TCT-64 Incidence, Predictors, and Impact of Post-discharge Bleeding Compared to Myocardial Infarction After Percutaneous Coronary Intervention

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calcification ≥50%, and collateral vessels compared to arteries with STO (p<0.001, all). Combination of these findings could distinguish CTO from STO (c-statistics=0.88 (95% CI=0.94-0.90), sensitivity=83%, specificity=77%, positive predictive value (PPV)= 55%, negative predictive value (NPV)=93%, p<0.001). Percutaneous coronary intervention (PCI) was attempted in 342 arteries and was successful in 279 arteries (82%). CT findings could predict the unsuccessful PCI (c-statistics=0.70 (0.65-0.75), sensitivity=63%, specificity=73%, PPV=91%, NPV=31%, p<0.001).

CONCLUSIONS Non-invasive coronary CT angiography could discern chronic total occlusion from subtotal occlusion, and also could predict the success of attempted PCI.

CATEGORIES IMAGING: Non-Invasive

TCT-62

Predicting Value of Platelet Reactivity on Bleeding and Major Adverse Cardiac Events in Eastern Asian Percutaneous Coronary Intervention Patients

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BACKGROUND Previous studies have shown that high and low platelet reactivity (HPR and LPR respectively) are associated with adverse events following percutaneous coronary intervention (PCI), however, therapy windows were not consistent in different studies. We aimed to determine the optimal cutoff value of platelet reactivity to prevent major adverse events (MACE) and bleeding in eastern Asian PCI patients.

METHODS Consecutive 6266 non-emergent PCI patients with aspirin and clopidogrel therapy were enrolled prospectively in the single-center, large-volume investigation from January to December 2013. Platelet reactivity (ADP-induced platelet-fibrin clot strength [MAADP]) was determined by thrombelastography. MACE and Bleeding Academic Research Consortium (BARC) classification≥2 bleeding were assessed between different categories of platelet reactivity and Syntax Score (SS).

RESULTS Overall, 475 MACE and 152 major bleeding (BARC grade≥2) events were recorded during one year follow-up. With receiver operating characteristic (ROC) curve, we determined the cutoff values of MAADP for MACE and major bleeding (45 mm and 34mm, respectively). Then, patients were classified according to MAADP (>45 mm, 34-45 mm, and <34 mm) and we evaluated the impact of platelet reactivity on MACE and major bleeding in different Syntax Score subgroups (SS<15 and SS≥15) with multivariable Cox survival analysis. In low SS group, MAADP>45 mm was the predictor of MACE (HR: 2.3; 95%CI: 1.6-5.9), but MAADP<34 mm did not show significant predicting value for major bleeding (HR: 1.3; 95%CI: 0.4-8.1). In high SS group, MAADP>45 mm was still the predictor of MACE (HR: 2.6; 95%CI: 1.3-6.3), while MAADP<34 mm show significant impact on major bleeding (HR: 1.8; 95%CI: 1.2-4.7).

CONCLUSIONS Platelet reactivity measured by thrombelastography could predict MACE and major bleeding in elective PCI patients, especially in those with high SS. Therapy window of anti-platelet drugs is narrow in eastern Asian population and further studies on tailored treatment of high-risk patients are needed.

CATEGORIES CORONARY: PCI Outcomes

TCT-63

One Year Results Of The REMEDEE Registry: Clinical Outcomes After Deployment Of The Abluminal Sirolimus Coated Bio-Engineerd Stent In A Multicenter, Prospective Post Market Registry

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BACKGROUND Drug-eluting stents (DES) reduce angiographic restenosis and enhance event-free survival compared with bare-metal stents after implantation in coronary arteries. Limitations of current DES remain stent thrombosis and neo-atherosclerosis related to impaired healing, and repeat revascularization due to (late-) in-stent-restenosis. Endothelial repair can be substantially enhanced by CD34+ endothelial progenitor cells. The Combo stent combines a CD34+ antibody layer to attract endothelial progenitor cells, and thus promotes stent healing, with the abluminal release of sirolimus to prevent neointima formation and restenosis. The aim of this registry is to evaluate the long term safety and performance of the abluminal sirolimus coated bio-engineered stent in routine clinical practice.

