intention-to-treat. A standard pair-wise meta-analysis was carried out using a DerSimonian-Laird random effects model. Risk distribution was expressed as odds ratio (OR) and 95% confidence interval (CI). Heterogeneity was graded using I² statistic. Trial sequential analysis is similar to interim analyses in a single trial, where monitoring boundaries are used to decide whether a trial could be terminated early when a p value is sufficiently small. Monitoring boundaries were generated using the O'Brenn-Fleming 2-spending and the required diversity adjusted information size was estimated.

RESULTS Six randomized trials (1,161 patients) were included in this meta-analysis. Pooled estimate tended to favor DES but the difference was not significant (OR 0.66, 95% CI 0.33-1.31, p = 0.235). Heterogeneity was moderate (I² = 56%). At trial sequential analysis, the cumulative z-curve did not cross the traditional boundary (1.96 cumulative Z-Score) and the trial sequential monitoring boundary (x-spending adjusted 95% CI 0.26-1.66), but neither futility boundary was overlapped indicating that, adding patients to the comparison, DES could produce a 50% relative risk reduction in 12-month TLR. The anticipated number of patients required was 1,871.

CONCLUSIONS DES may have superior anti-restenotic efficacy compared with DCB, but the difference is not significant. Trial sequential analysis advices that an adjusted number of 1,871 patients is required to show a significant TLR risk reduction with DES and, since futility boundary are not crossed, confirms that adding patients to this comparison the difference can become significant.

CATEGORIES CORONARY: PCI Outcomes

KEYWORDS Drug-eluting balloon, Drug-eluting stent, In-stent restenosis

TCT-496

5-year outcome of consecutive left main coronary artery percutaneous coronary interventions

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BACKGROUND Significant unprotected left main coronary artery stenosis (ULMCA) is an accepted indication for coronary bypass grafting (CABG). However CABG is no option in a number of clinical conditions. Percutaneous coronary intervention (PCI) can be performed even under these unfavorable conditions. We sought to describe the procedural characteristics and 5-year outcomes of the non-selected population undergoing ULMCA PCI at our tertiary care Institution.

METHODS All consecutive patients undergoing UL PCI at the Hungarian Institute of Cardiology between Jan. 1, 2007 and Dec. 31, 2008 are included in this study. The choice of devices including stents (bare metal or drug eluting (DES) stents), stenting strategy (single or two-stent technique) and the use of intraaortic balloon pumps were left to the discretion of the operator. 5-year follow-up data concerning survival, myocardial infarction (MI), repeat revascularization and coronary angiography were collected using the institutional database, contacting the patients, their families, other hospitals and the National Health Insurance database.

RESULTS 76 patients underwent ULMCA PCI at our institution during the study period. Their baseline clinical characteristics are shown in Table 1. The indication for ULMCA PCI was angina pectoris in 18 (24%), non-STEMI segment elevation acute coronary syndrome (ACS) in 32 (42%), ST-elevation myocardial infarction in 11 (15%), cardiogenic shock caused by MI in 13 (17%) and heart failure not related to ACS in 2 cases (2.5%). 61 patients (80%) received a DES in ULMCA. No patient suffered a peri-procedural MI or stroke. 30-day mortality was 14.5%, 5-year mortality 50%. In ROC analysis, EuroSCORE II was the best predictor of 5-year survival (AUC 0.727). Survival according to different SYNTAX score tertiles was not significantly different. 2 suffered a fatal MI, 3 patients had a non-fatal MI during follow-up. 3 patients had significant in-stent restenosis (ISR) in ULMCA all successfully treated by rePCI. Another 11 patients had rePCI and 3 CABG because of non-ULMCA ISR. In multivariate analysis, male gender, age, GFR, presence of diabetes mellitus and SYNTAX score emerged as independent predictors of 5-year event free survival. There was no acute stent thrombosis, we had one probable subacute stent thrombosis, one definite late stent thrombosis in the LAD (but not in the ULMCA) and one possible very late stent thrombosis.

CONCLUSIONS ULMCA PCI can be applied with good long-term results in patients who cannot undergo CABG because of the clinical scenario, comorbidities or advanced age. The clinical presentation and downstream disease have a major influence on the 5-year outcome of the patients.

CATEGORIES CORONARY: PCI Outcomes

TCT-497

Stent Fracture: Presentation And Outcomes

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BACKGROUND Stent fracture (SF) is a rarely reported complication of percutaneous coronary interventions (PCI). It is more commonly reported with older generation stents particularly the sirolimus eluting (Si-DES) stent technique and the use of sisteraortic balloon pumps was left to the discretion of the operator. 5-year follow-up data concerning survival, myocardial infarction (MI), repeat revascularization and coronary angiography were collected using the institutional database, contacting the patients, their families, other hospitals and the National Health Insurance database.

RESULTS 16 patients with 18 SF events were identified at median age of 62.0 (IQR 48.1-71.2) years, 0.6 (IQR 0.3-1.7) years after stent implantation;