BACKGROUND Prolonged dual antiplatelet therapy (DAPT) after coronary stent implantation is associated with higher risk for bleeding. Second-generation drug-eluting stents (G2-DES), cobalt-chromium everolimus-eluting stent (CoCr-EES) in particular, are reported to have lower risk for stent thrombosis (ST) compared with first generation DES or bare-metal stents. Therefore, the optimal DAPT duration after CoCr-EES implantation could be shorter than 6-12 months currently recommended in the guidelines. However, there has been no prospective study evaluating DAPT duration shorter than 6 months after CoCr-EES implantation.

METHODS STOPDAPT study is a prospective multicenter single-arm registry enrolling patients who agreed to follow the 3-month DAPT protocol (discontinuation of clopidogrel at 2- to 4-month and aspirin monotherapy thereafter) after successful CoCr-EES implantation. The primary endpoint was a composite of cardiovascular (CV) death, myocardial infarction (MI), stroke, definite ST and TIMI major/minor bleeding at 1-year. As a historical comparison group, we selected the CoCr-EES group in the RESET trial comparing CoCr-EES with sirolimus-eluting stent conducted in 2010, where nearly 90% of patients had continued DAPT at 1-year. With the 6.6% of performance goal based on the event rate of 4.4% in the RESET trial, a total of 1500 patients would yield 95% power at a level of one-sided type 1 error of 0.025.

RESULTS Between September 2012 and October 2013, a total of 1525 patients were enrolled in the study from 58 participating centers across Japan, and 1-year follow-up was completed in 1519 patients (99.6%). Thienopyridine was discontinued within 4-month in 1444 patients (94.7%). The event rates beyond 3-month were very low (CV death: 0.5%, MI: 0.1%, definite/probable ST: 0%, stroke: 0.7%, and TIMI major/minor bleeding: 0.8%). Cumulative 1-year incidence of the primary endpoint was 2.8% (Upper 97.5% confidence interval [CI] 3.6%), which was lower than the pre-defined performance goal of 6.6% (P<0.0001). Compared to CoCr-EES group in the RESET trial, cumulative incidence of the primary endpoint tended to be lower in the STOPDAPT than in the RESET (2.8% versus 4.0%, P=0.06) and adjusted hazard ratio was 0.64 (95%CI 0.42-0.95, P=0.03). The cumulative incidence of definite/probable ST was lower in the STOPDAPT than in the RESET (0 patient [0%] versus 5 patients [0.3%], P=0.03).

CONCLUSIONS Stopping DAPT at 3-month after CoCr-EES implantation was at least as safe as the prolonged DAPT regimen adopted in the previous randomized trial.

CATEGORIES CORONARY: Stents: Drug-Eluting

KEYWORDS Antiplatelet therapy, Dual antiplatelet therapy, Everolimus-eluting stents

TCT-557

New Generation Drug-eluting Stents vs. Bare Metal Stents for Primary Angioplasty in Patients > 75 Years With ST Elevated Myocardial Infarction: The ESTROFA-MI+75 study

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BACKGROUND Primary angioplasty is the best reperfusion treatment in ST elevated myocardial infarction. The prevalence of very elderly patients (> 75 years) undergoing primary angioplasty is progressively increasing as population is ageing. The benefit of the new generation drug-eluting stents over bare metal stents in terms of safety and efficacy is unknown for this important subgroup of patients in this setting.

METHODS Retrospective consecutive registry conducted in 31 centers of patients > 75 years with ST elevation myocardial infarction undergoing primary angioplasty.

RESULTS A total of 3,126 pts have been included, 2,132 (68.2%) treated with BMS and 994 (31.8%) treated with new generation DES. After exclusion of patients presenting with cardiogenic shock or requiring cardiac surgery for mechanical complications (14%) a propensity score matching was performed yielding two comparable groups of 580 patients each with well- balanced baseline clinical or angiographic characteristics. Outcomes at 12 months were: cardiac death and MI 10.2% with BMS and 5.2% with DES (p=0.01), TLR was 3.8% with BMS and 1.5% with DES (p=0.04), definite or probable thrombosis 4.3% with BMS and 2.4% with DES (p=0.06), definite thrombosis 3.7% with BMS and 1.3% with DES (p=0.03) and bleeding BARC > 2 0.7% with BMS and 1.2% with DES (p=0.3).

CONCLUSIONS In this registry of patients over 75 years undergoing primary angioplasty, most were treated with BMS. After propensity score matching clinical outcomes were significantly better in those treated with new DES without significant increase in severe bleeding events in follow up.

