Conclusions: Second generation PCB achieved similar degree of neointimal inhibition compared to 1st generation PCB technologies. However, they displayed a more favorable vascular healing profile.

TCT-592

Familial Hypercholesterolemic Swine In-Stent Restenosis Model, But Not Contemporaneous Injury+Treatment Model, Predicts Efficacy of Drug Coated Balloon in Peripheral Arteries

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Background: Juvenile domestic swine have been extensively used to test safety of various antirestenotic therapies in peripheral arteries but it generally fails to provide insights into efficacy. We investigated the potential of different combinations of balloon or stent injury + treatment models in familial hypercholesterolemic (FH) swine to predict the antirestenotic efficacy of drug-coated balloons.

Methods: Iliofemoral arteries of 32 FH swine were subjected to (1) denudation by a Fogarty catheter immediately followed by DCB or Control (uncoated PTCA balloon) treatment (De Novo Denudation + No Stent), (2) balloon overstretch and stent placement immediately followed by the same DCB or Control treatment (De Novo Overstretch + Stent), or (3) balloon overstretch and stent placement followed by the same DCB or Control treatment 14-21 days later (In-Stent Restenosis). In all models, the net neointimal proliferation was evaluated 28 days post-treatment by endovascular imaging (IVUS or OCT).

Results: As expected, the neointimal response was much more robust in the De Novo Overstretch + Stent than in the De Novo Denudation + No Stent model, but both De Novo FH swine models failed to show the difference between DCB and Control. In contrast, 2 separate studies employing the In-Stent Restenosis model on the basis of FH swine, demonstrated reduction of average stenosis by ~50% by DCB in comparison to Control (TABLE).

Conclusions: The peripheral in-stent restenosis model, in which neointimal proliferation was induced by stent placement in iliofemoral arteries of FH swine and diluted 2-3 weeks later by DCB or Control uncoated balloon, reliably differentiated the antirestenotic effect of DCB from the Control effect in peripheral arteries. In contrast, either De Novo model (of contemporaneous injury + treatment) developed in FH swine was not successful in that regard.

<table>
<thead>
<tr>
<th>Model</th>
<th>Imaging Modality</th>
<th>Average Percent Area Stenosis</th>
<th>Control (Uncoated Balloon)</th>
<th>Drug-Coated Balloon</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>De Novo Denudation + No Stent (n=16)</td>
<td>IVUS</td>
<td>17.3 ± 3.9%</td>
<td>19.0 ± 4.7%</td>
<td>0.24</td>
<td></td>
</tr>
<tr>
<td>De Novo Overstretch + Stent (n=11)</td>
<td>OCT</td>
<td>56.5 ± 14.5%</td>
<td>43.8 ± 13.4%</td>
<td>0.17</td>
<td></td>
</tr>
<tr>
<td>In-Stent Restenosis (n=16)</td>
<td>IVUS</td>
<td>58.3 ± 11.6%</td>
<td>25.5 ± 8.6%</td>
<td>&lt;0.001</td>
<td></td>
</tr>
<tr>
<td>In-Stent Restenosis (n=16)</td>
<td>OCT</td>
<td>47.0 ± 13.0%</td>
<td>27.3 ± 8.7%</td>
<td>0.003</td>
<td></td>
</tr>
</tbody>
</table>

TCT-593

Abstract Withdrawn

TCT-594

Efficacy and Safety of Drug-Elutting Balloon Compared to Drug-Elutting Stent for The Treatment of In-Stent Restenosis (ISR)

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Background: In recent studies, efficacy of drug-eluting balloon (DEB) angioplasty for the treatment of coronary in-stent restenosis (ISR) was demonstrated. However there is few data regarding efficacy and safety of DEB compared to drug-eluting stent (DES) in treating ISR.

Methods: Initially we tried to evaluate the efficacy and safety of DEB for ISR. Instead we compared the DEB data to other DES data prospectively obtained in our institution in the same period. In this prospective registry from 2009 to 2010, 107 patients with ISR, treated with a DEB (Paclitaxel-coated) (61 patients, 65 lesions) and DES (resolute zotarolimus-eluting) (46 patients, 50 lesions) were included. Nine month angiographic and 1 year clinical follow-up were completed for all patients. Dual antiplatelet agents were administered for both groups at least 9 months. Safety endpoints were cardiac death, myocardial infarction or stent thrombosis, and efficacy endpoints were more than 50% of ISR and repeated target lesion revascularization (TLR) during follow-up.

Results: Baseline clinical and angiographic data did not significantly differ between two groups. After 9 months TLR and ISR rates were significantly lower in DES group vs. DEB group with 6.0% vs. 21.5% respectively (p=0.02). Moreover, adverse cardiac events (composite of cardiac death, myocardial infarction) occurred in DES group (n=2) while there was no myocardial infarction in DEB group.

Conclusions: Substituting DEB for DES as a repeated revascularization tool might not be feasible in the maintenance of vascular patency in treating ISR.

TCT-595

Pantera Lux Drug Coated Balloon: Twelve-Month Results On 1’064 Patients 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, 1’064 patients were enrolled at 62 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: Seven hundred ninety-four men (74.6%) and 270 female (25.4%) with a mean age of 66.5 ± 10.7 yrs have been enrolled. Two hundred nineteen patients (20.6%) presented with congestive heart failure, 362 patients (34.1%) were diabetics and 51.8% (n=551) had a history of previous MI. The majority of patients presented with stable angina (n=328, 49.6%) followed by unstable angina (n=350, 32.9%). A total of 1’137 lesions were treated, mainly located in LAD (n=346, 38.3%) and RCA (n=410, 36.1%). The mean reference vessel diameter was 2.8 mm and the mean target lesion length was 15.7 mm. Nine hundred ninety-seven lesions (87.7%) were in-stent restenotic (ISR) lesions. Thereof 540 lesions were in a BMS (54.2%) and 448 lesions in a DES (44.9%). The majority of ISR lesions were diffuse (n=475, 49.0%, Mehran class II) or focal (n=316, 32.6%, Mehran class I). Follow-up compliance at 6 month follow up is 93.6%.

The MACE rate (hierarchical) at 6 months is 8.7% including 29 all death (2.9%, 19 cardiac death (1.9%)), 13 non-fatal MI (1.3%) and 44 clinically driven TVR (4.4%). In 32 cases (3.2%) a target lesion revascularization was needed. Twelve months MACE data will be presented.

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