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-site comparison for 5-yr MACCE rates, the pooled odds ratio (OR) = 0.58, and for country-country the OR = 0.59. By similar heterogeneity 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 across site-site or country-country strata. 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.

**REFERENCES**

**CATEGORIES CORONARY: PCI Outcomes**

**KEYWORDS** CABG, Clinical Trial, Stent, drug-eluting

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**RESULTS** PPMI occurred in 81 out of 704 patients (11.5%) according to the protocol definition, in 157 patients (19%), 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 PCI and only two (5.6%) in no-PPMI patients (p = 0.60). 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 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, Per-procedural MI

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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. Hence, the role of FFR-guided revascularization in DM is not well defined.

**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 lesions (≥1 FFR-negative: ≤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 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 (Defer Group, DG) while 72(32.1%) had only FFR-positive lesions, with resultant index revascularization. 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 (DFR Group, DG) while 72(32.1%) had only FFR-positive lesions, with resultant index revascularization. Whether FFR-guided revascularization is also valid in DM patients is unknown. Therefore we performed a retrospective study in our center.
were predictors of MACE. The presence of a lesion with a negative FFR was not a statistically significant predictor for MACE (OR 1.65, 95% CI 0.78-3.50, p=0.2) after adjustment for confounders.

**CONCLUSIONS** This study, the first to examine an FFR guided strategy in DM patients, shows similar MACE rates in both groups, however the event rates were numerically higher in the DM. The difference was mainly driven by a significantly higher rate of TLR and re-hospitalization for ACS, and a numerically higher rate of MI. Due to its limited power, this study should be considered as hypothesis generating, however it raises the question if an FFR-guided revascularization strategy is safe in patients with fast progressing plaque as in DM patients.

**CATEGORIES CORONARY:** PCI Outcomes  
**KEYWORDS** Diabetes, Fractional flow reserve, MACE

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**TCT-493**  
**Interventional Strategies for Coronary In-Stent Restenosis: A Hierarchical Bayesian Network Meta-Analysis of Randomized Trials**  
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**BACKGROUND** The management of coronary in-stent restenosis (ISR) is challenging and the most effective interventional treatment is still undefined. We aimed to compare different interventional strategies for coronary ISR to assess the relative efficacy in reducing target lesion revascularization (TLR).

**METHODS** Randomized trials comparing ≥ two different treatments were searched in PubMed, Embase, Scopus, Cochrane Library, Web of Science, and ScienceDirect electronic databases and major scientific websites. The search was performed from the date of databases inception to 30 December 2014. Patients of any age, gender, ischemic risk profile, and clinical presentation were included and any type of ISR, both bare-metal stent (BMS)-ISR and drug-eluting stent (DES)-ISR, first ISR and recurrent ISR, was considered. Trials comparing non-interventional treatments, variants of the same type of device, multiple strategies for ISR in the same group at the same time were excluded. The endpoint was TLR, defined as any repeated revascularization involving the target lesion, both percutaneous and surgical, at 6-12 months. Data used in this meta-analysis were intention-to-treat. A hierarchical Bayesian network meta-analysis was carried out using a random effects consistency model computed by Markov Chain Monte Carlo methods with Gibbs sampling based on 100,000 iterations following discard of 50,000 “burn-in” iterations. Posterior inference was expressed as odds ratio (OR) and 95% credibility interval (CrI). Heterogeneity was graded using I² statistic. Inconsistency was explored using network “node-split”.

**RESULTS** A total of 24 trials (4,880 patients) and 7 interventional treatments (Plain Balloon [PB], drug-coated balloon [DCB], DES, BMS, brachytherapy [BT], rotational atherectomy [ROTA], and cutting balloon [CUT]) were included in this meta-analysis. DCB and DES were associated with a significant reduction in the risk of TLR compared with all the other treatments. PB anti-restenotic effect was comparable with those of BMS, BT, ROTA, and CUT. No difference in TLR between DCB and DES was observed (DCB vs. DES: OR 1.11, 95% CrI 0.59-2.07).

