PCI for the Left Main Coronary Artery

A review of the current clinical trial data.

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With the availability of drug-eluting stents (DES) and the dramatic reduction in restenosis rates they have provided, the results of left main coronary artery (LMCA) stenting have certainly improved compared to preliminary experiences with bare-metal stents (BMS), which were limited by high restenosis rates and sudden deaths.[1-6] Encouraging results have been reported at midterm clinical follow-up in some observational registries with elective DES implantation in the LMCA, with a 1-year mortality rate of 0% to 5%.[7-12] In these registries, the need for target lesion revascularization (TLR) varied from 0% to 14%, and target vessel revascularization (TVR) varied from 0% to 19%. From these preliminary results, it is clear that patient selection, as well as lesion location, could be responsible for the differences among outcomes reported in these experiences.[9] Another important finding from these registries is that the main contributor to major adverse cardiac events (MACE) is the need for a repeat procedure, mostly due to the high incidence of scheduled angiographic follow-up and no apparent increase in the incidence of myocardial infarction (MI) or death.

LESION LOCATION

A multicenter registry conducted between 2002 and 2005 in five international centers has addressed the issue of lesion location in the unprotected LMCA and specifically analyzed nonbifurcation lesions.[13] Included in the registry were 147 consecutive patients who had a stenosis in the ostium and/or the midshaft of an unprotected LMCA and were electively treated with percutaneous coronary intervention (PCI) and a sirolimus-eluting stent (SES) (Cypher, Cordis Corporation, Bridgewater, NJ) or a paclitaxel-eluting stent (PES) (Taxus, Boston Scientific Corporation, Natick, MA). Patients with ST or non-ST elevation MI were excluded from the analysis. In 72 patients (almost 50%), intravascular ultrasound (IVUS) guidance was performed. At 886 ± 308-day clinical follow-up, only five patients (2.7%) had died (Table 1). Seven patients required TVR (five were treated with PCI, and two were treated with coronary artery bypass grafting [CABG]); of these patients, only one patient required TLR because of in-

TABLE 1. FOLLOW-UP MACE IN THE OSTIAL AND SHAFT MULTICENTER REGISTRY

Event	n (%)
Death	5 (3.4)
Cardiac death	4 (2.7)
TLR	1 (0.7)
TVR	7 (4.7)
MI	0
MACE	11 (7.4)

Abbreviations: MACE, major adverse cardiac events; MI, myocardial infarction; TLR, target lesion revascularization; TVR, target vessel revascularization.

stent restenosis in the shaft of the LMCA. Angiographic follow-up was performed in 106 patients (73%); the restenosis rate was only 0.9% with late loss of −0.01 mm. In this series, no cases of angiographically proven stent thrombosis were observed. This finding is mostly explained by the favorable anatomical location. Nevertheless, an important factor could have been that in almost 50% of the patients, IVUS guidance was used.

The Gruppo Italiano Studi Emodinamici-Societa' Italiana di Cardiologia Invasiva (GISE-SICI) registry was a retrospective, observational, multicenter registry promoted by the Italian Society of Invasive Cardiology in which 19 high-volume participating centers enrolled 1,453 consecutive patients who underwent PCI from January 2002 to December 2006.[14] The inclusion criteria for this registry was the presence of a > 50% stenosis of an unprotected LMCA; the exclusion criteria were ST-segment elevation MI or cardiogenic shock. From this registry, a total of 479 consecutive patients with ostial and shaft lesions who underwent DES (n = 334) or BMS (n = 145) implantation were analyzed with extensive multivariable and propensity score adjustments.[15] The decision to perform PCI instead of surgery was considered in the presence of suitable anatomy for stenting and by the preference of the patient and referring physician for the percutaneous approach, or in the presence of suitable anatomy and relative contraindications to surgery defined as a EuroSCORE ≥ 6. After the procedure, patients underwent dual-antiplatelet therapy for a minimum of 1 month to a maximum of 6 to 12 months, according to local practice. At 3-year follow-up, risk-adjusted survival rates were higher in patients treated with DES than in those treated with BMS. The adjusted hazard ratio (HR) for the risk of mortality after DES implantation relative to BMS implantation was 0.37 (95% confidence interval [CI], 0.15–0.96; *P* = .04). The adjusted HR for the risk of cardiac mortality was 0.31 (95% CI, 0.09–1.04; *P* = .06). The adjusted 3-year rates of TLR were not significantly lower in the DES group than in the BMS group (*P* = .6). The lack of benefit in TLR could be explained by higher mortality rates in the BMS group.

