Conclusions: Whilst GPIIb-IIIa inhibitor use was associated with a significant protective effect on Kaplan-Meier survival analysis, this disappeared when the significant baseline disparities seen in these patients were accounted for.

TCT-140
Prospective Multicenter Registry of 6 Months Dual Antiplatelet Therapy after new Generation Drug-eluting Stent Implantation: ESTROFA-DAPT Study.

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Background: Drug-eluting stents (DES) have been related to a certain risk of late thrombosis. The recommended duration of dual antiplatelet therapy (DAPT) with DES is 12 months. DAPT is not free from complications and is expensive. Trials with limited sample size suggest that a 6 month DAPT period could be enough with new generation DES. There are no prospective clinical registries assessing the safety of such an approach.

Methods: All consecutive patients treated with a new generation DES (Xience V, Xience Ve Prime, Endeavor Resolute, Promus Element, Biomatrix, Nobori, Osiri) were prospectively included in 20 different centers. Patients had to fulfill one of the following inclusion criteria in order to have 6 month DAPT period prescribed: silent ischemia, stable angina, low risk non-ST segment elevation myocardial infarction or acute coronary syndrome where 12 months DAPT was discarded due to high bleeding risk. Taking advantage of the ESTROFA-2 database (4,768 patients treated with new generation DES, 4,355 of them with 12 months DAPT) we will perform a propensity score matching of the six months DAPT from the ESTROFA-DAPT registry with the 12 months DAPT from the ESTROFA-2 registry.

Results: A total of 800 patients have been included so far in 20 centers. The baseline characteristics of the matched groups and the 1 year follow up results of the first 500 patients would be presented at the meeting sessions.

Conclusions: The ESTROFA-DAPT registry will provide data regarding safety of a 6 month DAPT period after new generation DES implantation.

TCT-141
The Disutility of Nuisance Bleeding: Insights from the TRANSLATE ACS Registry

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Background: Prolonged dual anti-platelet therapy (DAPT) is recommended after an acute coronary syndrome (ACS) to reduce ischemic events, but is associated with increased rates of major and minor bleeding. The incidence of even lesser degrees of ‘nuisance’ bleeding on DAPT and its impact on quality of life (QoL) are largely unknown.

Methods: We studied 9290 ACS patients from the TRANSLATE ACS study who were treated with PCI and discharged alive between April 2010 to Sept 2012. Bleeding post-hospital discharge was defined via the BARC bleeding definitions. Our primary outcome parameter was the 6 month EQ-5D-5L index score, based on the U.S. population preference weights. The EQSD visual analog scale (VAS) at 6 months was a secondary outcome. To determine the association between nuisance bleeding and 6-month QoL, we fit a mixed-effects linear regression model for 6 month EQSD index adjusting for baseline EQSD index, with site as random effect (hierarchical model) and others confounders of the relationship between bleeding and health status. We fit a similar model for EQSD visual analog scale (VAS).

Results: Of the 9,290 patients with ACS (mean age 61, 73% males, 89% Whites), 4,314 (44.5%) underwent immediate PCI for STEMI and 4,308 (46.4%) underwent PCI for non-STEMI. A total of 849 (9.1%) patients experienced BARC 1 type nuisance bleeding. Those who experienced BARC 1 bleeding had lower scores on all 5 EQSD domains (mobility, self-care, usual activities, pain and anxiety) and had a lower 5 point EQSD VAS score. After adjustment for confounders, nuisance bleeding by 6 month was independently associated with a decrement in QoL at 6 month (-2.04 points on EQSD VAS; 95% CI -0.93 to -3.15, P<0.001). Based on the EQSD index score, the utility decrement associated with nuisance bleeding was 0.026, 95% CI 0.015 to 0.037, P-value <0.001.

Conclusions: As assessed by GPIIb-IIIa and P-selectin in stable CAD patients, Prasugrel 5 mg inhibits platelet GPIIb-IIIa and P-selectin expression in the very elderly - Results from the GENERATIONS trial, a pharmacodynamic study in stable CAD patients

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Background: Platelet surface P-selectin and activated GPIIb-IIIa are markers of platelet activation, degradation and aggregation. In the TRITON trial prasugrel (P) therapy significantly reduced ischemic events vs. clopidogrel (C) therapy (P<0.001) in patients with NSTE-ACS. The effect of Pras on GPIIb-IIIa and P-selectin expression is unknown. As assessed by GPIIb-IIIa and P-selectin in stable CAD patients, Prasugrel 5 mg inhibits platelet GPIIb-IIIa and P-selectin expression in the very elderly - Results from the GENERATIONS trial, a pharmacodynamic study in stable CAD patients

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Background: Increasingly cardiologists need to place coronary artery disease patients at risk for treatment and future clinical trials of prolonged DAPT therapies.

Methods: This prospective, nonrandomized, multicenter, controlled study of the Endeavor zotarolimus-eluting stent (E-ZES) in real world Japanese patients was performed in two arms: patients who were enrolled at 106 medical institutions to receive DAPT for 3 months and then followed for 1 year, and a 12-month DAPT arm consisting of patients consecutively extracted from patients enrolled in the Endeavor Japan post-marketing surveillance. The analysis was done on an intent to treat basis. The

TUESDAY, OCTOBER 29, 2013, 3:30 PM-5:30 PM
TCT Abstracts/POSTER/Antiplatelets and Antithrombins
prespecified primary endpoint is the comparison of “NACCE” or net adverse cardiac and cerebrovascular events (death, myocardial infarction, cerebrovascular accident, and major bleeding) at 12 months after implantation. After performing propensity scoring to adjust for differences in baseline characteristics, the noninferiority of the 3-month DAPT arm to the 12-month DAPT arm will be assessed with respect to the incidence of NACCE.

