Cost-effectiveness of paclitaxel-coated balloon angioplasty for treatment of coronary restenosis in bare-metal stents

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Background: In-stent restenosis (ISR) is a persistent problem limiting the long-term success of percutaneous coronary intervention. Recent studies have demonstrated safety and efficacy of drug-eluting balloon (DEB) angioplasty for the treatment of coronary ISR. The cost-effectiveness of this practice is unknown.

Methods: A Markov state-transition decision analytic model was used to assess the comparative cost-effectiveness of two common treatment strategies for bare-metal stent (BMS)-ISR: 1) re-stenting with paclitaxel-eluting DES (drug-eluting stent) versus paclitaxel-eluting balloon angioplasty (SeQuent Please). The model accounted for varying procedural efficacy, complication rates, and cost estimates. Data on procedural outcomes associated with both treatment strategies were derived from the literature, and the cost analysis was conducted from a German health-care payer perspective. Efficacy was expressed as life-years gained. Cost-effectiveness was calculated by dividing the difference in mean costs by the difference in effectiveness.

Results: In the base-case analysis, initial procedure costs amounted to $4,497.27 for DEB angioplasty and to $4,128.81 for DES implantation. Over a 12-month time horizon, the DES strategy was found to be less costly ($5,154.47 versus $6,619.98) and slightly more effective in terms of life expectancy (0.983 versus 0.976 years) than the DES strategy. Extensive sensitivity analyses indicated that, in comparison with DES implantation, the cost advantage of the DES strategy was robust to clinically plausible variations in the values of key model input parameters. The variables with the greatest impact on base case Results were the duration of dual antiplatelet therapy after DEB angioplasty, the use of generic clopidogrel, and variations in the costs associated with the DEB device.

Conclusions: DEB angioplasty is a cost-effective treatment option for coronary BMS-ISR. The higher initial costs of DEB are more than offset by later cost savings, predominantly as a result of reduced medication costs. DEB angioplasty can be regarded as one of the rare innovative medical interventions that are cost-saving at equal or even increased effectiveness.

TCT-589

Reaching Further in the Treatment of Calcified Small Vessel Disease - is Rota-DEB an Option?

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Background: In spite of all the technical developments that have taken place in coronary artery disease treatment, small diffusely calcified vessels are yet challenging. Rotational atherectomy (ROT) has a undisputed role in the debulking of severely calcified arteries, followed by drug eluting stent implantation for best long term Results. There are cases, however, where delivering a stent proves to be impossible or inappropriate. In such patients (pts) drug eluting balloons (DEB) could provide a therapeutic option. AIMS: We present the preliminary Results of the experience of 3 cardiovascular intervention centers on the use of ROTA followed by DEB (ROTA-DEB).

Methods: All data on pts submitted to rotationa is prospectively collected in a database. Pts were prospectively selected to be treated with ROTA and then DEB after ROTA was performed, 13 patients (11.9%). Mean follow-up was 7.5 months. Lesions were assessed by QCA at the time of intervention. Post ROTA-DEB and at Fup, QCA was done after intra coronary administration of nitrates in the same plane as basal QCA and along the length of the artery after a minimum of 6 months. Lesions were assessed by QCA at the time of follow-up.

Results: In our multicenter registry, from 1/6/2009 to 3/15/2012, 204 consecutive pts were submitted to ROTA. of which 21 (10.3%) were followed by DEB (32 balloons (average size: 2.45 (2.4) mm x 21.66 (15.30) mm). Most common indications for DEB were: distal stenosis or lesion (58.5%) and diabetes in stent delivery (25%). Angiographic follow-up of a subset of patients (n=26) demonstrated late luminal loss of 0.30 ± 0.36 mm and 0.33 ± 0.37 mm for the in-DCB and in-segment analyses, respectively.

Conclusions: The Valentines II trial demonstrated the safety and efficacy of second-generation DOR ICAB as adjunct to POBA in an all-comer population with de novo coronary lesions. This approach achieved high procedural success with acceptable rates of bailout stenting and low MACE rates at mid-term follow-up, and offers an attractive alternative for revascularization of patients who are not good candidates.

TCT-590

Efficacy of Paclitaxel-eluting Balloon Catheter in Patients with Recurrences after Drug-eluting Stent Implantation for In-stent Restenosis

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Background: The efficacy of paclitaxel-eluting balloon (PEB) for in-stent restenosis lesions is proven; however, its efficacy for recurrences after drug-eluting stent (DES) implantation for in-stent restenosis lesion is still unclear. The aim of this study was to investigate the efficacy of PEB in patients with recurrences after DES implantation for in-stent restenosis.

