Table. 1-year outcomes according to bifurcation treatment

<table>
<thead>
<tr>
<th></th>
<th>Bifurcation (n=1,317)</th>
<th>No bifurcation (n=7,266)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>MACE (Cardiac death, MI or TLR)</td>
<td>8.79%</td>
<td>6.48%</td>
<td>0.002</td>
</tr>
<tr>
<td>Cardiac death</td>
<td>0.79%</td>
<td>1.10%</td>
<td>0.31</td>
</tr>
<tr>
<td>MI (any)</td>
<td>4.02%</td>
<td>3.05%</td>
<td>0.067</td>
</tr>
<tr>
<td>Per-procedural MI</td>
<td>2.28%</td>
<td>1.27%</td>
<td>0.004</td>
</tr>
<tr>
<td>TVR (any)</td>
<td>8.58%</td>
<td>6.41%</td>
<td>0.004</td>
</tr>
<tr>
<td>Definite/probable ST</td>
<td>0.70%</td>
<td>0.86%</td>
<td>0.56</td>
</tr>
</tbody>
</table>

TCT-404

Regular Drug Eluting Stent versus Dedicated Bifurcation Paclitaxel-Eluting Stent in Coronary Bifurcation Treatment – 9-month analysis of POLBOS study

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Background: POLBOS is the randomized, prospective, multicentre study planned to compare two intervention strategies for bifurcation treatment: provisional T-stenting (PTS) with any regular drug-eluting stent (DES) and dedicated bifurcation paclitaxel-eluting stent BiotOSS Expert (Balton, Poland).

Methods: Between September 2010 and December 2012 in four centres in Poland patients with stable CAD or NSTE-ACS were randomized to the group where BioT OSS Expert was implanted or to the group where regular DES was used. An angiographic control was planned at 12 months in all patients. The primary end-point of the study is the rate of death, MI, ST and TLR after 12 months. At the time of TCT 2013 complete clinical 9-month follow-up will be available as well as 90% of angiographic controls after 12 months.

Results: BioT OSS Expert was implanted in 119 patients (49.4%) and regular DES was implanted in 122 patients (50.6%). The average age of patients did not differ significantly between groups (BioT OSS vs DES: 66.5 vs 66.8 years). In BioT OSS group there were significantly more patients with NSTE-ACS (9.6% vs 3.5%), diabetes (32.2% vs 16.8%), prior MI and prior CABG. In DES group there were more patients addicted to smoking (13% vs 22.1%). The dominant vessel was LAD (BioT OSS vs DES: 51.2% vs 70.5%) followed by LMS (22.7% vs 13.9%, respectively). In DES group 35.4% of stents eluted paclitaxel (PES). There were following nominal stent parameters in BioT OSS group: 3.69±0.06 mm x 2.99±0.04 mm x 16.96±1.44 mm and in DES group: 3.27±0.04 mm x 2.06±1.96 mm. Except for 2 (1.6%) cases in DES group and 1 (0.8%) in BioT OSS group all stents were implanted successfully. There were 16% (BioT OSS) and 11.2% (DES) cases with second stent implanted within the side branch. At six months all patients were uneventful. Up to now control angiography has been performed in 76% of patients in BioT OSS group and in 74% in DES group. TLR was, respectively, 10.9% vs 8.9% (p=0.5). Nevertheless, within DES group TLR in PES subgroup was 12.8% and in –olimus subgroup – 5.7%.

Conclusions: 9-month follow-up showed that BioT OSS Expert provides satisfactory results which seem to be inferior to those obtained by means of –olimus eluting stents, but comparable with those of PES.

TCT-405

Regular Drug Eluting Stent versus Dedicated Bifurcation Sirolimus Eluting Stent BioStent Lim in Coronary Bifurcation Treatment - POLBOS II Randomized Study

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Background: The provisional T-stenting (PTS) is the recommended strategy for the coronary bifurcation treatment. However, results obtained with use of regular drug eluting stents (DES) are not optimal and relatively often associated with a side branch compromise and restenosis. Dedicated bifurcation stents are claimed to be a solution for these complications. POLBOS II study is the continuation of POLBOS study, which paclitaxel-eluting stent BiotOSS Expert was assessed in.

