

Stenting versus Bypass Surgery for the Treatment of Left Main Coronary Artery Disease

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Based on data comparing coronary-artery bypass grafting (CABG) with medical therapy, the current guidelines recommend CABG as the treatment of choice for patients with left main coronary artery (LMCA) disease. Percutaneous coronary intervention (PCI) can be selectively performed in patients who are candidates for revascularization but who are ineligible for CABG. Current evidence indicates that stenting results in mortality and morbidity rates compared favorably with those seen after CABG. Data from several extensive registries and a large clinical trial may have prompted many interventional cardiologists to choose PCI with stenting as an alternative treatment option for such patients. In addition, these data may inform future guidelines and support the need for well-designed, adequately powered, prospective, randomized trials comparing the two revascularization strategies.

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INTRODUCTION

Current practice guidelines recommend coronary artery bypass grafting (CABG) as the standard procedure for patients with unprotected LMCA disease.^{1,2} However, percutaneous coronary intervention (PCI) for LMCA disease was attractive to the interventional cardiologist, and data from several registries showed its feasibility and short- and mid-term-effectiveness. Nevertheless, PCI for LMCA disease has been confined to surgically high-risk patients and those with protected LMCA disease, or has been used as bailout procedures in patients with angioplasty complications.

The introduction of coronary stenting has led to a reevaluation of the role of PCI as a viable treatment option for LMCA disease, and the widespread availability of drug-eluting stents (DES), together with improved stenting techniques, has lowered the threshold for the use of PCI, instead of CABG, in patients with LMCA disease. There has been little evaluation, however, of the long-term safety and efficacy of PCI with stenting for unprotected LMCA disease, and no randomized trial has compared the two primary interventions (PCI vs. CABG) in a large population. We have therefore reviewed recent advances and the current status of percutaneous vs. surgical treatment for LMCA disease, focusing on whether PCI is an alternative to or a possible replacement for CABG in these patients.

PERCUTANEOUS CORONARY INTERVENTION WITH STENTING

Bare-metal stents and drug-eluting stents

Clinical results of stenting in patients chosen for PCI, either because of prohibitive

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surgical risk or as a bailout for angioplasty complications, depend mainly upon baseline clinical characteristics, such as left ventricular function and coexisting conditions. The ULTIMA registry enrolled 279 patients with unprotected LMCA stenosis who were treated with bare-metal stents (BMS); of these, 46% were inoperable or at high surgical risk. Among these high-risk patients, the in-hospital mortality was 13.7%, and the 1-year incidence of all-cause mortality was 24.2%; whereas among the 32% patients at low risk (age < 65 years, ejection fraction > 30%), there were no periprocedural deaths and the 1-year mortality rate was only 3.4%.³ In a series of elective, low-risk patients, who were also not at increased risk for CABG, PCI with BMS for unprotected LMCA disease showed favorable short- or mid-term outcomes (in-hospital mortality, 0-4.3%; mortality at 6-12 months, 2.5-10.8%).^{4,8} However, considerable risks of restenosis (18-31%) and repeat revascularization (7.3-33.6%) have limited the durability of LMCA stenting with BMS, because the development of restenosis in such patients may lead to worst-case outcomes, such as sudden death or acute MI.

With advances in stenting techniques, the availability of DES, and adjuvant pharmacotherapy such as clopidogrel, statins and antiplatelet therapy, many experienced interventional cardiologists now perform PCI with stenting for patients with unprotected LMCA disease. Several observational studies, although limited by its non-randomized nature, small number of patients, and short follow-up periods, have shown promising PCI outcomes using DES compared with BMS.⁹⁻¹¹ Most initial reports documented that DES afforded higher procedural success rates as well as lower rates of angiographic restenosis and TVR, with similar or lower rates of death and MI compared to BMS.

