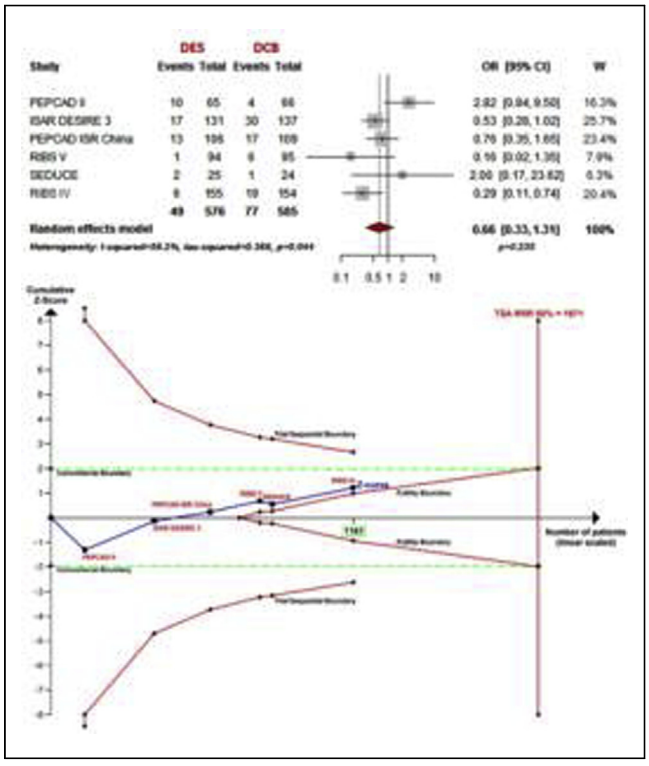
intention-to-treat. A standard pair-wise meta-analysis was carried out using a DerSimonian-Laird random effects model. Risk distribution was expressed as odds ratio (OR) and 95% confidence interval (CI). Heterogeneity was graded using I^2 statistic. Trial sequential analysis is similar to interim analyses 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'Brien-Fleming α-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 (I^2 = 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 (α-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 became 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 artery 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 recoronary 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-ST-segment elevation acute coronary syndrome (ACS) in 32 (42%), ST-elevation myocardial infarction in 11 (14,5%), 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.

Age, years ± SD [IQR]	70,1 ± 11,4 [61,8-78,2]
Male (%)	42 (55)
Hypertension (%)	62 (82)
Diabetes mellitus (%)	25 (33)
Dyslipidemia (%)	54 (71)
Previous myocardial infarction (%)	23 (30)
Previous PCI (%)	12 (16)
Previous CABG (%)	7 (9)
LVEF on echo, % ± SD [IQR]	45 ± 14 [35-55]
EuroSCORE II ± SD [IQR]	14,81 ± 17,27 [2,8-26,2]
Additive EuroSCORE ± SD [IQR]	10,2 ± 4,6 [7-15]
Logistic EuroSCORE ± SD [IQR]	25,25 ± 23,80 [6,1-47,9]
ACEF score ± SD [IQR]	1,82 ± 0,82 [1,2-2,3]
GFR, ml/min/1,73m^2± SD [IQR]	61,9 ± 29,5 [41,9-82,8]
SYNTAX score ± SD [IQR]	27,3 ± 12,2 [17-37,5]

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 stent. We sought to define our experience and outcome of subjects presenting to our center with SF.

METHODS We identified all mention of the term 'stent fracture' from all reports in the cardiac catheterization laboratory database over a 10 year period, from 2006 to 2015 (first quarter). All coronary SF were identified. Subjects who refused authorization for use of their medical record in research were excluded. The medical record and coronary angiograms of the remainder were reviewed. This study was approved by the Mayo Clinic IRB.