METHODS The multicenter, prospective, clinical outcomes after deployment of the abluminal sirolimus coated bio-engineered stent post market registry, the REMEDEE Registry, is an international registry to evaluate outcomes in an all-comers population of patients undergoing percutaneous coronary intervention with (attempted) Combo stent placement in the setting of routine clinical care. Baseline demographic, clinical, and angiographic data, as well as follow-up data up to five years will be obtained. Clinical endpoints are defined as a composite of cardiac death, non-fatal myocardial infarction (MI) not clearly attributable to a non-target vessel, or target lesion revascularization (TLR) (percutaneous or by coronary artery bypass grafting (CABG)) in consecutive patients undergoing percutaneous coronary intervention with (attempted) Combo stent placement. All events will be adjudicated by an independent Clinical Events Committee. Cumulative event rates are estimated by a Kaplan-Meier model.

RESULTS A total of 1000 patients were included in 9 European sites between June 2013 and March 2014, of which 30.4% patients presenting with acute coronary syndrome (ACS) (17.8% ST-segment elevation myocardial infarction). Mean age was 65±11 years, 73.9% of patients are male. 184 (18.4%) patients are diabetic, 25.3% of patients have had a previous myocardial infarction, 6.8% had previous CABG. The primary endpoint of one year target lesion failure will be available at the TCT conference 2015.

CONCLUSIONS This is the first multicenter, prospective, non-interventional trial evaluating the long term clinical outcomes of patients treated with a Combo stent.

CATEGORIES CORONARY: Stents: Drug-Eluting

KEYWORDS Clinical outcomes, Coronary artery disease, EPC Capturing Dual Therapy COMBO Stent

TCT-64

Incidence, Predictors, and Impact of Post-discharge Bleeding Compared to Myocardial Infarction After Percutaneous Coronary Intervention

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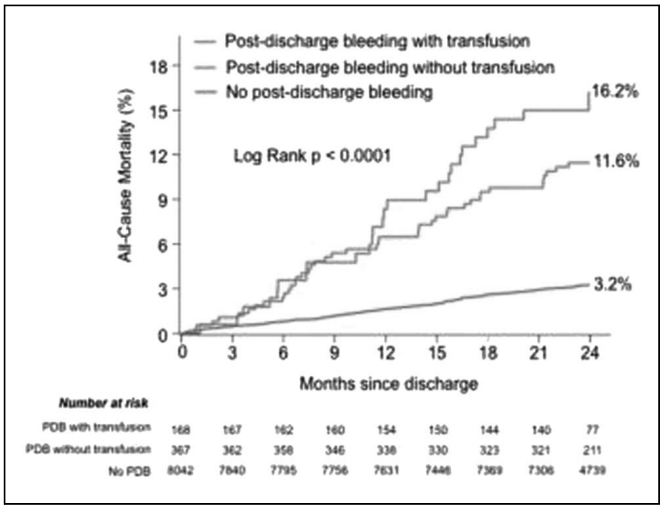
BACKGROUND The incidence, predictors, and prognostic impact of post-discharge bleeding (PDB) after percutaneous coronary intervention (PCI) with drug-eluting stent (DES) implantation are unclear. This study sought to characterize the determinants and consequences of PDB after PCI.

METHODS The incidence and predictors of clinically relevant bleeding events occurring within 2 years following hospital discharge were assessed from the prospective Assessment of Dual Antiplatelet Therapy With Drug-Eluting Stents (ADAPT-DES) study.

The effect of PDB on subsequent all-cause mortality within 2 years was estimated by time-adjusted Cox proportional hazards regression.

RESULTS Among 8,582 "all-comers" patients who underwent successful PCI with DES in the ADAPT-DES study, PDB occurred in 535/8,577 hospital survivors (6.2%) at a median time of 300 days (interquartile range: 130 to 509 days) after hospital discharge. Gastrointestinal bleeding (61.7%) was the most frequent source of PDB. Predictors of PDB included older age, lower baseline hemoglobin, lower platelet reactivity on clopidogrel, and use of chronic oral anticoagulation therapy. PDB was associated with higher crude rates of all-cause mortality (13.0% vs. 3.2%; p<0.0001; Figure). Following multivariable adjustment, PDB was strongly associated with 2-year mortality (HR: 5.03; 95% CI: 3.29-7.66; p<0.0001), with an effect size greater than that of post-discharge myocardial infarction (PDMI) (HR: 1.92; 95% CI: 1.18-3.12; p=0.009).



CONCLUSIONS Following successful PCI with DES in an unrestricted patient population, PDB is not uncommon, and has a strong relationship with subsequent all-cause mortality, greater that that associated with PDMI. Efforts to reduce PDB may further improve prognosis after successful DES implantation.

