

# 5-Year Outcomes Following Percutaneous Coronary Intervention With Drug-Eluting Stent Implantation Versus Coronary Artery Bypass Graft for Unprotected Left Main Coronary Artery Lesions

## The Milan Experience

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**Objectives** We sought to evaluate at 5 years the occurrence of cardiac death; cardiac death, and/or myocardial infarction (MI); cardiac death, MI, and/or stroke; target vessel revascularization; and major adverse cardiac and cerebrovascular events following percutaneous coronary intervention (PCI) with drug-eluting stent (DES) versus coronary artery bypass graft (CABG) in unprotected left main coronary artery lesions.

**Background** Preliminary results at 1 year showed comparable occurrence of major adverse cardiac and cerebrovascular events in our center between PCI and CABG.

**Methods** All consecutive patients with an unprotected left main coronary artery stenosis electively treated with DES implantation versus CABG in our center, between March 2002 and July 2004, were analyzed. A propensity analysis was performed to adjust for baseline differences between the 2 cohorts.

**Results** We included 249 patients in the study: 107 were treated with PCI and DES implantation and 142 with CABG. At 5-year clinical follow-up, no difference was found between PCI and CABG in the occurrence of cardiac death (adjusted odds ratio [OR]: 0.502; 95% confidence interval [CI]: 0.162 to 1.461;  $p = 0.24$ ). The PCI group showed a trend toward a lower occurrence of the composite end point of cardiac death and MI (adjusted OR: 0.408; 95% CI: 0.146 to 1.061;  $p = 0.06$ ). Percutaneous coronary intervention was associated with a lower rate of the composite end point of death, MI, and/or stroke (OR: 0.399; 95% CI: 0.151 to 0.989;  $p = 0.04$ ). Indeed, CABG was correlated with lower target vessel revascularization (adjusted OR: 4.411; 95% CI: 1.825 to 11.371;  $p = 0.0004$ ). No difference was detected in the occurrence of major adverse cardiac and cerebrovascular events (adjusted OR: 1.578; 95% CI: 0.825 to 3.054;  $p = 0.18$ ).

**Conclusions** At 5-year clinical follow-up, there was still no difference in the occurrence of major adverse cardiac and cerebrovascular events between elective PCI with DES implantation and CABG in unprotected left main coronary artery lesions in this single-center experience. There was an advantage of PCI in the composite end point of death, MI, and/or stroke, whereas a benefit in the need for reintervention was still found in CABG. (J Am Coll Cardiol Intv 2010;3:595–601) © 2010 by the American College of Cardiology Foundation

According to current guidelines, the treatment of unprotected left main coronary artery (ULMCA) disease with percutaneous coronary intervention (PCI) has a Class IIb indication (1). Registry data of PCI with drug-eluting stent (DES) implantation in ULMCA lesions have shown that this is a feasible and safe approach, at mid-term clinical follow-up (2–11). Recently, results from multicenter registries have reported favorable outcomes at up to 3-year clinical follow-up (12–14). Moreover, registries evaluating PCI with DES versus coronary artery bypass graft (CABG)

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in this subset of patients have reported encouraging results. The randomized SYNTAX (Synergy between Percutaneous

### Abbreviations and Acronyms

**CABG** = coronary artery bypass graft

**CVA** = cerebrovascular accident

**DAT** = dual antiplatelet therapy

**DES** = drug-eluting stent(s)

**MACCE** = major adverse cardiac and cerebrovascular events

**MI** = myocardial infarction

**PCI** = percutaneous coronary intervention

**ST** = stent thrombosis

**TLR** = target lesion revascularization

**TVR** = target vessel revascularization

**ULMCA** = unprotected left main coronary artery

Coronary Intervention with Taxus and Cardiac Surgery) study also reported noninferiority in 12-month major adverse cardiac and cerebrovascular events (MACCE) of PCI as compared with CABG in this subset of patients (15). We have previously reported no difference in the degree of protection against death, stroke, myocardial infarction (MI), and revascularization between PCI with DES and CABG for ULMCA at 1 year (16). The aim of the present study is to report 5-year clinical follow-up of the treatment of ULMCA stenosis with PCI and DES implantation versus surgical revascularization.

