacity in these patients.

For this study, researchers used ischemia-tolerant mesenchymal stem cells (itMSCs), which were grown under chronic hypoxic conditions.

“The premise was that stem cells may have immune modulatory properties, which are enhanced when grown under hypoxic conditions,” explained lead author Javed Butler MD, MPH, FACC, FAHA, MBA, division chief, cardiology, Stony Brook University, Stony Brook, NY, USA. “Virtually all previous studies of stem cell therapy for heart failure have centered on the concept that the cells must be injected directly into the heart to trigger new growth, but if stem cells have anti-inflammatory benefits, direct cardiac delivery may not be necessary to repair and stimulate the dysfunctional viable myocardium.”

Dr. Butler and colleagues randomized 11 patients with non-ischemic cardiomyopathy and left ventricular ejection fraction (LVEF) ≤ 40% to treatment with intravenous itMSC or placebo for 90 days, after which all patients were crossed over to the other treatment.

Researchers found no major differences in the primary safety endpoints, including all-cause mortality, all-cause hopitalization, and adverse events, 90 days after itMSC infusion. At this time, secondary endpoints, including cardiac remodelling as assessed by cardiac MRI, also did not differ between the two groups.

They did find, however, that treatment with itMSCs brought about improved health status and functional capacity, both considered prespecified endpoints. These improvements included the 6-minute walk test, with an increase of 36 meters over placebo (P=0.02); and the Kansas City Cardiomyopathy Questionnaire scores, with a 5.22-point increase in clinical summar score (P=0.02) and 5.65-point increase in funcitonal status score (P=0.06).

Researchers also noted that the infusion of itMSCs brought about significant changes in the levels of several inflammatory cells.

“To our knowledge, this trial represents the first experience with intravenously administered itMSCs in patients with any type of chronic cardiomyopathy. Further studies should explore the efficacy of serial dosing to produce more sustained immunomodulatory effects and thereby perhaps facilitate improvement in left ventricular structure and function, and in clinical outcomes,” concluded Dr. Butler.

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