Methods: e-MISAGO enrolled more than 3000 patients treated with the Misago stent in 94 European centers. All clinical data collected through an EDC platform are fully monitored and all reported serious adverse events are independently adjudicated. Primary safety (at 30 days) and efficacy endpoint (at 1 year) match the VIVA criteria.
Results: Patients (68% male) were 67±10 years old, 63% were smokers, 36% had diabetes mellitus (36% IDDM), 46% had hypercholesterolemia and 76% arterial hypertension. Patients had history of previous coronary artery disease in 32% of the cases and 14% previous myocardial infarction. Claudication and symptomatic ischemia concerned 99% and 96% of the patient population. Mean lesion length was 64.5±59.0 mm, with reference vessel diameter 6.3±1.3 mm. Mean lesions' stenosis was 88.6±12.4% and 43.3% of the lesions were totally occluded. On average 1.2±0.5 vessels per patient were treated with 1.2±0.45 stents per lesion. At baseline mean ABI was 0.59±0.22 and mean Rutherford score was 2.51±1.31. At 12 months ABI improved in 81% patients and the mean increased to 0.85±0.24; Rutherford score improved in 76% patients with mean value of 0.72±1.16. The overall composite adverse events rate of death, amputation, and revascularization was 9.7%.
Conclusions: The interim results from the e-MISAGO registry indicate promising device performance of the Misago RX nitinol stent at 1 year.

TCT-170

Vascular Injury Influences Drug Transfer and Vessel Healing Following Paclitaxel Coated Balloon Delivery in the Peripheral Arteries of Swine

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Background: The impact of vascular injury on drug transfer and vessel healing following Paclitaxel Coated Balloon (PCB) use has not been described. We hypothesized that the vessel uptake of paclitaxel and its resulting effect on healing is highly influenced by the degree of mechanical injury exerted to the vessel wall following balloon inflation.
Methods: A total of 19 PCB (Cotavance, Medrad, Inc. Indianola, PA) were inflated in the iliofemoral territory of 8 domestic swine targeting a 1.2:1 balloon to artery ratio (BAR). All arteries were harvested at either 14 (n=9) or 30 (n=10) days for the evaluation of tissue paclitaxel levels and histology. Based on the histological injury scores, all vessel segments were classified into IEL ruptured (IEL-R) or IEL non-ruptured (IEL-NR).
Results: A total of 19 iliofemoral arteries were included in the analysis. The IEL-R group had a higher BAR (1.44±0.08) compared to the IEL-NR (1.34±0.11, p=0.1). At 14 days, the median concentration of paclitaxel in the IEL-R group (1,251μg/g) was higher than in the IEL-NR group (465 μg/g, p=0.13). However, the% area of stenosis was comparable among both groups at 14 and 30 days (see table). At 30 days, Paclitaxel tissue levels were comparable among both groups. Fibrin and inflammatory scores were consistently higher in the IEL-R group compared to the IEL-NR group at both 14 and 30 days (see table).
Conclusions: The degree of mechanical injury induced by balloon dilatation seems to influence short-term drug transfer and long-term vessel healing following PCB use. The implications of these findings on clinical outcomes deserve further evaluation in the human setting.

Follow Up	IEL Rupture	Balloon to Artery Ratio	Fibrin Score	Mean Inflammation Score	Area Stenosis (%)	Median Concentration (μg/g)
15 Days	Yes	1.44 ± 0.08	3.00 ± 0	1.25 ± 0.5	5.34 ± 1.39	1251.00
	No	1.34 ± 0.11	1.74 ± 1.15	0.74 ± 0.45	5.78 ± 5.25	465.00
	p value	0.10	<0.001	0.13	0.75	0.13
30 Days	Yes	1.61 ± 0.26	1.78 ± 0.83	1.00 ± 0.5	11.43 ± 4.46	79.60
	No	1.39 ± 0.25	1.07 ± 1.27	0.67 ± 0.49	16.71 ± 10.45	66.50
	p value	0.06	0.11	0.13	0.10	0.06

TCT-171

Paclitaxel Balloon Delivery Results In Homogeneous In-Stent Neointimal Distribution and Reduction of Stent Edge Stenosis Progression in the Peripheral Swine Model

