TCT-573
Randomized comparison of Biolimus-eluting (Nobori) and Everolimus-eluting (Xience/Promus) stents in patients with multivessel coronary artery disease: 12-month follow-up data from COMPARE II study
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Background: The role of percutaneous coronary intervention (PCI) in the treatment of multivessel coronary artery disease (CAD) is still controversial and widely discussed. More liberal use of drug-eluting stents (DES) increased proportion of those patients undergoing PCI procedure, raising a need for more clinical evidence. The recent reported COMPARE II trial showed similar results of Biolimus-eluting Nobori stent (BES) and Everolimus-eluting Xience/Promus stent (EES) at 1-year in an all comers population. We aim to compare safety and efficacy outcomes in patients with multivessel CAD (a pre-specified study subset) treated with BES and EES in COMPARE II trial.

Methods: COMPARE II trial is a large randomized, multicentre, non-inferiority trial with total of 2707 patients enrolled at 12 sites across Europe, randomized in 1:2 ratio to the treatment with BES vs. EES with similar 12 months dual antiplatelet therapy. Primary endpoint was the composite of cardiac death (CD), non-fatal myocardial infarction (MI) and target vessel revascularization (TVR).

Results: Total of 683 patients with multivessel CAD have been enrolled in COMPARE II, 590 patients were in the BES and 230 in EES arms. There were no significant differences in baseline characteristics such as age (64.3 vs. 63.7; p=0.4), male gender (78.2% vs. 78.7%; p=0.9), or presence of diabetes mellitus (23.0% vs. 25.7%; p=0.4) in BES and EES arms respectively. The lesion length and reference diameters were also similar. At 12 months, rate of CD (1.1% vs 1.3%; p=1.0), MI (4.4% vs 5.7%; p=0.5), target lesion revascularization (4.2% vs 2.6%; p=0.04), TVR (5.7% vs 3.9%; p=0.4), target lesion failure (6.8% vs 7.4%; p=0.9) and composite of CD, non-fatal MI and TVR (6.8% vs 9.1%; p=0.09) were similar in BES and EES arms, Definite and propable stent thrombosis rate up to 12-months was also not different (1.1% in BES vs 1.3% in EES arm; p=1.0).

Conclusions: Although this substudy was not powered to detect differences between the two stents, the BES with biodegradable polymer, was found as safe and effective as the EES even in this challenging patients population. This adds valuable evidence about two stents, the BES with biodegradable polymer, was found as safe and effective as the EES.

TCT-574
Drug-eluting stent with biodegradable polymer in patients with STEMI – short and long term outcomes: data from e-NOBORI and NOBORI 2 trials
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Background: Use of Nobori, DES with biodegradable polymer, in the treatment of patients with STEMI was associated with favorable short- and long-term outcomes, confirming its safety and efficacy for the treatment of this high risk patient population.

TCT-575
Different Vessel Healing Patterns Following Delivery of Everolimus and Paclitaxel Eluted from Biodegradable Polymer Coated Stents Implanted in Porcine Coronary Arteries
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Background: The impact on healing and clinical outcomes of the individual DES components is still under debate. The aim of this study is to assess vascular effects exclusive to the type of antiproliferative drug, eluted via identical biodegradable polymer and form of stents implanted in the porcine model. The impact of type of antiproliferative drug, eluted via identical biodegradable polymer and form of stents implanted in the porcine model was examined. We selected stents each containing similar neointimal catch up phenomenon after paclitaxel and favorable long term biocompatibility, healing and efficacy after everolimus.

Methods: A total of 37 stents were implanted with 110% overstretch in coronary arteries of 14 domestic pigs: 13 biodegradable polymer coated paclitaxel eluting stents (BP-PES: LUC-Chopin2, Balton), 16 biodegradable polymer coated everolimus eluting stents (BP-EES: Carlo, Balton) and 8 control bare metal stents (BMS: Chopin2). Following 30 and 90 day observation (7 animals each) control coronary angiography was performed, animals sacrificed and stented segments harvested for histopathological evaluation.