Methods: It is a randomized multicenter study planned to compare two strategies for the bifurcation treatment – PTS with any regular DES or with a dedicated bifurcation sirolimus-eluting stent BioStent Lim (Balton, Poland) in patients with CAD or NSTE-ACS. An angiographic control was planned at 12 months in all patients. The primary end-point of the study is the rate of death, MI, ST and TLR after 12 months. The aim is to enroll 120 patients (60 in each group).

Results: The enrollment started in November 2012. To date, 75 patients (64% males) were randomized (40 in BiotOSS group, 35 in DES group). The average age was 64±9 yrs. The dominant vessel was LAD (50%) followed by LMS (33%). 72% of cases were true bifurcations. All stents were implanted successfully. There were 12.5 and 14.3% of

TCT-403

Impact of Bifurcation Lesion Treatment with DES on Clinical Outcomes: Results from the Prospective, Multicenter ADAPT-DES Study

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Background: ADAPT-DES was a prospective, multicenter, real-world registry of 8,585 consecutive pts at 11 international centers undergoing percutaneous coronary intervention (PCI) with DES designed to determine the frequency, timing, and correlates of early and late stent thrombosis (ST). Treatment of bifurcation lesions has been shown to be associated with an increased risk of ST and worse clinical outcome. We therefore analyzed the impact of bifurcation PCI on outcomes at 1 year.

Methods: Univariable and a fully adjusted multivariable analysis including propensity score stratification were performed to determine the relationship between bifurcation PCI and subsequent events.

Results: During the index procedure, bifurcation lesions were treated in 1,317 (15.7%) of 8,585 pts. Pts in the bifurcation group were less likely to be female (22.2% vs. 26.6%, p<0.001), diabetic (28.2% vs 33.2%, p<0.001), or have ACS (47.2% vs 52.5%, p<0.001). Both branches were stented in 19.1% of pts with bifurcation PCI had more total stents (2.10 vs 1.65, p<0.0001) resulting in longer total stent length (39.2 vs 31.2 mm, p<0.0001). Bifurcation lesions were more often in LAD territory (49.8% vs 37.0%, p<0.0001). Both branches were stented in 19.1% of all bifurcation lesions, and final kissing was done in 46.1%. The 1 year unadjusted rates of adverse outcomes are shown in the Table. In propensity adjusted models, bifurcation treatment was not independently associated with 1-year MACE (HR 95% CI) = 1.13 [0.89, 1.42, p=0.32], cardiac death (0.75 [0.31, 1.54], p=0.43), ST (0.64 [0.30, 1.36], p=0.24), or TVR (1.13 [0.89, 1.43], p=0.31).

Conclusions: These data, drawn from a large prospective registry of contemporary DES use, show that bifurcation lesion treatment is frequent, and is not necessarily associated with a worse prognosis at 1 year.
cases, respectively in a DES group and BiOSS group, with a stent implanted in SB. Moreover, stents with different diameters were used: 3.0 mm (n = 21), 3.25 mm (n = 1), 3.375 mm, and 3.5 mm. As a result, two patients experienced occlusion of the SB (8.2% at LM and above 6.6 cm² at proximal LAD). However, TLR-MB was necessary in 5 (7.9%) patients on HD despite optimal stent expansion. Cost analysis (cABG). The mean SYNTAX score was 35.5%. There was no peri-procedural death and perforation, while 8 (12.7%), and hemodialysis (HD) is 13 (20.6%). Mean EuroScore was 5.60 and 14.3% (7/49) MB STE (+), p = 0.28. The multivariate regression analysis (OR = 5.3.19, CI 1.197 – 23.809, p = 0.028; model including renal failure, CKMB preinterventional, SB final %DS, MB final STE, MB postdilatation, occlusion of secondary branch). The end-procedural ECG was analyzed using intracoronary ECG in the main branch territory is a sensitive newly discovered factor for prediction of in-stent restenosis after coronary stenting.