### Methods

All patients with ULMCA stenosis treated with PCI and DES implantation or CABG between March 2002 and July 2004 were analyzed. The decision to perform PCI or CABG depended on patient comorbidities and/or physician's choice. In all cases, the revascularization approach selected appeared suitable to guarantee complete revascularization. In general, if the patient had a contraindication to 1-year dual antiplatelet therapy (DAT) after PCI, then the patient was referred for CABG. Hierarchical study end points were the composite occurrence at 5 years of cardiac death; cardiac death or MI; cardiac death, MI, or stroke; repeat revascularization; cardiac death, MI, stroke, or repeat revascularization. Clinical follow-up was scheduled and obtained for all patients at 60 months.

In patients treated with PCI, DAT (i.e., aspirin 100 mg daily and clopidogrel 75 mg daily or ticlopidine 250 mg twice daily) was administered for at least 12 months. Detailed information on adherence as well as reasons and date for discontinuation of DAT was obtained in all patients. Angiographic follow-up was scheduled if non-invasive evaluation or clinical presentation suggested ischemia.

**Definitions.** Definition of hospital non-Q-wave MI was illustrated in the previous report (16).

In this report, the following MACCE were analyzed cumulatively at 5-year clinical follow-up: cardiac death, MI, cerebrovascular events, target lesion revascularization (TLR), and target vessel revascularization (TVR). The occurrence of stent thrombosis (ST) was defined on the basis of the Academic Research Consortium definitions (17) in the PCI group; whereas the occurrence of symptomatic graft occlusion was evaluated in the CABG group (15). Deaths were classified as either cardiac or noncardiac. Cardiac death was defined as any death due to a cardiac cause (e.g., MI, low-output failure, fatal arrhythmia), procedure-related deaths, and death of unknown cause. We defined TLR as any revascularization performed on the treated segment and TVR as any revascularization performed on the treated vessel considering also treatment of any segment in left anterior descending and circumflex artery. Cerebrovascular accident (CVA) was defined as stroke, transient ischemic attacks, and reversible ischemic neurological deficits adjudicated by a neurologist and confirmed by computed tomography scanning (15).

In this analysis, the following were included as cumulative MI: 1) all Q-wave MIs that occurred during hospital stay and at follow-up; and 2) all spontaneous MIs occurring after hospital discharge.

Q-wave MI was defined as the development of new pathological Q waves in 2 or more contiguous leads (according to the Minnesota Code as assessed by the electrocardiogram core laboratory) with or without creatine kinase or creatine kinase-myocardial band levels elevated above normal.

“Spontaneous” MI was defined as the occurrence after hospital discharge of any value of troponin and/or creatine kinase-myocardial band greater than the upper limit of normal if associated with clinical and/or electrocardiographic change.

The EuroSCORE (European System for Cardiac Operative Risk Evaluation), which is based on patient-, cardiac-, and operation-related factors, was used to stratify the risk of death at 30 days. According to the scoring system, the patients were stratified as high risk in the presence of a EuroSCORE  $\geq 6$  and as very high risk if EuroSCORE was  $\geq 13$ .

**Statistical analysis.** Data are presented as percentages and mean  $\pm$  SD. In general, differences in proportions were tested with chi-square test or Fisher exact test, and differ-

ences in location parameters of continuous variables were tested with a Student *t* test. Because of the nonrandomized nature of the study, a propensity score analysis was performed to minimize any selection bias due to the differences in clinical characteristics between the 2 treatment groups. Briefly, for each patient, a propensity score, indicating the likelihood of having PCI, was calculated by the use of a multivariable logistic regression that identifies variables independently associated with PCI. Variables included in the logistic regression analysis were age, sex, diabetes, hypertension, hypercholesterolemia, smoking, familiar history of coronary artery disease, unstable angina, renal failure, left ventricular ejection fraction, EuroSCORE, EuroSCORE  $\geq 6$ , right coronary artery disease, and right coronary artery treatment during the index procedure. The C statistic for the propensity score model was 0.78, indicating a good discrimination. Patients were subsequently divided into 4 subgroups according to the quartiles of the propensity score. The impact of PCI on cardiac death; cardiac death or MI; cardiac death, MI, or stroke; repeat revascularization and MACCE during hospital stay; and at 5-year follow-up was investigated in all 4 subgroups of patients with similar characteristics, between PCI and CABG. Exact logistic regression models based on permutation resampling were employed to perform unadjusted univariate analyses, stratified analyses using the propensity score quartiles as variable, and the subgroup analyses performed within each propensity score quartile. Results were reported as odds ratios (ORs) together with associated exact 95% confidence intervals (CIs). The SAS version 9.1 (SAS Institute, Cary, North Carolina) was used for the analysis.

