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.ug/mm2 n

**Background:** In-stent restenosis (ISR) is a more complex issue compared to DES in-stent restenosis (ISR). Paclitaxel coated balloons (PCB) are available as an option for DES-ISR. The efficacy of paclitaxel coated balloons (PCB) in an animal coronary ISR model.

**Methods:** Between May 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: death, MI, TLR).

**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 %). The 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 ± 0.22 mm and grade of stenosis (76.3 ± 8.7 %) were equal in both groups.ug/mm2 n

**Conclusion:** The safety Evaluation of Paclitaxel Coated Balloon as a “Same-Drug” and “Crossover-Drug” Treatment for Drug Eluting Coronary Stent In-Stent Restenosis in a Large Animal Model

**Background:** In-stent restenosis (ISR) is a more complex issue compared to BMS-ISR. Paclitaxel coated balloons (PCB) are available as an option for DES-ISR treatment. We aim to evaluate the vascular response to Lutonix PCB as treatment of a same drug DES-Coated balloon (PCB) and cross-over drug DES-ISR (Lutonix) in a large animal coronary ISR model.

**Methods:** 24 DES (8 EES: XIENCE PRO, 8 ZES: Resolute Integrity and 8 PES: Taxus Liberté) were implanted in naive porcine coronary arteries at a 1:1,1,1 frequency.

**Results:** DCB treatment groups display a similar larger lumina area (T4: 5.83 ± 3.23 mm2, T2: 6.32 ± 2.66 mm2, T3: 6.11 ± 1.3 mm2) compared to POBA treatment (T4: 5.43 ± 3.3 mm2, T2: 5.5 ± 2.3 mm2, T3: 5.72 ± 1.8 mm2). Neointimal area was significantly reduced in the DCB treatment group (T1: 2.90 ± 0.88, T2: 2.6 ± 1.3, T3: 3.22 ± 2.2) compared to POBA treatment groups (T4: 3.9 ± 2.1, T2: 4.11 ± 2, T6: 3.9 ± 3.5). In histology, similar degree of inflammation was observed among PCB treatment groups (T1: 19.9 ± 1.5, T2: 13.1 ± 1.1, T3: 19.1 ± 2.7) compared to a slight higher inflammatory scores in the POBA treatment groups (T4: 21.2 ± 3.1, T5: 21.3 ± 2.1, T6: 21.2 ± 2.1). Fibrin deposition was low in all groups (T1: 0.9 ± 0.4, T2: 0.6 ± 0.3, T4: 0.7 ± 0.09, T5: 0.41 ± 0.5), however when previous used in the fibron score was slightly higher (T3: 1.3 ± 0.9, T6: 1.6 ± 0.5).

**Conclusion:** The detection of Paclitaxel Contamination Resulting from the Simulated Clinical Use of Drug Coated Balloon Catheters

**Background:** Coating robustness and durability are important characteristics of the DCB device. Drug that is not firmly adhering on the balloon surface falls off and 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 Chemical Laboratory 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 for paclitaxel by HPLC (LLQ is 0.01ng/cm2.) The person formed the simulated clinical use test, the surfaces where paclitaxel could have fallen were swabbed and analyzed for paclitaxel 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 concentration is below 1 ng/cm2.