

criteria included acute or recent myocardial infarction (MI), left ventricular ejection fraction <30%, left main or ostial location, major bifurcation disease, chronic total occlusion, and target vessel thrombus. Routine angiographic follow-up was not performed. Planned clinical follow-up is at 1, 6, 12, and 18 months, and annually to 5 years. Results: Patients were predominantly male (62.7%), and 30.0% presented with medically treated diabetes. At baseline, target lesion length was 24.38 ± 8.21 mm and reference vessel diameter was 2.56±0.40mm. The study met its primary endpoint of 12-month target lesion failure (composite of target vessel related cardiac death/MI and ischemia-driven target lesion revascularization) with a rate of 3.2%, which was not significantly different (p<0.001) than a prespecified performance goal of 19.4% (based on historical outcomes with 32mm paclitaxel-eluting stents, the only long drug-eluting stent approved in the US when PLATINUM LL was initiated). At 1-year follow-up, there were 3 instances of target lesion revascularization (3.1%), 1 non-cardiac death, and no cardiac deaths, MIs, or stent thromboses. Two-year clinical follow-up will be reported.

Conclusions: The 1-year results of the PLATINUM LL study support the use of the PROMUS Element 32mm and 38mm stents in the treatment of long coronary lesions. Two-year results will be available for presentation for the first time at TCT in October 2012.

TCT-613

A Prospective Randomized Multi-Center Trial to Assess the Everolimus-Eluting Stent System (Promus Element) for Coronary Revascularization in a **Population of Unrestricted Patients**

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Background: A drug-eluting stent consists of 3 components of equal importance: a metallic platform, a polymer and a drug, all influencing acute and long term results both in safety and efficacy. The Platinum plus trial was designed to compare the Promus element stent to the Xience Prime. These stents have the same polymer poly (n butyl methacrylate) (PBMA) and poly (vinylidene fluoride co hexafluoropropylene) (PVDF-HFP)] and drug (Everolimus) but different platforms (platinum-chromium for the Promus element, cobalt chromium for the Xience prime) and distinct stent designs.

Methods: Methods. The trial was designed as a non-inferiority single blind randomized 2:1 trial (Promus G1/XienceG2 that recruited 2985 consecutive, all-comer patients in 48 European centers. The primary endpoint was TVF at 1 year.

Results: Results. Population consisted of 79% of males, mean age: 65 yrs ± 9 yrs. Indications were 42 % stable angina 31.2% ACS and 10.2 % silent ischemia. Risk factors were well balanced between the 2 populations as follows: hypertension (65.8% vs. 68.1%, hypercholesterolemia (66.08% vs. 65.5%), diabetes I (3.5% vs. 4.07%), diabetes II (24.8 % vs. 22.4%), insulin-treated diabetes (7.4% vs. 6.8%), family history (32.4% vs. 23.3%), current smoker (20.4% vs. 19.9%). Procedural success was 98.4% in recipients of Promus stents and 97.8 % for Xience prime. Mean number of stents implanted per patient was 1.7 $\pm 0.8.$ In-hospital complications included death N=3 and N=1 (0.15 % and 0.10 %) for Promus and Xience, respectively, MI N=7 (0.36%) and N=2 (0.19%), emergency CABG N=1 and N=0 (0.05% and 0 %), repeat PCI (N=4, N=1). The observed differences were statistically not significant.

Conclusions: Conclusion: No differences in acute results were observed between the 2 stents; the 30-day outcome will be available for the meeting.

TCT-614

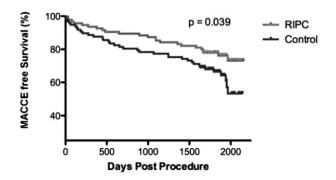
Remote ischemic preconditioning improves outcome out to 6-years following elective percutaneous coronary intervention: the CRISP-Stent trial.

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Background: Remote ischemic preconditioning (rIPC) attenuates MI4a in humans undergoing elective percutaneous coronary intervention (PCI). However the long-term impact of rIPC on clinical outcomes after PCI is unknown. We hypothesized that rIPC attenuation of MI4a would improve clinical outcome at 6-years.

Methods: We randomized 215 patients with normal cardiac troponin-I (cTnI < 0.04ng/mL), undergoing elective PCI to either rIPC (n = 110): three 5-minute blood pressure cuff inflations to 200mmHg around the upper arm with 5-minutes of cuff deflation between, or control (n = 105): a deflated cuff throughout, before PCI. Patients taking nicorandil or glibenclamide were excluded and randomization was stratified for diabetes mellitus (DM). Post-PCI serum cardiac troponin-I (cTnI) levels were recorded at

24-hours and major adverse cardiac and cerebral event (MACCE) rate determined at 6-years (90% follow-up, mean time to event or last follow-up: 1579.7 +/- 603.6 days). Results: The two groups were matched demographically. Median 24-hour cTnI was significantly lower in the rIPC group (0.06 vs. 0.16ng/mL, p=0.04). Mean cTnI was higher in those with MACCE (0.91 vs. 2.07ng/mL, p=0.05). MACCE rate at 6-years was significantly lower in the rIPC group (23 vs. 36, p=0.039, Figure). The non-DM subgroup (n=166) MACCE rate at 6-years was significantly lower following rIPC (17 vs. 29, p=0.045) but those with DM (n=49) did not derive benefit from rIPC (6 vs. 7, p=0.541).



Conclusions: Fewer patients receiving rIPC have post-PCI cTnI release and rIPC has a superior MACCE-free survival compared to control out to 6-years.

TCT-615

Coating Damage of Drug-Eluting Stent Occurs in Front Edge Strut: a Scanning Electron Microscopy Study

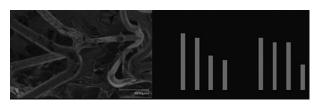
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Background: Although the use of drug-eluting stents (DES) appears to markedly reduce restenosis in patients undergoing percutaneous coronary interventions (PCI), there are ongoing discussions with regards to late and very late stent thrombosis (LST and VLST). Some reports have indicated that coarse irregularities of DES coating could play a role in promoting stent thrombosis. The aim of this study was to investigate whether and where damage to surface of DES occurs when the DES was delivered through a newly deployed

Methods: Fifteen coronary artery phantom models were constructed with a tube of approximately 3 mm inner diameter. Fifteen Paclitaxel-eluting stents (PES) were implanted in each curved tube (r=20 mm). Then, the other 15 PES were delivered to pass through the implanted stents with guide wire, and moved back and forth completely through them three times. The entire accessible surface area of these unexpanded and expanded stents was examined with a scanning electron microscope. Each PES was divided into 4 equivalent parts for qualitative assessment with/without damage of polymer. We named the most distal part as part 1 (P1) and the most proximal part as part 4 (P4), respectively.

Results: Damage was observed more frequently in distal part than in proximal part of both expanded and unexpanded stents (as shown in figures).



Conclusions: Placement of DES through an expanded stent could cause damage to polymer of DES. In such cases, the distal site of DES might be easy to fail to prevent restenosis and easy to occur LST and VLST.