TCT-654

Comparison in the 5-year Outcome of Percutaneous and Polytetrafluoroethylene-Covered Stents for Saphenous Vein Graft Lesions

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Background: Percutaneous intervention (PCI) for degenerated saphenous vein graft (SVG) lesions are well known for high rates of no-reflow, restenosis (ISR) and stent thrombosis. Covered stents have been tried in an aim to trap the debris to minimize no-reflow and ISR. Two types of covered stents have been used for SVG lesions: pericardium covered stent (PCS) & polytetrafluoroethylene (PTFE) covered stent. We present our long-term follow-up data following the use of both types of covered stents in our practice.

Methods: Between 1997 and 2004, 52 patients (mean age: 67.14 years) with 65 lesions in SVG were treated with PTFE covered stents as a part of multicenter trial (RECOVER S). Between 2003 and 2007, 33 patients (mean age: 67.78 years) with 48 SVG lesions were treated with pericardium-covered stents covered stents as a part of multicenter trial (SLEEVER II).

Results: All case had TIMI3 flow post PCI and there were no immediate post-procedural complications. There were no significant differences in the baseline characteristics except that mean length of PCS were significantly longer than PTFE covered stents (32.3 mm vs 25.1 mm, p<0.001). At 5-year follow-up, the rates of TLR was [PTFE: 12 (18.5%), PCS: 13 (27%) p=0.17], TVR was [PTFE: 14 (21.5%), PCS: 16 (33%) p=0.07]. During the 5-year follow-up period, 8 patients (15%) in the PCS group and 2 patients (6%) in the PTFE group had died; p=0.33. The MACCE defined as death, MI, clinically driven TVR occurred in 34 of 52 PTFE patients (63%) vs. 18 of 33 PCS patients (54.5%) p=0.2. There were two reported cases of definite very late stent thrombosis in the PCS group, but none in the PTFE group.

Conclusions: The 5 year follow-up data shows no significant differences in the clinical endpoints between the two covered stents, although numerically it was slightly worse in the PCS group. The rates of TLR and TVR are not discouraging in either stents given the complexity of SVG lesions. Considering the complexity of the lesions treated and the absence of no-reflow, covered stents may provide additional protection. Since there are no very long-term follow-up with other stents in SVG, we cannot compare these results with the traditional stents.

TCT-655

Outcomes of high-risk patients undergoing percutaneous coronary interventions in the ambulatory versus in-hospital setting

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Background: In this study, we investigated the safety of ambulatory percutaneous coronary intervention (PCI) in high-risk patients according to age, creatinine, ejection fraction (ACEF) scores.

Methods: The ambulatory PCI group consisted of all consecutive PCI with same-day discharges at Mount Sinai Hospital from January 1, 2003 to March 31, 2011 who had follow-up data. The overnight group consisted of all PCI outpatients in 2004 who were then hospitalized for at least one night. Patients were stratified into two groups based on ACEF score: low (<1.100) and high (≥1.100). The primary endpoint was a 30-day major adverse cardiac events (MACE: readmission, all-cause death, and myocardial infarction (MI).

Results: Out of 4932 patients, 3216 or 65.2% were in the ambulatory group and the rest (1716) were in the control group. The average age was 61.5 years and were no significant differences in baseline characteristics. Overall 30-day MACE occurred in similar frequency in both groups (Table), in high and low ACEF scores.

Conclusions: This “trumpeting” may also partially explain the observed use of more Xience stents per lesion compared to Resolute (1.18±0.45 vs. 1.15±0.42, p=0.02) in the Resolute All Comers (RAC) trial. The primary cause for secondary stenting in RAC was “to stabilize target lesion” which includes procedural complications including dissection or perforations.

TCT-653

Assessment of endothelial function in patients randomly treated with a polymer-free sirolimus eluting stent and its bare-metal equivalent: results of the VESTASYNS II trial

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Background: Endothelium dysfunction is among the possible causes related to higher thrombosis rates after 1st generation DES. Whether the presence of durable polymer or high anti-proliferative drug dose, or both, can be responsible for this phenomenon is not clear. In the present study we compared the endothelial function following the implant of a polymer-free DES with a nanotin-microporous hydroxyapatite surface coating impregnated with a low-dose of Sirolimus (55μg) to a BMS equivalent coated with a hydroxyapatite surface (Vestacor stent).

Methods: The VestaSync II is a randomized, double-blinded trial with 20 pts (10 in each group) with de novo lesions in native coronary arteries of 3.0-3.5mm diameter and ≤18mm in length. The primary goal was to compare the vasomotoricity after implantation of stents with the same platform, with and without drug elution. Endothelial function was assessed with atrial pacemaker stimulation (20 ppm over basal cardiac frequency until reach 150 ppm) and the lumen diameter was measured at 5 mm of proximal and distal stent edges and in a control segment, in different stages (at rest, at successive phases of stimuli and after nitroglycerin LC infusion).

