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 activity tolerance. A potential solution to alleviate the pain 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-386

Predictors of In-Hospital Mortality in Patients Undergoing Pericardiocentesis in United States
Paul Herrmann1, Chad Zack2, Vladimir Lahker1, Alfred Bose1, Riyaz Bashir1
1Temple University School of Medicine, Philadelphia, PA

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
Wang Xiao1, Nie Shaoping1, Liu Xiaohui1, Kang Junping1, Lv Qiang1, Du Xin1, Ma Changsheng1
1Beijing Anzhen Hospital, Capital Medical University, Beijing, China

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) and severe moderate LVD (EDD 52.7mm to 70.0mm in males, EDD 46.3mm to 70.0mm in females), and no LVD (EDD<52.7mm in males, EDD<46.3mm in females) were 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 1.85, 95% CI 1.32-2.61, p<0.001) and follow-up mortality (HR 1.46, 95% CI 1.03-2.05, 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.