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

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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)-induced ISR. The analysis compared DEB (SeQuent Please) versus paclitaxel-eluting balloon angioplasty (SeQuent Please). The model accounted for varying procedural efficacy rates, 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 healthcare system perspective. Effectiveness 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 DEB 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 DEB 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 antplatelet 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, expressed as life-years gained. Cost-effectiveness was calculated by dividing the difference in mean costs by the difference in effectiveness.

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

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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 (ROTAX) is a and undated 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 ROTAX followed by DEB (ROTAX-DEB).

Methods: All data on pts submitted to rotationa is prospectively collected in a database. Pts were either treated with ROTA-DEB and after the procedure, angiography (coronary angiography, respectively) after a minimum of 6 months. Lesions were assessed by QCA at the time of intervention. Post ROTA-DEB and at Fup, QCA was done after intra coronary angiography. pts who showed a marked improvement in clinical status. At 12 months, freedom from major cardiac adverse events was 90%. Fup-angiography of those pts was obtained at a median of 424 ± 254 days. QCA analysis showed an average luminal loss (LLL) of ≤ 6% to >75%. LLL > 50% was present in 1 pt.

Conclusions: Although these are still small numbers, Results seem very promising. Considering the complexity of the lesions. For very severe, diffusely calcified coronary artery disease, ROTA-DEB constitutes a good therapeutic option when a stent cannot be implanted.

TCT-590
Efficacy of Paclitaxel-eluting Ballon 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 lesion recurrences is proven; however, its efficacy for recurrences after drug-eluting stent (DES) implantation for in-stent restenosis remains 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 ± 15.0 mm vs 15.0 ± 11.7 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 (1.13 ± 0.69 mm vs 1.26 ± 0.68 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-589
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 Materials and processes. In this study, we intended to evaluate the in vivo histological and biological 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, the balloon injury was constructed from a 10x15-mm balloon catheter (PACCO-CATH, Medrad) or PBA (n = 6, PACCO-CATH, Medrad) or POBA (n = 6, control group). Imaging evaluation (QVA, IVUS) was performed in all animals at baseline, treatment time (2 weeks) and 28 days following implantation. At termination, stented segments were harvested for histopathological evaluation.

Results: At last follow up angiographic %DS was significantly reduced in both generations of PCB when compared to controls (2nd Gen PCB: 11.5 ±11.1% vs 1st Gen BMS: 0.0% vs 1st Gen BMS: 11.1% vs. 1st Gen BMS: 0.0%; p ≤ 0.001). These findings were confirmed in postmortem histopathological analysis (see table) displaying an ~35% reduction of %AS and neointimal thickness in both PCB groups. Vessel healing defined as fibrin deposition, neointimal maturation and medial cell loss scores were significantly improved in 2nd Gen PCB when compared to 1st Gen PCB. Endothelialization was completed in all 3 groups.