performed to either DCB application or no further treatment. Provisional stenting was discouraged, but allowed in both groups. Follow-up angiograms were done after 9 months. For quantitative coronary angiographic analysis CAAS II was used. Primary efficacy endpoint was late lumen loss (LLL).

Results: 64 patients were randomized to DCB or POBA treatment. Minimal lumen diameter (0.58 ± 0.22 mm) and grade of stenosis (76.3 ± 8.7 %) were equal in both groups. Baseline ulcer as a bail out lesion that show only chronic A or B dissection according to the NHLBI classification and recor not beyond 30 % the use of DCBs is a sound strategy.

TCT-286
Treatment Of Coronary In-Stent Restenosis With Paclitaxel-Coated Balloon Catheter: 36- Month Clinical Results
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Background: Paclitaxel-coated balloons (PCB) have been proven to be effective for the treatment of coronary in-stent restenosis (ISR) after bare-metal stent (BMS) or drug-eluting stent (DES) implantation. This study aims to evaluate the long-term safety and efficacy of the second-generation SeQuent Please PCB in coronary ISR in routine real-world practice.

Methods: Between March 2009 and February 2011, all consecutive patients with ISR lesions treated with the SeQuent Please PCB at our institution were prospectively included. Patients were followed up for 36 months by clinical observation. The primary endpoint was the clinically driven target lesion revascularization (TLR) rate at 36 months. The secondary endpoint was the rate of major adverse cardiac events (MACE) defined as a composite of cardiac death, myocardial infarction, and TLR at 36 months.

Results: 63 patients with 73 ISR lesions (39 BMS, 34 DES) were included. Mean age was 67.4±11.7 years. 77.8 % were male and 55.6 % were diabetics. The majority of patients presented with current smoking (61.9 %). The target lesion was mainly located in the right coronary artery (42.5 %) and the left anterior descending coronary artery (38.4 %). The mean reference vessel diameter was 3.0±0.5 mm and the mean target lesion length was 19.7±6.6 mm. Procedural success was 100 %.

TCT-287
Safety Evaluation of Paclitaxel Coated Balloon Compared to a Slight Higher in DCB treatment groups display a similar larger lumen area (T1) followed by implantation of self-expanding stents in the injured segments. At day 14, the in-stent restenosis sites were treated with two clinically proven DCBs (In.Pact® and Lutonix, Medtronic). 3 ug/mm2 n=6, and (Lutonix® BARF. 2 ug/mm2 n=6), a novel DCB (Ranger™ Boston Scientific, 2 ug/mm2 n=6), and an uncoated balloon control (Sterling™ Boston Scientific, n=6). At day 0, 14 and 42 quantitative vascular analysis and histology at termination.

Results: The difference (Δ) in angiographic percentage diameter stenosis between day 14 and day 42 showed significant inhibition of neointimal proliferation with smaller deltas from baseline in the DCB groups when compared to control (Control: Δ60%, Ranger: Δ0%, In.Pact®: Δ5%, Lutonix®: Δ10%). The histological data also showed less neointima and percentage area of stenosis in all DCB groups. Fibrin, a characteristic hallmark of paclitaxel in arterial tissue, was equivalent in all DCBs and twice as high as in control. Ranger DCB showed a slightly higher endothelialization score than In.Pact (Control: 3.0, Ranger: 2.57, In.Pact: 1.85±0.55, Lutonix: 2.52±0.35, p=0.005). In.Pact and In.Pact had the lowest score of neointima maturity (Control: 2.9±0.11, Ranger: 1.87±0.06, In.Pact: 1.0±0.74, Lutonix: 1.18±0.49, p<0.05). All DCBs showed significant inhibition of neointimal formation when compared to the uncotted balloon control. The In.Pact DB provided strongest neointimal inhibition but less complete healing. The Ranger DCB provided satisfactory neointimal inhibition and a slightly better healing when compared to In.Pact.

TCT-289
Detection of Paclitaxel Contamination Resulting from the Simulated Clinical Use of Drug Coated Balloon Catheters
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Background: Coating robustness and durability are important characteristics of the DCB design. Drug that is not firmly adhering on the balloon surface falls off and could potentially lead to paclitaxel contamination of work surfaces in the catheterization lab and expose lab personnel to a toxic chemotherapeutic agent.

Methods: This study sought to determine the coating durability of the Lutonix drug coated balloon compared to the Medtronic drug coated balloon and to evaluate the amount of paclitaxel that does not adhere to the balloon and is transferred to work surfaces during simulated clinical procedural handling. A swab method in the ChemolGLO™ Kit was used for quantifying trace amount of drug on surface. Both the Medtronic devices and the Lutonix devices were evaluated in a simulated clinical use study by three independent physicians at three hospitals. After each physician performed the simulated clinical use test, the surfaces where paclitaxel could have fallen were swabbed and analyzed by HPLC (LLQ is 0.01ng/cm2.) The person performing the swabbing was blinded to the testing devices.

Results: The paclitaxel analysis results from this study and statistical analysis are summarized on table 1.The ANOVA analysis indicates that paclitaxel surface concentrations of the Lutonix devices and the Medtronic devices are statistically different.