In a direct comparison, 103 patients with unprotected LMCA disease were randomly assigned to receive BMS (n = 50) or DES (n = 53) implantation and were followed for 6 months, at which time the DES group showed a statistically significant reduction in binary restenosis (6% vs. 22%) and target-lesion revascularization (TLR) (2% vs. 16%), as well as a significant reduction in the rate of major adverse cardiac events (death, MI, or TLR; 13% vs. 30%), all of which were entirely attributable to reduction in repeat revascularization rate.¹²

Safety concerns in DES

Recently, concerns have been raised regarding the long-term safety of DES, with particular regard to late stent thrombosis and late mortality.¹³⁻¹⁵ Increasing concern over stent thrombosis, which may have more catastrophic consequences in patients undergoing unprotected LMCA stenting, and a lack of long-term clinical data, have hampered the widespread use of PCI with DES as an alterna-

tive to CABG.

However, recent data alleviate concerns about the safety of PCI with DES in the treatment of unprotected LMCA disease.¹⁶⁻¹⁸ A recent multicenter registry evaluated the occurrence of late and very late stent thrombosis in 731 patients undergoing elective LMCA stenting with DES.¹⁶ At 30 months, four patients had definite stent thrombosis (two acute, one subacute, and one late) and three had probable thrombosis, for a combined incidence of definite or probable thrombosis of 0.95%. The cumulative rates of death, MI, and TVR were 6.2%, 1.5%, and 12.9%, respectively. Older age, lower ejection fraction, and EuroSCORE were identified as predictors of thrombotic events. A report from the DELFT registry, which included 358 patients undergoing LMCA stenting with a minimum of 3 years follow-up, noted that the incidence of definite, probable, and possible stent thrombosis were 0.6%, 1.1%, and 4.4%, respectively.¹⁷ Among the overall registry population, cardiac death occurred in 9.2% of patients, and MI, TLR, and TVR were noted in 8.6%, 5.8%, and 14.2% of patients, respectively. Compared to emergent PCI, elective PCI was associated with excellent 3-year rates of mortality (6.2% vs. 21.4%), reinfarction (8.3% vs. 10.0%), and TLR (2.8% vs. 6.6%). In a recent clinical study, the ISAR-LEFT MAIN trial, in which 607 patients were treated with DES, the 2-year rate of definite or probable stent thrombosis was about 0.5-1.0%. In a large real-world observation (the MAIN-COMPARE registry), the incidence of definite thrombosis at 3 years was 0.6%.¹⁸ These results indicated that DES implantation in patients with unprotected LMCA disease results in relatively lower, or, at worst, similar rates of stent thrombosis and long-term mortality than seen when DES is used in subsets of patients with other coronary lesion.¹⁹

To prevent stent thrombosis, dual antiplatelet therapy is emphasized, and clopidogrel (75 mg daily) is recommended for at least 1 year in patients treated with DES who are not at an increased risk of bleeding.²⁰ The long-term benefits of clopidogrel use beyond 6 or 12 months are, however, unclear in such patients.²¹⁻²³ Although the risk-benefit ratio of long-term clopidogrel therapy is not well-studied, many clinicians prolong dual antiplatelet therapy for up to several years or indefinitely after LMCA stenting with DES. Despite the various durations of applied clopidogrel treatment (at least 3 months, to life),¹⁶⁻¹⁸ the overall incidence of early and late stent thrombosis were very low, and similar among studies. Additional studies with large populations and longer-term follow-ups are warranted to evaluate the antithrombotic benefit vs. major bleeding risk of long-term clopidogrel use, and to determine the optimal duration of clopidogrel therapy after DES placement in patients with LMCA disease.

STENTS VERSUS SURGERY

The choice of PCI or CABG for treatment of unprotected LMCA disease depends on several clinical and anatomical features, making optimal patient selection crucial for appropriate treatment of LMCA disease and achievement of favorable long-term outcomes.^{18,24} In patients with very complex anatomical features, which are not feasible for stenting and concomitant diffuse multivessel disease, CABG is preferred so as to avoid procedural and future thrombotic risks and to provide more complete revascularization. However, in patients with relatively simple LMCA disease, such as ostial/shaft LMCA disease or isolated LMCA disease (with or without one or two-vessel involvement), PCI is an alternative, and in some cases a preferred strategy in order to reduce surgical risks (e.g., stroke and in-hospital events following major surgery).