Methods: From November 2004 to December 2011, 159 consecutive lesions who underwent revascularization for recurrences after DES implantation were enrolled in this study [77 treated with PEB and 82 treated with conventional balloon angioplasty (BA)]. Follow-up angiogram was obtained 6 months after the procedure. We compared characteristics of patients and lesions between the two groups (PEB group vs BA group).

Results: No significant differences were observed in clinical characteristics between the two groups. Angiographic characteristics before the procedure were similar between the two groups (Reference diameter: 3.07 ± 0.56 mm vs 3.07 ± 0.55 mm, p = 0.9; Lesion length: 18.0 ± 5.0 mm vs 15.0 ± 7.0 mm, p = 0.1; Minimal lumen diameter: 0.85 ± 0.53 mm vs 0.95 ± 0.58 mm, p = 0.3). Acute gain was also similar between the two groups (1.33 ± 0.69 mm vs 1.26 ± 0.60 mm, p = 0.5). At the 6-month angiographic follow-up (follow-up rate: 94%), the incidence of recurrent restenosis (29.2% vs 59.7%, p = 0.0003) and target lesion revascularization (23.6% vs 40.3%, p = 0.036) was significantly lower in the PEB group than in the BA group. Late lumen loss was significantly lower in the PEB group than in the BA group (0.46 ± 0.63 mm vs 0.82 ± 0.73 mm, p = 0.0017).

Conclusions: In patients with recurrent restenosis after DES implantation for in-stent restenosis (in stent lesions), PEB provided much better clinical, angiographic outcomes than conventional BA.

TCT-591

Biological Efficacy and Vessel Healing of Second Generation Paclitaxel Coated Balloons: A Comparative Study with the original PACCOCATH Technology in the Ilio-Femoral In-Stent Restenosis Model in the Familial Hypercholesterolemic Swine

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Background: In comparison to the original PACCOCATH formulation, second generation PCB have improved coating uniformity and decreased drug content variability by modifying coating Methods and processes. In this study, we intended to evaluate the biological efficacy and vascular healing response of 2nd generation PCB in comparison to a 1st generation balloons technologies containing identical coating formulation and drug concentration.

Methods: A total of 18 Ilio-femoral arterial segments of 8 FHS were included in the study. At baseline and 28 days following initial injury, all stents were randomized to either a 2nd gen. PCB (n=6, Cotavance V2, Medrad), 1st gen. PCB (n=6, PACCOCATH, Medrad) or POBA (n=6, control group). Imaging evaluation (QVA, IVUS) was conducted in all animals at baseline, treatment time (2 weeks) and 28 days following initial injury. At termination, stented segments were harvested for histopathological evaluation.

Results: At last follow up angiographic %DS was significantly reduced in both generations of PCBs when compared to controls (2nd Gen PCB: 11.5±11.6% vs 1st Gen PCB: 11.0% vs POBA: 46.5±10.3%, p=0.001). These findings were confirmed by histopathological analysis (see table) displaying an ~35% reduction of %SA and neointimal thickness in both PCB groups. Vessel healing defined as fibrin deposition, neointimal maturity and medial cell loss scores was significantly improved in 2nd Gen PCB when compared to 1st Gen PCB. Endothelialization was completed in all three groups.
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 (uncoted PTCA balloon) treatment (De Novo Denudation + No Stent), (2) balloon overstitch and stent placement immediately followed by the same DCB or Control treatment (De Novo Overstretch + Stent), or (3) balloon overstitch 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 neoinflammatory 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 dilated 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 (comparing contemporaneous injury + treatment) developed in FH swine was not successful in that regard.

TCT-593
Abstract Withdrawn

TCT-594
Efficacy and Safety of Drug-Elutinng Balloon Compared to Drug-Elutinng 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 (Palixatcel-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 will be presented.

Conclusions: Treatment with the Pantera Lux Paclitaxel 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.

<table>
<thead>
<tr>
<th>Model</th>
<th>Imaging Modality</th>
<th>Average Percent Area Stenosis</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>
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<tr>
<td>De Novo Overstretch + Stent (n = 11)</td>
<td>OCT</td>
<td>56.5 ± 14.5%</td>
<td>43.8 ± 13.4%</td>
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<tr>
<td>In-Stent Restenosis (n = 16)</td>
<td>IVUS</td>
<td>58.3 ± 11.6%</td>
<td>25.5 ± 8.6%</td>
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<tr>
<td>In-Stent Restenosis (n = 16)</td>
<td>OCT</td>
<td>47.0 ± 13.0%</td>
<td>27.3 ± 8.7%</td>
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