Therapy using stem cells, bone marrow cells, appears safe for patients with ischemic cardiomyopathy

November 18 2013

Alan W. Heldman, M.D., of the University of Miami Miller School of Medicine, and colleagues conducted a study to examine the safety of transendocardial stem cell injection (TESI) with autologous mesenchymal stem cells and bone marrow mononuclear cells in patients with ischemic cardiomyopathy.

An effective proregenerative treatment for ischemic cardiomyopathy would address a major unmet need for many patients. An unresolved issue is whether mesenchymal stem cells have similar safety and possibly greater efficacy than bone marrow mononuclear cells, according to background information in the article.

The included 65 patients with ischemic cardiomyopathy and compared injection of mesenchymal stem cells (n=19) with placebo (n = 11) and bone marrow mononuclear cells (n = 19) with placebo (n = 10), with 1 year of follow-up. The primary measured outcome was treatment-emergent 30-day serious adverse event rate defined as a composite of death, heart attack, stroke, hospitalization for worsening heart failure, perforation (rupture), tamponade (compression of the heart due to collection of blood or fluid), or sustained ventricular arrhythmias.

No patient had treatment emergent-serious adverse event at day 30. Exploratory analyses of 1-year incidence of serious adverse events was 31.6 percent for mesenchymal stem cells, 31.6 percent for bone marrow

cells, and 38.1 percent for placebo. Over 1 year, the Minnesota Living with Heart Failure score (a measure of quality of life) improved with mesenchymal stem cells and with bone marrow cells but not with placebo. The 6-minute walk distance increased with mesenchymal stem cells only.

"These results provide the basis for larger studies to provide definitive assessment of safety and to assess efficacy of this new therapeutic approach," the authors write.

More information: doi:10.l001/jama.2013.282909