TCT-546 Performance of the Dual AntiPlatelet Therapy (DAPT) Score in the ADAPT-DES Study.

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TCT-544

The impact of residual mitral regurgitation ≤1+ following MitraClip therapy on long-term outcome

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BACKGROUND MitraClip (MC) therapy is an approved option for high-risk patients (pts) with relevant mitral regurgitation (MR) with its success being defined as reduction to MR≤2+. The aim of this study was to assess mid- and long term clinical and functional results following MC therapy in pts with optimal acute results (residual MR≤1+ [rMR≤1+]).

METHODS Out of 699 consecutive pts (75.3±8.8 years, 60.5% male, 66.6% functional [FMR], logEuroSCORE 24.7%±6.5) treated at our center, three subgroups were determined (rMR≤1+ [n=355]; rMR=2+ [n=275]; rMR≥3+ [n=69]) and retrospectively analyzed on their impact on outcome measures. We obtained follow-up (FU) information at clinical visits 6 months and annually thereafter for up to 5 years. A total of 367 pts (52.5%) died during the FU period.

RESULTS Among the subgroups, age, gender, cardiovascular risk profile and risk stratification by EuroSCORE and STS score were comparable. However, cardiomyopathy (70.8%, p<0.001), history of myocardial infarction (35.4%, p=0.005), functional MR (71.8%, p<0.001) and previous CRT therapy (28.0%. p=0.0044) were significantly more represented in rMR≤1+ pts. Further, left ventricular ejection fraction (LVEF) values were lower in these pts (rMR≤1+: 40.6%±15.8 vs rMR≥3+: 45.5%±16.9, p=0.04). Procedural-, device- and radiation times and procedural complications were highest in pts with rMR≥3+ (p<0.001 for all). Although comparable improvement in functional status was determined in all pts, Kaplan-Meier estimates for death differed significantly, displaying lowest rates for rMR≤1+ (p[logrank]<0.001). In Cox regression analyses, rMR≥3+ vs rMR≤1+ (HR 1.86 [1.33-2.60], p<0.001) and rMR=2+ vs rMR≤1+ (1.36 [1.09-1.69], p=0.006) were both predictive of death. Further subgroup analyses revealed superior outcome for pts with LVEF>30% and rMR≤1+, whereas comparable outcomes were determined for pts with LVEF≤30%, irrespective of rMR.

CONCLUSION Following MC therapy, all successfully treated pts display beneficial clinical and functional results. However, an optimal result (rMR≤1+), especially when associated with LVEF >30%, has an impact on long-term survival. These results might add to an ongoing trend towards a more refined pre-procedural stratification and intra-procedural decision-making.

CATEGORIES **STRUCTURAL:** Valvular Disease: Mitral

ADJUNCT PHARMACOLOGY AFTER PCI: DAPT

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TCT-545

Individualizing DAPT Duration after Coronary Stenting for Patients at High Bleeding Risk – The LEADERS FREE trade-off score

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BACKGROUND The LEADERS FREE trial has shown that a Biolimus A9 coated polymer-free metallic stent (DCS) was both safer and more effective than a bare metal stent (BMS) when used with one month dual antiplatelet therapy (DAPT) only in patients at high bleeding risk (HBR). It remains unknown whether individual adjustments of DAPT duration might be justified in such patients. The aim of this study was to design a trade-off score encompassing the risks for both coronary thrombotic events (CTE) and major bleeding events (MB) after percutaneous coronary intervention (PCI) in HBR patients treated with one month DAPT, in order to identify those patients with either an excess thrombotic risk or an excess bleeding risk.

METHODS Using data from 2423 HBR patients treated with either a DCS or a BMS and enrolled in the LEADERS FREE trial, independent predictors of CTE (defined as the composite of stent thrombosis or myocardial infarction) and MB (defined as the occurrence of a Bleeding Academic Research Consortium type 3, 4 or 5 bleed) were identified.