CATEGORIES CORONARY: Stents: Drug-Eluting

KEYWORDS Acute myocardial infarction, Drug-eluting stent, Elderly

TCT-558

Simple Versus Complex Stenting in Unprotected Left Main Bifurcation Coronary Intervention: A Comprehensive Meta-analysis

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BACKGROUND Percutaneous intervention of distal bifurcation unprotected left main coronary arteries (UPLMCA) are technically demanding with less favorable outcomes. The optimal treatment strategy to improve long-term outcomes is uncertain.

METHODS Studies comparing simple approach (provisional stenting) versus complex stenting (elective two stent technique) were considered for inclusion. A search strategy using Medline, Embase, Cochrane database and the proceedings of the international meetings were included. Information about study design, inclusion criteria and sample characteristics were extracted. Meta-analysis of pooled event rates was compared between these two stenting approaches.

RESULTS 16 studies including 5978 patients who were treated with simple versus complex bifurcation stenting for UPLMCA bifurcations were analyzed. There were no differences in the rates of myocardial infarction (OR 0.81, CI 0.15-4.2), stent thrombosis (OR 0.8, CI 0.2-1.7), target vessel revascularization (OR 0.4, CI 0.6-2.7) or mortality (OR 0.92, CI 0.3-2.8) between simple versus complex stenting approaches at 1 year. However, at 5 years of follow-up there was a significant difference in the rates of target vessel revascularization (OR 0.4, CI 0.3-0.7, p=0.001) favoring the simple approach. There was no difference in the mortality (OR 0.94, CI 0.75-1.19), stent thrombosis (OR 0.83, 0.32-2.1) or myocardial infarction (OR 1.16, CI 0.7-1.7) using either approach at 5 years of follow-up.

CONCLUSIONS Percutaneous intervention for UPLMCA should favor a simple approach over complex approach to optimize long-term outcomes.

CATEGORIES CORONARY: Stents: Drug-Eluting

KEYWORDS Left main bifurcation, Left main coronary artery, PCI - Percutaneous Coronary Intervention

TCT-559

Long-term Clinical and Angiographic Impact of Stent Fracture on Second Generation Drug-eluting Stent Implantation: Comparison between Xience Everolimus- and Nobori Biolimus-eluting Stents

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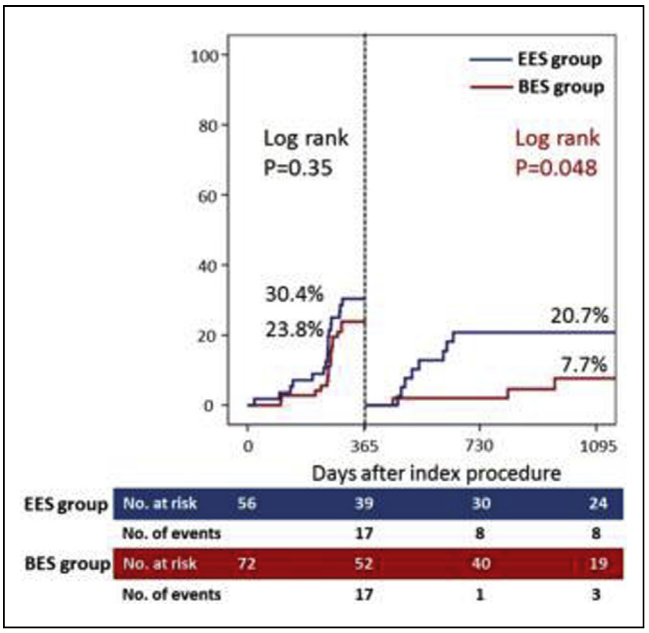
BACKGROUND Stent fracture (SF) after drug-eluting stent implantation has been reported to be associated with in-stent restenosis (ISR),

target lesion revascularization (TLR), and stent thrombosis. This study aimed to assess the long-term clinical and angiographic impact of SF on Xience everolimus-eluting stent (EES) and Nobori biolimus-eluting stent (BES) implantation.

METHODS From 2010 to 2013, 3246 lesions (1783 patients) were treated with EES and 1618 lesions (986 patients) with BES, in which follow-up angiography was performed within one year after index procedure. SF was defined as the separation of stent segments or stent struts at follow-up angiography. The mid-term angiography was performed at 8 months and the late-term at 20 months. ISR was defined as more than 50% restenosis. Late catch-up phenomenon was defined as ISR, excluding that within one year after index procedure.

RESULTS SF was observed in 1.7% (56/3246) of the lesions treated with EES and 4.4% (72/1618) with BES. The median follow-up duration of the study population was 1028 days (the first and third quarters, 838 and 1275 days). The mid-term restenosis rate showed no significant difference between the EES and BES groups (40.7% versus 30.6%, p=0.26). The late catch-up phenomenon rate was significantly lower in the BES group (18.2% versus 2.4%, p=0.04). Very late stent thrombosis was none in the EES group, on the other hand, occurred in one patient in the BES group. The three-year cumulative rates of any TLR did not significantly differ between the 2 groups (44.8% versus 29.7%, p=0.07). A landmark analysis of the cumulative rates of any TLR within and beyond one year is shown in the figure.

