TCT-306
Use Of The Novel Sideguard Dedicated Bifurcation Stent; A Real World Experience

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Background: PCI treatment of bifurcation disease is technically challenging and associated with both lower procedural success and higher MACE rates than observed in non-bifurcation lesions. The optimal treatment strategy for bifurcation lesions remains unclear and dedicated bifurcation stents have been developed to address some of the challenges associated with bifurcation lesions. The Sideguard stent is a novel nitinol self-expanding dedicated bifurcation stent that flares proximally at the ostium of the side branch (SB) thereby achieving full ostial coverage. The aim of this study is to report clinical utility and outcomes of the Sideguard stent in patients undergoing treatment to bifurcation coronary lesions in a real world setting in a large tertiary UK centre.

Methods: Data was prospectively collected from over a 1-year period from March 2010-2011.

Results: Over a 1-year period, 1630 PCI procedures involving 1954 lesion were performed in our centre of which 315 were bifurcation lesions (16.1%); 246 were treated with single stent strategy (78.1%) whilst 69 were treated with 2 stent strategy (21.9%). 90 lesions were treated with the Sideguard dedicated side branch stent in 38 patients. The mean age of the patients was 58.2±12.0 years old (men=SD) and 35/40 lesions were true bifurcation lesions (87.5%). The sideguard stent was successfully used in all 38 cases including several that would have been technically difficult using conventional bifurcation techniques. There were no peri-procedural complications and MACE event rates were 5.3% at 1 year (TVR at 3 months in 1 patient and MI at 7 months in a second patient).

Conclusion: In one of the largest clinical experiences to date, the Sideguard stent can be used to treat complex bifurcation lesions in a straightforward manner, with excellent short and long term clinical outcomes and is not subject to the limitations associated with conventional bifurcation PCI techniques such as maintenance of access to the SB, having a guidewire secured in the main vessel throughout the procedure and ability to fully cover the ostium of the SB.

TCT-307
Impact of Acute Coronary Syndrome on Clinical Outcomes in Patients with Coronary Bifurcation Lesions Treated with Drug-Eluting Stents

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Background: No prior study has addressed the impact of clinical presentations on outcomes in patients with coronary bifurcation lesions. Therefore, we examined the independent prognostic value of acute coronary syndrome (ACS) in patients with coronary bifurcation lesions treated with drug-eluting stents (DES).

Methods: We enrolled 1,668 patients, using data from “The COBIS (Coronary Bifurcation Stenting) registry”. The primary objective was to compare the 2-year cumulative risk of major adverse cardiac events (MACE) in patients with ACS to those with stable angina.

Results: Nine hundred sixty nine patients presented with ACS and 699 patients presented with stable angina. Baseline clinical, angiographic and procedural characteristics of the 2 groups are listed in Table. Two-year MACEs were 7.3% in patients with ACS and 5.2% in stable angina patients (p=0.04), mainly driven by higher TLR rate. However, cardiac death, MI, TLR, and stent thrombosis (ST) were similar in non-bifurcation lesions. The optimal treatment strategy for bifurcation lesions associated with both lower procedural success and higher MACE rates than observed in non-bifurcation lesions. The optimal treatment strategy for bifurcation lesions remains unclear and dedicated bifurcation stents have been developed to address some of the challenges associated with bifurcation lesions. The Sideguard stent is a novel nitinol self-expanding dedicated bifurcation stent that flares proximally at the ostium of the side branch (SB) thereby achieving full ostial coverage. The aim of this study is to report clinical utility and outcomes of the Sideguard stent in patients undergoing treatment to bifurcation coronary lesions in a real world setting in a large tertiary UK centre.

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Conclusion: In one of the largest clinical experiences to date, the Sideguard stent can be used to treat complex bifurcation lesions in a straightforward manner, with excellent short and long term clinical outcomes and is not subject to the limitations associated with conventional bifurcation PCI techniques such as maintenance of access to the SB, having a guidewire secured in the main vessel throughout the procedure and ability to fully cover the ostium of the SB.

TCT-308
Left Main Bifurcation Stenting: Long Term Followup of Simultaneous Kissing Stents in 140 Consecutive, Unselected Patients

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Background: Stenting the left main stem (LMS) is accepted. Most lesions involve the bifurcation. Whilst a single stent strategy is established generally, this is not the case at the LMS bifurcation. We present the results of simultaneous kissing stenting (SKS) for this indication.

Methods: A single operator registry. We treated consecutive, unselected patients with bifurcation LMS disease a multi- vessel disease with SKS and maximal revascularisation, from 2004, using drug-eluting stents (DES) and recorded clinical status at baseline, 30d, and 1 and 2 years.

Results: 140 patients completed 1 year follow-up. Mean age was 67 years, 75% were male, 35% were non-elective, the New York Risk Score estimation of in-hospital mortality was median 0.6% (range 0.1-64) and EuroSCORE 2.6 (0.9-6.7). SKS were deployed successfully in 100% cases and DES in 94.3%. 2.0±0.9 other vessels were diseased and 1.9±0.8 treated. The 30d mortality was 6% [NY Risk 2(0.6-64)] and all deaths were in the acute coronary syndromes. The mortality rate at 1 year was 11% (2% elective), and at 2 years 13%. 8/10 out-of-hospital deaths were attributable to probable (1) or possible (7) stent thrombosis and 7 were not surgical candidates. Ischemia-driven TVR was 4% at 1 year, and 6% at 2 years. There was 1 stroke, 1 STEMI and no emergency CABG at 2y.