RESULTS Between 3 and 365 days post PCI, 137 patients (5.6%) sustained a CTE, and 132 (5.4%) suffered a MB. Subsequent mortality after CTE and MB was 23.0% and 21.2% respectively at one year. Advanced age and renal insufficiency were predictors of both CTE and MB, especially the former. Multivessel coronary disease, a history of prior MI or presentation with ACS, and the use of a BMS were associated only with an increased risk of CTE. The need for long-term oral anticoagulation, and a low hemoglobin level at baseline were predictors of an increased risk of MB. Using an integer score, we identified a group (21.2% of patients) for whom the thrombosis risk was at least twice the bleeding risk and another (7.5% of patients) for whom the bleeding risk was at least twice the thrombosis risk. The former group might benefit from a DAPT course > 1 month, while the latter might benefit from maximal bleeding avoidance strategies.

CONCLUSION A simple trade-off score, applicable shortly after PCI, may assist in optimizing individual anti-thrombotic regimens for HBR patients.

CATEGORIES **CORONARY:** Pharmacology/Pharmacotherapy

TCT-546

Performance of the Dual AntiPlatelet Therapy (DAPT) Score in the ADAPT-DES Study

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BACKGROUND The optimal duration of dual antiplatelet therapy (DAPT) after percutaneous coronary intervention (PCI) remains in dispute, particularly after 12 months. The DAPT Score was developed from the DAPT trial to identify pts who may benefit the most from extended therapy. We sought to assess the performance of the DAPT risk score in the all-comers Assessment of Dual AntiPlatelet Therapy with Drug-Eluting Stents (ADAPT-DES) registry, and to test the utility of additional predictors of events on its performance.

METHODS Patients free from ischemic or hemorrhagic events after 1 year of DAPT after successful DES implantation were analyzed. The DAPT score was calculated for each pt and outcomes between 1 and 2 years were examined according to the DAPT trial median score (≥2 vs. <2). ROC curves for the DAPT score were built for ischemic events (myocardial infarction [MI] or stent thrombosis [ST]) and clinically relevant bleeding. High-platelet reactivity (HPR) was then added to the ischemic model, and HPR, chronic oral anticoagulation therapy, history of anemia, and baseline hemoglobin were added to bleeding model. Interaction between pts remaining on DAPT and risk score quartile was tested for ischemic and bleeding events, after adjustment for propensity after the first year post-PCI.

RESULTS Among 8,582 pts in ADAPT-DES, 5,397 were event-free after 1 year, 3617 (67.0%) of whom remained on DAPT. Between 1 and 2 years, ischemic and hemorrhagic events occurred in 413 and 124 pts, respectively. Pts with higher vs. lower DAPT scores (≥2 vs. <2) had higher 1-2 year rates of ischemic events (5.6% vs 3.0%, p<0.0001), but similar rates of bleeding (2.2% vs 2.4%, p=0.73). The DAPT score had moderate

discrimination for MI or ST between 1 and 2 years (c-statistic=0.615, compared with 0.68 in DAPT trial) and adequate calibration (PHL=0.41). The addition of HPR did not significantly improve discrimination for ischemic events (c-statistic=0.628, p=0.27). The DAPT score was ineffective in predicting bleeding between 1 and 2 years (c-statistic=0.508) but had adequate calibration (PHL=0.11). The addition of HPR and other bleeding correlates significantly improved the discrimination for bleeding (c-statistic=0.606, p<0.0001). The results were similar in pts maintained on DAPT vs aspirin only beyond 1 year after PCI.

CONCLUSION In the in the ADAPT-DES registry, the DAPT score was reasonably predictive for ischemic events between 1 and 2 years after PCI, but was not useful to predict bleeding events. Prediction of bleeding can be significantly improved by addition of variables not incorporated in the DAPT score.

CATEGORIES **CORONARY:** Pharmacology/Pharmacotherapy

TCT-547

Comparison of Clinical Outcomes Between Ticagrelor and Prasugrel in Patients with ST-Segment Elevation Myocardial Infarction

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BACKGROUND Although new ADP-receptor antagonist such as prasugrel or ticagrelor has been known to improve clinical outcomes in patients with acute coronary syndrome, there are few studies which compared prasugrel and ticagrelor in patients with ST-segment elevation myocardial infarction (STEMI). Moreover, their safety profiles as well as clinical impacts were not well studied in Asian patients.

