Results: Indications for CTO-PCI were mainly: angina in 52.8% of cases, acute coronary syndromes in 13.2% (63% of whom had diabetes and 30% of those without diabetes), and silent ischemia in 29.6% (397 cases). Clinical follow-up was obtained in 92.5% of cases at a mean of 50.2±28.9 months. Patients with silent ischemia were older (64.0±11.8 vs. 62.7±10.2 years, p=0.037) and more frequently diabetics (33.2% vs. 24.9%, p=0.001). Procedural success rate was similar (74.6 vs. 74.4%, p=ns, respectively) as well as all-causes mortality at follow up (Silent ischemia 10.7 vs. sympt 12.9%, p=ns) and cardiac death (6.1 vs. 7.4%, p=ns). However, patient oriented major adverse cardiovascular and cerebrovascular events (MACCE) were lower in asymptomatic patients (17.4 vs. 13.3%, p=0.034) at follow up.

Conclusions: Our study shows that CTO PCI in patients with silent ischemia is a safe procedure in experienced hands and that procedural success is a predictor of improved outcome in this subgroup of patients. Same efforts should be made to offer CTO recanalization to asymptomatic patients in the presence of ischemia as in symptomatic patients.

TCT-55
Outcomes of Transfemoral Bivalirudin are Equivalent to Transradial PCI: “Old Dogs Don’t Need to Learn New Tricks”
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Background: In this study, we sought to compare the clinical outcomes in patients undergoing percutaneous coronary interventions (PCI) with transfemoral access using bivalirudin versus transradial access using heparin or low molecular weight heparin (LMWH). Recent trend towards transradial PCI is putting pressure on older physicians to use transradial access. Data suggests that the use of bivalirudin is superior to heparin when analyzing overall outcomes in coronary PCI via transaxial approach. There is a paucity of data when comparing use of bivalirudin in transfemoral coronary PCI versus transradial coronary PCI with heparin/LMWH.

Methods: 631 patients at a high volume university medical center undergoing coronary PCI were retrospectively divided into two groups (femoral artery access with bivalirudin and radial artery access with heparin/LMWH). Cardiology fellows obtained access in greater than 90% of all patients.

Results: All-cause mortality, vascular complications, bleeding events within 72 hours, and transfusion rates were not statistically significant between the two groups.

Conclusions: In this single center study, transradial coronary PCI using heparin or LMWH has no advantage over transfemoral coronary PCI using bivalirudin in terms of overall mortality and bleeding outcomes. Further studies to evaluate transradial coronary PCI using Bivalirudin are warranted.

TCT-56
PEPCAD China ISR: A Prospective, Multicenter, Randomized Trial of Paclitaxel-Coated Balloon versus Paclitaxel-Eluting Stent for the Treatment of DES In-Stent Restenosis - 9-Month Angiographic and 12-Month Clinical Results
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Background: Treatment of drug-eluting stent in-stent restenosis (DES-ISR) is still challenging with no established best strategy. The intention of PEPCAD China ISR was to demonstrate the efﬁcacy of paclitaxel-coated balloon (PCB) angioplasty in a non-European patient population with DES-ISR.

Methods: PEPCAD China ISR was a 220 patient randomized (1:1), single blind prospective multicenter trial conducted in China. Patients with DES-ISR received either PCB (SeQuent® Please, B.Braun Melsungen AG, Germany) or paclitaxel-eluting stent (PEPCAD; Taxus® Liberté, Boston Scientific, Natick, MA, USA) treatment. The primary endpoint was in-segment late lumen loss at 9 months. Secondary endpoints included 9-month % diameter stenosis (DS), binary restenosis rate, and 12-month target lesion failure (TLF) defined as the composite of cardiac death, target vessel myocardial infarction or ischemia-driven target lesion revascularization. In addition, definite/probable stent thrombosis (ST) rates were documented.

Results: There were no signiﬁcant baseline differences between both treatment groups in terms of patient, lesion or procedural characteristics. At 9 months, in-segment late lumen loss in the PCB group was non-inferior to the DES group (0.46±0.51 mm vs. 0.55±0.61 mm, difference: -0.06 mm with 95%CI: [-0.23, 0.10], p for non-inferiority=0.0005). The 9-month in-segment %DS, binary restenosis, 12-month TLF, and definite/probable ST rates were no statistical differences between both treatment groups (29.0 ± 21.3 vs. 30.8 ± 23.3, p=0.59; 18.6% vs. 23.8%, p=0.39; 16.5% vs. 16.0%, p=0.92; 0.9% vs. 1.0%, p=1.00, respectively).

Conclusions: In a randomized trial of 220 patients, angioplasty with a PCB was non-inferior to FES implantation when used to treat DES-ISR. Based upon these as well as prior randomized trial data, PCB angioplasty offers an effective treatment for DES-ISR without the necessity of implanting additional metal layers for drug release (ClinicalTrials.gov identifier: NCT 01622075).

TCT-57
Impact Of Coronary Artery Calcification On Clinical Events In Patients Undergoing Coronary Artery Bypass Grafting: Analysis From The ACUITY (Acute Catheterization And Urgent Intervention Triage Strategy) Trial
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Background: The treatment of calcified coronary lesions by percutaneous coronary intervention (PCI) has been shown to be associated with poor outcomes and an increased rate of complications. However, the impact of coronary calcification in patients undergoing coronary artery bypass grafting (CABG) is unknown.

Methods: Following coronary angiography, CABG was performed in 755 patients presenting with an acute coronary syndrome (ACS) in the ACUITY trial. Patients were divided in 3 groups (severe, moderate, none/mild) according to the presence and extent of calcified coronary lesions as assessed by an independent angiographic core laboratory. Major ischemic outcomes were assessed at 1 year.

Results: One of more severely calcified lesions was present in 103 (13.6%) patients, moderate calcification was present in 249 (33.0%) patients and none/mild calcification is present in 403 (53.4%) patients. Patients with severely calcified lesions were more likely to be older, have lower body mass index, have hypertension and renal insufficiency at baseline. Angiographically, they were more likely to have more lesions and higher TIMI risk score. There were no differences between groups in the rates of multivessel disease or number or type (arterial vs. venous) of grafts performed. The presence of severe calcification compared to moderate or none/mild was associated with a significant higher unadjusted rate of death (11.8% vs. 3.7% vs. 4.5%, p=0.006), death/MI (31.1% vs. 19.7% vs. 16.4%, p=0.006) and MACE (32.0% vs. 22.6% vs. 20.8%, p=0.059) at 1 year. By multivariable analysis, the presence of severe lesion calcification was identified as an independent predictor of 1-year death/MI (HR 1.77 [95% CI 1.8, 2.66], p=0.006) and MACE (HR 1.49 [95% CI 1.01, 2.21], p=0.04).

Conclusions: The presence of severely calcified coronary lesions was associated with significantly worse ischemic outcomes after CABG in patients with ACS.