## Results

Baseline clinical characteristics are summarized in Table 1.

A total of 249 patients were treated: 142 with CABG and 107 with PCI and DES implantation. In the PCI group, 52 patients had paclitaxel- and 55 sirolimus-eluting stent implantation. Patients treated with PCI were younger ( $63.6 \pm 10.3$  years vs.  $67.5 \pm 9.7$  years;  $p = 0.002$ ), less frequently had hypertension (58.8% vs. 76.0%;  $p = 0.006$ ) and renal failure (1.9% vs. 8.4%;  $p = 0.02$ ), but more often presented with unstable angina (31.8% vs. 21.8%;  $p = 0.08$ ). Diabetes mellitus was present in 20 (18.7%) patients of the PCI group and 33 (23.2%) of the CABG group ( $p = 0.44$ ). No patient included in this study had a malignancy at the time of the procedure. More patients treated with CABG had additional disease in the right coronary artery (69.0% vs. 40.4%); this was treated during the index procedure in 48.3% versus 16.9% of the patients, respectively ( $p = 0.0001$  for both comparisons). All other variables were similar. Eighty-seven (81.3%) patients treated with PCI had distal ULMCA stenosis: 77 were bifurcations and 10 trifurcations. Both branches were stented in most of the patients (73.6%), probably reflecting the complexity of bifurcation

**Table 1. Clinical Characteristics of the Patients Treated With PCI Versus CABG**

	PCI (n = 107)	CABG (n = 142)	p Value
Age, yrs	63.6 $\pm$ 10.3	67.5 $\pm$ 9.7	0.0026
Diabetes mellitus	20 (18.7%)	33 (23.2%)	0.44
Smokers	53 (49.5%)	84 (59.1%)	0.16
Hypertension	63 (58.8%)	108 (76.0%)	0.006
Hypercholesterolemia	75 (70.0%)	98 (69.0%)	0.89
EuroSCORE	4.4 $\pm$ 3.6	4.3 $\pm$ 3.4	0.85
EuroSCORE $\geq 6$	34 (31.7%)	41 (28.8%)	0.67
Renal failure	2 (1.9%)	12 (8.4%)	0.02
Disease in RCA	42 (40.4%)	98 (69.0%)	0.0001
RCA treatment	18 (16.9%)	68 (48.3%)	0.0001
LVEF, %	52.0 $\pm$ 10.4	52.2 $\pm$ 11.4	0.91
Unstable angina	34 (31.8%)	31 (21.8%)	0.08
SYNTAX score	28.8 $\pm$ 10.4	29.4 $\pm$ 5.78*	0.90

Data presented as n (%) or mean  $\pm$  SD unless otherwise noted. \*The SYNTAX (Synergy between Percutaneous Coronary Intervention with Taxus and Cardiac Surgery) study scores were calculated in 80 of 142 CABG patients.

CABG = coronary artery bypass graft; EuroSCORE = European System for Cardiac Operative Risk Evaluation; LVEF = left ventricular ejection fraction; PCI = percutaneous coronary intervention; RCA = right coronary artery.

treated and our bifurcation stenting strategy at the time of the report. No differences were observed in SYNTAX scores between the 2 study groups.

In-hospital and 1-year outcome have been previously reported (16). Table 2 illustrates the occurrence of MACCE in-hospital and at 1 and 5 years. At a median follow-up time of 61.9 months (interquartile range [IQR]: 57.8 to 67.2 months), 26 patients (18.3%) in the CABG versus 17 patients (15.9%) in the PCI group died. Among them, 17 (11.9%) were adjudicated as cardiac death in the CABG cohort and 8 (7.5%) in the PCI group. Eleven patients (7.7%) in the CABG arm experienced a MI whereas only 1 patient (0.9%) did in the PCI group. Target lesion revascularization was performed in 12 (8.4%) versus 20 patients (18.7%) in the CABG and PCI groups, respectively. Twelve patients (8.4%) in the CABG group and 30 patients (28%) in the PCI arm underwent a TVR. Among the 30 patients in the PCI group, only 6 underwent a surgical revascularization. Cerebrovascular accident occurred in 6 patients (4.2%) in the CABG group and in only 1 patient (0.9%) in the PCI group.