The same registry also analyzed 2-year outcome data from the 334 patients with ostial or midshaft lesions (group 1) to the patients with 777 bifurcations (group 2). The adjusted HR for the risk of 2-year MACE in patients in group 2 versus patients in group 1 was 1.5 (*P* = .024). However, there was a significant difference between patients with bifurcations who were treated with two stents and those in group 1 (*P* = .001) but not between patients with bifurcations who were treated with one stent and those in group 1 (*P* = .38).[16]

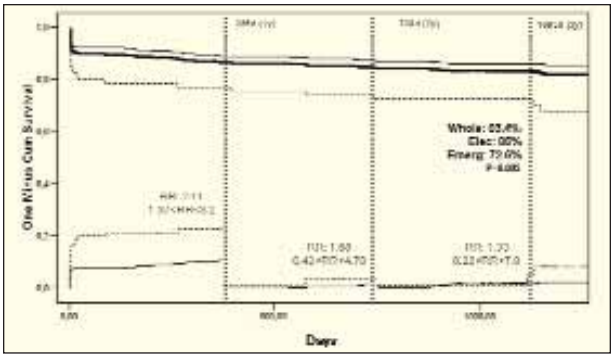

Figure 1. Survival from MI and death at 3 years in the whole, elective, and emergent population from the DELFT registry. Abbreviation: RR, relative risk. (Adapted with permission from J Am Coll Cardiol. 2008;51:8.)

LATE AND VERY LATE STENT THROMBOSIS

Some concerns have been raised regarding the risk of late and very late stent thrombosis and longer-term results after DES implantation in the LMCA.[17-26] Recently, some studies with a larger sample size and longer-term follow-up tried to give an answer to these concerns and to identify the associated predictors for adverse outcomes in this population.[14,16,27-32]

In DELFT (Drug-Eluting Stent for Left Main), an international, multicenter, retrospective registry,[28] 358 consecutive patients who underwent PCI with DES implantation for de novo lesions on unprotected LMCAs from April 2002 to April 2004 were analyzed and stratified according to their EuroSCORE values.[33] Patients with acute coronary syndrome and/or cardiogenic shock were included in the registry. The 3-year incidence of cardiac death was 9.2%, and the incidence of MI, TLR, and TVR were 8.6%, 5.8%, and 14.2%, respectively. MACE occurred in 32.1% of the patients. Stent thrombosis occurred in two patients (0.6%) at 0 and 439 days: one acute stent thrombosis (0.3%) and one very late stent thrombosis (0.3%). Acute stent thrombosis occurred in a patient with acute coronary syndrome who underwent emergent PCI and received a single DES for a significant ostial lesion. Very late stent thrombosis occurred in a patient with stable angina who underwent an elective PCI and received three DES for a significant lesion located in the distal LMCA. One-year dual-antiplatelet therapy was recommended, and thus at the time of the stent thrombosis event, the patient was no longer on this therapy. Both events occurred in patients who were classified as very high-risk patients (EuroSCORE 9 and 11). No cases of definite stent thrombosis resulted in cardiac death. Probable stent thrombosis was adjudicated in four patients (1.1%), and possible stent thrombosis was adjudicated in 16 patients (4.4%).

When the patients were stratified according to emergent versus elective indication for PCI in unprotected LMCA, a higher rate of cardiac death was observed in emergency cases (21.4% vs 6.2%; *P* < .001). Of note, most of the events occurred within 1 year in both groups of patients (72.7% and 85.4% in the elective and emergent group, respectively), whereas the cumulative event rate tended to stabilize over time (Figure 1).