Conclusion:SKS of 1.1,1 LMS bifurcation stenosis

TCT-309
Outcomes Following Unprotected Left Main Stenting with Everolimus-Eluting Stents: the Milan Experience

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Background: Second-generation drug-eluting stents for the treatment of coronary artery disease (CAD) are believed not only to be more effective but also safer. Our aim was to assess the clinical outcomes after everolimus-eluting stent (EES) implantation in patients undergoing percutaneous coronary intervention for unprotected left main CAD.

Methods: All consecutive patients from our single-center prospective registry treated for unprotected critical left main stem stenosis with EES implantation from October 2006 to June 2010 were analyzed. The study endpoints were all-cause mortality, myocardial infarction (MI), major adverse cardiac event (MACE), target vessel revascularization (TVR), target lesion failure (TLF) and target lesion revascularization (TLR).

Results: A total of 62 patients were included: the mean age was 67±11.4 years and 75.8% were male. The mean clinical follow-up was 723.5 days (interquartile range 265.8–1073.0 days). 53.2% underwent PCI with Xience V/Xience Prime (Abbott Vascular, Redwood City, California, USA) and 46.8% with Promus/Promus Element™ (Boston Scientific, Natick, MA, USA). 43.5% of patients had left main stenosis associated with triple vessel coronary artery disease and the mean left ventricular ejection fraction was 55±8 8.1%. Regarding the procedure, 21.0% had an intra-aortic balloon pump inserted prior to intervention and intravascular ultrasound guidance was
utilized in 58.1% of cases. Furthermore, a 2-stent strategy was used as the initial strategy in 40.3% of procedures with final kissing balloon inflation successfully performed in 74.2%. At 30 days, there was one (1.6%) incidence of TLF, with no other adverse events. Overall, all cause mortality occurred in 6.5% at follow-up with no MI or definite/probable stent thrombosis. Moreover, MACE occurred in 21.0% of patients, with TVR in 16.1%, TLF in 4.8% and TLR in 4.8%.

Conclusion: The new EES appear to be safe and effective for the treatment of unprotected left main stem stenosis at median follow-up of 723.5 days. Clearly this needs to be demonstrated at longer-term follow-up.

TCT-310
Treatment of bifurcations with the dedicated Sideguard nitinol stent compared with conventional 2-stent strategies
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Background: Clinical observations revealed that strut malapposition and Side Branch (SB) occlusion is common after bifurcations treatment with PCI. Current techniques for bifurcation stenting seem to fail to ensure scaffolding of the SB and complete apposition of stent struts in the bifurcation. Struts floating in the ostium can disturb blood flow and increase risk of focal restenosis and stent thrombosis, limiting the success of stent procedures in bifurcations lesions.

Methods: The dedicated Sideguard stent (Cuppella Medical Device, Galway, Ireland) was deployed as SB stent in 2 coronary bifurcation bench models (45° and 70° SB angle). Commercially available drug eluting stents were used as Main Vessel stents and malapposition quantified from micro-CT with the Sideguard dedicated SB nitinol stent (2.5mm and 2.0mm diameter) was compared with conventional 2-stent stenting techniques (crush, n=5; cutout, n=3 and t-stenting, n=2).

Results: Rate of malapposed struts within the bifurcation after kissing balloon post-dilatation using the same balloon sizes and inflation pressure was on average 36.7 ± 8.6% with conventional techniques, reduced to 16.4 ± 7.5 % with the Sideguard (p=0.0008). Area of the SB ostium jawed by stent struts was reduced to 8.3% when using the Sideguard compared to an average of 32.8% after conventional 2-stent techniques (p=0.0004). Furthermore, the Sideguard device avoid overlap of multiple stent layers, resulting in less strut malapposition in the Main Vessel proximal to the SB compared to crush or cutout technique (8.2% vs. 39.1%, p=0.0018 and 26.1%, p=0.024).

Conclusion: Use of the Sideguard as SB stent may offer complete stent scaffolding of the SB ostium while reducing struts malapposition in the bifurcation ostium and proximal to the SB compared to conventional 2-stent approaches.

TCT-311
Healing Responses After Bifurcation Stenting with the Dedicated TRYTON Side-branch Stent in Combination with XIENCE V Stents: an Angiography and Optical Coherence Tomography Study
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Background: There is an ongoing controversy regarding the efficacy and safety of different bifurcation stenting techniques, and dedicated bifurcation stents have been proposed as a potential alternative. We evaluated healing responses, as assessed with optical coherence tomography (OCT), and clinical and angiographic outcome, 9 months after percutaneous coronary intervention (PCI) of coronary bifurcation lesions with the dedicated TRYTON Side-Branch Stent.