Symptomatic graft occlusion occurred in 4 patients (2.8%) treated with CABG; definite and/or probable ST was adjudicated in 0.93% of patients that underwent PCI (only 1 definite ST and no probable ST). The only definite ST was a late ST in a paclitaxel-eluting stent implanted in the proximal left anterior descending artery at 3.9 months while on DAT. The patient experienced an anterior acute MI successfully treated with repeat PCI. Possible ST at 5-year follow-up was adjudicated in 6 patients (5.6%).

**Table 2. Occurrence of MACCE In-Hospital and at 1 and 5 Years**

Time of MACCE	CABG (n = 142)	DES (n = 107)
In-hospital, n (%)		
Death	3 (2.1)	0
Cardiac death	2 (1.4)	0
MI	37 (26.0)	10 (9.3)
QW-MI	5 (3.5)	0
TVR	3 (2.1)	0
TLR	3 (2.1)	0
CVA	2 (1.4)	0
1 year, n (%)		
Death	12 (8.1)	3 (2.8)
Cardiac death	7 (4.9)	2 (1.8)
MI	7 (4.9)	1 (0.9)
TVR	8 (5.6)	21 (19.6)
TLR	8 (5.6)	17 (15.8)
CVA	3 (2.1)	1 (0.9)
5 years, n (%)		
Death	26 (18.3)	17 (15.9)
Cardiac death	17 (11.9)	8 (7.5)
MI	11 (7.7)	1 (0.9)
TVR	12 (8.4)	30 (28.0)
TLR	12 (8.4)	20 (18.7)
CVA	6 (4.2)	1 (0.9)

CVA = cerebrovascular accidents; DES = drug-eluting stent(s); MACCE = major adverse cardiac and cerebrovascular event; MI = myocardial infarction; QW = Q-wave; TLR = target lesion revascularization; TVR = target vessel revascularization; other abbreviations as in Table 1.

Baseline characteristics of the patients with a possible ST are illustrated in Table 3.

Notably, only 34% of the patients in PCI and 2% in CABG groups were on long-term DAT at the time of last clinical follow-up. Regarding the adherence to any antiplatelet therapy (aspirin or clopidogrel/ticlopidine), 12 (8.4%) patients in CABG and 8 (7.4%) in PCI groups were not on any antiplatelet therapy at the time of last clinical contact.

Interestingly, no patient treated with PCI for ostial and/or shaft lesion died of cardiac cause or had an MI or a CVA during follow-up; only 1 patient had a TLR.

**Study end points.** At a median of 61.9 months (IQR: 57.8 to 67.2 months), no difference in cardiac death was observed (11.9% in CABG vs. 7.5% in PCI; unadjusted OR: 0.59; 95% CI: 0.21 to 1.5;  $p = 0.34$ ; adjusted OR: 0.502; 95% CI: 0.16 to 1.46;  $p = 0.24$ ). No significant difference was also found, despite the presence of a trend in favor of PCI, in the composite end point of cardiac death and MI (16.9% in CABG vs. 8.4% in PCI; unadjusted OR: 0.41; 95% CI: 0.16 to 0.95;  $p = 0.04$ ; adjusted OR: 0.408; 95% CI: 0.14 to 1.06;  $p = 0.06$ ). A potential benefit of PCI over CABG was suggested (confirming 1-year results) (16) in the composite end points of cardiac death, MI, and cerebrovascular events (20.4% in the CABG group vs. 11.2% in the PCI group; unadjusted OR: 0.38; 95% CI: 0.16 to 0.86;  $p = 0.02$ ; adjusted OR: 0.43; 95% CI: 0.17 to 0.97;  $p = 0.04$ ) (Fig. 1). Conversely, there was a potential advantage of CABG in the occurrence of TVR (8.4% vs. 28.0%, respectively) at both unadjusted (OR: 4.19; 95% CI: 1.9 to 9.6;  $p = 0.0001$ ) and adjusted analysis (OR: 4.41; 95% CI: 1.82 to 11.3;  $p = 0.0004$ ).