**CONCLUSIONS** DCB and DES are the most effective interventional strategies for ISR and PB alone should no longer be considered. BMS, BT, ROTA and CUT present anti-restenotic effects similar to PB.

**CATEGORIES CORONARY:** PCI Outcomes  
**KEYWORDS** Drug-eluting balloon, Drug-eluting stent, Restenosis, in-stent

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**TCT-494**  
**Long term outcomes and symptom resolution with PCI and medical therapy in patients re-presenting with stable angina post CABG**  
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**BACKGROUND** Patients presenting with recurrent angina after a remote history of coronary artery bypass grafting (CABG) represent a challenge in adequately resolving symptoms due to native disease progression, and graft attrition. While the favored treatment modalities consist mainly of medical therapy or percutaneous coronary intervention (PCI), there is limited data available on the subsequent clinical outcomes. We therefore report the long term outcomes of patients with a history of CABG who underwent repeat angiography for recurrence of stable angina.

**METHODS** We retrospectively collected clinical data on patients with a history of prior CABG who underwent angiography after presenting with angina between Jan 2008 and Dec 2012. Treatment allocation was at the discretion of the treating physician, and all further treatments are required to optimize outcomes. Patients presenting with an ACS were excluded. A total of 173 consecutive patients (mean age 67.6 yrs, 88% male) underwent coronary angiography after presenting with angina. 173 patients were treated medically, 114 patients treated with PCI. Patients assigned to medical therapy had lower cardiac risk at the time they underwent CABG angiography, with higher rates of diabetes and prior PCI. PCI group had lower rates of peripheral vascular disease, hypertension, and atrial fibrillation. The PCI group had similar rates of angina pattern (49% chest pain induced vs 51% effort induced), that remained constant between both groups (p=0.39). In the PCI group, one year and five year event-free survival rates were 63.3% and 47.7%, respectively. In the medical group, the one year and five year event-free survival rates were 60.3% and 46.8%, respectively. At one year, PCI was associated with a statistically significant lower rate of angina symptoms (5.6% vs 10.2%, p=0.05).osis rates at 1 year in the medical group (21.4% vs 7.0% in the PCI group (p<0.001). This was driven mainly by MI and rehospitalization for cardiac causes (18.2% and 25.4% respectively in the medical group compared to 5.3% and 12.3% for the PCI group). Over a mean follow-up period of 3 years, there was no difference in all-cause mortality in either cohort (Medical 7.5%vsPCI 4.3% p=0.18). One year mortality was higher in vein graft PCI group than native vessels (0% vs 8%, P<0.05).

**CONCLUSIONS** In patients presenting with recurrent angina after previous CABG, patients treated with PCI had higher angina burden than those treated medically. Equivalent symptomatic improvements was achieved with PCI and medical therapy. There was significant difference in MACE in the PCI group compared to medical therapy with a trend to mortality benefit at 3yrs. Native vessel PCI had better 1yr outcomes than SVG-PCI in these subgroups. Once patients present with angina post CABG, continuing symptom burden and recurrent clinical events remain problematic and further treatments are required to optimize outcomes.

**CATEGORIES CORONARY:** PCI Outcomes  
**KEYWORDS** Angina, Percutaneous coronary intervention, elective, Prior CABG

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**TCT-495**  
**Drug-Eluting Stent and Drug-Coated Balloon for Coronary In-Stent Restenosis: A Pair-Wise Meta-Analysis of Randomized Trials Implemented with Trial Sequential Analysis**  
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**BACKGROUND** Drug-eluting stent (DES) and drug-coated balloon (DCB) seem to be the most effective treatments for coronary in-stent restenosis (ISR). We performed a meta-analysis of randomized trials comparing DES and DCB for ISR in the attempt to define whether one of these treatments presents a higher anti-restenotic efficacy.

**METHODS** Randomized trials comparing DES and DCB for ISR were searched in PubMed, Embase, Scopus, Cochrane Library, Web of Science, and ScienceDirect electronic databases. No clinical or angiographic restrictions were imposed. The endpoint was target lesion revascularization (TLR) at 12 months, defined as any repeated revascularization involving the target lesion, both percutaneous and surgical. Data used in this meta-analysis were