**Results:** There were 1,205 patients enrolled in the 3-month DAPT arm and 1,345 patients included on the 12-month DAPT arm. Baseline characteristics of both groups were: men, 75.4% and 74.3%; mean age, 68.7 and 67.6 years; diabetes, 32.6% and 35.9%; acute coronary syndrome, 40.7% and 36.3%; number of lesions, 1,453 and 1,738; target vessel lesions: LMOCA (0.3% and 0%), LAD (51.3% and 43.4%), LCX (18.4% and 18.4%), and RCA (30.0% and 38.2%); de novo lesions, 99.3% and 97.5%; reference vessel diameter, 2.71 mm and 2.58 mm; pre-minimum lumen diameter, 0.81 mm and 0.75 mm; pre-% diameter stenosis, 70.0% and 71.0%; lesion length, 15.7 mm and 16.8 mm; and total stent length, 21.4 mm and 24.4 mm.

**Conclusions:** Baseline characteristics of both arms were similar. The present study will provide insight into the optimal duration of DAPT after E-ZES implantation. Per-protocol analysis results will be presented at TCT in 2013.

**TCT-144**

**Randomized Comparison Study Assessing the Impact of Cilostazol on Heart Rate and Arrhythmias by 24-hour Ambulatory Holter Electrocardiographic Monitoring after Drug-Eluting Stent Implantation in Coronary Artery Disease**

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**Background:** Cilostazol may have a positive chronotropic or pro-arrhythmic effect, despite its beneficial effects on vasodilation and antiplatelet aggregation. However, it is unknown whether adjunctive cilostazol can contribute to tachycardia or arrhythmias after drug-eluting stents (DES) implantation. The aim of this study was to determine the impacts of adjunctive cilostazol on 24-hour heart rate and arrhythmias in patients undergoing DES implantation.

**Methods:** This randomized, multicenter, prospective trial compared triple antiplatelet therapy (aspirin, clopidogrel, and cilostazol, TAT; n = 113) and dual antiplatelet therapy (aspirin and clopidogrel, DAT, n = 114) at baseline and 6-month in patients receiving DES. The primary end points were 24-hour heart rate (24-HR), 24-HR ≥70 bpm, and 24-HR increase ≥5 bpm at 6-month follow-up using 24-hour Holter electrocardiographic monitoring. Secondary end points were counts or presences of premature ventricular complex (PVC), nonsustained ventricular tachycardia, sustained ventricular tachycardia, premature atrial complex, and supraventricular tachycardia at 6-month.

**Results:** The two groups had similar baseline characteristics. At 6-month follow-up, the 24-HR (75.4 ± 11.7 bpm vs. 69.3 ± 10.0, p < 0.001), presence of 24-HR ≥70 bpm (71.4% vs. 47.1%, p < 0.001), and presence of 24-HR increase ≥5 bpm (44.8% vs. 24.5%, p = 0.002) were significantly higher in the TAT versus DAT group. Multivariate analysis showed that the use of cilostazol (OR: 3.10, 95% CI: 1.08-9.95), 10.0, p = 0.016) was a strong predictor of 24-HR increase ≥5 bpm at follow-up. In addition, 24 total counts of PVCs (472 ± 1497 beats vs. 86 ± 209 beats, p = 0.016) was significantly higher in the TAT versus DAT group among the secondary end points.

**Conclusions:** Cilostazol in addition to DAT appears to result in an increase in 24-HR and total counts of PVCs after DES implantation. Some caution should be exercised for the use of cilostazol in patients with tachycardia or a large number of PVCs when planning DES implantation.

**TCT-145**

**Do Baseline Hemoglobin And Hematocrit Influence The On-Treatment Platelet Reactivity To Clopidogrel Measured By The VerifyNow P2Y12 Assay?**

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**Background:** It has been well known that the inhibition of platelet aggregation (IPA) by anti-platelet agents was important to reduce the thrombo-embolic events in patients with ST segment elevation myocardial infarction (STEMI). However, the periprocedural IPA by anti-platelet agents was not well known.

**Methods:** We compared the peri-procedural IPA between prasugrel and adjunctive cilostazol to dual anti-platelet therapy (Triple anti-platelet therapy; TAP) in patients with STEMI undergoing primary percutaneous coronary intervention (PCI). We prospectively randomized 70 consecutive clopidogrel-naive patients with STEMI planned PCI to either prasugrel [loading dose (LD) 60 mg; 37 patients] or TAP (LD aspirin 300 mg, clopidogrel 600 mg, and cilostazol 200 mg; 33 patients). Primary end points of the study were the platelet reactivity unit (PRU) or % inhibition by the VerifyNow P2Y12 assay at pre-PCI and pre-discharge.

**Results:** The drug loading to pre-PCI time was similar between prasugrel and TAP groups (25.4 ± 10.42 minutes vs. 25.5 ± 10.56 minutes, p = 0.957). PRU at pre-PCI was significantly lower in prasugrel than in TAP (269.1 ± 71.69 vs. 306.5 ± 48.67, p = 0.012). The lower PRU and greater % inhibition also observed in prasugrel than in TAP at pre-discharge (108.2 ± 60.51 vs. 238.1 ± 73.40, 63.6 ± 18.51% vs. 16.8 ± 17.91%, p < 0.001 respectively). No differences in in-hospital bleeding complications between two groups were observed.

**Conclusions:** Our study demonstrates that prasugrel could produce a significantly greater peri-procedural as well as in-hospital IPA compared with TAP in patients with STEMI undergoing primary PCI.