No difference in the occurrence of MACCE was observed in PCI versus CABG (32.4% vs. 38.3%, respectively) both for the unadjusted (OR: 1.41; 95% CI: 0.79 to 2.51;  $p = 0.26$ ) and adjusted analysis (OR: 1.57; 95% CI: 0.82 to 3.05;  $p = 0.18$ ) (Fig. 2).

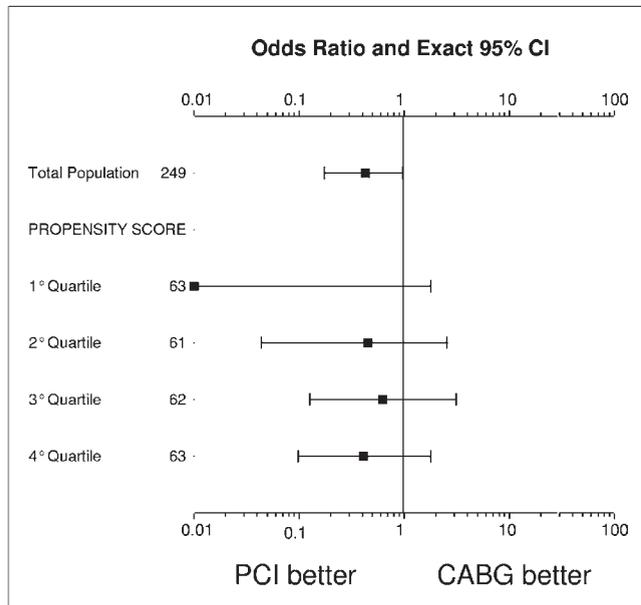
## Discussion

The main findings of this single-center study are: 1) there was still no difference at a median of 61.9 months (IQR: 57.8 to 67.2 months) in the occurrence of MACCE between elective PCI with DES implantation and CABG for ULMCA disease; 2) the benefit of PCI in the composite end point of cardiac death, MI, and cerebrovascular events that we reported at 1 year was still present at a longer term clinical follow-up; and 3) the advantage of CABG was confirmed in the lower need for repeated revascularization. According to current guidelines, the treatment of ULMCA disease with PCI has a Class IIb indication (1). Some retrospective studies evaluating surgical treatment for this disease reported an in-hospital mortality rate varying from

**Table 3. Clinical Characteristics of the Patients Who Underwent Possible ST**

Patients	EuroSCORE	SYNTAX Score	Age, yrs	LVEF, %	Distal Location	Stent Type	Stenting Technique	Time of the Event, Months	DAT at Event
1	13	45.0	83	28	Yes	SES	Crush	8.1	No
2	11	53.5	77	20	Yes	PES	Crush	14.8	No
3	5	25.0	60	35	Yes	SES	V-stenting	32.9	Yes
4	4	33.0	69	65	Yes	PES	Crush	31.7	No
5	7	45.5	73	35	Yes	SES	Provisional	46.3	Yes
6	4	35.0	62	50	Yes	PES	Culotte	62.2	Yes

DAT = dual antiplatelet therapy at the time of possible ST; LVEF = left ventricular ejection fraction; PES = paclitaxel-eluting stent(s); SES = sirolimus-eluting stent(s); ST = stent thrombosis; other abbreviations as in Table 1.



**Figure 1. Composite End Point of Cardiac Death, MI, and CVA at 5 Years**

The figure shows the advantage of percutaneous coronary intervention (PCI) with drug-eluting stent implantation as compared with coronary artery bypass graft (CABG) in the composite end point of cardiac death, myocardial infarction (MI), and cerebrovascular accidents (CVA) at 5-year clinical follow-up. This advantage was present in the overall population and according to quartiles at propensity score analysis. CI = confidence interval.

1.7% to 7.0% and a 1-year mortality rate of 6% to 14% (18–21).