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;

Patients presented with stable angina- 9 (56%) and acute coronary syndrome-6 (38%): 4 with unstable angina and 1 each with STEMI and NSTEMI. Clinical characteristics are given in the table. SF type was severe (complete separation of stent segments) in 2 (13%) cases; moderate (fracture > 1 strut) in 6 (38%) cases and minor (single strut fracture) in 8 (50%) cases. SF site is given in the table. In-stent restenosis (ISR) was reported in all: median percent stenosis 75 (IQR 58, 90) %. The types of stents involved were: bare metal- 3(17%); older generation DES- 6(33%)-5 of which were sirolimus eluting stents; covered: 1(6%); newer generation DES: 4(22%); Unknown 5(28%). One patient had 2 types of stent with fracture. Six (33%) of these stents were implanted at a previous site of ISR. SF was managed by repeat stenting in 9 (50%); PTCA-1 (6%); observation- 4 (22%); CABG- 4 (22%). At median 3.5 (IQR 2.25, 4) years of follow up, 9 patients (56%) had at least one cardiovascular event (CV death, hospitalization or revascularization) including recurrent ISR- 3(19%) and recurrent chest pain syndromes unrelated to coronary stenosis-3 (19%). There was no significant relationship between the management of the SF event (PCI, CABG or medical management) and outcome (p=0.66).

CONCLUSIONS SF is a rare occurrence, can be associated with any stent type, and invariably presents with some degree of ISR. It is associated with significant long-term morbidity regardless of management. A diagnosis of ISR should raise suspicion for SF especially in newer generation DES where the thin struts may make angiographic visualization of SF difficult.

Variable	N (%)
Subjects (n=16)	
Women	7 (44%)
Race (white)	16 (100%)
Comorbidities	
Hypertension	14 (88%)
Diabetes Mellitus	3 (19%)
Dyslipidemia	15 (94%)
Any history of smoking	10 (63%)
Chronic Kidney Disease	1 (6%)
Prior CABG	8 (50%)
Stent Fractures (n=18)	
Stent site- native vessel	
RCA - proximal, distal	4 (22%)-3,1
Mid-LAD	6 (33%)
Ramus intermedius	1 (6%)
Circumflex - proximal, OM	4 (22%) 1,3
Stent site- graft	
LAD- LIMA, SVG	2 (19%) 1,1
Ramus intermedius	1 (6%)
Native vessel at site of prior graft anastomosis	3 (17%)

CATEGORIES CORONARY: Complications

KEYWORDS PCI - Percutaneous Coronary Intervention, Restenosis, in-stent, Stent fracture

TCT-498

Impact of duration of dual antiplatelet therapy on clinical outcomes 1 year after implantation of abluminally coated drug eluting stent with bioresorbable polymer

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BACKGROUND Duration of dual anti-platelet therapy (DAPT) after implantation of DES remains controversial despite clear guidelines. Our aim was to compare clinical outcomes in patients treated with bioresorbable polymer Nobori DES, who were under DAPT for a minimum of 12 months with those who stopped DAPT earlier

METHODS Information was obtained from 2 large prospective, multicenter, multinational, single-arm, observational NOBORI registries on duration of DAPT for 11448 patients. 8124 patients were treated with DAPT continuously for 12 months, 3324 had stopped DAPT at different time intervals (no-DAPT): 316 patients within 1 month (DAPT<1M), 3008 patients between 1 month and 12 months (DAPT<12M). We analyzed impact of DAPT duration on clinical outcomes at one year.

RESULTS In the DAPT cohort patients were younger, had higher frequency of diabetes and presented less often with hypertension and renal failure or previous stroke. No-DAPT patients were older, had more often hypertension, renal failure and previous stroke. DAPT patients had more lesions at bifurcations and were more often complex (type C). Access site in DAPT cohort was more often femoral. TLF rate at 1 year in DAPT<1M subgroup was 7.4%, any death or MI was 8.0%, and Cardiac Death or MI rate was 6.4%. For DAPT<12M it was 1.6%, 1,2% or 1.0% respectively. Target vessel failure rate was lowest at 1.9% in DAPT<12M subgroup, followed by DAPT group with 2.7% and DAPT<1M with 8.6%. As expected, definite and probable stent thrombosis rate was significantly higher in DAPT<1M subgroup 1.9%, while it was low in DAPT<12 and in DAPT subgroup (0.3%).

