of treatment outcomes that may limit the generalizability and quality of the study findings. The aim of this study was to determine whether there existed significant heterogeneity of treatment by center, country, or baseline risk factors for 5-year MACCE rates in the SYNTAX trial.

METHODS Patient level-data from the 5-year results of the SYNTAX study were analyzed for the presence of geographical heterogeneity (site/country) in the effect of treatment (CABG vs PCI) on 5-yr MACCE rates. Fixed and random effects models examined potential interactions, followed by generalized linear mixed models testing effects of clinical co-variates, such as diabetes, smoking rates, lesion characteristics and procedural variations

RESULTS For site-site comparison for 5-yr MACCE rates, the pooled odds ratio (OR) = 0.58, and for country-country the OR=0.59. By simple homogeneity testing, site-stratum differences neared significance (73 analyzed sites, X2=93.8, p=0.051), whereas no country-stratum differences (15 countries, X2=25.7, p=0.080) were observed. For random effects models with site or country as the cluster variable, intra-class correlation was minimal (ICC site = 1.4%, ICC country = 0.6%), with no significant heterogeneity of treatment effects observed. Adjusted regression models for age (ICC = 1.6%), male gender (ICC=1.2%), had no interaction effect on overall OR for MACCE (OR=0.59, 95% CI 0.48, 0.72, p<0.001). Wide variability in incident baseline risk factors (smoking, diabetes, PVD) was observed - not accounting for significant site-site or geographic treatment interaction in the adjusted models (ICC 1.0%-1.3%). Similarly, we observed wide ranges across sites for, Left Main disease rates (range 21-57%), TVR (range 8-31%), and PCI revascularization rates (range 8-31%), even when pooled by country. Adjusting for Left Main versus 3-vessel disease in the random effects models suggested PCI was protective of MACCE (OR=0.61, p<0.0001), with no difference between LM and 3-vessel disease (p=0.185), across site or country strata.

CONCLUSIONS As expected for this RCT, site-site and regional differences exist. Nonetheless, geographic variability in standard risk, responsiveness to treatment, and vulnerability to adverse outcomes, assessed by current models for heterogeneity analysis in clinical trials, shows no significant treatment effect. These findings highlight the utility and generalizability of the 5-year outcomes of the SYNTAX study.

CATEGORIES CORONARY: PCI Outcomes

KEYWORDS CABG, Clinical Trial, Stent, drug-eluting

TCT-491

Incidence of Peri-Procedural Myocardial Infarction after Bifurcation Percutaneous Coronary Intervention According to Different Definitions: Insight from the Tryton IDE randomized trial

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BACKGROUND The incidence of peri-procedural myocardial infarction (PPMI) in patients treated with percutaneous coronary intervention (PCI) varies largely between studies, and its clinical relevance still remains a matter of debate. We sought to examine the incidence of PPMI after bifurcation PCI using different definitions from the TRYTON randomized trial.

METHODS The TRYTON trial randomized 704 patients with bifurcation undergoing PCI to the Tryton side branch (SB) stent with main branch (MB) DES vs. provisional SB treatment with MB DES. In the current study, we reported and compared the incidence of PPMI after PCI, defined according three different definitions: per protocol (CK-MB 3× ULN), 3rd universal (troponin rise of > 5 × ULN), and SCAI (CK-MB rise of ≥10 × ULN).

RESULTS PPMI occurred in 81 out of 704 patients (11.5%) according to the protocol definition, in 137 patients (19.5%), according to the troponin-based third universal definition, and in 1.0% according to the SCAI definition, with no significant difference between the Tryton and provisional group (Table). Access site (femoral vs radial; OR 0.60, 95% CI 0.37-0.98), main vessel lesion length (OR 1.04, 95% CI 1.00-1.07), and main vessel diameter stenosis (OR 1.02, 95% CI 1.00-1.05), the use of devices other than angioplasty balloon (OR 3.77, 95% CI 1.02-13.86), and the use of "non-study" stents were identified as independent predictors of per-protocol PPMI. At 12-month follow-up, there were no cardiac death in PPMI and two (5.9%) in no-PPMI patients (p=0.61). Patients who experienced protocol-defined PPMI had significantly more target vessel revascularizations (11.1% vs. 5.1%; p=0.02).

Definition used	Tryton	Provisional	Combined	p-value
Protocol: CK-MB rise of > 3x ULN	13.6% (47/345)	10.1% (34/336)	11.5% (81/704)	0.19
3rd universal: troponin rise of > 5 × ULN	20.0% (71/355)	18.9% (66/349)	19.5% (137/704)	0.72
SCAI: CK-MB rise of ≥10 × ULN	1.4% (5/355)	0.6% (2/349)	1.0% (7/704)	0.26

CONCLUSIONS The incidence of PPMI varies significantly (by tenfold) according to the definition used. However, PPMI, independent of the PPMI definition, was not associated with an increase in cardiac mortality at 1-year follow-up. These findings are important and may have important implications when designing and selecting components of a primary composite endpoint for PCI randomized trial.

CATEGORIES CORONARY: PCI Outcomes

KEYWORDS Bifurcation stenting, Peri-procedural MI

TCT-492

Clinical Outcomes of a Fractional Flow Reserve-Guided Revascularization Strategy in Patients With Diabetes Mellitus. Results from a Single Center Registry

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BACKGROUND Previous studies have shown that deferral of revascularization in lesions with a fractional flow reserve (FFR) > 0.80 is safe and associated with significantly lower incidence of major adverse cardiovascular events (MACE) as compared to angiographically guided revascularization. DM patients have an accelerated atherosclerosis progression compared to patients without DM. Whether FFR-guided revascularization is also valid in DM patients is unknown, therefore we performed a retrospective study in our center.

METHODS We assessed all consecutive DM patients that underwent FFR-guided revascularization between January 2011 and December 2013, and followed them until May 2015. We further divided these patients into two groups according to the presence or absence of ≥1 FFR-negative lesion (≥ 0.80) remaining after index revascularization. DM was defined as self-reported by treatment with anti-diabetic medication or diet. The primary endpoint was the incidence of MACE defined as a composite of death, myocardial infarction (MI), target lesion revascularization (TLR) or rehospitalization for acute coronary syndrome (ACS). Target lesion was defined as the lesion(s) in which the FFR was performed. Logistic regression analysis was performed to assess for predictors of MACE.

RESULTS Of the 224 DM patients that underwent FFR-guided revascularization, 152(67.9%) had ≥1 FFR-negative lesion (Defer Group, DG) while 72(32.1%) had only FFR-positive lesions, with resultant index revascularization (Revascularization Group, RG). Overall, baseline characteristics were well matched between groups, however there were more females (37.5% vs 23.6%, p=0.04) in the DG, while rates of smoking (19.7% vs 34.7%, p=0.02) and prior PCI (41.4% vs 56.9%, p=0.03) were higher in the RG. The MACE rate was 34.2% in the DG and 26.4% in the RG, p= 0.24. The incidence of death was similar in both groups 15.8% vs 15.3% p=0.92. However a significantly higher rate of TLR (13.2% vs 4.2%, p=0.038) and rehospitalization for ACS (33.6% vs 19.4%, p=0.03) was observed in the DG group. Similarly a numerically higher incidence of MI was also observed but did not reach significance (7.2% vs 4.2%, p=0.56). Logistic regression analysis showed that increasing age, elevated HbA1c and renal insufficiency