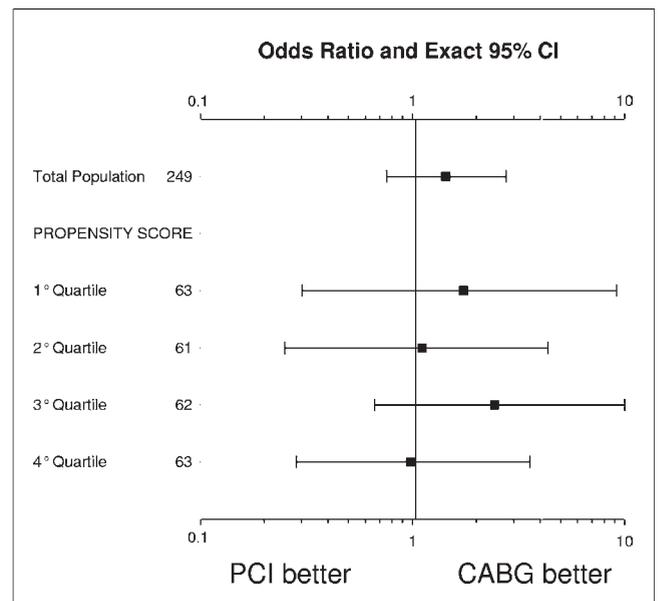
Encouraging 1-year and more recently 3-year results have been reported for PCI with DES implantation in this particular subset of patients (2–11). Observational, nonrandomized registries (5,13,16) reported thus far have shown no difference in the occurrence of MACCE between patients treated with DES compared with the ones treated with CABG in this subset of patients. The most important limitations of these registries were the different baseline clinical characteristics of the 2 populations (PCI and CABG) adjusted with propensity score analysis and the duration of follow-up.

More recently Seung et al. (22) in the MAIN COMPARE (Revascularization for Unprotected Left Main Coronary Artery Stenosis: Comparison of Percutaneous Coronary Angioplasty versus Surgical Revascularization) registry reported the outcomes in 1,102 patients treated with PCI at a median follow-up of 1,017 days (IQR: 688 to 1,45 days) compared with the outcomes in 1,138 patients undergoing CABG at 1,152 days (IQR: 681 to 1,590 days) of follow-up. In the propensity-matched cohort, there was no significant difference between the 2 revascularization strategies in the risk of death (hazard ratio [HR] for the stenting group: 1.18; 95% CI: 0.77 to 1.80) or the risk of the composite outcome (HR for the stenting group: 1.10; 95% CI: 0.75 to 1.62) of death, MI, and

cerebrovascular events. The rates of TVR were indeed significantly higher in the group that received stents than in the group that underwent CABG (HR: 4.76; 95% CI: 2.80 to 8.11). Similar results were observed between patients that received bare-metal stent versus CABG (Wave #1) and patients that received DES versus CABG (Wave #2).

In the SYNTAX trial, patients were stratified according to the presence of ULMCA disease (15). The SYNTAX trial enrolled and randomized 705 patients with ULMCA lesions: 348 in the CABG group versus 357 in the PCI group. The primary end point of noninferiority in 12-month rate of MACCE was met in PCI group (13.7% and 15.8%, respectively;  $p = 0.44$ ). Moreover, although the rate of repeat revascularization among patients with ULMCA disease was significantly higher in the PCI group (11.8% vs. 6.5% in the CABG group;  $p = 0.02$ ), this result was offset by a significantly higher rate of stroke in the CABG subgroup (2.7% vs. 0.3% in the corresponding PCI subgroup;  $p = 0.01$ ). Despite the encouraging results, it is important to point out that even if ULMCA subanalysis was pre-specified, the results should be taken as hypothesis generating because of the lack of adequate statistical power and needs to be tested in larger, adequately powered randomized trials.

In our study, because of the nonrandomized nature, an adjusted analysis using the propensity score was performed to take into account differences in baseline clinical charac-



**Figure 2. MACCE at 5 Years**

The figure shows there is no difference in the occurrence of major adverse cardiac and cerebrovascular events (MACCE) in percutaneous coronary intervention with drug-eluting stent as compared to coronary artery bypass graft at 5-year clinical follow-up. No difference was present in the overall population and according to quartiles at propensity score analysis. Abbreviations as in Figure 1.

teristics between the study groups. Still no difference was observed at a median of 61.9 months (IQR: 57.8 to 67.2 months) in the occurrence of MACCE between elective PCI with DES implantation and CABG for unprotected ULMCA disease (32.4% vs. 38.3%, respectively) both for the unadjusted (OR: 1.41; 95% CI: 0.79 to 2.51;  $p = 0.26$ ) and adjusted analysis (OR: 1.57; 95% CI: 0.82 to 3.05;  $p = 0.18$ ). Interestingly, our study also confirmed that the benefit of PCI over CABG in reducing the composite end point of cardiac death, MI, and cerebrovascular events observed at 1 year (16) was sustained at 5 years (20.4% in the CABG group vs. 11.2% in the PCI group; unadjusted OR: 0.38; CI 95%: 0.16 to 0.86;  $p = 0.02$ ; adjusted OR: 0.43; 95% CI: 0.17 to 0.97;  $p = 0.04$ ).

