TCT-274

Drug-eluting balloons in 001 bifurcated lesions: 1 year clinical and 7-months angiographic outcomes
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Background: In the DES era, the best strategy to treat 001 bifurcated lesions remains unanswered. This is the first prospective registry assessing the efficacy and safety of second generation of drug-eluting balloon (DEB) (EurocorGm), (3.0g/m2 balloon surface area), in patients with 001 bifurcated lesions placed in secondary branches.

Methods: After 2.7 years, 51 patients with 001 bifurcated lesion and clinical evidence of myocardial ischemia related to the target lesion were prospectively included in this multicenter (8 centers) registry. After optimal dilatation, a PEB was in placed in 001 bifurcated lesions. The DEB could not be used and patients were excluded from the registry.

Results: One Year Results of the PATENT-C First-in-Human Trial

Conclusions: As demonstrated by this multicenter registry, second generation of PEB is a safe strategy, technically easier and it seems to be effective at midterm follow up with a 14% MACE at 1 year.

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A Novel Drug-Coated Scoring Balloon for the Treatment of Coronary In-Stent Restenosis: One Year Results of the PATENT-C First-in-Human Trial
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Background: Scoring balloons are useful in the acute treatment of in-stent restenosis, fibro-calcific and bifurcation lesions but have not shown to affect the restenosis rate as compared to conventional balloons. A novel paclitaxel-coated scoring balloon (SB) was developed to overcome these limitations. Prior studies in a coronary swine model showed an reduction in restenosis using these SB and no evidence of local or systemic adverse effects.

Methods: SB were coated with paclitaxel admixed with a specific excipient. Patients at 5 sites (4 in Germany and one in Brazil) with bare metal stent in-stent restenosis (ISR) were randomized 1:1 to treatment with either a drug-coated or bare SB. Baseline and 6-month follow-up quantitative coronary angiography was performed by an independent blinded core lab and all patients were evaluated clinically at 30 days, 6 and 12 months. The primary endpoint was angiographic in-segment late lumen loss (LLL). Secondary endpoints included clinically driven target lesion revascularization (TLR), major adverse cardiovascular events (MACE), stent thrombosis (ST) and other clinical and angiographic variables. Patients will be followed clinically for 2 years.

Results: A total of 61 patients were randomized (28 uncoated and 33 coated SB); mean age 63.3 yrs, males 72%, and presence of diabetes 38%. At 6-month angiographic follow-up, the mean intimal loss was 0.48±0.51 in the uncoated SB group versus 0.09±0.43 mm in the drug-coated SB group (p=0.002; ITT analysis). The rate of binary restenosis was 41% in the uncoated SB group versus 6.5% in the drug-coated SB group (p<0.05). At one year, the MACE rate was 32% with the uncoated SB vs. 6.7% with the drug SB (p<0.05).

Conclusions: A novel paclitaxel-coated coronary SB has been developed and achieved successful results in a first-in-human randomized controlled trial [ClinicalTrials.gov Identifier: NCT01495533].

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Characterization of vascular response and pharmacokinetics after application of paclitaxel-coated angioplasty balloons in non-diseased swine coronary arteries
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Background: Drug-coated balloons (DCB) rapidly transfer antirestenotic drug along the arterial vessel wall without a metallic implant. DCBs, coated with a mixture of paclitaxel and an excipient (to modulate drug release), may have clinical application in treating coronary in-stent restenosis and in peripheral arterial stenoses. This study characterizes the in vivo elution of paclitaxel and vascular compatibility of the novel Agent™ Paclitaxel-coated PTCA balloon for coronary vasculature.

Methods: The Agent DCB TransPAX coating consists of 80% Paclitaxel/20% excipient (2ug/mm2 dose density [Boston Scientific Corporation, Natick MA], “test DCB”). Controls included a commercially available paclitaxel-coated balloon (3ug/mm2, Pantera Lux [Biotronik AG, Switzerland] “control DCB”) and an uncoated balloon (“POBA”). Balloons were inflated distal to a marker stent (BMS) or a BMS was implanted prior balloon inflation in the same position. The level of paclitaxel was measured at time points through 28d and vascular response was analyzed 28d post implantation.

Results: The level of paclitaxel in the coronary arteries was equivalent between test DCB and control DCB (reaching 50% of initial levels between 7 and 14d). Vessel areas were similar and endothelialization of luminal surfaces was nearly complete in all groups by 28d. Neointimal area was similar between test DCB and POBA; both were statistically less than control DCB. Medial smooth muscle cell loss and inflammation were greater in control DCB vessels compared to test DCB vessels followed by POBA. Similarly, mean fibrin score (intima/media) was highest in the control DCB, followed by test DCB vessels and then POBA vessels (See table).