In the Late and Very Late Stent Thrombosis Following Drug-Eluting Stent Implantation in Unprotected Left Main Coronary Artery: a Multicenter Registry, 731 consecutive patients with unprotected LMCA stenosis were electively treated with SES or PES implantation in five centers between March 2002 and March 2006.[27] Patients with ST or non-ST elevation MI were excluded. Of these patients, 176 (24%) were diabetic, and 333 patients (45.5%) had unstable angina. The median and interquartile range of EuroSCORE was 3 (2–6); a EuroSCORE ≥ 6 was present in 36% of patients. In 337 patients (46.1%), IVUS guidance was used. Among them, 559 (76.5%) had a distal LMCA lesion location, and in this subset of lesions, the stenting strategy adopted was a provisional (crossover) approach in 283 patients (50.6%), "Crush" was used in 120 (21.5%), "V" stenting in 80 (14.3%), "Modified T" in 52 (9.3%), and "Culotte" in 24 (4.3%). Final kissing-balloon inflation was performed in 64% of cases. The median duration of dual-antiplatelet therapy was 8.8 months (interquartile range, 6–20.7). Four patients (0.54%) had definite stent thrombosis: three patients had early thrombosis (two acute and one subacute), and only one had late definite stent thrombosis at 3.9 months while on dual-antiplatelet therapy (an acute anterior MI and angiographically proven stent thrombosis in the proximal left anterior descending artery was successfully treated with repeat PCI). No cases of very late definite stent thrombosis were recorded. Probable stent thrombosis occurred in three patients. Therefore, a total of seven of 731 patients (0.95%) had a definite or probable stent thrombosis. At univariate exact logistic (unconditional) analysis, age (odds ratio [OR], 1.07; 95% CI, 1–1.16; *P* = .03), left ventricular ejection fraction (LVEF) (OR, 0.94; 95% CI, 0.9–0.98; *P* = .007), and EuroSCORE (OR, 19; 95% CI, 1.07–1.34; *P* = .003) were correlated to definite or probable stent thrombosis. At conditional univariate analysis, only LVEF (OR, 0.94; 95% CI, 0.89–0.99; *P* = .03) and EuroSCORE (OR, 1.22; 95% CI, 1.06–1.41; *P* = .008) were associated with definite or probable stent thrombosis. Possible (eight late and 12 very late) stent thrombosis occurred in 20 patients (2.7%). Clinical characteristics were unfavorable in most of these patients: eight of 20 (40%) were older than 75 years, and 13 of 20 patients (65%) had an LVEF < 40% and a EuroSCORE ≥ 6. At 29.5- ± 13.7-month follow-up, a cumulative total of 45 patients (6.2%) died, 31 (4.2%) of which were from cardiac death. Eleven patients experienced an MI, and nine of them were not in the target vessel. Ninety-five patients (12.9%) had a TVR, and 76 (10.4%) had a TLR. Angiographic follow-up was performed in 548 patients (75%) and restenosis occurred in 77 (14.1%). At univariate exact logistic (unconditional) analysis, age (OR, 1.06; 95% CI, 1.03–1.09; *P* = .0001), LVEF (OR, 0.94; 95% CI, 0.92–0.96; *P* < .0001), EuroSCORE (OR, 1.21; 95% CI, 1.13–1.3; *P* < .0001), unstable angina (OR, 3.73; 95% CI, 1.54–11.6; *P* = .002), and IVUS guidance (OR, 0.93; 95% CI, 0.16–0.93; *P* = .03) were correlated to cardiac death. At conditional analysis, only unstable angina (OR, 3.25; 95% CI, 1.33–9.05; *P* = .007), LVEF (OR, 0.79; 95% CI, 0.87–0.97; *P* < .0001), and EuroSCORE (OR, 1.18; 95% CI, 1.04–1.23; *P* = .003) were correlated to cardiac death.

