cases, respectively in a DES group and BiOSS group, with a stent implanted in SB. Nominal stent parameters were as followed: in BiOSS group: 3.79±0.34x16.2±1.42mm vs 3.57±0.28x18.56 ±4.44mm). Up to now there was no MACE. At the time of TCT we are to finish the enrollment and present initial 3-month clinical follow-up.
Conclusions: Collected data demonstrate comparable immediate clinical results for both studied group. Full data enable to answer the question if BiOSS LIM comparable to regular DES and if it is superior to BiOSS Expert stent assessed in POLBOS study.

TCT-406

Dedicated Bifurcation Stent BiOSS in the Treatment of Distal Left Main Stem Stenosis – Polish and Bulgarian Registry

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Background: Coronary artery disease of left main stem (LMS) is a particular form of atherosclerosis, and the most optimal treatment is still debated. The aim of this study was to assess the effectiveness and safety profile of the distal LMS stenosis treatment with the dedicated bifurcation stent BiOSS: in subgroup I paclitaxel-eluting BiOSS Expert (Balton, Poland) and in subgroup II sirolimus-eluting BiOSS LIM.
Methods: The enrollment of patients with CAD and NSTE-ACS started in January 2010 in two centers in Poland and Bulgaria. Decision for LMS stenting was based on the Heart Team consensus. We are to gather the group of 100 patients equally distributed. Control angiography is planned at 12 month is all patients. The primary end point is the rate of death, myocardial infarction, in-stent thrombosis or target lesion revascularization (TLR) at 12 month after PCI. Here, we present 6-month clinical data.
Results: So far we have enrolled 86 patients (56 in BiOSS Expert group, 30 in BiOSS LIM group). The average age was 62.8 ± 10.1 yrs and 20% were female. PCI was performed in NSTE-ACS in 16% of patients. Moreover, 78% were with hypertension, 60% with dyslipidemia, 24% with diabetes, 37% with prior MI, 45% with prior PCI and 11% with prior CABG. The mean SYNTAX score was 22.97 ± 6.4 and logistic EuroScore – 4.1% ± 2.8% (NS differences between subgroups). All BiOSS stents were implanted successfully. The nominal stent parameters were as followed: subgroup I - 4.01 ± 0.26 mm x 3.37 ± 0.37 mm x 17.67 ± 1.27 mm and subgroup II - 3.98 ± 0.23 mm x 3.23 ± 0.17 mm x 16.87 ± 2.27 mm. Side branch stent was implanted, respectively, in 26% and 23% of patients. 71% of procedures were performed from radial access, whereas 29% from femoral access. In 20% of cases 7F catheter was applied, and in 80% - 6F. At 6 months there were no death or MI. Target lesion revascularization was performed in 4 patients (4.6%) only in BiOSS Expert subgroup.
Conclusions: Dedicated bifurcation BiOSS stents seems feasible devices with promising effectiveness and safety profile in distal LMS bifurcation stenosis. Full angiographic data will answer the question if the used drug is more important or maybe the stent design is crucial.

TCT-407

The ischemia in distal main branch region at the end of coronary bifurcation stenting predicts in-stent restenosis at 12 months follow-up From Intracoronary Electrocardiogram (ECG) and Myonecrosis After Bifurcation Stenting (COSIBRIA&CO) (ClinicalTrials.gov Identifier:NCT01268228)

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Background: There is uncertainty about influence of periprocedural ischemia and myonecrosis on long-term results of coronary artery bifurcation stenting (PCI). Restenosis remains an unresolved issue, and identification of its predictive factors may allow further insight into the underlying process. The aim of the study is to explore the influence of end-procedural ischemia (detected with intracoronary electrocardiography (icECG) and post-procedural myonecrosis (troponin and creatine-phosphokinase – MB (CK-MB) elevation) on revascularization rates (TLR) at 12 months after PCI.
Methods: After placement of intracoronary guidewires in main branch (MB) and side branch (SB) an uninsulated proximal ends of wires were connected to unipolar V leads. Intracoronary unipolar ECGs (icECG) were recorded before, during and after stent placement and at the end of procedure. The maximal ST-segment elevation during intervention and 5 min after the procedure was recorded in SB and MB.
Results: We studied 142 patients with different types of bifurcation lesions with stable/unstable angina: 69% were males, mean age 69±9, diabetics 33.6%. The main treated vessel was LAD (77%). True bifurcation lesions (Medina xx1) were 53%. 131 (92%) patients were followed for more than 12 months. The TLR at 12 months of follow-up was 7.6% (10/131). There was a significant difference in the TLR rate among patients with final ST elevation in the MB territory – MB STE (-): 3.7% (3/82) vs.14.3% (7/49) MB STE (+), p=.032. On the other hand we found no significant difference in TLR among patients with final SB ST elevation – SB STE (+) 8.9% (4/41) vs. 7.0% (6/86) SB STE (-) p=.469. The final ST elevation in the main branch at the end of bifurcation PCI was the only independent predictor for TLR at 12 months on multivariate regression analysis (OR=5.3.19, CI 1.197 – 23.809, p=.028; model including renal failure, CKMB preinterventional, SB final %DS, MB final STE, MB postdilatation, occlusion of secondary branch).
Conclusions: The end-procedural ischemia detected by intracoronary ECG in the main branch territory is a sensitive newly discovered factor for prediction of in-stent restenosis after coronary bifurcation 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 proven to show clinical benefits 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 sequential application of DCBs to the main (MB) and side branch (SB) with provisional T-stenting of the MB with a BMS, 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 to 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 32 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 posteriolateral 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 save therapy for de novo bifurcation lesions and even LM bifurcations respond favorably.

TCT-409

Impact Of Rotational Atherectomy For Heavily Calcificated Unprotected Left Main Disease

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Background: Percutaneous intervention (PCI) for unprotected left main lesions (ULM) is escalating with the improvement in device technology. However, heavily calcificated lesions remain one of the main limitations for PCI, which were associated with in-stent restenosis and stent thrombosis. However, there is a little data regarding PCI for severe calcified ULM lesion using rotational atherectomy (ROTA). 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 procedural success, cardiac death, target lesion revascularization (TLR) and TLR for main branch (TLR-MB) 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 peri-procedural 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, TLR-MB 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 6.3 cm2at proximal LAD. However, TLR-MB was necessary in 5 (7.9%) patients on HD despite optimal stent expansion.

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