No More Debate Over Left Main Stenting Versus Bypass Surgery*

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Traditionally, left main coronary artery disease had been regarded as a dominion of the cardiac surgeons on the basis of results from the classic trial comparing medical treatment and bypass surgery (1,2). However, several brave pioneers in interventional cardiology have continued to evaluate the performance of “less invasive” coronary stenting for the left main coronary artery stenosis due to its anatomical characteristics, including easy accessibility, large caliber, short lesion length, and lack of tortuosity (3–5). Furthermore, the widespread use of drug-eluting stents with advanced adjuvant technique and pharmacological treatment have lowered the threshold to perform left main stenting instead of bypass surgery for left main coronary artery disease (6–9). Subsequently, several clinical trials to compare left main stenting and bypass surgery were conducted.

The LE MANS (Left Main Coronary Artery Stenting) trial was the first randomized comparison of left main stenting (n = 52) and bypass surgery (n = 53) (10). Drug-eluting stents were placed in 35% of the left main stenting group, and left internal mammary artery grafts were used in 72% of the bypass surgery group. The primary endpoint was an absolute change in left ventricular ejection fraction at 1 year, which was significantly higher in the percutaneous coronary intervention (PCI) group than in the coronary artery bypass grafting (CABG) group (3.3 ± 6.7% vs. 0.5 ± 0.8%; p = 0.047). During 28 months of follow-up, there was a trend toward better long-term survival after PCI (p = 0.08). However, repeat revascularization was significantly higher in the PCI group (relative risk: 1.27; 95% confidence interval: 1.05 to 1.54; p = 0.01).

In this issue of *JACC: Cardiovascular Interventions*, Buszman et al. (11) reported the 10-year results of LE MANS trial. At 10 years, ejection fraction tended to be higher in the PCI group than in the CABG group (55% vs. 50%; p = 0.07) (11). In addition, the results indicated no significant difference in the rate of mortality between the PCI and CABG groups (21.6% vs. 30.2%; p = 0.41), myocardial infarction (8.7% vs. 10.4%; p = 0.62), stroke (4.3% vs. 6.3%; p = 0.68), and repeated revascularization (26.1% vs. 31.3%; p = 0.64). Therefore, the LE MANS investigators showed that stenting and bypass surgery for left main coronary artery disease have similar outcomes at 10-year follow-up, supporting left main stenting as a relatively simple, effective, and durable treatment option for left main coronary artery disease. Although this study was highly valued for the very long-term follow-up, several limitations should be commented upon. First, the change in ejection fraction, which was noted as the study primary endpoint, appeared to be a nonspecific endpoint to definitely compare PCI and CABG for left main coronary artery disease. In addition, at 10 years, ejection fraction could be evaluated in <50% of the baseline population. Second, although the authors made an effort to achieve a complete follow-up of mortality data through a national registry, the population size was small and was, therefore, not adequately powered for comparing clinical outcomes. Therefore, the result of this study should be considered hypothesis generating. Third, practice patterns, including a high rate of bare-metal stent implantation in the PCI group and a low rate of internal mammary artery graft use, were

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outdated compared with contemporary standards. Nevertheless, this study has undeniable historical value in providing a scientific rationale for subsequent clinical trials.

Following this trial, 2 landmark studies have been conducted and recently reported their 5-year outcomes. Left main subgroup analysis (n = 705) from the SYNTAX (Synergy Between PCI With TAXUS and Cardiac Surgery) trial showed that at 5 years, there were no significant differences in the rates of death (12.8% vs. 14.6%; p = 0.94) or myocardial infarction (8.2% vs. 4.8%; p = 0.2) between the PCI and CABG groups. However, the stroke rate was lower (1.5% vs. 4.3%; p = 0.03), and the revascularization rate was higher (26.7% vs. 15.5%; p = 0.003) after PCI (12). The PRECOMBAT (Premier of Randomized Comparison of Bypass Surgery Versus Angioplasty Using Sirolimus-Eluting Stent in Patients With Left Main Coronary Artery Disease) trial demonstrated that at 5 years, the composite of death, myocardial infarction, stroke, or ischemia-driven target vessel revascularization occurred similarly between groups (17.5% in the PCI group and 14.3% in CABG group; p = 0.26). The 2 groups did not differ significantly regarding death from any cause, myocardial infarction, or stroke as well as their composite (8.4% and 9.6%, respectively; p = 0.66). However, ischemia-driven target vessel revascularization occurred more frequently in the PCI group than in the CABG group (11.4% and 5.5%; p = 0.012) (13). Therefore, the 2 clinical trials showed that the safety aspect of procedure (death, myocardial infarction, or stroke) was not significantly different between PCI and bypass surgery. Accordingly, the current guideline already endorses left main stenting as a potential alternative to bypass surgery in two-thirds of the anatomic entity of left main coronary artery disease (14,15).

In addition, outcomes of left main stenting steadily improve (16). The ASAN MAIN (ASAN Medical Center-Left MAIN Revascularization) registry enrolled 2,618 patients with unprotected left main coronary disease between 1995 and 2010. All left main stenting was performed by experienced operators. This registry demonstrates that during the last 16 years, clinical outcomes of patients receiving left main stenting have progressively improved with respect to the safety and efficacy of the procedure, although patient comorbidities and left main stenosis complexity have worsened over time. As a result, in the late drug-eluting era (years 2007 to 2010), 51.8% of patients with significant left main coronary disease underwent left main stenting. These improved outcomes could be explained by the synergistic effects of the introduction of drug-eluting stents, a progressive increase in the use of intravascular ultrasound, simplified distal left main stenting, and optimized pharmacological treatment, as well as an accumulation of experience. Furthermore, contrary to early meta-analyses, several recent meta-analyses showed a survival benefit of PCI over CABG, although more clarification is needed (17,18).

Currently, 2 adequately powered clinical trials, the EXCEL (Evaluation of XIENCE PRIME Everolimus-Eluting Stent System [EECSS] or XIENCE V EECSS Versus Coronary Artery Bypass Surgery for Effectiveness of Left Main Revascularization) (NCT01205776) and NOBLE (Nordic-Baltic-British Left Main Revascularization) (NCT01496651) trials have randomized more than 3,100 patients with left main coronary artery disease to PCI with contemporary drug-eluting stents versus CABG. These studies can better define the relative merits of contemporary PCI and CABG in patients with left main coronary artery disease. In the fall of 2016, the primary results of both studies will be presented. Perhaps then there will be no more debate about clinical equipoise between left main stenting and CABG!

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