Results: As shown in the figure, there was a negative variation in luminal diameter between basal and maximum stimuli at proximal (10%) and distal (8%) edges of both groups. Among control segments this variation was less than 3%, an acceptable variation of QCA method.

Conclusions: The elution of sirolimus does not seem to interfere in endothelial function 8 months after polymer-free hydroxyapatite coating stent implantation.
Conclusions: In this single-center registry, patients who underwent ambulatory PCI had no worse outcomes than those who stayed at least one night, at high and low ACEF scores.

TCT-656
Low Incidence of Stent Thrombosis in Asian Races: Multicenter Registry in Asia 7 Years Follow-Up Result
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Background: The aim of this study was to evaluate the frequency, predictors and the clinical outcome of stent thrombosis after DES implantation and bare metal stent (BMS) implantation in Asian races.

Methods: A total of 14,577 consecutive patients who underwent successful DES implantation and BMS implantation were included in this study. We evaluate the frequency, predictor of stent thrombosis.

Results: At a mean follow-up of 78.5±29.9 months in DES and 81.8±26.4 months in BMS. The cumulative incidence of stent thrombosis were subacute stent thrombosis (SAT): 0.5% with DES and 0.6% with BMS, late stent thrombosis (LAST): 0.18% with DES and 0.1% with BMS, very late stent thrombosis (VLAST): 0.18% per year with DES and no BMS. Independent predictors of stent thrombosis are bifurcation lesion (OR=1.90, 95% CI: 1.83 to 2.42, p=0.00), ejection fraction (OR=0.90, 95% CI: 0.86 to 0.94, p=0.03). Only 0.2% of the patients were died because of the myocardial infarction after stent thrombosis in both groups.

Conclusions: The incidence of stent thrombosis in Asian races is relatively low (0.5%) with DES and 0.6% with BMS of SAT, which is lower than recent results in the Western population. The incidence of late stent thrombosis was significantly lower in Asian patients than in Western populations.

TCT-657
Multi Center, Prospective, Randomized, Single Blind, Consecutive Enrollment Evaluation Of Elixir DESyneTM Novolimus-Eluting Coronary Stent System With Durable Polymer To Endeavor Zotarolimus-Eluting Coronary Stent System: 3-Year Clinical and 9-Month Angiographic And IVUS Results: EXCELIA II Study
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Background: Aims: To evaluate safety and effectiveness of the Elixir DESyneTM Novolimus-Eluting Coronary Stent System (CSS) compared to the Endeavor Zotarolimus-Eluting CSS through assessment of clinical, angiographic, and IVUS endpoints.

Methods: 210 patients were randomized 2:1 either to the DESyne CSS loaded with 5mcg per mm of stent length of Zotarolimus eluted via a durable phospholipid copolymer or, to the Endeavor CSS loaded with 10mcg per mm of stent length of Zotarolimus eluted via a durable phosphoryl choline polymer. All patients were analyzed for the primary endpoint of late lumen loss (LLL) assessed by QCA at 9 months. All patients also underwent observation for secondary endpoints which included a Device-oriented Composite Endpoint (DoCE) defined as cardiac death, MI not clearly attributable to a non-intervention vessel, and clinically indicatively-indicated Target lesion revascularization (TLR); and stent thrombosis assessed at 1, 6, 9, and 12 months and annually through 5 years. Stents were also assessed for angiographic endpoints at 9 months including: in-stent and in-segment LLL. A subset of patients underwent IVUS evaluation including percent neointimal obstruction at 9 months. The study met the non-inferiority endpoint and also demonstrated superiority of the DESyne CSS as compared to control.

Results: Table 1 summarizes 9-month angiographic and IVUS results and clinical results through 2 years which trend lower for the DESyne stent.

Table 1: 9-month Angiographic, IVUS and Clinical Results

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>DESyne</th>
<th>Endeavor</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>In-stent LLL</td>
<td>0.11 ± 0.32</td>
<td>0.63 ± 0.42</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Clinically-indicated TLR</td>
<td>1.4</td>
<td>5.6</td>
<td>0.18</td>
</tr>
<tr>
<td>24-month DoCE (%)</td>
<td>4.3</td>
<td>9.0</td>
<td>0.14</td>
</tr>
<tr>
<td>Clinically-indicated TLR</td>
<td>1.4</td>
<td>7.0</td>
<td>0.045</td>
</tr>
</tbody>
</table>

Conclusions: The study met the non-inferiority endpoint and also demonstrated superiority of the DESyne CSS as compared to control. Clinical results through 3 years and a review of angiographic and IVUS results will be presented.

TCT-658
Do Drug Eluting Stents Improve Survival in All Comers?
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Background: Drug eluting stents (DES) have been shown to significantly decrease restenosis with subsequent need for lesion and/or vessel revasculatization when compared with bare metal stents (BMS) in selected patient groups in both randomized controlled trials and in observational registries. If their use in all-comers is also associated with a survival benefit over a longer follow-up is controversial.

Methods: Retrospective analysis of the MIDAS registry for patients who underwent PCI with BMS between January 1 1997-December 31 1998 (pre DES era, group 1; N=