Methods: Consecutive patients with coronary bifurcation lesions and significant involvement of the side-branch underwent PCI with the TRYTON Stent and an additional XIENCE V stent in a modified cutout technique. Primary endpoint of the study was the ratio of uncovered to total stent struts at the lesion site, as assessed with OCT 9 months after PCI. Secondary endpoints were the rate of in-segment restenosis and late lumen loss at 9 months, as assessed with quantitative coronary angiography (QCA). Clinical endpoints included the rate of target lesion revascularization (TLR), target vessel revascularization (TVR), myocardial infarction (MI), cardiac death, and stent thrombosis at 1 year.

Results: Between January and June 2010, 20 patients (mean age 68±10; 65% male, 25% diabetes, 95% LAD/Diagonal) were included. Implantation of the TRYTON stent was successful in 18 (90%). Failures were due to inability to cross the bifurcation with TRYTON in 1, TRYTON dislodgment during removal of jailed wire in the other. Angiographic follow-up was available in 18 (90%) at 9.7±4 months. OCT was performed in 15 (75%), two additional patients with severe restenosis precluding OCT, 1 without TRYTON stent). At 1 year, 6 patients had undergone TLR (30%), of which 4 were TLR (20%). Three of these restenoses were silent. Four occurred at the proximal main branch stent edge. Five patients suffered MI (25%), 4 of which were periprocedural and without clinical consequences. There were no deaths nor stent thromboses.

Conclusion: In patients with complex bifurcation anatomy, a TLR rate of 20% was seen after implantation of the dedicated first generation TRYTON Side-Branch Stent in combination with XIENCE V stents. OCT and QCA may help to understand healing responses and failures. Nine months’ OCT and angiographic follow-up will be presented.

TCT-312
Effect and mechanisms of coronary bifurcation angle from 3-D on clinical outcomes after percutaneous treatment with stents-results from DKCRUSH-Ii trial
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Background: The role of bifurcation angle (BA) in predicting clinical outcomes after stenting bifurcation lesions remains to be unclear. The aim of the present study was to investigate the dynamic change of BA and its predictive value for patients with coronary bifurcation lesions treated by stents.

Methods: 347 patients were completely studied from our DKCRUSH-II study. BA was calculated by 3-D quantitative coronary analysis. Primary endpoint was the occurrence of composite major adverse cardiac events(MACE) at 12-month, including cardiac death, myocardial infarction(MI) and target vessel revascularization(TVR).

Results: Stenting was associated with increase of proximal BA (153.6 ± 21.490) and the reduction of distal BA. The cut-off value of distal BA for predicting MACE was 600. Distal BA in <600 group had slight reduction after stenting (-1.96±21.380 vs. -12.12±23.580, p=0.001); two-stent technique was associated with significant reduction of distal BA (14.45±14.200, compared to PS group [13.51±13.73], p=0.003); the TLR, TVR and MACE rate was 16.5%, 19.0% and 21.5% in one-stent group (n=79), compared to 3.8% (p=0.002), 7.5% (p=0.016) and 9.8% (p=0.024) in two-stent group (n=133), respectively, further, the rate of TLR, TVR and MACE in DK group (n=108) was 2.8%, 6.5%, and 8.3%, compared to 14.4%, 17.3%, and 20.2% in PS group (p=0.003, p<0.019, and p=0.017). Among patients inno600 group, there were no differences in distal BA, ST, MI, MACE, death, TVR and LVT between one-vs. two-stent groups; after stenting procedure, there was only slight change of distal BA in LAD-LCX subgroup (from 88.540±21.330 at baseline to 82.440±31.720 post-stenting), compared to either LAD-D, or LCX-OM, or RCA (all p>0.01).

Conclusion: Complex stenting was associated with significant reduction of distal BA. Two-stent, as DK crushing stenting, had reduced rate of MACE in patients in <600 group, compared to one-stent technique.

TCT-313
Clinical Outcomes of Left Main Crossover Stenting without Opening of Left Circumflex Coronary Artery
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Background: Simple crossover stenting in non-left main (LM) bifurcation lesion without opening of stent strut in the ostium of side branch demonstrated a favorable outcome. However the safety and efficacy of the same strategy for LM crossover stenting has not been validated yet.

Methods: Among the patients who successfully underwent LM to LAD crossover stenting due to LM or ostial left anterior descending coronary artery (LAD) disease, the clinical outcomes of the patients with non-significant residual stenosis (<70%) in ostial LCX after stenting were evaluated. The 3-year outcome analyzed by the composite of cardiac death, myocardial infarction, repeat revascularization, and stent thrombosis.

Results: Among the included 106 patients, 88 (83%) patients were deferred without any additional procedure in ostial LCX. Preinterventional and post-75% diameter stenosis (DS) of ostial LCX were 23±14% and 33±16%, respectively (p<0.001). The rate of MACE was 11.4% (cardiac death 4.5%, myocardial infarction 2.2%, repeat revascularization 9.1%, and stent thrombosis 2.2%, respectively). Purely ostial LCX related MACE was 20%. Event free survival curve was obtained (see the attached figure).