METHODS Between November 2011 and October 2015, a total of 1440 patients with STEMI who underwent successful primary percutaneous coronary intervention (PCI) were analyzed from the Korea Acute Myocardial Infarction Registry-National Institute of Health (ticagrelor 963 and prasugrel 477 patients). We did not include patients who discontinued or switched antiplatelet medications during admission. Primary study outcome was major adverse cardiac outcomes (MACE: the composite of cardiac death, MI, stroke or target-vessel revascularization [TVR]) during 1-year follow-up (median 353 days [interquartile range 190-378]). We also analyzed the incidence of all-cause mortality, cardiac mortality, MI, stroke, TVR, definite or probable stent thrombosis and in-hospital outcomes including in-hospital bleeding events (TIMI major or minor bleeding).

RESULTS Ticagrelor group was more elderly (61.7 vs. 55.9 years, p <0.001) and had more female patients (19.5 vs. 9.0%, p <0.001). Although prevalence of hypertension, history of cerebrovascular disease and MI were higher in ticagrelor group, other atherosclerotic risk factors were similarly prevalent between 2 groups. During PCI, prasugrel group more received transfemoral approach (66.0 vs. 75.9%, p <0.001), and thrombi aspiration or glycoprotein IIb/IIIa inhibitor were similarly used during procedure. MACE occurred in 73 patients (5.1%) during 1-year follow-up. There were no differences in incidence of MACE (5.3 vs. 4.6%, p = 0.612), all-cause death (3.5 vs. 3.1%, p = 0.760), cardiac death (2.5 vs. 2.9%, p = 0.605), MI (0.9 vs. 0.8%, p = 0.856), TVR (1.6 vs. 0.8%, p = 0.331), stroke (0.8 vs. 0.2%, p = 0.286), stent thrombosis (0.7 vs. 0.8%, p = 0.759) or in-hospital bleeding events (4.3 vs 6.7%, p = 0.055) between two groups. Analysis by propensity score matching (429 pairs) did not significantly affect the results. The incidence of in-hospital bleeding events was still comparable between two groups (4.2 vs. 6.8%, p = 0.133) and there were also no significant difference in incidence of MACE (3.5 vs. 4.9%, hazard ratio [HR] 0.79, 95% confidence interval [CI] 0.41-1.54, p = 0.490), all-cause death (2.6 vs. 3.3%, HR 0.83, 95% CI 0.38-1.84, p = 0.650), cardiac death (1.6 vs. 3.0%, HR 0.56, 95% CI 0.23-1.41, p = 0.221), MI (0.7 vs. 0.9%, HR 0.76, 95% CI 0.17-3.51, p = 0.729), TVR (1.4 vs. 0.9%, HR 1.38, 95% CI 0.37-5.09, p = 0.630), stroke (0.2 vs. 0.2%, HR 1.18, 95% CI 0.07-18.86, p = 0.907) and stent thrombosis (1.4 vs. 0.7%, HR 1.76, 95% CI 0.42-7.26, p = 0.437) after matching.

CONCLUSION Ticagrelor and prasugrel showed similar efficacy and efficacy profiles for the treatment of STEMI in the Korean multicenter registry.

CATEGORIES **CORONARY:** Acute Myocardial Infarction

TCT-548

Short versus long DAPT following PCI, a systematic review and meta-analysis

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BACKGROUND Dual antiplatelet therapy (DAPT) remains the cornerstone therapy in the prevention of ischemic events following PCI. However, the mandatory duration of DAPT in new-generation drug-eluting stents (DES) remains a matter of debate. We aimed to evaluate efficacy and safety of short-term (≤6 months) versus long-term (≥12 months) duration of DAPT.

METHODS PubMed, EMBASE, Cochrane databases, and international meetings were searched for randomized clinical trials (RCT) comparing short versus long DAPT. A systematic review and meta-analyses of major trials was performed with primary outcome: all-cause death, myocardial infarction, stent thrombosis, stroke, and major bleeding.