TCT-408
Excellent results after treatment of de novo bifurcation lesions with DCB only strategy
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Background: Application of drug-coated balloons (DCB) for the treatment of in-stent restenosis has been shown to provide clinical benefit in several randomized trials. While the superiority of DCBs compared to DES in de novo lesions is still controversial, there have been promising results when used in small coronary vessels and bifurcation lesions. While so far most bifurcation studies investigated the outcome after simultaneous application of DCBs to the main (MB) and side branch (SB) with provisional T-stenting of the MB with a DES, we report first results after DCB only intervention without additional stenting of the MB or SB.

Methods: Between January and July 2011 we performed 47 DCB interventions in bifurcation lesions with SB ≥ 2 mm. Bifurcations were treated with a DCB if they showed an acceptable angiographic result after careful preparation as recommended by the German Consensus Group. All patients were scheduled for follow-up angiography 4 months after index procedure. Patients who did not attend the follow-up were interviewed for MACE within 4 months after index procedure.

Results: Most interventions could be performed according to the planned DCB only strategy without additional stenting (n=42). Follow-up angiograms were obtained in 12 DCB only interventions. Most lesions were de novo lesions (n=30) with 40.6% located in the bifurcation distal left main coronary artery (LM)/left anterior descending artery (LAD)/left circumflex artery (LCX). Others were found in LAD/diagonal branch (21.9%), LCX/obtuse marginal branch (18.7%) or right coronary artery/right posterior descending artery (18.7%). 4 months after index procedure no patient had experienced any MACE. Follow-up angiograms showed restenosis in 3 out of 32 interventions representing 9.4%. 2 restenoses developed in the distal main branch and 1 in the side branch. All 3 patients had received DCB treatment for LM/LAD/LCX bifurcations and suffered from most severe coronary artery disease, but had been non eligible for bypass surgery for various reasons. Conclusions: DCB only intervention without additional stenting seems to be a safe therapy for de novo bifurcation lesions and even LM bifurcations respond favorably.

TCT-409
Impact Of Rotational Atherectomy For Heavily Calcified Unprotected Left Main Disease
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Background: Percutaneous intervention (PCI) for unprotected left main lesions (ULL) is escalating with the improvement in device technology. However, heavily calcified lesions remain one of the main limitations for PCI, which are associated with in-stent restenosis and stent thrombosis. However, there is little data regarding PCI for severe calcified ULM using rotational atherectomy (ROTO). This study aims to evaluate safety and feasibility of PCI using ROTA for ULM.

Methods: Between January 2005 and November 2011, consecutive 63 patients treated with DES implantation using ROTA were included in this study. Study end points are contrast usage, lesion revascularization (TLR) and TLR for main branch (TLMB) including within LM toward LAD at 1-year. Results: Age was 71.3±8.8 years old, male gender is 42 (66.7%), diabetes mellitus is 8 (12.7%), and hemodialysis (HD) is 13 (20.6%). Mean EuroScore was 5.60 and SYNTAX score was 35.5%. There is no peri-procedural death and perforation, while periprocedural MI occurred in 6 (9.5%). At 1-year, cardiac-death occurred in 5 (7.9%) patients and TLR occurred in 16 (25.4%). Notably, TLMB occurred in 9 (14.3%) and was more frequently observed in HD patients as compared to non hemodialysis (non HD) patients (38.5% vs. 4.0%, p=0.001). IVUS finding demonstrated the majority of patients achieved optimal stent expansion with MSA above 8.2cm² at LM and above 6.3cm²at proximal LAD. However, TLMB was necessary in 5 (7.9%) patients on HD despite optimal stent expansion.