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CLINICAL RESEARCH

CORONARY

Left Main Stenting in Comparison With Surgical Revascularization

10-Year Outcomes of the (Left Main Coronary Artery Stenting) LE MANS Trial

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ABSTRACT

OBJECTIVES This study has reported 10-year clinical follow-up of patients enrolled in the prospective, randomized LE MANS (Left Main Stenting) trial.

BACKGROUND The very long-term outcome after left main stenting in comparison with surgical revascularization remains unknown.

METHODS In this prospective, multicenter trial, we randomly assigned 105 patients with unprotected left main coronary artery stenosis with low and medium complexity of coexisting coronary artery disease according to SYNTAX (Synergy Between Percutaneous Coronary Intervention With Taxus and Cardiac Surgery) score to percutaneous coronary intervention (PCI) with stenting (n = 52) or coronary artery bypass grafting (CABG) (n = 53). Drug-eluting stents were implanted in 35%, whereas arterial grafts to the left anterior descending artery were utilized in 81%. Currently, the mean long-term follow-up was collected at 9.8 ± 1.0 years. Follow up for all-cause mortality is complete, whereas the incidence of major adverse cardiovascular and cerebral events (MACCE) was reported from 90% of patients. Ambulatory follow-up was completed in 46 (43.9%) patients.

RESULTS At 10 years, there was a trend toward higher ejection fraction in stenting when compared with surgery (54.9 ± 8.3% vs. 49.8 ± 10.3%; p = 0.07). The mortality (21.6% vs. 30.2%; p = 0.41) and MACCE (51.1% vs. 64.4%; p = 0.28) were statistically not different between groups; however, numerically the difference was in favor of stenting. Similarly, there was no difference in the occurrence of myocardial infarction (8.7 vs. 10.4%; p = 0.62), stroke (4.3 vs. 6.3%; p = 0.68), and repeated revascularization rates (26.1% vs. 31.3%; p = 0.64). The probability of very long-term survival up to 14 years was comparable between PCI and CABG (74.2% vs. 67.5%; p = 0.34; hazard ratio: 1.45, 95% confidence interval: 0.67 to 3.13); however, there was a trend toward higher MACCE-free survival in the PCI group (34.7% vs. 22.1%; p = 0.06; hazard ratio: 1.71, 95% confidence interval: 0.97 to 2.99).

CONCLUSIONS In patients with unprotected left main coronary artery stenosis with low and medium complexity of coexisting coronary artery disease, stenting offers numerically, but statistically nonsignificant, favorable long-term outcome up to 10 years in terms of safety and efficacy outcome measures, therefore, constitutes an alternative therapy for CABG. (J Am Coll Cardiol Intv 2016;9:318–27)

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For more than a decade, left main stenting has completed a rough clinical and investigational route from an experimental and controversial treatment up to a recommended revascularization strategy in a certain subset of patients (1,2). More importantly, left main stenting has been adopted before in clinical routine practice as a response to previously published landmark randomized trials, which reported at least a comparable outcome when compared with coronary artery bypass revascularization (CABG) with regard to safety outcomes such as survival, incidence of myocardial infarction, or stroke (3–6). Furthermore, it has been commonly used in patients who are not eligible or who refuse CABG. This immense progress was possible due to technological refinements such as introduction of bare-metal stents (BMS) and first- and second-generation drug-eluting stents (DES), intravascular imaging techniques, growing experience of operators, as well as heart team referrals. Although many aspects of left main stenting have been extensively investigated, a few questions remain to be answered. The outcome of left main stenting with second-generation DES in comparison with CABG will be definitively addressed in the EXCEL (Evaluation of XIENCE PRIME Everolimus Eluting Stent System [EECSS] or XIENCE V EECSS or XIENCE Xpedition EECSS or XIENCE PRO EECSS Versus Coronary Artery Bypass Surgery for Effectiveness of Left Main Revascularization) trial (NCT01205776). In the current study, for the first time, we report very long clinical and ambulatory 10-year outcome of patients included in the LE MANS (Left Main Coronary Artery Stenting) trial, in which left main percutaneous and surgical revascularization were first compared nearly a decade ago (4).

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METHODS

Study design, protocol, and 1-year results were reported previously (4). Briefly, we enrolled 105 patients with at least 50% diameter stenosis of the unprotected left main coronary artery (ULMCA), with or without multivessel coronary artery disease, eligible for equal revascularization both with percutaneous coronary intervention (PCI) and CABG. All patients had to be symptomatic with documented myocardial ischemia. Exclusion criteria included acute myocardial infarction, total occlusion of the left main, comorbid conditions or coronary anatomic considerations that increased the surgical risk to a EuroSCORE of 8 or more, stroke or transient ischemic attack within 3 months, renal dysfunction, or contraindication to antiplatelet therapy.

On the basis of a joint decision by the lead interventional and surgical investigators, 122 patients were suitable for both procedures; 105 gave consent and were randomized to either PCI (n = 52) or CABG (n = 53). Both groups were comparable with regard to basic clinical and angiographic characteristics. All randomized patients underwent their assigned therapy (no crossovers).

PERCUTANEOUS REVASCULARIZATION. Left main stenting was performed according to the previously reported LE MANS protocol (7). Direct stenting of the left main was a preferred strategy except for cases with critical luminal narrowing, for which pre-dilation was performed with small balloons (2.0 to 2.5 mm). For distal left main stenosis, stenting across the bifurcation toward the left anterior descending was performed first, and then provisional stenting of the circumflex artery with T-stenting or "culottes" technique was preferred. The crush stent technique was avoided. Post-dilation with kissing balloon angioplasty was always used to finish the distal left main stenting procedure. DES were used for the left main with a reference diameter <3.8 mm, and BMS were implanted if the left main reference diameter was ≥3.8 mm. On the basis of these criteria, the left main was treated with DES in 35% of PCI patients. Stent length and diameter were selected on the basis of online quantitative coronary angiography (balloon to artery ratio 1:1.1) and post-dilated at high pressure (at least 16 atm). A control intravascular ultrasound was recommended to assess the final results.

SURGICAL REVASCULARIZATION. Operations were performed using standard anesthetic techniques. All but 1 operation were performed through a median sternotomy, with standard cardiopulmonary bypass and moderate systemic hypothermia. One patient underwent off-pump CABG. Left internal mammary artery grafts were used in 72% of CABG patients, and radial artery grafts were used in 9%.

FOLLOW-UP AND DATA COLLECTION. A detailed follow-up schematic is presented in Figure 1. Follow up data on all-cause mortality were obtained from the National Health System registry, which guarantees complete data collection. Follow-up on major adverse cardiovascular events, including myocardial infarction, stroke, and repeated revascularization either with PCI or CABG, was obtained either by telephone conversation or ambulatory visit and

ABBREVIATIONS AND ACRONYMS

BMS = bare-metal stent(s)

CABG = coronary artery bypass grafting

DES = drug-eluting stent(s)

LVEF = left ventricular ejection fraction

MACCE = major adverse cardiac and cerebrovascular event(s)

PCI = percutaneous coronary intervention

ULMCA = unprotected left main coronary artery