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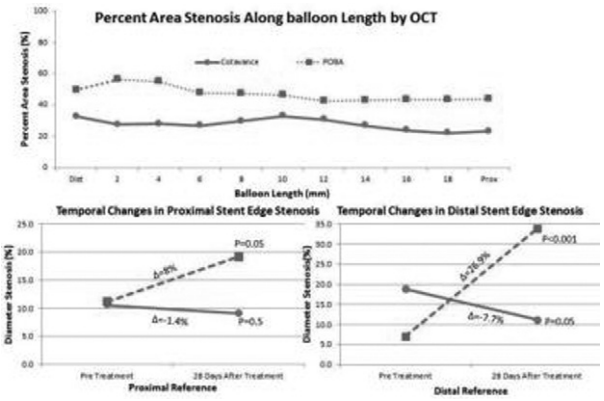
Background: Due to the mechanism of drug transfer, Paclitaxel coated balloons (PCB) are thought to result in non-uniform inhibition of neointima. We sought to investigate the pattern of neointima distribution along the stented and reference(edges) segments following PCB dilatation as compared to POBA controls in a peripheral swine model.
Methods: 16 Iliofemoral arteries were injured with balloon overstretch followed by a BMS deployment. At 14 days, the in-stent restenosis was treated with either a PCB (Cotavance, Medrad Inc, PA) or an identical uncoated balloon (POBA). At 28 days following balloon inflation, all segments were analyzed by QVA and OCT. The OCT percent area stenosis (%AS) was analyzed every 2mm along the treated segment. Percent diameter stenosis (%DS) was analyzed within 5mm proximal and distal to the stent marker by QVA.
Results: The efficacy of PCB was demonstrated by the 43% reduction of%AS by OCT (27.3±9% versus POBA: 47±13%, p=0.006). In the test for homogeneity of variances, there was no significant longitudinal variation between segments treated with PCB (p=0.2) or POBA (p=0.6, see figure). At follow up, POBA demonstrated a progression in neointimal proliferation at distal (26.9% increase, p<0.001) and proximal (8.0% increase, p=0.05) vessel reference segments. Conversely, PCB exhibited neointimal regression in the distal (-7.7%, p=0.05) and proximal (1.4%, p=0.5) reference segments.
Conclusions: In vivo OCT analysis showed a homogeneous inhibition of neointimal formation following paclitaxel delivery. In addition the use of PCB reduces neointimal proliferation at the borders of the stent.



TCT-172

Drug-Coated Balloon for Peripheral Arteries: Results from preclinical experiments using the Freeway DCB

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Background: Drug-coated balloons (DCB) have emerged as a potential alternative in treating PAD. This study aimed to evaluate the tissue concentrations and efficacy of using the Freeway DCB in porcine peripheral arteries. Thus no further extrapolation from coronary preclinical experiments is needed.
Methods: Measurements of tissue paclitaxel concentration at 1h, 1 day, 3 days and 9 days after dilation of peripheral arteries with Freeway™ balloon (Paclitaxel-eluting DEB) for 1 or 2 min in a total of 92 porcine arteries. Inflation time dependent determination of the paclitaxcel concentration in the blood plasma Inflation time dependent determination of the remnant paclitaxel concentration on the inflated balloon Histological investigations in a porcine post-overstretch injury (1.3:1 balloon/artery ratio) model after 2 min inflation of Freeeway™ (Paclitaxel-eluting DEB) or conventional balloon Measurement of area stenosis (%) Measurement of neointimal area (mm2)
Results: Tissue Ptx concentrations: 1 hour post 238 μ molar at 1 min, 502 μ molar at 2 min of inflation 1 day post 26 μ molar at 1 min, 129 μ molar at 2 min 3 days post 19 μ molar at 1 min, 35 μ molar at 2 min 9 days post 4 μ molar at 1 min and, (still to come) at 2 min Plasma concentrations: 1 hour post 0,6 ng/ml at 1 min, 2,3 ng/ml at 2 min Remnant Paclitaxel on the balloon 28% after 1 min,19% after 2 min Post-overstretch injury (1.3:1): Femoralis neointima area of 0,62 mm2 for DCB vs 1,51 mm2 for POBA p<0.05 Iliaca 0,62 mm2 for DCB vs 1,24 mm2 for POBA p<0.05 Area stenosis: Femoralis 12,5% for DCB vs. 35,9% for POBA p<0.05 Iliaca 16% for DCB vs. 32,3% for POBA p<0.05
Conclusions: The new dataset for peripheral arteries from porcine preclinical experiments shows paclitaxel tissue concentration comparable to coronary results one hour post inflation after 1 minute of inflation of the DCB. After 2 minutes, the concentration in tissue was approx. double. This effect holds true for later time points up to 9 days. Safety has been established in plasma measurements, and efficacy was significant in both Femoralis and Iliaca as compared to POBA after balloon overstretch.

POSTERS