Conclusions: The presence of Medina classes 0,1,1 and 1,1,1, and the presence of significant RCA disease, but not stenting technique, are independent predictors of increased rates of CAE following LMCA PCI.

TCT-414

Dedicated 2-stent versus 1-Stent Strategy in Diabetic Patients with Complex ‘True’ Bifurcation Lesion PCI using Everolimus-Eluting Stent

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Results: The baseline characteristics were well matched between two PCI strategies. In-hospital major adverse cardiac event (MACE) and postprocedure MI (CK-MB >3x Normal, 8.3% vs. 10.34%, P=0.65). At 1-year follow-up, MACE tended to be lower for the 2S compared to the provisional 1S approach with the time to event analysis depicted in Figure 1 (P=0.08).

Conclusions: The conservative provisional 1S technique tended to have greater MACE events compared to the dedicated 2S technique in diabetic patients after treatment of complex true bifurcation lesions using newer generation DES.

TCT-415

Optimized Final Kissing Balloon Post-dilatation For Provisional Bifurcation Stenting

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Background: Main vessel stenting with final kissing balloon dilatation (FKBD) is widely employed, but many technical variations are possible that may affect the final result. In this study, two different FKBD strategies were investigated.

Methods: Finite element simulations were used to virtually deploy and post-dilate three stent platforms within three bifurcation models, mimicking a range of coronary bifurcation anatomies. Stents were sized according to the distal branch diameter and deployed to a diameter of 3.2mm following the compliance charts. During a second step, a shorter (but larger) balloon was used to post-dilate the proximal stent segment. Two FKBD strategies were evaluated: “simultaneous FKBD” (n=27) and “modified FKBD” (n=27). In the simultaneous FKBD, both the side and main branch balloon were simultaneously inflated and deflated with a maximal balloon pressure of 12atm. In the modified FKBD, the side branch balloon was inflated to a pressure of 12atm, and then deflated to 4atm. Subsequently, the main branch balloon was inflated to a pressure of 12atm. Eventually, both balloons were fully deflated. The following quantitative measures were used to compare both FKBD strategies: percentage of side branch obstruction, ellipticity index (the ratio of the maximal to the minimal diameter in the proximal stent segment) and percentage of malapposed struts (defined as strut-artery distance of more than 100 micron). The accuracy of the computer simulation results was evaluated by comparing the virtually predicted stent deformations with stent deformations observed during microCT visualised in-vitro bench testing.

Results: Modified FKBD results in a lower ostial stenosis as compared to simultaneous FKBD (15.5±9% vs. 20.1±11%, p<0.001) and also reduces the elliptical stent deformation (ellipticity index = 1.17±0.05 vs. 1.36±0.06, p<0.001). The amount of malapposed strut was not influenced by the FKBD technique (modified FKBD: 6.3±3.6%, simultaneous FKBD: 6.4±3.4%, p=0.212).

Conclusions: The modified FKBD procedure reduces the elliptical stent deformation and optimises the side branch access while avoiding stent distortion within the main vessel.

TCT-416

Impact of Diabetes Status on Long-Term (6 years) Outcomes after Percutaneous Coronary Intervention of Left Main Disease: Result from a Real World Experience of 1,528 Consecutive Patients

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Background: Scant data exist regarding the impact of diabetes mellitus (DM) status on percutaneous coronary intervention (PCI) for left main (LM) coronary artery disease. We sought to compare the impact of the presence of DM at baseline among pts undergoing LM PCI on long-term ischemic outcomes.

Methods: Data from all consecutive patients from a single center were prospectively collected. Pts were stratified according to the presence or absence of DM at baseline. Coronary angiograms were analyzed by an independent angiographic core laboratory and all events adjudicated by an independent clinical events committee. Adverse ischemic outcomes were compared between the 2 groups up to 6-year follow-up.

Results: Between Jan 2004 and Dec 2010, 1,528 consecutive pts underwent LM PCI. DM was present in 369 (24.1%) pts. Pts with DM were more likely to have increased weight, prior MI, hypertension, dyslipidemia and prior stroke. Angiographically, DM pts presented more frequently with 3-vessel-disease, 1,1,1 Medina bifurcation and higher baseline SYNTAX score. Despite having more lesions treated and more stents implanted, DM pts had higher residual SYNTAX score after revascularization. One-year dual antiplatelet therapy compliance rates were high among the complete cohort (95.3%) and similar between both groups. At 6-year follow-up, no differences were seen in rates of all-cause death (0.0% vs. 4.7%, p=0.36) and definite/probable stent thrombosis (ST; 1.6% vs. 1.7%, p=0.90) between groups. However, DM pts had a higher rate of target lesion revascularization (TLR; 8.4% vs. 4.4%, p=0.005), target vessel revascularization (TVR; 13.6% vs. 8.1%, p<0.003), and stroke (4.9% vs. 1.3%; p=0.002). By multivariate analysis,
DM was identified as a strong independent predictor of stroke (HR = 3.09; 95% CI 1.50-6.29; p = 0.001) and TLR (HR = 2.10; 95% CI 1.30-3.38; p = 0.002) and TVR (HR = 1.66; 95% CI 1.15-2.39, p = 0.006).

Conclusions: Among this large series of consecutives pts undergoing LM PCI, DM was not associated with an increase in death or ST, but was independently predictive of stroke, TLR and TVR at 6-year follow-up.

TCT-417
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 conduit (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 90 day 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) and another LRC (15 impella, 18 IABP) PCI procedures were performed. 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 > 8 normal, stroke or TVR a trend for less MACCE for Impella 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 assist during intervention was associated with a lower risk of major adverse events at 90 days compared to the use of a IABP.

TCT-418
Confirmation of the Prognostic Capability of the SYNTAX Score-II Among 1,528 Patients Who Underwent Left Main PCI

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Background: Recently, the SYNTAX score-2 (SxS-2) was developed in an attempt to improve the SYNTAX score (SxS). Its prognostic value was investigated in a prospective study. Our aim was to compare the SxS-II derived for PCI and CABG using patients' baseline clinical characteristics. Patients were divided and compared according to whether the SxS-II indicated PCI vs. CABG as the most favorable strategy of revascularization.

Methods: Data from all consecutive patients from a single center undergoing LM PCI were prospectively collected. Coronary angiograms and the resulting SYNTAX scores (SxS) were assessed by an independent angiographic core laboratory, and then the SxS-II was calculated for both PCI and CABG using patients' baseline clinical characteristics. Patients were divided and compared according to whether the SxS-II indicated PCI vs. CABG as the most favorable strategy of revascularization.

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 assist during intervention was associated with a lower risk of major adverse events at 90 days compared to the use of a IABP.

TCT-417
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 coronary bifurcations.

Methods: Methods: 126 patients/lesions were prospectively enrolled in the multicenter (13 sites), non-randomized, single-arm DESolve Ns 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 1st procedure), was evaluated within the treated segment covered by the study device at an independent angiographic core laboratory. All SBs >1.0 mm in diameter (by visual estimation) were considered for analysis.

Results: 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: Conclusions: In the prospective, non-randomized, single-arm, multicenter DESolve Ns 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.

TCT-420
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: 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) (15.5% 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: 0.24-0.85; 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.