POSTERS

TCT-686

T-stenting with Two Drug-Eluting Stents Versus One Drug-Eluting Stent with Side Branch PTCA: Long-Term Pathological Findings in Bifurcation Lesions

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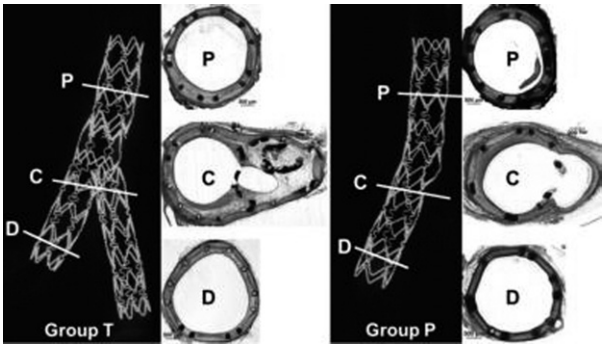
Background: In bifurcations, 2-stent strategy is usually associated with higher restenosis rate than a 1-stent strategy (provisional stenting).
Methods: 15 ovine coronary bifurcations received main vessel Cypher stents and then were allocated to group T (n=8; T-stenting of the side branch with Cypher) or group P (n=7; PTCA of the side branch). At 180 days, the proximal, carina and distal segments of the bifurcation underwent radiographic and histologic evaluation.
Results: All morphometric and qualitative data were comparable between groups at the proximal and distal sections. At the carina section, group T showed a significantly greater degree of neointimal growth (5.06±1.42 mm2 versus 2.21±0.69 mm2, p<0.001) and percent area stenosis (51.4±13.3% versus 31.1±7.2%, p=0.004) compared with group P. Both inflammation score (1.14±0.48 versus 0.36±0.38, p=0.005) and fibrin deposition (14.66±8.17% versus 0.79±2.10%, p<0.001) were significantly higher in group T. Granulomas and giant cells were observed in group T but absent in group P. Stent fracture was more prevalent (87.5% vs. 28.6%, p<0.05) and severe (multiple fracture: 87.5% vs. 14.3%, p=0.01; major fracture: 62.5% vs. 0%, p<0.05) in group T than group P, mostly involving the connectors at the side branches. Neointimal eccentricity was insignificantly higher in group T than group P (0.94±0.06 versus 0.89±0.12, p=0.45).
Conclusions: Compared with balloon angioplasty, side branch T-stenting induced more neointimal growth which was likely related to higher incidence of fractures, persistent inflammation and fibrin deposition.



TCT-687

First-in-man (FIM) study of dedicated bifurcation sirolimus-eluting stent BiOSS (Bifurcation Optimization Stent System) Lim - 9 months results

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Background: The best treatment strategy for a coronary bifurcation stenosis is still unknown. However, dedicated bifurcation stents are the most promising solution. The BiOSS® Lim is a dedicated coronary bifurcation balloon expanding stent made of 316L stainless steel releasing sirolimus from the surface of a biodegradable coating comprised of copolymer of lactic and glycolic acid. The polymer releases sirolimus in a time-controlled process lasting ca 8 weeks. The stent consists of two parts with different diameters connected with two 1.5-mm bridges. The BiOSS stent is mounted on a dedicated bifurcation balloon (Bottle®, Balton, Poland) with markers of proximal and distal stent edges and third marker at the mid part showing the proximal end of its smaller distal part. The stent delivery is a rapid exchange system.
Methods: 35 patients with stable CAD were included into the prospective, feasibility and safety assessment registry. The patients with STEMI or Medina type 001 bifurcation lesions were excluded. The primary end-points of the study were MACEs (in-hospital and after 1, 3, 6, 12 months). An angiographic control was planned at 9 months in all patients. Provisional T-stenting was the obligatory strategy. A double antiplatelet therapy was applied for at least 6 months. Here are presented results up to the 3rd month, however at the time of TCT 2012 9 months data will be available.
Results: The average age of enrolled patients (67% males) was 69±10 years. 18 (51.4%) patients had hypertension, 8 (22.8%) were diabetic, 7 (20%) had a history of prior PCI and 3 (8.6%) patients had previous CABG. The dominant vessel was LAD (40%) followed by LMS (34.3%), LCx (17.1%) and RCA (8.6%). The true bifurcation was present in 68.6%. All BiOSS® stents were implanted successfully (avg. pressure 14atm), without any periprocedural complication. There were only 5 (14.3%) cases with second stent implanted in the side branch. There were 2 (5.7%) MI type 4a. At one and three months all patients were uneventful.
Conclusions: The dedicated bifurcation BiOSS® Lim stent is a feasible device with promising safety and short-term clinical effectiveness. Long-term data are pending.

