Background: Refractory angina pectoris despite medical therapy in patients who are not amenable for revascularization procedures is a relatively common clinical problem. The quality of life of these no-option patients with so-called therapy-refractory angina pectoris is poor as these patients need to change their life style according to their level of pain and angina. A potential solution to alleviate the symptoms of reversible subendocardial ischemia is to redistribute intramyocardial blood flow from the less ischemic subepicardial myocardium towards the under-perfused and ischemic subendocardial myocardium. This can be achieved by implanting a Reducer in the coronary sinus (CS). The hourglass-shaped stent-like device creates over time a narrowing thereby increasing the venous pressure and thus allowing intramyocardial flow reversal relieving the symptoms of pain due to ischemia.

Methods: The COSIRA (Coronary Sinus Reducer for Treatment of Refractory Angina) is a prospective, multicenter, randomized, double-blind, sham-controlled clinical trial of the safety and effectiveness of the CS Reducer. The trial is ongoing, and more than 80 patients have been enrolled in Europe and Canada. It consists of baseline assessments, implantation of the Reducer in the study group, and assessments of both study and sham-control groups at hospital discharge, 30 days, 3 months and 6 months.

Results: The primary endpoint of this trial is a decrease in two or more CCS grades from baseline to six-month post-procedural evaluation in Reducer and control groups. A parallel CS Reducer registry is ongoing, in which patients with refractory angina are treated with CS Reducer implantation on a compassionate use basis.

Conclusions: The 6 months safety results of the COSIRA trial as well as the safety and efficacy results of the Reducer registry will be presented at TCT 2012.

TCT-385

Comparative Economic Outcomes in Cardiogenic Shock Patients Managed with the Minimally Invasive Impella or Extracorporeal Life Support

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Background: Despite advances in cardiovascular medicine, acute decompensated heart failure and post-cardiotomy shock is associated with alarmingly high mortality rates. Until recently, temporary mechanical support has included the intra-aortic balloon pump (IABP) and extracorporeal membrane oxygenation (ECMO). The Impella 5.0 device is a minimally invasive microaxial pump, designed to provide superior clinical support for these failing patients in a cost-effective manner.

Methods: This retrospective study compares the economic outcomes of patients receiving circulatory support with either ECMO or the Impella LP5.0, and builds on our previously published clinical study on these patients. Hospital resource data was collected for both study arms, to include blood product costs, perfusion costs, ICU costs, and length of stay (LOS) for 29 Impella and 31 ECMO patients.

Results: In a well-matched clinical sample of Impella and ECMO patients, total mean costs to the hospital were reduced by 12% for the initial index stay of Impella patients. This reduction was driven by a significant 61% reduction in blood product costs (p<0.001), confirming the minimally invasive design of the Impella cardiac assist device. Related, there was a 100% reduction in perfusion costs, as Impella patients do not require perfusion assistance. Additionally, ICU costs were reduced in the Impella arm by 25%, driven primarily by 4.8 fewer ICU days of stay for Impella patients.

Conclusions: For patients requiring emergent hemodynamic support, the Impella cardiac assist device appears to offer a less invasive alternative that not only improves outcomes but also reduces costs over ECMO therapy. These findings have significant operational implications for providers, both in the single-payer Canadian system, as well as in the U.S. healthcare system as providers embrace recent health reforms.

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Predictors of In-Hospital Mortality in Patients Undergoing Percardiocentesis in United States

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Background: The national rates of in-hospital mortality in patients undergoing pericardiocentesis in the United States are not known.

Methods: The Nationwide Inpatient Sample (NIS) database was used to identify patients who underwent pericardiocentesis from 2005 to 2009. We used risk-adjusted logistic regression to analyze the predictors of in-hospital mortality.

Results: A total of 49,850 patients underwent pericardiocentesis during the five-year study period. The in-hospital mortality was noted to be 15.5%. The following factors were identified as significant independent predictors of in-hospital death: shock (OR 4.65; 95% CI 3.99-5.41), renal failure (OR 1.24; 95% CI 1.06-1.45), peripheral vascular disease (OR 1.32; 95% CI 1.04-1.67), neurologic disorders (OR 1.74; 95% CI 1.38-2.20), metastatic cancer (OR 1.74; 95% CI 1.45-2.09), coagulopathy (OR 1.91; 95% CI 1.60-2.26), electrolyte abnormalities (OR 1.55; 95% CI 1.38-1.74) and liver disease (OR 1.58; 95% CI 1.20-2.09).

Conclusions: In this observational study, we found that the in-hospital mortality after pericardiocentesis continues to be high in United States. Shock, renal failure, peripheral vascular disease, neurologic disorders, metastatic cancer, coagulopathy, electrolyte abnormalities, and liver disease were significantly associated with an increased risk of in-hospital mortality.

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Short- and Long-term Outcomes of Coronary Revascularization in Patients with Severe Left Ventricular Dilatation

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Background: Patients with coronary artery disease accompanied by severe left ventricular dilatation (LVD) are at higher risk for heart failure and death. However, their clinical and angiographic profiles, short- and long-term outcomes after revascularization are unknown.

Methods: A total of 4,283 patients (median age 60.0 years; 77.4% male) with coronary artery disease undergoing percutaneous or surgical revascularization in our center from July, 2003 to September, 2005 were stratified according to end-diastolic dimension (EDD). Patients with severe LVD (EDD>70 mm), mild/moderate LVD (EDD 52.7 mm to 70.0 mm in males, EDD 48.3 mm to 70.0 mm in females) and no LVD (EDD<48.3 mm in females) was compared for outcome analysis.

Results: Patients with severe LVD had more complex lesions (eg. chronic total occlusions, multi-vessel disease) with more prior myocardial infarction, valvular impairments and renal dysfunction (all p<0.001). Patients successfully discharged were followed up for a median of 548 (455-669) days. Severe LVD was significantly associated with increased in-hospital mortality (5.4% vs 1.6% vs 1.0%, p<0.001) and composite ischemia (all-cause mortality, myocardial infarction, stroke and repeat revascularization) (6.9 % vs 2.5% vs 2.1%, p<0.001) compared with mild/moderate LVD and no LVD groups. By multivariable analysis, severe LVD was a significant independent predictor of in-hospital (HR 1.858, 95% CI 1.532-2.261, p<0.001) and follow-up mortality (HR 1.460, 95% CI 1.037-2.054, p=0.030) after revascularization.

Conclusions: Patients with severe LVD have more co-morbidities and complex coronary lesions. Severe LVD in patients undergoing coronary revascularization was an independent predictor of early and late mortality and adverse ischemic outcomes.