CATEGORIES CORONARY: Stents: Drug-Eluting

KEYWORDS Bleeding, Drug-eluting stent, Myocardial infarction

TCT-65

Two-Year Outcomes in Real-World Patients Treated With a Thin-Strut, Platinum-Chromium, Everolimus-Eluting Stent in the PROMUS Element Plus US Post-Approval Study (PE-Plus PAS)

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BACKGROUND The PE Plus Post-Approval Study (PE Plus PAS) was designed to examine long-term outcomes among patients treated with advanced generation, everolimus-eluting, platinum chromium PROMUS Element stents (Boston Scientific, Marlborough, MA) in unselected patients treated in routine practice. This is the first report of 2-year results from this large multicenter post-approval study.

METHODS PE Plus PAS was a prospective, open-label, multicenter observational study enrolling 2684 patients at 52 sites in the US. Follow-up was at 30 days, 6 months, and 1 year, and will continue annually through 5 years. The primary endpoint was 12-month cardiac death or myocardial infarction (CD/MI) in 'PLATINUM-like' patients who received PROMUS Element Plus in PE Plus PAS, PE PROVE and patients from the PLATINUM Workhorse/Small Vessel trials compared to a performance goal (3.2%) derived from outcomes in SPIRIT IV and the PLATINUM trial. The PLATINUM-like patient cohort was defined as all patients that met the criteria for enrollment in the PLATINUM trial. A Clinical Events Committee adjudicated major adverse cardiac events and their relatedness to the study stent.

RESULTS In the PE Plus PAS, 30% of patients were female, mean age was 64 years, 37% had medically treated diabetes, and more than three-quarters were treated for hyperlipidemia and hypertension. At baseline, mean lesion length was 17±10 mm and mean reference vessel diameter was 2.9±0.5 mm (in 3595 treated lesions). PLATINUM-like patients accounted for 29% of the overall PE Plus PAS patient population. For the primary endpoint, 12-month CD/MI in PLATINUM-like patients was 1.8% (33/1855) with a upper 1-sided 95% confidence interval of 2.3%, which was significantly less than the prespecified performance goal of 3.2% (Pnoninferiority<0.001). In the overall PE Plus population, 12-month major adverse cardiac events were low.

CONCLUSIONS The 2-year results from the PE Plus PAS will be available for presentation for the first time at TCT 2015 and will show favorable performance and safety for the PROMUS Element Plus everolimus-eluting stent at 2 years in an unselected patient population.

CATEGORIES CORONARY: Stents: Drug-Eluting

KEYWORDS Clinical outcomes, Coronary artery disease, Drug-eluting stent, everolimus

TCT-66

Long-term Clinical Outcomes of Percutaneous Coronary Intervention Using Drug-Eluting Stent for Native Coronary Chronic Total Occlusion

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BACKGROUND The benefit on prognosis after successful recanalization of chronic total occlusion (CTO) lesions is uncertain.

METHODS A total of 1173 consecutive patients (mean age 60 years, 82.7% men) with CTOs of native coronary vessels in which percutaneous coronary intervention (PCI) was attempted was enrolled from March 2003 and May 2014. All successful procedures (1004 patients, 85.6%) were performed by drug-eluting stent implantation.

RESULTS During a median of 4.6-year of follow-up, the cumulative incidence of all-cause death was not significantly different between the successful and unsuccessful CTO-PCI (8.0% vs. 7.1%, P = 0.83). The cumulative rate of target vessel revascularization (TVR) and coronary artery bypass grafting (CABG) was remarkably less in patients with successful PCI compared with those with unsuccessful PCI (TVR; 4.4% vs. 20.9%, P < 0.001, CABG; 0.4% vs. 16.7%, P < 0.001). The adjusted risks of all-cause death (hazard ratio [HR] 1.19, 95% confidence interval [CI] 0.59 - 2.43, P = 0.62) and the composite of death or myocardial infarction ([MI], HR 1.06, 95% CI 0.56 - 2.03, P = 0.96) remained comparable between groups, whereas the adjusted risk of TVR and CABG was significantly higher in patients with unsuccessful CTO PCI. Among 879 subjects who eventually had a complete revascularization state for the non-CTO vessels, the risks of death or the composite of death or MI were not different between patients who further underwent successful recanalization of the remaining CTO and those who did not. This finding was consistent regardless of whether the patient had a multi-vessel disease including CTO or only had a single CTO.

CONCLUSIONS Successful CTO-PCI compared with unsuccessful PCI was not associated with lesser risk for 4.6-year mortality, but was associated with significantly less subsequent CABG.