<table>
<thead>
<tr>
<th>Balloon Treatment</th>
<th>Test DCB</th>
<th>Control DCB</th>
<th>POBA</th>
<th>ANOVA P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>EEL Area (m²)</td>
<td>2.87±1.29</td>
<td>3.05±1.08</td>
<td>2.59±0.79</td>
<td>0.58</td>
</tr>
<tr>
<td>EEL Area (m²)</td>
<td>1.68±0.94</td>
<td>1.84±0.80</td>
<td>1.65±0.56</td>
<td>0.81</td>
</tr>
<tr>
<td>Neointimal area</td>
<td>0.11±0.08</td>
<td>0.31±0.27</td>
<td>0.12±0.18</td>
<td>0.03</td>
</tr>
<tr>
<td>% Stenosis</td>
<td>7.38±5.20</td>
<td>16.91±13.08</td>
<td>8.92±12.70</td>
<td>0.09</td>
</tr>
<tr>
<td>Mean PGs/Collagen Score (Media)</td>
<td>1.17±0.72</td>
<td>2.07±0.65</td>
<td>0.79±0.81</td>
<td>0.0007</td>
</tr>
<tr>
<td>Medical SMC Loss Score (Circumference)</td>
<td>1.13±0.74</td>
<td>1.94±0.60</td>
<td>0.63±0.83</td>
<td>0.003</td>
</tr>
<tr>
<td>Mean Fibrin (Intima/Media) Score</td>
<td>0.88±0.91</td>
<td>1.61±0.79</td>
<td>0.04±0.14</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Mean Inflammation (Intima/Media) Score</td>
<td>0.71±0.66</td>
<td>1.19±0.39</td>
<td>0.33±0.89</td>
<td>0.003</td>
</tr>
</tbody>
</table>

Abbreviations: EEL—external elastic lamina, IEL—internal elastic lamina, PG—proteoglycan, SMC—smooth muscle cell

Conclusions: These results show the Agent DCB results in equivalent tissue levels with less nominal drug than the control DCB and support the safety of the Agent DCB in porcine coronary arteries.

TCT-277

Synergy of Drug Coated Balloons plus Second-generation Drug Eluting Stents versus Second-generation Drug Eluting Stents: A Propensity Matched Analysis
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Background: Limited data are available as to whether the combination of drug coated balloons (DCB) plus drug eluting stents (DES) would be more efficacious than DES in lesion revascularization (TLR) of patients at high risk for restenosis. A combination of paclitaxel (present in coated balloons) and a limus drug may exert a synergistic effect in preventing target lesion revascularization (TLR).

Methods: Between 2009 and 2013, 68 patients (82 lesions) were treated with a combination of DCB and implantation of a second-generation DES. These were compared to 513 lesions treated with conventional second-generation DES in the same period. Primary endpoint was TLR at 1- and 2-years of follow-up.

Results: The DCB plus DES group had more in-stent restenosis (ISR); 42.3% vs. 9.5%, p < 0.001 and higher prevalence of diabetes mellitus (DM); 36.4% vs. 22.2%, p = 0.007 compared to the DES group. After propensity matching, there were no
significant differences in the 77 matched pairs. Stent profiles were also similar in both groups. Kaplan-Meier analysis (Figure) demonstrated no significant differences in 1-year (5% vs. 2.5%, p = 0.59) or 2-year (20.7% vs. 11.5%, p = 0.25) TLR between the two groups.

Conclusions: In our study, no additional benefit of DCB plus DES combination was found when compared to conventional DES implantation. However, a large randomized study is essential to evaluate the efficacy of DCB plus combination.

TCT-277
Predictors of Recurrent Restenosis After Treatment of In Stent Restenosis With Paclitaxel-Coated Balloon
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Background: Recently, paclitaxel-coated balloon (PCB) has emerged as a potential alternative to the current treatment of in-stent restenosis. However, the recurrent restenosis still occurs in some cases. The predictors of recurrent restenosis are incompletely understood. The aim of this study was to evaluate the predictors of recurrent restenosis in patients treated with PCB for in-stent restenosis.

Methods: Data of the patients treated with PCB (SeQuent please) for in-stent restenosis between 2008 and 2012 were collected. A total of 453 patients with 539 lesions [bare-metal stent restenosis (BMS-ISR); 113 lesions, drug-eluting stent restenosis (DES-ISR); 426 lesions] were analyzed in this study. Follow-up angiogram was obtained in 476 lesions 6 months after procedure (follow-up rate: 88.3%). We evaluated the predictors of recurrent restenosis in patients treated with PCB for in-stent restenosis.