In the MAIN-COMPARE (Revascularization for Unprotected Left Main Coronary Artery Stenosis: Comparison of Percutaneous Coronary Angioplasty Versus Surgical Revascularization) registry, Park et al evaluated 1,102 patients with unprotected LMCA disease who underwent stent implantation and 1,138 patients who underwent CABG in Korea between January 2000 and June 2006.[34] Adverse outcomes (death; a composite outcome of death, Q-wave MI, or stroke; and TVR) were compared with the use of propensity-score matching in the overall cohort and in separate subgroups according to type of stent. In the overall matched cohort, there was no significant difference between the stenting and CABG groups in the risk of death (HR for the stenting group, 1.18; 95% CI, 0.77–1.8) or the risk of the composite outcome (HR for the stenting group, 1.1; 95% CI, 0.75–1.62). The rates of TVR were significantly higher in the group that received stents than in the group that underwent CABG (HR, 4.76; 95% CI, 2.8–8.11). Comparisons of the group that received BMS versus the group that underwent CABG and of the group that received DES versus the group that underwent CABG produced similar results, although there was a trend toward higher rates of death and the composite endpoint in the group that received DES. In summary, there was no significant difference in the rates of death or of the composite endpoint of death, Q-wave MI, or stroke between patients receiving stents and those undergoing CABG; however, stenting, even with DES, was associated with higher rates of TVR than CABG.

In the same registry, 756 patients with unprotected LMCA stenosis underwent elective stenting under IVUS guidance, and 219 used conventional angiography.[35] In

201 matched pairs of overall population, there was a tendency of lower risk of 3-year mortality with IVUS guidance compared with angiography guidance (6% vs 13.6%; log-rank *P* = .063; HR, 0.54; 95% CI, 0.28–1.03). In particular, the 3-year incidence of mortality was lower in 145 matched pairs of patients receiving DES with IVUS guidance than with angiography guidance (4.7% vs 16%; log-rank *P* = .048; HR, 0.39; 95% CI, 0.15–1.02). In contrast, the use of IVUS guidance did not reduce the risk of mortality in 47 matched pairs of patients receiving BMS (8.6% vs 10.8%; log-rank *P* = .346; HR, 0.59; 95% CI, 0.18–1.91).

In the main analysis by Palmerini[14] from the retrospective multicenter GISE-SICI registry, 1,111 patients were treated with DES and 342 were treated with BMS. During a 2-year follow-up, risk-adjusted survival free from cardiac death was significantly higher in patients treated with DES than in those treated with BMS. The propensity-adjusted HR for risk of 2-year cardiac mortality after DES versus BMS implantation was 0.49 (95% CI, 0.32–0.77). The benefit of DES in reducing cardiac mortality was obtained during a period of 3 to 6 months and maintained up to 2 years.[14]

A total of 291 patients from four French centers were included in the French Left Main Taxus registry.[31] Acute MI and cardiogenic shock were the only exclusion criteria. The patients were 69 ± 11 years of age, 29% were diabetic, and 25% had three-vessel disease. For distal LMCA lesions (78%), the provisional side-branch "T-stenting" approach was used in 92% of cases, and final kissing-balloon inflation was used in 97%. In total, 24 TLRs were recorded, and the TLR rate increased from 7.8% at 1-year follow-up to 8.7% at 2-year follow-up (6.6% underwent repeat PCI and 2.2% underwent CABG). Diabetes was associated with a 3.31-fold increase in risk of TLR (95% CI, 1.48–7.39; *P* = .003). The cardiac death rate increased from 3.1% at 1 year to 5.4% at 2 years. A 1-point-higher EuroSCORE was associated with a 15% higher risk of cardiac death (95% CI, 2.9–28.2; *P* = .013). In patients with distal LMCA, the presence of a T-shaped bifurcation lesion was associated with a 3.5-fold increase in the risk of cardiac death (95% CI, 1.05–11.9; *P* = .041). Incidence of Q-wave or non-Q–wave MI was 0.9% and 3.1%, respectively. In total, 44 MACE were recorded, and the cumulative rate of device-oriented MACE was 12.2% at 1 year and 15.8% at 2 years. At 2-year follow-up, the cumulative rate of stroke was 0.8%. The incidence of definite and probable stent thrombosis was 0.7%, whereas the incidence of any stent thrombosis was 3.8%.