CONCLUSIONS The long-term clinical impact of SF could be different between EES and BES implantation.



CATEGORIES CORONARY: Stents: Drug-Eluting

KEYWORDS Drug-eluting stent, second generation, Long-term follow up, Stent fracture

TCT-560

In-stent restenosis assessed by optical coherence tomography (OCT) indicates smooth coronary arterial healing process in second generation drug eluting stents (DES)

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BACKGROUND In second generation DES era, in-stent restenosis (ISR) is not commonly seen but is still encountered occasionally. The pathophysiology and mechanism of ISR after second generation DES implantation have not been fully clarified.

METHODS Patients who underwent follow-up coronary angiography (CAG) after first (Cypher and Taxus) and second generation DES (Nobori, Promus Element, Resolute Integrity, and Xience) implantation were examined. The first scheduled CAG was performed at six to nine months after percutaneous coronary intervention (PCI) and the second at 18 to 24 months after PCI. ISR was defined as lesions more than 75% diameter stenosis at follow-up CAG. Optical coherence tomography (OCT) was performed at the time of revascularization to ISR. Then OCT imaging of second generation DES ISR of early (<1 year) and late (≥ 1 year) phase were compared with first generation DES ISR, retrospectively.

RESULTS From April 2008 to January 2010, first generation DES were implanted in 805 lesions. From January 2011 to December 2014, second generation DES were implanted in 1269 lesions in our hospital. ISR rate were significantly lower in second generation DES ISR (9.6% (N=77) vs 4.0% (N=51), p<0.05). In qualitative OCT assessment of second generation DES ISR in total, each ratio of homogeneous, layered, heterogeneous, lipid rich attenuation, calcified nodule tissue morphologies were 54.0% and 16.2%, 18.9%, 5.4%, and 5.4% respectively. Compared with first generation DES ISR, both in early and late ISR cases, homogeneous morphology was significantly higher in second generation DES ISR (61.1% vs 36.0%, and 47.3% vs 8.0%, respectively, p<0.05).

CONCLUSIONS Homogeneous tissue morphology assessed by OCT was more frequently found in second generation DES ISR than first generation DES ISR, especially in early phase (<1 year). This finding suggests that neointimal hyperplasia is main mechanism in second generation DES early ISR and arterial healing process is smooth like bare metal stents implantation.

CATEGORIES CORONARY: Stents: Drug-Eluting

TCT-561

Final Five-Year Outcomes Following Implantation of the Promus Element® Platinum Chromium Everolimus-Eluting Stent in De Novo Coronary Artery Lesions in Small Vessels (SV) and Long Lesions (LL): Results of the PLATINUM Small Vessel and Long Lesion Trials

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BACKGROUND The thin-strut, everolimus-eluting, platinum chromium PROMUS Element stent (Boston Scientific, Marlborough MA) has shown favorable early outcomes up to 4 years post-implantation for the treatment of de novo long lesions or lesions in small-caliber vessels, but long-term follow-up has not been previously reported.

METHODS PLATINUM SV and LL are prospective, single-arm, multinational studies that enrolled patients with angina pectoris or documented silent ischemia and a single de novo native coronary artery target lesion. PLATINUM SV enrolled 94 subjects with baseline vessel diameter ≥2.25 mm to <2.50 mm and lesion length ≤28 mm, and PLATINUM LL enrolled 102 patients with a target lesion >24 to ≤34 mm long with vessel diameter ≥2.50 to ≤4.25 mm. Follow-up was performed for 5 years.

RESULTS Patients were predominantly male (SV: 72.3%, LL: 62.7%) and approximately one third had diabetes (SV: 42.6%, LL: 30.0%). The mean baseline reference vessel diameter (RVD) in SV was 2.0 ± 0.3 mm and lesion length was 14.2 ± 7.0 mm. For the LL study, RVD was 2.6 ± 0.4 and mean lesion length was 24.4 ± 8.2 mm. The primary endpoint, 1-year target lesion failure (TLF,; cardiac death, myocardial infarction (MI) related to the target vessel, ischemia-driven target lesion revascularization [TLR]), was 2.4% for SV and 3.2% for LL, both significantly less than prespecified performance goals (P<0.001 for each). At 5 years, TLF, TLR, cardiac death, MI and ARC stent thrombosis (ST) had occurred in 6 (7.0%), 3 (3.6%), 5 (5.9%), 2 (2.4%), and 0 (0%) patients respectively in the SV trial and TLF, TLR, cardiac death, MI and ARC stent thrombosis (ST) had occurred in 13 (13.6%), 7 (7.5%), 5 (5.9%), 1 (1.3%), and 0 (0%) patients respectively in the LL trial.