ONE YEAR FOLLOW-UP RESULTS FROM PRESERVE-AMI: A RANDOMIZED, DOUBLE-BLIND, PLACEBO CONTROLLED CLINICAL TRIAL OF INTRACORONARY INFUSION OF AUTOLOGOUS CD34+ CELLS IN PATIENTS WITH LEFT VENTRICULAR DYSFUNCTION POST STEMI

Oral Contributions
Room 7B
Sunday, March 15, 2015, 12:02 p.m.-12:13 p.m.

Session Title: Highlighted Original Research: Stable Ischemic Heart Disease and the Year in Review
Abstract Category: 27. Stable Ischemic Heart Disease: Therapy
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Background: ST segment Elevation Myocardial Infarction (STEMI) affects 160,000 annually in the US. Guidelines direct immediate revascularization and adjunctive medical therapies. Yet STEMI victims remain at risk for infarct expansion, heart failure, reinfarction, repeat revascularization and death. In pre-clinical studies, human CD34+ stem cells are angiogenic within ischemic myocardium, improving perfusion and function. A precedent Phase 1 study demonstrated feasibility, safety and bioactivity of intracoronary infusion of autologous CD34+ cells in patients with LV dysfunction (LVD) post-MI and identified a threshold dose of 10M cells associated with improved infarct region perfusion.

Methods: PreSERVE-AMI is a Phase 2, randomized, double-blind, placebo-controlled trial performed at 60 sites in the US. Those with LVD (EF ≤48% by CMR) ≥4 days post-STEMI underwent mini bone marrow harvest and were randomized 1:1 to (A) autologous CD34+ cells (minimum dose of 10M±20% cells in autologous serum) or (B) autologous serum. (A) or (B) was delivered via stop-flow method for intracoronary infusion. The primary efficacy endpoint was change in resting myocardial perfusion measured by gated SPECT over 6 months. Ventricular function was also assessed (CMR). The primary safety endpoint was occurrence of AEs, SAEs and MACE (CV mortality, heart failure, reinfarction, revascularization).

Results: 161 patients were randomized and received intracoronary infusion (from Jan 2012 to Dec 2013). Mean age was 57.3±10.6 and 81% were men. The updated data through one year of follow-up will be presented.

Conclusion: PreSERVE-AMI represents the largest study of cell-based therapy for STEMI completed in US and will determine endpoints, sample size and suitability of autologous CD34+ cell therapy for upcoming Phase 3 study in patients with LVD post STEMI who are at risk for death and major morbidity.