Conversely, the advantage of CABG in reducing the need for repeated revascularization was once again confirmed. The lower need for revascularization in CABG suggests that at least "first-generation" DES (exclusively used in this preliminary phase of our experience from 2002 to 2004) are still an imperfect solution that are unable to completely eliminate restenosis in complex settings such as bifurcational lesions and multivessel disease. However, it might be fair to point out that routine angiographic follow-up was part of this initial protocol to detect early left main stent restenosis and that many TLR were angiographically rather than clinically driven. Angiographic follow-up was performed in 96 (89.7%) of the patients; 95% of restenosis occurred in patients with treatment of distal ULMCA and were focal. The low rate of intravascular ultrasound guidance (28.9%) as well as the more generous use of stents without a properly sized post-dilation could clearly have played an important role in the occurrence of TLR in PCI group. Interestingly, there were 3 new TLR in the PCI and 4 in the CABG groups from 1 to 5 years, which suggests that at least in this preliminary experience, a late catch-up phenomenon was not observed.

From a safety perspective, the cardiac death rates (11.9% in CABG vs. 7.5% in PCI) reported at 61.9 months (IQR: 57.8 to 67.2) clinical follow-up are quite reassuring considering the risk profile of the patients included in the analysis (EuroSCORE >6 in approximately 30% of the patients) (Table 1). Interestingly, in the CABG group, 2.8% ( $n = 4$ ) had a symptomatic graft occlusion versus 0.93% ( $n = 1$ ) of definite and/or probable ST (only 1 definite ST and no probable ST). The only definite ST was a late ST in a paclitaxel-eluting stent implanted in the proximal left anterior descending artery at 3.9 months while on DAT. The patient experienced an acute anterior MI successfully treated with re-PCI. Possible ST at 5-year follow-up was adjudicated in 6 patients (5.6%), 4 out of 6 had a left ventricular ejection fraction <35%, and all of them had a distal left main true bifurcation lesion (Table 3). Notably, only 34% of the patients in PCI group were on long-term DAT at the time of last clinical follow-up.

Considering these encouraging long-term results and the technical development in PCI (second-generation DES, higher use of intravascular ultrasound and fractional flow reserve, new imaging techniques such as optimal coherence tomography, and assessment of clopidogrel responsiveness) as well as in CABG (higher percentage of off-pump-no-touch technique), there is now a clear need for a prospective, randomized trial adequately powered to detect a difference in the composite end point of cardiac death, MI, and CVA at 5-year clinical follow-up to evaluate the optimal revascularization treatment in unprotected ULMCA lesions. Questions remain unanswered regarding the need to include revascularization in the primary end point and the exclusion of patients with extensive triple-vessel disease, in addition to left main stenosis.

**Study limitations.** The major limitation is that this is an observational and not a randomized study. This limit was mainly due to the exploratory nature of the study. Although the small number of patients enrolled in the present study represents an important limitation, we nevertheless performed a propensity score adjustment to reduce the disadvantage caused by the higher-risk profile of the patients treated with CABG. Moreover, despite the numerical difference, the small sample size allows us to detect as statistically significant only very large differences in mortality rates between the 2 study groups.

Another limit of the study was the fact that in CABG group, because of the retrospective nature of the study, we could not analyze all the baseline angiograms in order to calculate SYNTAX score as also reported in Table 1.

## Conclusions

In this single-center observational experience, there was still no difference in the occurrence of MACCE between elective PCI with DES implantation and CABG in ULMCA lesions, at a median clinical follow-up of 61.9 months (IQR: 57.8 to 67.2 months). This study confirmed a possible advantage of PCI in the composite end point of death, MI, and/or stroke, whereas a benefit in reducing the need for repeated revascularization was still observed in CABG.

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**Key Words:** coronary bypass grafting ■ drug-eluting stent ■ unprotected left main coronary artery.