CONCLUSIONS: MI and BRH are associated with comparable and durable mortality risks over one year in ACS patients undergoing PCI.

CATEGORIES CORONARY: PCI Outcomes

KEYWORDS: Dual antiplatelet therapy, Myocardial infarction, PCI - Percutaneous Coronary Intervention

TCT-488

Comparison of clinical outcomes between a novel prolonged stent inflation protocol with conventional rapid/inflation/deflation method

Srikanth Vallipuram,1 Srikanth Kasula,1 Naga Venkata Krishna Chand Pothenimi, Shiv Kumar Agarwal,3 Zubair Ahmed,1 Abdul Hakeem,1 Uretsky Barry1
1University of Arkansas for Medical Sciences, Little Rock, AR;
2University of Arkansas for Medical Sciences, Little Rock, AR;3UAMS, Little Rock, United States

BACKGROUND: There is no consensus regarding the duration of stent inflation to achieve optimal stent expansion. We have devised a novel inflation protocol named “pressure optimization protocol (POP)” that uses pressure stabilization for at least 30 seconds at peak inflation pressure as an endpoint. We have previously shown by OCT that POP improves stent expansion vs rapid inflation/deflation, is safe, and requires approximately 100 seconds to achieve pressure stability. To determine whether POP is safe in long-term follow-up, we determined target vessel failure (TVF - composite of target vessel revascularization, myocardial infarction and cardiac death) in our single-center cohort and compared it to a contemporaneously treated group who underwent a rapid inflation/deflation deployment technique.

METHODS: 736 patients who underwent PCI using either routine stent inflation (non-POP, n=320) or POP (n=416) between Jan 2009 - March 2014 were included. Baseline clinical, lesion and PCI characteristics were recorded. The primary endpoint was target vessel failure.

RESULTS: Mean inflation time in POP group was significantly longer than rapid inflation/deflation group (104 ± 45 s vs. 19 ± 17 s, p < 0.001). At a mean follow-up duration of 1211 days (range 0-291) cumulative survival free from TVF (Figure 1) was significantly better in the POP group compared to the rapid inflation/deflation group (89.9% vs 82.5%; log rank chi² = 18.7; p<0.0001).

CONCLUSIONS: Prolonged stent inflation using pressure optimization appears to improve long-term outcomes after stent implantation in our center. This prospective quality improvement analysis needs to be confirmed in a randomized controlled trial.

CATEGORIES CORONARY: PCI Outcomes

KEYWORDS: Stent malapposition, late-acquired, Target vessel revascularization

TCT-489

Complete percutaneous revascularization in ischemic heart failure improves survival – report from the COMMIT-HF registry

Łukasz Pyka,1 Michał Hawranek,1 Mateusz Tajshta,1 Jarosław Gorol,1 Anna Kurek,1 Adam Krajewski,1 Andrzej Lekston,1 Marek Gierlotka,1 Mariusz Gasior1
1Medical University of Silesia, Silesian Center for Heart Diseases, Zabrze, Poland

BACKGROUND: Heart failure (HF) is the major cause of death in cardiovascular disease. In a post-STICH environment, we lack data on the role of PCI in systolic HF patients. Complete revascularization of myocardium remains one of the key unanswered questions in ischemic HF.

METHODS: The COMMIT-HF is an ongoing single-center systolic HF registry (inclusion criteria: HF with LVEF <35%, exclusion: ACS). A total of 1798 patients were enrolled since 2009. Among them we have selected a group of patients with multivessel CAD qualified for PCI. The subjects were divided into complete (n=188) and incomplete revascularization (n=159) groups. Completeness of revascularization was defined as successful PCI of every angiographically significant lesion in all arteries with a diameter of 2mm with a patent surgical graft. All of the analyzed patients are followed up for a period of at least 12 months with all-cause mortality defined as primary endpoint.

RESULTS: Patient characteristics are presented in Table 1. Both groups showed no significant differences in clinical status and echocardiographic parameters, however there was a higher comorbidity rate in the incomplete revascularization group. Drug-eluting stents were implanted more frequently in the complete revascularization group (65.9% vs. 52.8%, p<0.01), with no other significant differences in PCI strategy with very low and comparable complication rates. All-cause mortality was significantly higher in the incomplete revascularization group both after 12-month (6.4% vs 20.1%, p<0.001) and 24-month (14.2% vs 27.2%, p=0.004) follow-up period. In multivariate analysis complete revascularization was an independent factor improving survival (OR 0.33, 95% CI 0.14-0.74, p<0.007).

CONCLUSIONS: Our observational study shows, that in an unselected ischemic HF population angiographically-driven complete percutaneous revascularization has led to improved 12 and 24-month survival. If possible, complete revascularization in ischemic HF should always be considered and is a definite candidate for further randomized studies.

CATEGORIES CORONARY: PCI Outcomes

KEYWORDS: Complete coronary revascularization, Heart failure, PCI - Percutaneous Coronary Intervention

TCT-490

Synta 5-Year Outcomes - Does Geographical Variability Impact Treatment Effects?

Andrew K. Roy,1 Bernard Chevalier,1 Thierry Lefevre,1 Patrick W. Serruys,1 Keith D. Dawkins,2 Pieter Kappetein,1 Friedrich-Wilhelm Mohr,3 Antonio Colombo,3 Ted Feldman,4 Marie-Claude Morice1
1Générale de Santé, Institut Cardiovasculaire Paris Sud, Massy, France; 2Thoraxcenter, Rotterdam, Netherlands; 3Boston Scientific Corporation, Marlborough, MA; 4Erasmus MC, Rotterdam, Netherlands; 5Heart Center Leipzig, University of Leipzig, Leipzig, Germany; 6EMO GVM Centro Cuore Columbus/San Raffaele Hospital, Milan, Italy; 7Evaston Hospital, Evanston, United States

BACKGROUND: The use of multiple geographical sites for randomized cardiovascular trials may sometimes lead to important heterogeneity

CONCLUSIONS: MI and BRH are associated with comparable and durable mortality risks over one year in ACS patients undergoing PCI.
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 simple heterogeneity testing, site-stratum differences reached significance (73 analyzed sites, X2=93.8, p<0.05), 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 adjusted 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

Maciej Lesiak,1 Antonio L. Bartorelli,1 Maik J. Grundeken,1 Philippe Genereux,1 Joanna J. Wykrzykowska,1 Dominic P. Francesc,6 Indulis Kumsars,1 Annapoona Kini,1 Thierry Lefere,1 Hector M. Garcia-Garcia,2 Geza Fontos,1 Pieter R. Stella,1 Imre Ungi,3 Linn L. Laak,1 Yoshinobu Onuma,16 Martin Leon,17 Philippe Genereux,4 Joanna J. Wykrzykowska,5 Dominic P. Francese,6 Hendrik J. van Suylen,12 Patrick W. Serruys,18

**RESULTS** PPMI occurred in 81 out of 704 patients (11.5%) according to the protocol definition, in 157 patients (22%), 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 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 0.77, 95% CI 1.02-1.83), and the use of “non-study” stents were identified as independent predictors of per-protocol PPMI. At 12-month follow-up, there were no cases of death in PCI and two (5.6%) in no-PPMI patients (p=0.65). Patients who experienced protocol-defined PPMI had significantly more target vessel revascularizations (11.1% vs. 5% p=0.02).

**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) 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 undertook 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, and in 1.0% according to the

**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 1.8% 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=0.05) 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