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Acute hemodynamic improvement after Parachute® Ventricular Partitioning Device implantation

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Background: Myocardial infarction (MI) is frequently followed by left ventricular (LV) remodeling, heart failure and increased long-term morbidity and mortality. Parachute® Ventricular Partitioning Device offers an additional strategy to medical therapy with exclusion of the infarcted wall to decrease end diastolic volumes, thereby decreasing myocardial work and wall stress and to receive an immediate hemodynamic benefit as well as a better clinical outcome. Before and after the implantation, invasive hemodynamic measurements (including right heart study) were performed in all patients to evaluate the acute hemodynamic changes.

Methods: We implanted the Parachute® device in 8 patients between September 2012 and March 2013 who had a prior myocardial infarction with an apical aneurysm and abnormal wall motion. All procedures were done percutaneous via the right femoral artery. Invasive hemodynamic measurements were taken before and after device implantation in all patients.

Results: Implantation was successful in all patients, except dislocation of the device from the proper landing zone requiring removal with a snare from the left ventricle. The remaining 7 patients showed a significant increase in three parameters: stroke volume (SV), cardiac output (CO) and cardiac index (CI). The SV had an average increase in 35.9% (± 14.6 ml). Also the CO had an increase in 30.5% (± 0.8 l/min) while the CI increased by 32.3% (± 0.5 l/min/m²). Heart rate, pulmonary capillary wedge pressure, mean pulmonary arterial pressure and right atrial pressure remained essentially unchanged. No vascular complications and no other adverse events occurred during the hospital course in all patients.

Conclusions: The data demonstrate the feasibility and acute hemodynamic efficacy of percutaneous LV partitioning in congestive heart failure with a prior anterior MI. Implantation of a Parachute® device resulted in an immediate reduction in LV volumes and an increase in LV ejection fraction proving the concept of device efficacy in this specific patient population.

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The Current Use of Impella 2.5 in Acute Myocardial Infarction Complicated by Cardiogenic Shock: Results from the USpella Registry

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Background: Early mechanical circulatory support with a percutaneous ventricular assist device may improve outcome. However, the optimal timing to initiate hemodynamic support to achieve maximal benefits has not been well characterized. We aimed to evaluate the preprocedural characteristics and outcomes of patients with an acute myocardial infarction (AMI) complicated by cardiogenic shock (CS) who received hemodynamic support with Impella 2.5 prior to their percutaneous coronary intervention (Pre-PCI) compared to those who received support following their PCI (Post-PCI).

Methods: A total of 154 consecutive patients from 38 U.S. hospitals participating in the USpella Registry were included in the present analysis. The primary endpoint was survival to discharge. Secondary endpoints included the assessment of hemodynamics and in-hospital complications. Independent predictors for mortality were also identified.

Results: Patients in the Pre-PCI group had a higher prevalence of diabetes (p = 0.015), peripheral vascular disease (p = 0.008), chronic obstructive pulmonary disease (p = 0.047), prior stroke (p = 0.043) and extensive revascularization with more lesions (p = 0.006) and vessels (p = 0.01) treated when compared to the Post-PCI group. The incidence of in-hospital complications was similar between the two groups. At discharge, patients in the Pre-PCI group had significantly better survival (65.1%) compared with patients in the Post-PCI group (40.7%) (p = 0.003). Survival in the Pre-PCI group remained favorable in subgroup analysis. In multivariate logistic regression analysis, the institution of hemodynamic support prior to the PCI was an independent predictor of in-hospital survival (Odds ratio for mortality 0.37, 95% confidence interval: 0.17-0.79, p = 0.011).

Conclusions: In patients with AMI complicated by CS, the institution of hemodynamic support with Impella 2.5 prior to PCI is associated with a more complete revascularization and improved survival.

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Patients with 3-vessel Coronary Artery Disease and Impaired LVEF undergoing PCI with Impella 2.5 Hemodynamic Support Have Improved 90-Day Outcomes Compared to Intra-Aortic Balloon Pump: A Subanalysis of The PROTECT II Trial

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Background: PROTECT II demonstrated a trend of improved outcomes in patients with impaired LVEF and left main or 3-vessel disease (3VD) undergoing PCI with hemodynamic support using Impella 2.5 (IR2.5) or intra-aortic balloon pump (IABP). However, it is unclear if this trend was due to a specific benefit in a patient subpopulation, or if certain patients may derive particular benefit from PCI with IR2.5 support. We therefore evaluated the efficacy of the IR2.5 vs. IABP in the PROTECT II study exclusively in patients with 3-vessel coronary disease.

Methods: For this pre-specified analysis, patients in PROTECT II were stratified upon enrollment into the left main or 3VD subgroups and then randomized to IR2.5 or IABP. Patients enrolled in the 3VD substrata were required to have LVEF ≤ 30%. We evaluated the 30- and 90-day outcomes among the 3VD group (n = 325, IR2.5 167, IABP 158).

Results: The groups were well matched, except for prior CABG and symptomatic heart failure, which were more common in the IR2.5 group (both p < 0.01). Patients were at high risk for adverse outcomes, with mean risk scores for IR2.5 vs. IABP, including Adding EuroScore 8.4 ± 3.6 vs. 8.3 ± 3.6 (p = 0.73), STS mortality and mortality 27.1 ± 4.4 vs. 29.5 ± 15.6 (p = 0.15), respectively. The mean number of lesions treated was 3.0 ± 1.5 vs. 2.9 ± 1.4 (p = 0.61). While on a per-pt basis rotational atherectomy use was similar between groups (12.6% vs. 9.5%, p = 0.38), the number of passes per pt and per lesion was higher in the IR2.5 group (both p < 0.005). At 30 days after PCI with IR2.5 or IABP, patients who received IR2.5 support trended toward reduction in the primary outcome of incidence of major adverse events (MAE): 32.9% vs. 42.4% (p = 0.078). At 90 days after PCI there was a significant difference favoring IR2.5 for incidence of MAE was 39.5% vs. 51.0% (p = 0.039).

Conclusions: Patients with 3VD and reduced LVEF show improved outcomes at 90 days when PCI was performed using the IR2.5 hemodynamic support device.