Results: At 30 days, BP-PES most effectively limited angiographic late loss (PES: 0.40, EES: 0.43 vs. BMS: 0.5[0.5-0.2], p=0.04). This findings were confirmed with the least neointimal formation in BP-PES in histology expressed as neointimal thickness (NT): EES: 0.38 [0.3-0.4] vs PES: 0.12 [0.1-0.2] vs BMS: 0.35 [0.3-0.4] mm, p<0.01 at a cost of significantly delayed endothelialisation (EES:100% vs PES:40:4% vs BMS:97.5%±5% vs<0.01) and higher inflammation (EES:1 vs PES: 2.1±1.3 vs BMS:1±0.01). At 3 months late loss was numerically lowest in everolimus stents (EES: 0.38±0.3 vs PES: 0.52±0.4 vs BMS:0.51±0.3 mm; p=0.69). Compared to one month, neointimal proliferation stabilized in EES, with lowest NT among groups, whereas it increased fourfold in BP-PES and 30% in BMS (EES: 0.35[0.3-0.5] vs PES: 0.53[0.5-0.8] vs BMS: 0.46[0.4-0.5] mm; p<0.01). Endothelialization was complete and inflammation low in all studied stents.

Conclusions: Different patterns of vascular response were observed emphasizing different properties of locally delivered drug, with typical neointimal catch up phenomenon after paclitaxel and favorable long term biocompatibility, healing and efficacy after everolimus.
TCT-577

COMPARE II – 1 Year Outcomes of a large randomized all-comers study

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Background: The newer generation drug eluting stents (DES) have shown advantages over first generation DES, particularly relating to long term safety. However, comparative data for contemporary DES is still insufficient. We aim to compare safety and efficacy between Nobori DES, eluting Biolimus A9 from an abulminable biodegradable polymer (BES) and Xience/Promus DES eluting everolimus from a permanent polymer (EES).

Methods: COMPARE II, a prospective, randomized (2:1), controlled, multi-centre study, enrolled 2578 patients (1795 arm with BES and 782 with EES) with limited exclusion criteria. The primary endpoint was a composite of safety (cardiac death, non-fatal myocardial infarction-MI) and efficacy (target vessel revascularization-TVRS) at 1 year. Dual anti-platelet therapy was 12 months for both arms. The primary hypothesis was non-inferiority of BES vs EES. Data were independently monitored and adverse events were adjudicated by an independent clinical event committee.

Results: No significant differences were detected for any of the baseline characteristics. The patients (74% male) were ~63 years old. 22% had diabetes mellitus, 20% history of MI, 18% and 6% respectively had prior PCI or CABG. In both groups 58% of patients were treated for de novo coronary lesions, 33% for stented lesions. The BES and EES were similar (B2C: 63.6%, 14% ostial, 6% bifurcated, 20% thrombosed. Lesions were longer in EES (17.7mm vs. 16.4mm in BES, p=0.02), while mean number of stents per lesion was similar (1.4±0.8). The 1 year primary endpoint was 5.2% in BES arm vs 4.8% in EES arm, confirming the hypothesis of non-inferiority hypothesis (p=0.0001). There were no significant differences in any of the secondary endpoints: 0.8% vs 0.8% patients suffered cardiac death, 2.8% vs 2.5% had a MI, 2.9% vs 2.2% underwent TVR, and 2.7% vs 2.2% TL from the BES and EES arm respectively. Definite and probable stent thrombosis rate was 0.8% in BES and 1.0% in EES. Conclusions: In the largest prospective randomised all-comer trial, the Nobori BES is non-inferior compared to the Xience/Promus EES. Primary and secondary endpoints in this real-life population were not significantly different between both stent groups, with similar, low cardiac death and ST rates.

TCT-578

First-in-human Evaluation of a Novel Sirolimus-eluting Stent with a Bioabsorbable Polymer for the Treatment of Single, De Novo, Non-complex Coronary Lesions

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Background: Despite the marked efficacy of first generation drug-eluting stents (DES) on reducing neointimal hyperplasia (NIH), restenosis, and the need for repeat target lesion revascularization (TLR) compared to bare metal stents, concerns regarding deliverability, efficacy, and long-term safety led to the development of new DES technologies. The BioMim™ device (Meril Life Sciences Pvt. Ltd., Gujarat, India) is a novel DES system that incorporates an ultra-thin stent platform (0.026" strut thickness), a biodegradable polymer and sirolimus. We report the initial human evaluation of the BioMim™ stent for the treatment of de novo coronary lesions.

Methods: The mer-T1 trial was a prospective, non-randomized, single-arm, single-center first-in-man evaluation of the safety, feasibility and performance of the novel BioMim™ SES for the treatment of coronary lesions. Lesion criteria were single de novo stenosis 50% by BMI and measured in native vessels 2.5-3.5mm in diameter and <19mm in length. Left main and bifurcation lesions, in-stent restenosis, thrombus and total occlusion were excluded. Clinical follow-up (FU) at 1.8-12 and 24 months, and all patients were assigned to 8-month angiographic FU. Primary endpoint was in-stent late lumen loss (LLL) at 8 months. MAC (major adverse cardiac events) was defined as cardiac death, MI and renal failure. MACE (major adverse cardiovascular events) was defined as cardiac death, MI and repeat TLR.

