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 to clopidogrel, and use of chronic oral anti-coagulation 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 (PDIMI) (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 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 3505 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% (93/5185) 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.