Results: Recurrent restenosis occurred in 13 lesions (13.3%) of BMS-ISR and 79 lesions (20.9%) of DES-ISR. Target lesion revascularization was performed to 7 lesions (7.1%) of BMS-ISR and 54 lesions (14.3%) of DES-ISR. Late lumen loss was lower in BMS-ISR than in DES-ISR (0.17 +/- 0.50 mm vs. 0.29 +/- 0.57 mm, p=0.04). Previous stent size ≤ 2.5mm (odds ratio [OR]: 1.84, 95% confidence interval [CI]: 1.13 to 3.02, p=0.01), total occlusion lesions (OR: 2.74, CI: 1.15 to 6.36, p=0.04), and percentage diameter stenosis after procedure > 35% (OR: 1.72, CI: 1.03 to 2.85, p=0.04) were independent predictors of recurrent restenosis.

Conclusions: Small vessels, total occlusion lesions, and residual stenosis >35% were the predictors of recurrent restenosis in patients treated with PCB for in-stent restenosis.

TCT-279
Comparison Of Two Paclitaxel-Coated Balloons In The Treatment Of Coronary In-Stent Restenosis: A Single Center Experience
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Background: In randomized clinical trials, efficacy and safety of paclitaxel-coated balloon (PCB) angioplasty for the treatment of bare-metal stent (BMS) and drug-eluting stent (DES) restenosis was demonstrated. However there is few data if different PCBs perform equally. This study aims to evaluate the long-term efficacy of two second-generation PCBs in treating coronary in-stent restenosis (ISR).

Methods: Between October 2010 and February 2012, all consecutive patients with ISR lesions treated with the SeQuent Please PCB (B. Braun, Melsungen, Germany) or with the DIOR® PCB (Eurocor GmbH, Bonn, Germany) at our institution were prospectively included. Patients were followed up for 24 months by clinical observation. The primary endpoint was the clinically driven target lesion recanalization (TLR) rate at 24 months. The secondary endpoint was the rate of major adverse cardiac events (MACEs), defined as a composite of cardiac death, myocardial infarction, and TLR at 24 months.

Results: 65 patients with 74 ISR lesions were included. 43 ISR lesions (21 BMS, 22 DES) were treated with the SeQuent® Please PCB and 31 (11 BMS, 20 DES) with the DIOR® PCB. Baseline clinical, lesion characteristics and procedural data did not significantly differ between two groups. The TLR rate was significantly lower in patients with the SeQuent® Please PCB compared with the DIOR® PCB (4.7% vs. 22.6%, p = 0.03) at 24 months. The number of patients who suffered a MACE was not statistically different across study groups, but a strong trend towards better clinical outcome was discovered in the SeQuent® Please PCB group (9.3% vs. 25.8%, p = 0.058).

Conclusions: This real-world practice registry suggests that there are significant differences in terms of TLR between two clinically available PCBs. The SeQuent® Please PCB demonstrated lower TLR rate compared to the DIOR® PCB at 24 months follow-up.

TCT-280
Drug—Coated Balloon Versus Drug—Eluting Stent For In—Stent Restenosis: A Meta—Analysis Of Randomized Controlled Trials
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Background: The treatment of coronary in-stent restenosis (ISR) is challenging. Drug—eluting stent (DES) implantation for ISR has not showed satisfactory results. Drug—coated balloon (DCB) has been recently compared with DES for ISR treatment with controversial results.

Methods: A systematic literature review in Pubmed/MEDLINE, Embase, Scopus, ISI Web of Science, ScienceDirect electronic databases was performed to identify randomized controlled trials (RCTs) comparing DCB with DES in ISR. No filters or language restrictions were imposed. The keywords used were the following: “drug coated balloon,” “drug eluting balloon,” and “paclitaxel eluting balloon”. The endpoint was a composite of major adverse cardiovascular events (MACE) at 12 months, reported as pooled risk ratio (RR) with 95% confidence interval (CI). A DerSimonian-Laird random-effects model was used. Heterogeneity was graded with I2 statistic.

Results: A total of 4 randomized controlled trials comparing DCB and DES were identified. The pooled analysis showed a similar risk of MACE at 12 months between the two treatments (RR 1.04, 95% CI 1.03–1.05, p=0.83). The heterogeneity degree was low (8.7%). However, differently from the others, PECAP II trial exhibited a clear risk reduction with DCB (RR 0.45). To exclude a significant impact of this trial on pooled RR, a sequential one study removal was performed. Excluding PECAP II the pooled RR tended toward a modest RR reduction associated with DES (RR 1.17, 95% CI 0.82–1.67, p=0.38).

Conclusions: DES implantation for ISR compared with DCB might lead to a modest reduction in the risk of MACE at 12 months.