TCT-12
Short Versus Long-Term Clinical Outcomes In A Randomized Comparison Of Zorotimus- and Sirolimus-Eluting Coronary Stents
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Background: The primary endpoint of head-to-head comparisons of coronary drug-eluting stents is traditionally assessed after 9-12 months. However, the optimal time point for assessment of the primary endpoint remains unsettled.

Methods: We randomized 2,332 patients to zorotimus-eluting Endeavor™ stent (E-EES, n=1,162) or sirolimus-eluting Cypher™ stent (C-EES, n=1,170) implantsation. Endpoints included a composite of cardiac death, myocardial infarction or target vessel revascularization (MACE) and definite stent thrombosis. This trial is registered with ClinicalTrials.gov, number NCT0060478

Results: At 5-year follow-up, MACE rates were similar in patients treated with E-EES and C-EES (197 [17%] vs. 182 [16%]; odds ratio [OR]=1.10, 95% confidence intervals [CI]: 0.88-1.37; p=0.40). This finding reflected oppositely directed MACE rates within year 1 (93 [8%] vs. 46 [4%]; OR=2.13, 95% CI: 1.48-3.07; p<0.001) and year >1 through 5 (104 [10%] vs. 136 [12%]; OR=0.78, 95% CI: 0.59-1.02; p=0.071). Definite stent thrombosis was more frequent after E-EES than C-EES implantation at 1-year (13 [1.1%] vs. 4 [0.3%]; OR=3.34, 95% CI: 1.08-10.3; p=0.036) while the opposite was found for year >1 through 5 (1 [0.1%] vs. 21 [1.8%]; OR=0.05, 95% CI: 0.01-0.35; p=0.003). In the E-EES and C-EES group, 26 of 88 (30%) and 54 of 70 (77%) of target lesion revascularisations occurred between 1 and 5 years, respectively.

Conclusions: A traditional 1-year primary endpoint is insufficient to predict 5-year clinical outcomes in patients treated with coronary drug-eluting stent implantation. Long-term clinical data from routine clinical care populations should be a prerequisite for unrestricted use of new coronary drug-eluting stents.

TCT-13
Final Five Year Results From The All-comer COMPARE Trial: A Prospective, Randomized Trial of Everolimus-Eluting vs. Paclitaxel-Eluting Stents
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Background: Longterm results with drug eluting stents are important considering late differences in stent thrombosis, neoatherosclerosis and catch-up phenomena that has been observed in several stent studies. Furthermore, little is known of longterm results with the everolimus-eluting stent, specifically in comparison with the paclitaxel-eluting stent.

Methods: 1800 consecutive patients scheduled for PCI have been randomized to receive a Xience V® (EES) or Taxus Liberté® (PES) stent. Inclusion criteria were: patients eligible for PCI and a life expectancy of >5 years. Major exclusion criteria were: no expected dual platelet therapy for 12 months, cardiac shock at presentation, planned major surgery within 1 month. The primary end point is the composite of: all death, non fatal myocardial infarction (MI) and target vessel revascularization (TVR) at 12 months. The secondary end points are: A) The combined endpoint of cardiac death, MI, ischemic driven target lesion revascularization rate at 12 months follow-up, B) the combined endpoint of all death, MI and TVR rate at 3 and 5 years follow-up.

All patients will be monitored to up 60 months follow-up. Adjudication of events and core lab analysis of unscheduled angio is done independently by Cardialysis, Rotterdam, The Netherlands. A post-hoc SYNTAX score analysis will be done in the subgroup of multivessel and/or left main treated.

Results: No differences in patient baseline characteristics and lesion characteristics were present between both groups. Clinical presentation was similar in both groups (EES versus PES: Stable angina 40 vs 41%, Unstable angina 12 vs 12%, Non STEMI 22 vs 24%, STEMI 27 vs 23%, respectively). Overall 1.4 lesions per patient have been treated with an average of 1.6 stents per lesion and an average 2.3 stents per patient, reflecting real world situation with pronounced vessel disease patients. The adjudication of events between 3 and 5 year follow-up is in progress and will be ready first week September 2013.

Conclusions: COMPARE is the first trial that will show adjudicated longterm data of EES and in comparison to PES. These 5 year results may have clinical implications, specifically for those patients with high SYNTAX scores.

TCT-14
Very Long-term Results of BioFreedom First-In-Man, a Randomized Trial comparing Polymer-Free BioFreedom™ stents with Durable Polymer Taxus Liberté™ Stents
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Background: US guidelines currently recommend 12 months of uninterrupted DAPT after implantation of DES. Prolonged and more powerful DAPT regimens have been shown to reduce the risk of bleeding. There is an emerging need for new stents that are less dependent on prolonged DAPT. The BioFreedom™ stent (BFD) releases Biolimus A9™, without using a polymer or binder. Based on animal model, 98% of the drug diffuses to the vessel wall within 1 month, leaving a BMS in place. It is reasonable therefore to consider that the stent offers a potential safety advantage and a reduced need for prolonged DAPT compared to a polymer based DES. This First-In-Man trial aims to demonstrate the safety and effectiveness of the BFD compared to the Taxus Liberté™ paclitaxel-eluting stent (PES).

Methods: The BioFreedom FIM is a prospective, multi-center, randomized trial. 182 patients were enrolled and randomized to BFD Standard Dose (SD, 15.6 µg/mm), or BFD Low Dose (LD, 7.8 µg/mm), or Taxus Liberté™ DES. The primary endpoint was in-stent Late Loss (LL) at 12 months. The main secondary endpoints are IVUS volumetric analysis at 4, 12 and 36 months; MACE (death, MI, emergent bypass of clinically-driven TLN) and ST rates (ARC defined) at 30 days, 4 years and then yearly up to 5 years.

Results: The in-stent LL was non inferior in BFD SD (p non-inferiority = 0.001) and trended towards superiority with medians of 0.17mm [0.09, 0.39] vs. 0.35mm [0.22, 0.49] (p=0.003). In the E-ZES and C-SES group, differences in stent thrombosis, neo-atherosclerosis and catch-up phenomena that is observed within 3 years. An ongoing trial is studying the possibility of using this stent in patients with high bleeding risk, unable to tolerate a prolonged course of DAPT. The BioFreedom FIM 4-year follow-up will be reported for the 1st time during this presentation.

Conclusions: The safety and efficacy of the polymer free BioFreedom has been shown out to 3 years. An ongoing trial is studying the possibility of using this stent in patients with high bleeding risk, unable to tolerate a prolonged course of DAPT. The BioFreedom FIM 4-year follow-up will be reported for the 1st time during this presentation.