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BACKGROUND PROMUS Element (PE) Plus, a thin-strut everolimus-eluting platinum chromium coronary artery stent, has shown favorable outcomes up to 3 years after implantation in a large post-approval study representative of clinical practice. Adverse event rates in diabetic patients, small vessel disease and long stent subgroups remained low at 3 years. Analyses of the 4-year clinical outcomes will provide insight into the long term safety and efficacy of the PE Plus stent in a broad, unselected patient population.

METHODS PE Plus PAS is a prospective, observational 'all-comers' registry that enrolled 2683 patients at 52 US sites. The primary and secondary endpoints of 12-month cardiac death or myocardial infarction (CD/MI) and annualized ARC definite/probable stent thrombosis (ST), respectively, were assessed in 'PLATINUM-like' patients implanted with a PE Plus stent. Patients who met the enrollment criteria for the PLATINUM trial were pooled from PE Plus PAS (N=776), PE PROVE (N=269) and PLATINUM Workhorse/Small Vessel (N=862) studies. Additional clinical end points were tested in overall PE-Plus PAS population.

RESULTS The mean age of patients in this study was 64 years, 70% were male, 37% had diabetes-mellitus, and >75% were treated for hypertension or hyperlipidemia. The 12-month rate of CD/MI in PLATINUM-like patients (1.8%) was significantly less than the prespecifed performance goal (3.2%; based on PLATINUM and SPIRIT IV trials; $p<0.0001$). Annualized ST was 0.23% between 1 and 2 years, and 0.18% between 2 and 3 years; both rates were significantly below the prespecified annual 1% performance goal ($p<0.0001$). As previously reported, 1-year cardiac events in overall PE Plus PAS were low: CD/MI 2.3% (1.5% CD, 1.1% MI), 5.9% TVR, and 0.7% ST. Low event rates were sustained at 3 years: the rate of CD/MI was 7.0% (4.3% CD and 3.3% MI), 12.7% TVR and 1.7% ST. Favorable clinical outcomes were observed at 3 years in patients with long lesions (10.0% CD/MI; ST 2.9%), small vessels (7.8% CD/MI; ST 2.2%) and diabetes (9.5% CD/MI; ST 3.5%).

CONCLUSION Over long-term follow-up, PE Plus everolimus-eluting stent demonstrates favorable efficacy in this large 'real-world' study of patients in routine clinical practice. The full 4-year results from PE Plus PAS overall population, including different subgroups, will be presented for the first time at TCT 2017.

CATEGORIES CORONARY: Stents: Drug-Eluting

TCT-730

Five-year risk of target lesion revascularization in patients with and without an acute coronary syndrome treated with drug-eluting stents: a pooled analysis of individual participant data from three randomized SORT OUT trials

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BACKGROUND Limited data exist clarifying the long-term risk of target lesion revascularization (TLR) associated with distinct first and newer-generation drug-eluting stents (DES) in patients presenting with and without acute coronary syndromes (ACS).

METHODS We pooled individual patient data from the 3 randomized SORT OUT all-comer trials of DES, for which 5-year outcomes were available: SORT OUT III (Endeavor zotarolimus-eluting stent (E-ZES) vs. Cypher sirolimus-eluting-stent (SES)); SORT OUT IV (Xience V/Promus everolimus-eluting stent (EES) vs. SES), and SORT OUT V (Nobori biolimus-eluting stent (BES) vs. SES). Relative risks (RR) were calculated for TLR, using SES as reference. Landmark analyses were performed for the timeframe between 12 months to 60 months after DES deployment.

RESULTS Complete data were available for 2844 patients presenting with ACS and 3680 presenting without ACS. Among patients with an ACS, 1446 received SES, 449 E-ZES, 436 EES, and 513 BES. Of these, 154 (5.4%) were subjected to TLR, with similar 5-year rates observed for those who received E-ZES (6.2%), EES (3.9%), or BES (5.3%), when compared with SES (5.7%). However, during the timeframe 12-60 months, all newer-generation DES (E-ZES: 1.7%; EES: 1.6%; BES: 2.4%) performed better than SES (4.0%). A total of 243 (6.6%) patients underwent TLR in the non-ACS group. Findings were comparable with those for the ACS group, but with less strong effect size estimates.

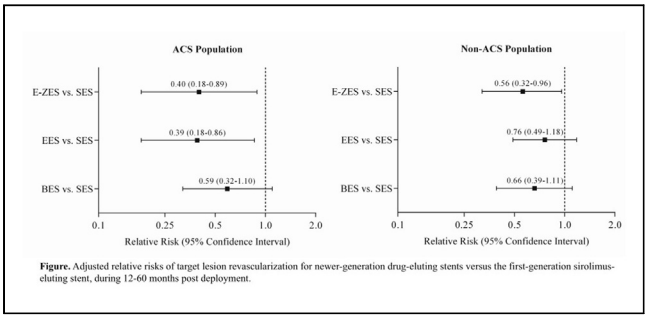

Figure. Adjusted relative risks of target lesion revascularization for newer-generation drug-eluting stents versus the first-generation sirolimus-eluting stent, during 12-60 months post deployment.

CONCLUSION Beyond the first year after placement, newer generation DES offered better protection against TLR than the first-generation SES, in patients both with and without ACS.

CATEGORIES CORONARY: Stents: Drug-Eluting

TCT-731

Nine-month clinical outcomes in patients with diabetes treated with polymer free sirolimus-eluting stents and dual-anti platelet therapy (DAPT) for 6 months versus DAPT for 12 months

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BACKGROUND Diabetes mellitus is known to be associated with worse clinical outcomes in patients with coronary artery disease (CAD) undergoing percutaneous coronary interventions (PCI) with drug-eluting stents (DES). Defining the optimal duration of dual antiplatelet therapy (DAPT) after DES implantation is still controversially discussed. The objective of this subgroup analysis of the all-comers ISAR 2000 registry was to assess the safety and efficacy of a short DAPT (<6 month) versus a longer DAPT (>6 month) in diabetic patients electively treated with the polymer-free sirolimus coated ultrathin strut drug eluting stent (PF-SES).

METHODS Patients who received the PF-SES were investigated in a multicenter all comers observational study. The primary endpoint was the 9-month target lesion revascularization (TLR) rate whereas secondary endpoints included the 9-month MACE and procedural success rates.

RESULTS 167 Patients were treated with DAPT for ≤ 6 month (S-DAPT group) and 350 patients underwent DAPT treatment for 12 month (L-DAPT group). There was no significant difference in the overall MACE rate (4.6% versus 3.1%, p=0.441), the 9-month accumulated stent thrombosis rates (0.8% versus 0.3%, p=0.51) or the accumulated rate of bleeding complications (5.3% versus 3.4%, p=0.341).