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Pantera Lux Drug Coated Balloon: Twelve-Month Results On The Diabetics Subgroup Of The International DELUX Registry
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Background: In recent years, drug coated balloons have emerged as treatment option for PCI. The present registry aims to evaluate the safety and efficacy of the Pantera Lux Paclitaxel Coated Balloon in a real world setting.

Methods: Between April 2010 and April 2011, 363 diabetic patients were enrolled at 50 sites in 12 countries. Clinical follow-up was performed at 1, 6 and 12 months. The primary endpoint was MACE, a composite of all death, non-fatal MI and clinically driven TVR, at 6 months. Secondary endpoints include MACE at 1 and 12 months. All reported MACE were adjudicated by an independent clinical events committee.

Results: Two hundred fifty-nine men (71.3%) and 144 female (28.7%) with a mean age of 67.4±10.2 years have been enrolled. One hundred forty-two patients (59.4%) were insulin dependent. Eighty-six patients (23.7%) presented with congestive heart failure and 195 patients (53.7%) had a history of previous MI. The majority of patients presented with stable angina (n=184, 50.7%) followed by unstable angina (n=107, 29.5%). A total of 388 lesions were treated, mainly located in LAD (n=144, 37.1%) and RCA (n=136, 35.1%). The mean reference vessel diameter was 2.9 mm and the mean target lesion length was 16.6 mm. Three hundred forty lesions (87.6%) were in-stent restenotic (ISR) lesions. Therof 165 lesions were in a BMS (48.5%) and 172 lesions in a DES (50.6%). The majority of ISR lesions were diffuse (n=159, 43.8%), Mehren class II or focal (n=104, 31.6%, Mehren class I). Follow-up compliance at 6 month follow up is 93.9%. The MACE rate (hierarchical) at 6 months is 11.2% including all 11 death (3.2%, 6 cardiac death [1.8%], 7 non-fatal MI [2.1%] and 20 clinically driven TVR (5.9%). In 15 cases (4.4%) a target lesion recanalization was needed. Twelve months MACE data will be presented.

Conclusions: Treatment with the Pantera Lux Paclitaxel Coating Balloon showed excellent acute and mid term performance in diabetic patients with mainly ISR lesions. Efficacy and safety are demonstrated by low recanalization rates and low non-fatal MI rate.

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Acute Delivery and Long Term Retention of Sirolimus Nanoparticles Using a Novel Porous Angioplasty Balloon in the Porcine Coronary Model
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Background: Drug coated balloons using Paclitaxel have demonstrated to be clinically effective for the treatment of in-stent restenosis. In this study, we aimed to evaluate the feasibility of delivering drug coated balloons in diabetics: Insights from the PEPCAD-DES study

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Background: The PEPCAD-DES Study showed a significantly lower late loss with the use of a drug coated balloon in comparison to a healthy population. Purpose of this study was to investigate the impact of diabetes mellitus on late lumen loss and angiographic restenosis in patients, who were treated with a drug-coated balloon (DCB) in comparison to balloon angioplasty alone (POBA) for in-stent-restenosis (ISR) of drug-eluting stents (DES).

Methods: 110 patients with an ISR of either Cypher-, Taxus- or XienceV-stent in a native coronary artery with indication for percutaneous coronary intervention were included in six centers in Germany. Exclusion criteria were: acute myocardial infarction, chronic total occlusion, lesion in grafts, bifurcation lesion, left main lesion, restenosis and in-stent restenosis, contraindication for acetylsalicylic acid or clopidogrel. All patients were scheduled for control angiography at 6 months.

Results: 38 patients were randomized to POBA and 72 patients to DCB. Of these 26 (36.1%) pts. of the DCB-group and 13 (34.2%) were diabetics. DCB as compared with POBA significantly reduced late loss in diabetics and non-diabetics, respectively. At angiographic 6 month follow-up late lumen loss (LLE) in patients treated with a DCB (n=26) was 0.31±0.72 mm in diabetics, and 0.39±0.54 mm in non-diabetics (n=42). In patients treated with POBA LLL was 1.45±0.85 mm in the diabetic subgroup and 0.91±0.71 mm in non-diabetics (n=24). Rates of target lesion revascularization(TLR) rates were significantly lower with DCB versus POBA for non-diabetics (15.2% vs. 36.0%; p=0.045), but not for diabetics (15.4% vs. 38.5%; p=0.107) Overall rates of major adverse cardiac events (MACE) were significantly lower with DCB.

Conclusions: Paclitaxel coated balloon angioplasty was superior to POBA for treatment of DES-ISR and reduced significantly MACE-rates in diabetics and non-diabetics. DCB effect on late loss was more effective in patients without diabetes.