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ACUTE CORONARY SYNDROMES

Unique US trial shows bone-marrow stem cells to be safe for AMI

SEPTEMBER 16, 2010 | Lisa Nainggolan

Minneapolis, MN - The first randomized, double-blind, placebo-controlled US trial of bone-marrow stem cells in patients with ST-elevation MI (STEMI) has shown the therapy to be safe and to improve left ventricular volume compared with placebo [1].

Dr Jay H Traverse (Minneapolis Heart Institute, MN) and colleagues report the findings in the September 2010 issue of the *American Heart Journal*. Traverse told **heartwire** that this small, phase 1 trial differs in some ways from the European trials that have been performed with bone-marrow-derived stem cells in MI, which he admits are "considerably larger."

This is the first time all patients have received the same number of cells—100 million—whereas in European studies, for example **REPAIR-AMI**, some patients got three times as many cells as others. "Meta-analyses suggest there is a dose-response effect, so if you're giving people different numbers of cells, this introduces another variable that may affect the results," Traverse observes.

And this US study took "all-comers, including those with cardiac arrest, cardiogenic shock, or [who underwent therapeutic] hypothermia," he notes, adding that "most of the other trials have excluded this type of patient." And this trial is the first to have delivered stem cells by intracoronary infusion—using a small hollow catheter advanced to where the stent is placed—in an attempt to eliminate the potential confounding effects of repeated episodes of ischemia and reperfusion induced by the stop-flow technique used in Europe, he says.

TIME will tell, but financial support for stem-cell trials lacking

Traverse and colleagues randomized 40 patients with moderate to large anterior STEMI to 100 million autologous bone-marrow-derived mononuclear cells or placebo in a 3:1 ratio, three to 10 days after successful PCI. Patients were assessed six months later, and all remain alive to date.

Demonstrating safety "was the main goal of this study," Traverse said, and there were no major adverse events. There was no difference in one of the secondary end points—EF—between the two treatment groups, with both demonstrating improvement, but for the other—LV volume—there was improvement in the stem-cell group compared with placebo (p<0.01).

Traverse and colleagues are now involved with the **TIME** trial, "which will be the first adequately powered study to assess whether the timing of administration of stem cells following a heart attack is important," he explains. Patients will be randomized on either day 3 or day 7 after MI; enrollment is expected to be completed in the spring of 2011, with preliminary results available six months later, he says.

Traverse says he hopes that autologous bone-marrow stem cells will be approved for use in MI in the next few years, "because the safety profile is so good" but adds that the problem will be "the financial support to pay for these trials. I would anticipate that more proprietary-type products will get approved before bone marrow does for acute MI, even though it's probably the most straightforward and probably the safest of these kinds of therapies."

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Source

1. Traverse JH, McKenna DH, Harvey K, et al. Results of a phase 1, randomized, double-blind, placebo-controlled

trial of bone marrow mononuclear stem cell administration in patients following ST-elevation myocardial infarction. *Am Heart J* 2010; 160: 428-434. 

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