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-year 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 comparison for 5-year MACCE rates, the pooled odds ratio (OR) was 0.58, and for country-country the OR was 0.59. By similar heterogeneity testing, site-stratum differences nearly 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/country or geographic treatment interaction in the adjusted models (ICC 1.0%-1.2%). 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 adjusted. Adjusting for Left Main versus non-Left Main 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

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**TCT-491**

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

Maciej Lesiak,1 Antonio L. Bartorelli,2 Maik J. Grundeken,3 Insight from the Tryton IDE randomized trial

**RESULTS**

Patients who experienced protocol-deﬁned PPMI had signiﬁcantly more target vessel revascularizations (11.1% vs. 5.1%, p = 0.02).

**CONCLUSIONS**

The incidence of PPMI varies signiﬁcantly (by tenfold) according to the deﬁnition used. However, PPMI, independent of the 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

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**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 cardiac vascular 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 uncertain and 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 = 0.044) in the DG, with 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 15.2%, 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.