performed to either DCB application or no further treatment. Provisional stenting was descruited 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. There was no bail-out stent. Only angiographic follow-up was achieved in 75 % of the patients. The remaining 25 % had telephone follow-up. No patient was lost to follow-up, no patient died. There was 1 non ST-elevation myocardial infarction in the POBA group. Restenosis rate was 25 % in the POBA group vs. 6.6 % in the DCB group (p=0.003). The target lesion revascularization was necessary in 3 patients of the POBA vs. 1 patient of the DCB group. The primary endpoint LLL was 0.15 mm in the DCB vs. 0.48 mm in the POBA group (p=0.003).

Conclusions: Our results underscore the potential of DCBs as stand alone therapy for bifurcation lesions. Therefore, in bifurcation lesions that show only class A or B dissection according to the NHIHL 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
Javier Benezech1, Santiago Camacho-Freire1, Alejandro Gutierrez-Barrios1, Antonio Aguirre1, Jesús Oneto1
1Hospital Universitario de Jerez, Jerez de la Frontera, Cadiz

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) 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 unstable angina (61.9 %), 9.9 % of lesions 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 lumen length was 19.7±6.6 mm. Procedural success was 100 %. Coronary dissection occurred in 2 patients (3.2 %), requiring additional stent implantation. Follow-up rate was 92.1 %. The TLR rate was 4.8 % at 36 months. Cumulative MACE at 36 months was 11.1 %, with 4.8 % cardiac death and 3.2 % myocardial infarction. No vessel thrombosis was documented. The TLR rate did not differ for PCB angioplasty for BMS-ISR compared with DES-ISR (2.9 % vs. 7.1 %, p=0.58).

Baseline lesion characteristics and procedural data did not differ except for a longer lesion length for DES-ISR vs. BMS-ISR (T4: 3.37±0.3; T5: 4.±0; T6: 3.9±0.2). The neointima hyperplasia was assessed showing a similar low score in response to a PCI of 1±1.5; T4: 1±1.2; T5: 1±1.0; T6: 1±1.0. All treatment groups showed an extremely low thrombosis score (T1:0±1.0; T2:0.2; T3:0.2±0.1; T4:0.1±0.2; T5:0.1; T6:0.1). Conclusions: Lutonix PCB, in a “cross-over” or “same drug” treatment, seem to be a safe strategy for DES-ISR without significantly increasing inflammation or fibrin deposition in a large animal preclinical model.

TCT-288
First in Vivo Evaluation of Efficacy of a Novel Peripheral Drug-Coated Balloon in a Familial Hypercholesterolemic Swine Model of In-Stent Restenosis
Carlos A. Gongora1, Masahiko Shibuya1, Barbara A. Huibregtse2, Jenn McGregor3, Yaping Cheng4, Gerard B. Condit1, Geng-Hua Yi1, Greg L. Kaltu1, Juan Granada1
1Cardiovascular Research Foundation, Orangeburg, NY, 2Boston Scientific, Marlborough, MA

Background: Drug coated balloons (DCBs) employ different coating technologies to deliver the antirestenotic drug without permanent polymer carrier. The ideal formulation should maximize the neointimal inhibition with the least drug possible, while ensuring adequate healing and containing the particulate release from the coating. We evaluated the efficacy of a novel drug coated balloon technology with two clinically proven DCBs and an uncoted balloon control group in a familial hypercholesterolemic swine (FHS) model.

Methods: Twenty four peripheral arteries of 6 FHS were injured at day 0 with an uncotted balloon, 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: 3 ug/mm2 n=6, and Lutonix BAR, 2 ug/mm2 n=6), a novel DCB (Ranger™ Boston Scientific, 2 ug/mm2 n=6), and an uncotted balloon control (Sterling™, Boston Scientific, n=6). At day 0, 14 and 42 quantitative vascular analysis and histology at termination. Results: The difference (∆) 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: Δ20%, In.Pact: Δ55%, 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±0.34, In.Pact: 1.85±0.55, Lutonix: 2.52±0.35, Lutonix: 2.41±0.69) and In.Pact had the lowest score of neointima maturity (Control: 2.9±0.11; Ranger: 1.87±0.66, In.Pact: 1.88±0.74, Lutonix: 1.88±0.49). p = (0.05).

Conclusions: All DCBs showed significant inhibition of neointimal formation when compared to the uncotted balloon control. The In.Pact DCB provided strongest neointimal inhibition but less complete healing. The Ranger DCB provided satisfac-tory 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
Charisse Ward1, Carlos I. Mena1
1Yale University, New Haven, CT

Background: Coating robustness and durability are important characteristics of the DCB design. Drug that is not firmly adhering on the balloon surface could be released in a fashion that may contaminate the device. 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 CheetahLLOM 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 on which the paclitaxel could have been 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.

<table>
<thead>
<tr>
<th>Devices</th>
<th>Sample Size</th>
<th>Average Paclitaxel Concentration (ng/cm²)</th>
<th>Standard Deviation</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lutonix</td>
<td>21</td>
<td>0.34</td>
<td>0.27</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Medtronic</td>
<td>18</td>
<td>20.39</td>
<td>17.15</td>
<td></td>
</tr>
</tbody>
</table>

Conclusions: This study revealed 15 out of 18 Medtronic devices were over the decontamination level, none of the 21 Lutonix devices was over the decontamination level. This study emphasized the importance of drug contamination in handling the Medtronic drug coated balloon catheters. Drug decontamination is recommended after each use of the Medtronic DCB catheters to ensure the drug surface concentration is below 1ng/cm2.