Results: A total of 30 patients/lesions. Mean age 49.9 years, 30% diabetics, and 43% had previous MI. By angiographic analysis, baseline median lesion length, reference diameter and % diameter stenosis 15.51mm (12.74-20.27), 2.94mm (2.71-3.33), and 80.5 (67.0-90.7), respectively. Overall, 30 stents implanted (1 stent/lesion). Angiographic success (residual stenosis <20% + final TIMI flow grade 3) and procedural success (angiographic success without MACE in index hospitalization) were 100%. At 8 months FU (26/30), in-stent LLL was 0.15mm (0.09-0.33); with no binary restenosis. Clinical FU at 12 months (30/30) showed no MACE or stent thrombosis.

Conclusions: In this first-in-human evaluation the novel BioMim™ SES had excellent performance with high procedural success and efficacy on inhibiting NIH at 8 months. There were no MACE or stent thrombosis up to 1 year.

TCT-579

One year clinical outcome of biodegradable and permanent polymer drug-eluting stents for multivessel disease or long lesion (≥28mm) in patients with stable and unstable angina

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Background: New generation drug eluting stents (DES) which release everolimus or zotarolimus have been shown to be safe and effective, but these permanent polymer DESs also increase potential risk because of inflammatory reaction and delayed healing. In this point, biodegradable polymer biolimus-eluting stent (BES) could enhance clinical outcomes. The purpose of this study was to compare 1 year clinical outcome of everolimus-eluting stent (EES), zotarolimus-eluting stent (ZES) and BES in multivessel disease or long lesions.

Methods: Of total 3089 patients in single tertiary hospital from Jan 2008 to May 2011, 604 patients who treated with DES in multivessel (≥2 vessels) or long lesion (≥28mm) who presented with stable or unstable angina were enrolled. Major adverse cardiovascular event (MACE) was defined as composite endpoints of death, myocardial infarction (MI) and revascularization through 12 month.

Results: BES, EES and ZES were implanted in 149 (24.7%), 270 (44.7%) and 185 (30.6%) patients. Demographics, past history and medications were not different among 3 groups. Total number of stents was similar (BES 2.2±1.0, EES 2.3±1.2 and ZES 2.2±1.3, p=0.755) but there were differences in stent diameter (BES 3.01±0.30, EES 3.11±0.36, ZES 2.99±0.41, p=0.002) and stent length (BES 45.4±18.7, EES 52.0±27.1 and ZES 52.8±30.2, p=0.017). 1 year MACE showed no significant differences among groups (BES 26.3%, EES 44.7%, ZES 28.9%, p=0.096). There were no differences in death, MI and revascularization.

Conclusions: In multivessel or long lesion, biodegradable polymer and permanent polymer DES showed similar clinical outcomes at 1 year. Long-term follow-up is warranted to discriminate clinical safety and efficacy.

TCT-580

COMPARE II: 1 Year Clinical Data of the Treatment of Long Lesions (>20mm)

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Background: Treatment of long lesions (LL) remains a challenge in interventional cardiology, with a high proportion of restorosity to restorosity. Our aim was to evaluate the clinical outcomes of the patients with LL treated with a Nobori biolimus eluting stent (BES) versus patients treated with an everolimus eluting stent (EES) in a real world / all-comer situation as an substudy of COMPARE II trial.

Methods: Within the prospective, randomized, multi-center COMPARE II study, a total of 667 patients with long lesions (>20 mm) were treated, of which 403 were randomized 2:1 to the Nobori BES and 224 to the Xience EES. The primary endpoint was the composite of safety (cardiac death, non fatal myocardial infarction) and efficacy (target vessel revascularization) at 12 months. Data was independently monitored and all adverse events were adjudicated by an independent clinical event committee.

Results: Baseline demographics were very similar between the two study arms: no differences were found in risk factors except for current smoking (31.1% in BES arm vs 23.2% in EES arm; p<0.05). Lesions were complex (B2C: 77.2% vs 75.3%), with a high incidence of chronic total occlusion (35.4% vs 39.3%), ostial location (13.0% vs 11.3%) and thrombus present (16.8% vs 13.9%). The mean lesion length (mm) was 24.6±12.3 in the BES arm versus 25.2±12.6 in the EES arm, treated with 1.67±0.90 vs 1.57±0.80 stents per lesion, respectively. At 12 months follow-up, the primary