Tamburino et al evaluated all consecutive patients undergoing SES or PES implantation in unprotected LMCA disease at a single institution.[29] The primary endpoint was long-term MACE, defined as cardiac death, nonfatal MI, or TLR; stent thrombosis was also evaluated. A total of 210 patients were included. The in-hospital MACE rate was 1%. During a mean follow-up at 28 ± 14.5 months, MACE occurred in 26 patients (12.5%), cardiac death in nine patients (4.3%), and TLR in 17 patients (8.2%). The cumulative MACE-free survival rate was 89%, 87.4%, and 85.4% at 1, 2, and 3 years, respectively. Stent thrombosis occurred in three patients (1.4%): one case was definite and the other two were probable/possible stent thrombosis; there were no cases of very late stent thrombosis. Binary restenosis occurred in 8.3%. EuroSCORE > 6 was the only independent predictor of MACE (HR, 2.24; 95% CI, 1.05–4.77; *P* = .04). However, there was a trend toward an increased risk of MACE associated with distal unprotected LMCA location (HR, 2.14; 95% CI, 0.87–5.29; *P* = .10).

PES VERSUS SES

The only randomized trial so far that has addressed the topic of the choice of DES was the ISAR-Left Main (Intracoronary Stenting and Angiographic Results: Drug-Eluting Stents for Unprotected Coronary Left Main Lesions) study.[36] The aim of this trial was to compare the safety and efficacy of PES and SES for treatment of unprotected LMCA disease. The study was composed of 607 patients with symptomatic coronary artery disease undergoing PCI for unprotected LMCA: 302 were assigned to receive PES, and 305 were assigned to receive SES. The primary endpoint of noninferiority was met at 1 year (MACE were 13.6% in PES vs 15.8% in SES; relative risk [RR], 0.85; 95% CI, 0.56–1.29). The cumulative incidence of death, MI, or TLR was 13.6% in the PES group and 15.8% in the SES group (RR, 0.85; 95% CI, 0.56–1.29; *P* = .44). The secondary endpoint was angiographic restenosis on the basis of the LMCA area analysis at follow-up angiography. Angiographic restenosis was 16% with PES and 19.4% with SES (RR, 0.82; 95% CI, 0.57–1.19; *P* = .3). Mortality at 2 years was 10.7% in the PES group and 8.7% in the SES group (RR, 1.14; 95% CI, 0.66–1.95; *P* = .64) confirming that MACE were comparable between PES and SES (RR, 0.99; 95% CI, 0.69–1.42). There were also no differences observed in stent thrombosis rates (in PES, definite stent thrombosis was 0.3% and probable stent thrombosis 0%; in SES, definite stent thrombosis was 0.7% and probable stent thrombosis 0.3%) and TLR rates (9.2% in PES vs 10.7% in SES; P = .47). The ongoing Everolimus- and Zotarolimus-Eluting Stents for Treatment of Unprotected Left Main Coronary Artery Disease (ISAR-LEFT-MAIN-2) prospective, randomized trial is evaluating the performance of two second-gen-

eration DES (everolimus and zotarolimus eluting) in left main coronary lesions. The primary endpoint is incidence of MACE defined as a composite of death, MI, and TLR at 1 year. The study hypothesis is that zotarolimus-eluting stents are not inferior to the everolimus-eluting stents in reducing the rate of MACE at 1 year.

CONCLUSION

The Synergy Between Percutaneous Coronary Intervention With Taxus and Cardiac Surgery (SYNTAX) study,[37] probably the latest, most important trial that has been conducted in this subset of patients, is discussed by Ted Feldman, MD, FESC, FACC, FSCAI, and Issam D. Moussa, MD, FACC, FSCAI, on page 28 of this issue. Despite these very encouraging results, we should take into account that the subgroup analysis of left main patients, despite being prespecified, had no power to detect a noninferiority of PCI versus CABG. Therefore, these results should be interpreted with some caution and should mostly be considered as hypothesis-generating rather than conclusive. In our opinion, only a prospective, randomized trial adequately powered with at least a 5-year follow-up will provide conclusive information on the optimal treatment of unprotected LMCA lesions, which we hope to see in the future. ■

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