

Results of the CHILL-MI trial presented

October 31 2013

A clinical trial shows that rapidly cooling patients who have suffered ST-elevation myocardial infarction (STEMI, the most serious form of a heart attack) prior to restoring blood flow is safe and feasible. The findings of the CHILL-MI trial were presented today at the 25th annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium. Sponsored by the Cardiovascular Research Foundation (CRF), TCT is the world's premier educational meeting specializing in interventional cardiovascular medicine.

CHILL-MI was a prospective, randomized multicenter efficacy trial that builds on initial findings from the pilot RAPID MI-ICE trial, which showed significantly reduced infarct size when patients were cooled below 35°C before angioplasty. The primary endpoint for CHILL-MI was myocardial infarct size as a percentage of myocardium at risk, assessed by magnetic resonance imaging (MRI) at 2-6 days after the procedure.

This study enrolled 120 patients in nine centers with large anterior and inferior STEMIs with infarct duration of less than six hours. Patients underwent PCI and were randomized to the traditional standard of care or hypothermia induced by rapid infusion of up to 2,000 ml cold saline combined with endovascular cooling. In the hypothermia group, cooling was initiated before PCI and continued for one hour after reperfusion with a target temperature of 33°C followed by spontaneous rewarming.

Due to the time required for cooling, door-to-balloon time was impacted by an average of nine minutes in the hypothermia group. The primary



endpoint, infarct size in relation to the area at risk was non-significantly reduced by 13 percent (p=0.15) with similar myocardium at risk between both groups. Although the trial missed its primary endpoint, exploratory analysis indicates an effect in the early anterior patient population with a 33 percent reduction of infarct size.

At 45±15 days there was no mortality. However, the incidence of clinical heart failure was 14 percent in the control group and 3 percent in the hypothermia group (p

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