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Left Ventricular Assist Improves 90 Day Outcomes With Unprotected Left Main Coronary Intervention: Analysis From The Protect II Trial

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Background: Patients with severe left ventricular (LV) dysfunction undergoing intervention (PCI) on the unprotected left main coronary (ULM) or the last remaining unprotected (LRC) are susceptible to peri-procedural heart failure or hypotension which may limit the effectiveness of revascularization efforts.

Methods: The Protect II trial compared an LV assist device (Impella 2.5) to intra-aortic balloon counterpulsation (IABP) in patients undergoing high risk coronary intervention. We report the results of outcomes from the subset of study subjects treated with ULM or LRC intervention.

Results: A total of 448 patients were treated in the Protect II trial and of these 102 underwent ULM (34 Impella, 35 IABP) or another LRC (15 impella, 18 IABP) PCI per protocol definition. Of the ULM/LRC cohort (N=102), 50% had class 3 or 4 heart failure, and the mean LVEF was 26%. Procedural differences between the two groups included a trend for more use of rotational atherectomy (RA), (22.4% vs 9.4%, p=0.071) with Impella; when RA was used, patients on Impella were treated with longer atherectomy runs (94.1 vs 36.5 sec, p=0.026). Duration of device support was much shorter (1.6 vs 10.8 hours, p=0.013) with Impella compared to IABP. Comparing 90 day composite major adverse cardiac and cerebrovascular events (MACCE) of death, large myocardial infarction (MI) with CK-MB > 8x normal, stroke, target vessel revascularization procedures, Impella use was associated with less MACCE compared to IABP use (16.7% vs 34.0%; p=0.047). The difference in MACCE was mainly driven by fewer strokes (0% vs 5.7%) and repeat procedures (0% vs 11.3%) with Impella.

Conclusions: In this subgroup analysis of a randomized trial, in patients with severe LV dysfunction undergoing PCI to the ULM or LRC, the use of Impella LV support during intervention was associated with a lower risk of major adverse events at 90 days compared to the use of a IABP.

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Side branch patency after implantation of the novel DESolve bioresorbable vascular scaffold system in the treatment of de novo coronary lesions

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Background: The DESolve® novolimus-eluting bioresorbable vascular scaffold system (Elixir Medical Co., Sunnyvale, CA) is a novel bioresorbable vascular scaffold device that combines a PLLA-based scaffold ( strut thickness 150 µm) coated with a potent antiproliferative sirolimus metabolite – Novolimus (5 µm per mm of scaffold length). Our aim was to investigate the occurrence of side branch (SB) compromise after implantation of the DESolve device in single de novo obstructive lesions.

Methods: Subjects: 126 patients/lesions were prospectively enrolled in the multicenter (13 sites), non-randomized, single-arm DESolve Nt trial. Lesion criteria were < 14 mm in length located in a native coronary vessel measuring 2.75-3.5 mm in diameter. SB compromise, defined as vessel occlusion (TIMI flow 0) at 1 month post procedure, was evaluated within the treated segment covered by the device at an independent angiographic core laboratory. All SBs >1.0 mm in diameter (by visual estimation) were considered for analysis.

Results: Overall, there were 71 SBs >1.0 mm found in 123 coronary segments treated by 126 scaffolds (3 lesions did not receive the study device; 3 lesions received 2 study devices). The majority of SBs (96%) had pre-procedure TIMI 3 flow. During the procedure, neither guide wire protection nor intervention was performed in any SB. At post-procedure, SB occlusion was detected in only 3 cases, representing a 4.2% SB compromise rate. Importantly, there were no adverse clinical events during hospitalization associated with SB occlusion.

Conclusions: In the prospective, non-randomized, single-arm, multicenter DESolve Nt trial, SB compromise – as determined by vessel occlusion after implantation of the novel DESolve bioresorbable vascular scaffold, was relatively low (4.2%) and was not associated with adverse clinical events during index hospitalization.

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First- versus Second-generation Drug-Eluting Stents for the Treatment of Coronary Bifurcations

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Background: Randomized controlled trials have demonstrated that second-generation drug-eluting stents (DES) for the treatment of obstructive coronary artery disease is associated with comparable, if not improved, clinical outcomes as compared to their first-generation counterparts. The aim of this study was to compare the long-term clinical outcomes associated with first- versus second-generation DES for the treatment of coronary bifurcation lesions.

Methods: This was a retrospective study of consecutive de novo bifurcation lesions, excluding those at the left main, treated with either second-generation DES (everolimus-eluting or zotarolimus-eluting stents) between October 2006-October 2011 (199 bifurcation lesions in 192 patients) or first-generation DES (sirolimus-eluting or paclitaxel-eluting stents) between April 2002-December 2005 (289 bifurcation lesions in 273 patients).

Results: Second-generation DES use in this setting was associated with less major adverse cardiac events (MACE) (23.1% vs 14.4%, p=0.02) as well as lower target vessel revascularization (TVR) (5.5% vs 8.3%, p=0.01) at 2-year follow-up. Target lesion revascularization, both per patient (12.6% vs 7.4%, p=0.02) and per bifurcation (11.8% vs 7.0%, p=0.03), was also improved with second-generation DES over the same follow-up period. Propensity-score adjusted analysis suggested that first-generation DES was an independent predictor of both MACE (HR 0.53; 95% CI 0.33; 0.85; p=0.01) and TVR (HR 0.44; 95% CI 0.24; 0.83; p=0.01).

Conclusions: Our results suggest that the use of second-generation DES for the treatment of bifurcation lesions is associated with better clinical outcomes as compared to first-generation DES, largely due to a lower need for repeat revascularization.