Aqueous Oxygen Therapy for ST Segment Elevation Myocardial Infarction: AMIHOT Trial Safety Report and Enrollment Completion

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Background: Although rapid coronary reperfusion in ST segment elevation myocardial infarction (STEMI) improves left ventricular function and mortality, epicardial vessel patency does not fully ensure nutrient flow at the tissue level. Animal and Phase I human testing of the TherOx® Aqueous Oxygen (AO) System (TherOx Inc., Irvine, California) suggests that percutaneous coronary infusion of autologous blood mixed with hyperoxemic saline may help overcome the downstream barrier to oxygen delivery in ischemic zones and improve myocardial salvage following percutaneous intervention for STEMI.

Methods: A Phase II randomized international trial is designed to evaluate the efficacy of regional AO therapy in STEMI; a sub-selective catheter positioned in the infarct artery delivers AO for 90 minutes at 75 ml/min. Contrast echocardiography performed following intervention and before randomization is repeated at 24 hours, and days 30 and 90. Resting SPECT myocardial perfusion scans are obtained day 14. Primary endpoints include regional wall motion scores, SPECT perfusion defects, and ST segment resolution.

Results: Two hundred patients have been randomized after 20 run-in cases. None of the 100 patients assigned to treatment experienced hemodynamic or electrophysiologic instability during infusion. Repeat angiography when performed following AO therapy documented perfusion catheter stability and maintenance of TIMI 3 flow. Planned interim analysis performed after randomization of the first 200 patients demonstrated no safety concerns and there were no unanticipated major cardiac events. Enrollment of the 270 patient cohort is to be completed by January, 2003.

Conclusion: Preliminary results suggest that regional hyperoxicemic therapy appears to be safe and can be readily applied in institutions performing primary angioplasty for STEMI. Conclusions regarding the promise of this new therapeutic modality to improve recovery of left ventricular function requires longer-term follow-up.

Sex Disparities in the Treatment of Non–ST-Segment Elevation Acute Coronary Syndromes

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Background: No large-scale examination of sex disparities in the management of acute coronary syndromes (ACS) has been done since publication of the revised ACC/AHA Guidelines for the Diagnosis and Treatment of non-ST-elevation acute coronary syndromes (NSTE ACS).

Methods: We conducted a retrospective data analysis from the CRUSADE Initiative, which enrolls US pts with NSTE ACS (ST-segment depression or transient elevation or positive cardiac markers). We examined sex differences in the use of acute and discharge medications, in-hospital procedures, discharge interventions, and in-hospital outcomes.

Results: Of the 35,835 pts (41% women) in the study, women were older and had more diabetes and hypertension but less prior MI or revascularization (Table). Women less often received acute aspirin, heparin, GPI Ila-IIia or ACE inhibitors. Discharge treatments were similarly disparate for use of aspirin, beta blockers, ACE inhibitors, and statins. Women were at higher risk for death (5.6% vs 4.3%, p<0.001), post-admission MI (4.0% vs 3.5%, p=0.03), CHF (12.1% vs 8.8%, p<0.001), stroke (1.1% vs 0.8%, p<0.003), and RBC transfusion (17.2% vs 13.2%, p<0.01).

Conclusion: Despite having higher-risk characteristics at presentation and greater in-hospital risk, women with NSTE ACS are consistently treated less aggressively than men. Lower use of evidence-based therapies was observed in women even after adjusting for important differences between groups.