TCT-68
The use of Percutaneous Left Ventricular Assist Device vs Intra-aortic Balloon Pump for Hemodynamic Support During High Risk PCI
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Background: Protex II study evaluated the effect of circulatory support with Impella vs Intra aortic balloon pump (IABP) in high risk patients undergoing high risk PCI with depressed LV function and complex anatomy. The results of the study were confounded by an imbalanced and more vigorous use of rotational atherectomy (RA) in the Impella arm which made the interpretation of the composite endpoint difficult. We sought to evaluate the safety and effectiveness of Impella 2.5 in high risk percutaneous coronary intervention (HRPCI) compared to the IABP in a more homogeneous population, without the confounding effect of RA.

Methods: A total of 375 eligible patients underwent HRPCI without the use of rotational atherectomy (88% Protex II study). A composite of 10 major adverse events (MAE) endpoint including death, myocardial infarction, stroke, any repeat revascularization, was assessed at 30 and 90 days.

Results: Baseline and procedural characteristics were balanced between the study arms: age 67 ± 10 years old, 86% CHF, 51% diabetes, 67% had prior myocardial infarction, and 26% renal insufficiency. The LVEF was 24 ± 5.6% and Syntax was 29 ± 12. Patients treated with the Impella device had significant improved outcomes at 30 day and 90 day compared to IABP arms (29.3% vs 41.9%, p = 0.011 and 35.5% vs 50.5%, p = 0.0003).

Conclusions: Patients undergoing high risk PCI supported with Impella had superior outcomes compared to those with IABP.

TCT-69
PEPCAD-DES: A randomized, multicenter, single blinded trial comparing paclitaxel coated balloon angioplasty with plain balloon angioplasty in drug-eluting-stent restenosis – 12 months results
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Background: We evaluated the impact of paclitaxel-coated balloon angioplasty for treatment of drug-eluting stent restenosis compared with uncoated balloon angioplasty alone. (NCT0098439)

Methods: In this prospective, single-blind, multicenter, trial we randomly assigned 110 patients with Instant-Restnosis of drug eluting stents to undergo treatment either with paclitaxel coated balloon (SoQuent Please, BBraun, Melsungen) or balloon angioplasty alone. Primary endpoint was in-stent late lumen loss at 6 months. Secondary clinical endpoint was composite of cardiac death, myocardial infarction attributed to the target vessel or TLR.

Results: There was no difference in patient baseline characteristics. Lesion length was 11.2 ± 6.5mm in the DCB- and 12.2 ± 8.2mm in the POBA-group (p = ns). Post PCI, for the stented segment and the total segment minimal lumen diameter and diameter stenosis were not different. Clinical follow-up after 12 months was 100%. Treatment with DCB was superior to balloon angioplasty alone with an in-stent late loss of 0.43±0.61mm vs. 1.03±0.77mm (p<0.001). Minimal lumen diameter was significantly larger and percent diameter stenosis significantly lower with use of the DCB for both the stented and total segment. Restenosis rate was reduced from 58.1% to 17.2% (P<0.001) and the clinical endpoint at 6 months was reduced from 50% to 16.7% (P<0.001), respectively. After 12 months the effect of DCB persisted (clinical endpoint 52.6% vs. 16.7%; p<0.01) and TLR 36.8% vs. 15.3%, p=0.005, respectively. There was one probable stent thrombosis in the POBA group. Clinical follow-up after 2 years will be completed in May 2013 and presented.

Conclusions: Paclitaxel coated balloon angioplasty was superior to balloon angioplasty alone for the treatment of instant-restenosis of drug-eluting stents. The favorable effects of the DCB-therapy persisted over 12 months.

TCT-70
Comparison of Efficacy and Safety between Sirolimus, Paclitaxel, Everolimus-Eluting Stent and SeQuentTM Please, a Drug-Eluting Balloon on the Outcome of Patients with Diffuse In-stent Restenosis after Bare Metal Stent Implantation
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Background: The aim of this study is to compare the safety and efficacy of Sirolimus (SES), Paclitaxel (PES), Everolimus-eluting stent (EES) and SeQuent™ Please, a drug-eluting balloon (DEB) on the outcome of patients with diffuse in-stent restenosis (D-ISR) after bare metal stent (BMS) implantation.

Methods: A prospective analysis of 1078 patients with 1251 D-ISR lesions (427 SES, 363 PES, 232 EES and 229 DEB) in six high volume Asian centers after successful stent implantation (SES: LAD 48.7%, LCX 27.9%, RCA 24.6%; PES: LAD 22.9%, RCA 31.1%; EES: LAD 50.0%, LCX 21.0%, RCA 29.0%; DEB: LAD 54.0%, LCX 23.0%, RCA 23.0%) was performed. The study endpoints were major adverse cardiac events (MACE) and target lesion revascularization (TLR) at 12 and 24 months.

Results: See table for clinical results.

Conclusions: (1) The use of SES, PES, EES and DEB in patients with D-ISR seems to be favorable in terms of in-hospital clinical outcome. (2) Patients treated with DEB showed higher restenosis rate and TLR compared with DES.

TCT-71
Intravascular ultrasound-guided systematic two-stent techniques for coronary bifurcation lesions reduced late stent thrombosis and ST-elevation myocardial infarction
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Background: Effect of intravascular ultrasound (IVUS)-guided complex approaches using drug-eluting stent (DES) for coronary bifurcation lesions on clinical outcome has been yet not studied.

Methods: From May 26, 2007 to March 24, 2010, 628 patients received two-stent techniques (324 in IVUS-guided, 304 in Anglo-guided group) were prospectively studied. We compared the major adverse cardiac event (MACE, including cardiac death, stent thrombosis [ST], myocardial infarction [MI], target lesion/vessel revascularization) at 12-month follow-up, and after adjusting by using propensity score matching.

Results: Between 12-month after a stent procedure, patients in the Anglo-guided group had a significantly increased in-stent restenosis. The unadjusted late ST rate was 6.9%, 5.3% and 4.3% in the Anglo-guided group was 4.3%, significantly different to 0.6% in the IVUS-guided group (p = 0.003; 1.2% 0.6% and this translated into the significant differences in overall (6.9% vs. 1.2%, p < 0.001) and definite (5.3% vs. 0.6%, p < 0.001) ST, MI (8.9% vs. 4.6%, p = 0.038) and cardiac death (3.3% vs. 0.9%, p = 0.049) between two groups. By propensity score matching, 123 paired patients were matched, the late ST at 12-month follow-up was 4.9% in Anglo-guided group, and it was 0% in the