CONCLUSIONS The results indicate that continuation of DAPT within the first month of stent implantation remains crucial. After the first month, shorter duration of DAPT does not have negative impact on the one year clinical outcomes and that such practice is feasible treatment option for patients who have received new generation DES. Whether bioresorbable polymer and abluminal coating, as applied on Nobori DES, have some effects on these findings remain to be seen when results of dedicated randomized study becomes available.

CATEGORIES CORONARY: PCI Outcomes

TCT-499

Long Term Clinical Outcomes of Newly Diagnosed Diabetes and Prediabetes among Patients with Acute Myocardial Infarction

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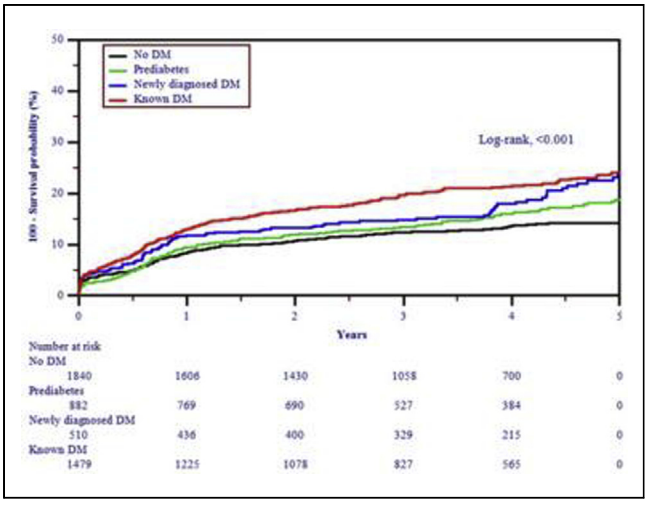
BACKGROUND Recent studies have demonstrated that newly diagnosed diabetes mellitus and prediabetes is common among patients with acute myocardial infarction. We examined the 5-years clinical outcomes of known diabetes mellitus, newly diagnosed diabetes mellitus and prediabetes among acute myocardial infarction undergoing primary percutaneous coronary intervention.

METHODS We retrospectively analyzed a total of 4,748 acute myocardial infarction patients who successfully underwent PCI from January 2004 to December 2009 in COREA-AMI (COnvergent REgistry of cAtholic and chonnAm university for AMI) registry. Patients were stratified into four groups: "known diabetes" (n=1494[31.5%]; reported on the case report form), "newly diagnosed diabetes" (n=517 [10.9%]; no diabetes history and HbA1c≥6.5), "prediabetes" (n=884 [18.6%]; no diabetes history and 5.7≤HbA1c≤6.4, "no diabetes" (n=1853[39.0%]). Primary outcomes were all-cause mortality and major adverse cardiovascular and cerebrovascular event (composite of cardiac death, non-fatal MI, stroke, target vessel revascularization).

RESULTS Newly diagnosed diabetes was associated with greater 5-years mortality (adjusted hazard ratio (HR) 1.421, 95% CI 1.106-1.824 and p=0.006) and greater 5- years MACCE (adjusted HR 1.291, 95% CI 1.022-1.630 and p=0.032). Known diabetes was also associated with greater 5-years mortality (adjusted HR 1.471, 95% CI 1.228-1.762 and p<0.001) and greater 5-years MACCE (adjusted HR 1.449, 95% CI 1.225-1.713 and p<0.001). Prediabetes was associated with greater 5-years MACCE (adjusted HR 1.219, 95% CI 1.002-1.484 and p=0.048), but 5-years mortality was similar to those of normal patients.

CONCLUSIONS In addition to known diabetes, newly diagnosed diabetes and prediabetes are also an independent risk factor for long-term MACCE in patients with acute myocardial infarction.



CATEGORIES CORONARY: PCI Outcomes