TCT-688

Treatment of bifurcation lesions with a Drug Eluting Stent with biodegradable polymer.

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Background: Coronary bifurcations are frequently encountered in contemporary interventional practice and clinical outcomes are in general inferior when compared to non-bifurcation lesions. Therefore, our aim was to study the short and long-term safety and performance of the Nobori® drug-eluting stent in this lesion subset.
Methods: NOBORI 2 and eNOBORI are two large, prospective, single-arm, multi-centre registries that enrolled 3067 and 7750 patients respectively, out of which 728 and 616 had at least 1 bifurcation lesion treated (BFL). In NOBORI 2, all bifurcations were included and all adverse events were adjudicated by an independent clinical event committee, while in eNOBORI, only true bifurcations were considered and adjudication is ongoing (including stent thrombosis). The primary endpoint was Target Lesion Failure (TLF) defined as composite of cardiac death (CD), target vessel related myocardial infarction (TV-MI) and target lesion revascularization (TLR). We report short and long term results of patients with BFL compared to patients without BFL treated (NBFL).
Results: In the BFL group, the number of treated lesions was higher (2.4±1.5 vs 2.0±1.6; p<0.001), more complex (B2/C: 73% vs 54%; p<0.001) and more frequently ostial (21.1% vs 11.1%; p<0.001) and located in the LAD (55.0% vs 43.6%) and LM (5.1% vs 1.6%) than in NBFL group. TV-MI (2.1% vs 0.3%) and TLF (2.5% vs 0.7%) rates were higher in the BFL group at 1 month follow-up. In the cohort followed-up to 3-year, TV-MI (3.2% vs 2.1%) and TLR (4.4% vs 3.1%), results remained similar between the groups while cardiac death rate was significantly lower in BFL group (0.8% vs 2.7%, p<0.01). TLF was comparable at 3-year (6.7% vs 6.4%), with a very low number of definite and probable stent thrombosis in both subgroups (0.7% vs 0.9%).
Conclusions: Good short and long-term clinical outcomes with a low rate of TLF and stent thrombosis indicate that Nobori® Biolimus A9 eluting stent, with its specific open cell design and biodegradable polymer, is safe and highly effective for the treatment of challenging bifurcation lesions, despite their complexity and frequent localization in left main coronary artery.

TCT-689

Impact of Final Kissing Ballooning on Stent Expansion, Apposition, and Neointimal Hyperplasia in Coronary Bifurcation Lesions Treated with 1-Stent Technique

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Background: Recent studies did not support mandatory performing of final kissing ballooning (FKB) after main vessel (MV) stenting. We sought to investigate the impact of FKB on stent expansion, apposition, and neointimal hyperplasia in coronary bifurcation lesions treated with 1-stent technique.
Methods: Postprocedural and 9-month follow-up intravascular ultrasound (IVUS) images were studied in 94 bifurcation lesions treated by MV stenting with FKB (FKB group) and in 68 bifurcation lesions treated by MV stenting only (non-FKB group). Analysis included 4 distinct locations, namely, MV proximal stent, MV carina (between the most proximal part of the carina and >5 mm distal to the carina in the MV stent), MV distal stent, and side branch (SB) ostium (>5 mm distal to the carina).
Results: Postprocedural minimum stent area (MSA) of the MV and stent expansion were not significantly different in both groups (6.1±2.1 mm2 versus 5.7±1.6 mm2, p=0.11, and 98.1±23.8% versus 96.6±29.1%, p=0.72, respectively). Inadequate stent apposition tended to be found less frequently in the FKB group than in the non-FKB group (3.2% versus 10.3%, p=0.09). At follow-up, minimum lumen area of the MV was not significantly different between the 2 groups (5.3±2.2 mm2 versus 5.0±1.6 mm2, p=0.26). No significant differences in the percent neointimal area were observed between the 2 groups.