**TCT-807****Optical coherence tomography, physiologic vascular function, safety and efficacy preclinical studies of porcine peripheral vessels dilated with drug-coated balloon**

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**Background:** This study conducted imaging, pharmacokinetic, safety and efficacy studies to characterize the paclitaxel (PTX) coating of the Freeway™ (Eurocor, Germany) peripheral vessel drug-coated balloon (DCB).

**Methods:** Fifty-seven domestic swine underwent Freeway™ overstretch balloon dilation for 1 and 2 minutes of both femoral and iliac (4-5 and 6-8 mm diameter, respectively) arteries, controlled by angiography and optical coherence tomography (OCT). Tissue PTX concentrations and the vascular function were measured at 1h, 1, 3 and 9 days. Neointimal growth was quantified by OCT and computerized planimetry by a blinded observer 5 weeks post-DCB use in a randomized (DCB vs. non-coated control balloon) pre-clinical study.

**Results:** The peripheral artery tissue PTX levels were 141.9±37.9 vs. 566.3±179.9, 43.2±13.6 vs. 149.4±71.8, 23.4±8.4 vs. 30.0±16.6 and 3.2±2.4 vs. 4.0±1.1 ng/mg using 1 vs. 2 min balloon inflation time at 1h, 1, 3 and 9 days post-DCB use, respectively. OCT revealed severe vessel injury after gross overdilation of peripheral vessels including dissection and thrombus formation without acute vessel closure. Five-week histopathology showed similar fibrin and inflammation score in DCB/plain balloon groups. Similar to the findings of histomorphometry, quantitative OCT resulted in significantly ( $p < 0.05$ ) lower %diameter and (%area) stenosis in Freeway as compared to plain balloon group (16.3±4.8 vs 22.5±6.4% in femoral and 19.7±4.0 vs 28.3±6.5% in iliac arteries). OCT proved to be more sensitive as compared to angiography in assessment of vascular stenosis and showed shrinkage (constrictive remodeling) of the vessels at the most severe stenosis site. DCB led to increased vasoconstrictor tone and impairment of endothelium-dependent vasodilation in a tissue PTX dose-dependent manner.

**Conclusions:** In a pre-clinical porcine model, PTX tissue concentration from the Freeway™ DCB is related to time of balloon inflation. DCB reduced the neointimal hyperplasia in peripheral arteries compared to uncoated balloons. Vascular function impairment was directly associated to higher tissue PTX concentration, which might limit the technical effort to deliver higher amount of drug into the arteries.

**TCT-808****Index of Microcirculation Resistance for Invasive Assessment of Coronary Microcirculation in a Porcine Model – Papaverine dose and Evolution in Time of Hyperemic Response**

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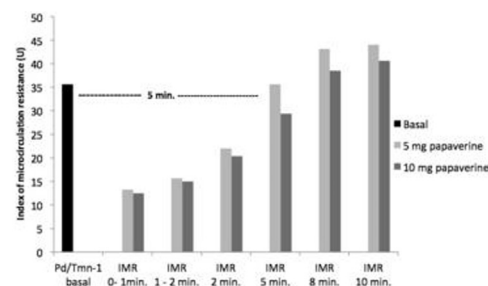
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**Background:** The index of microcirculation resistance (IMR) allows the invasive evaluation of the coronary microcirculation status given way to new research possibilities. Our purpose is to compare two doses of intracoronary papaverine, 5 and 10 mg, for the induction of maximal hyperemia and IMR evaluation and to assess their evolution in time.

**Methods:** Measurements of IMR were performed in 8 pigs. A pressure wire, 0.014 PressureWire™ Certus (St. Jude Medical), was positioned in left anterior descending artery. IMR was measured in resting and in maximal hyperemia induced with intracoronary papaverine, 5 and 10 mg, and after 2, 5, 8 and 10 minutes. For IMR assessment with microcirculation disruption we selectively injected 40 µm Embosphere® Microspheres (CeloNova BioSciences).

**Results:** A total of 112 IMR measurements were done. The coefficient of variation within the 3 transit time measurements in hyperaemia was 10 %. There were no

differences between the two doses of papaverine regarding Pd response and IMR values,  $11 \pm 4$ , 5 U with 5 mg de papaverine and  $10, 6 \pm 3$  U with 10 mg ( $p=0.612$ ). Evolution in time of IMR was also similar with the two doses and differences with resting values disappeared after 5 minutes (Figure). With microcirculation compromised IMR increased to a mean value of  $41 \pm 16$  U ( $p=0.001$ ).



**Conclusions:** IMR provides invasive and real time assessment of coronary microcirculation. A 5 mg dose of intracoronary papaverine is as effective as a 10 mg dose in inducing maximal hyperemia. After 5 minutes of papaverine administration there is no significant differences to resting conditions.

**TCT-809****Comparison of Symplicity Flex™, Multi-Electrode Prototype and the Symplicity Spyr™ Renal Denervation Catheters in a Porcine Model**

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**Background:** Renal denervation (RDN) by radio frequency (RF) energy using the Symplicity Flex catheter (Medtronic, Inc. Santa Rosa, CA) significantly reduces blood pressure in patients with resistant hypertension. Continued development of catheter design resulted in a multi-electrode prototype and culminated in the Symplicity Spyr catheter design, with an aim to maintain equivalent ablation performance. This study compares the function of the Symplicity Flex, the Multi-Electrode prototype (ME) and the Symplicity Spyr Denervation Catheters deployed in porcine model with regard to RF-induced changes in tissue and degree of renal nerve ablation in porcine renal arteries.

**Methods:** The vascular and nerve responses following RDN by RF energy was evaluated quantitatively in normal swine at 28 days post-treatment by histology and by renal norepinephrine quantification. Naïve animals were used as control.

**Results:** Histologically, all treated renal arteries showed RF-induced lesions. Symplicity Flex showed an average circumferential extension of the RF lesion in the arterial media of 23% and 2220 microns in depth. Corresponding values for ME and Symplicity Spyr arms were 22% and 25% extension and depth of RF changes as 2104 and 2357 microns respectively; there were no statistically significant differences between the three treatment arms. Endothelialization was >95% for all sections in all arms. All three arms showed consistent average renal nerve ablation: nerve damage was present in 59% of the sections for each vessel in the Symplicity Flex group and in 63% and 65% of the sections of the ME and Symplicity Spyr arms respectively. All three treated arms showed a significant drop in tissue norepinephrine as compared to the control naïve animals. Immunohistochemistry showed that Symplicity Flex, ME and Symplicity Spyr treatment significantly decreased both functional renal artery sympathetic nerves and cortical terminal axons as compared to the naïve animals without statistical differences between treatments.

**Conclusions:** The Symplicity Flex, ME Prototype and Symplicity Spyr Renal Denervation Catheters produced equivalent and consistent RF lesions, denervation efficacy and vascular safety.

**TCT-810****Long-term Safety of Everolimus-Eluting Bioresorbable Vascular Scaffold versus Cobalt-Chromium XIENCE V Stent in a Porcine Coronary Artery Model**

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**Background:** An everolimus-eluting bioresorbable vascular scaffold (BVS, Abbott Vascular, Santa Clara, CA) has shown promising clinical results; however, only limited preclinical data has been published. We present detailed pathologic responses to BVS versus XIENCE V® (XV) in a porcine coronary model extending form 1 month (mo.) to 42 mo.

**Methods:** A total of 332 devices (261 BVS and 71 XV) were implanted in 2 or 3 main coronary arteries of 135 non-atherosclerotic swine. The animals were euthanized and