LMCA lesion characteristics (severe calcification, distal LMCA involvement with relation to major branches), the extent of extra-LMCA (concomitant multivessel disease, the status of distal run-off), and patient clinical characteristics (age, diabetes, ejection fraction, and other co-morbidities) are important in patient selection. Patient/physician preference is also influential. The selection of patients for PCI may be optimized as follows: 1) PCI with stenting is a reasonable option for patients with unprotected LMCA disease at high surgical risk or with protected LMCA disease, 2) patients presenting with acute coronary syndrome who have culprit LMCA occlusion and hemodynamic instability requiring emergent revascularization, and 3) isolated ostial or mid-shaft LMCA disease. For patients with anatomic and clinical characteristics suitable for both CABG and PCI, the benefits and risks of PCI versus CABG and patient/physician preference, need to be weighted.

The potential benefit of bypass surgery over stenting in patients with multi-vessel or LMCA disease is that, in bypass surgery, a graft is placed on the midcoronary vessel well beyond the area of disease, whereas stents directly relieve the offending lesion. Thus, not only has the culprit lesion been directly treated, but there are prophylactic benefits in the event that the patient develops new disease. If a patient receives a stent and develops a new disease beyond the stented area, that patient is still at a very high risk, but in patients who receive bypass grafting, the development of a more proximal disease is irrelevant. However, although the benefits of bypass surgery are well-known, the CABG procedure results in a large portion of the myocardium being supplied solely by the venous graft, which has limited patency, whereas successful LMCA stenting provides long-term patency and revascularization of the entire coronary arterial vasculature.

Current evidence supporting PCI or CABG for LMCA disease

To date, a large body of data supports the feasibility, efficacy, and safety of stenting as compared with CABG for treatment of unprotected LMCA disease. We also expect that longer-term (5-year and 10-year) data will soon be forthcoming.

Registry data

Although several studies have reported on the mid-term safety and feasibility of stenting in LMCA disease, long-term benefits of PCI compared with bypass surgery are less clear, in part because they have been evaluated less extensively. Several, small observational studies have compared PCI with stenting of unprotected LMCA to CABG.²⁵⁻²⁸ The early clinical events of left main stenting are similar or superior to those of bypass surgery because of a significant increase in periprocedural MI²⁵ or cerebrovascular events²⁶ in the CABG patients. Longer-term mortality up to approximately 1 year was similar in the PCI and the CABG groups. However, the risk of TVR was consistently higher with PCI than with CABG.

The MAIN-COMPARE registry is the first long-term study comparing PCI with stenting with bypass surgery for LMCA disease.¹⁸ This study evaluated 2,240 patients with unprotected LMCA disease who underwent stenting (BMS, 318 and DES, 784) or CABG (1,138) at 12 major cardiac centers in Korea, where left-main stenting is far more common than in Western countries. Outcome measures were compared during the first 3 years after treatment and included death; a composite outcome of death, Q-wave MI, or stroke; and TVR using propensity-score matching. The risks of death and the composite of death, Q-wave MI, or stroke were similar in the PCI and CABG groups and these results were consistent when either BMS or DES was compared with concurrent CABG. However, the rate of TVR was significantly lower in the CABG group than in the PCI group with hazard ratios varying by the type of stent. DES recipients were almost 6-fold more likely, and BMS recipients almost 10-fold more likely, to require revascularization, compared to those who underwent surgery.

Randomized clinical trials

The LeMANS trial was the first randomized comparison of PCI with stenting (52 patients) and CABG (53 patients) for the treatment of unprotected LMCA stenosis, with or without multivessel CAD.²⁹ DES were placed in 35% of PCI patients and left internal mammary artery grafts were used in 72% of CABG patients. At 1 year, the primary endpoint of absolute change in left ventricular ejection fraction was significantly greater in the PCI than in the

CABG group ($3.3 \pm 6.7\%$ vs. $0.5 \pm 0.8\%$; $p = 0.047$), whereas the secondary endpoints, survival and MACCE, were comparable in the two groups. Although this was a prospective, randomized initial trial comparing outcomes of stenting versus CABG for LMCA disease, the results were limited by the small number of patients and the non-specific and inconclusive primary endpoint chosen to evaluate treatment effects.

As shown in the left main subsets (348 patients treated with CABG and 357 treated with PES) from the SYNTAX (SYnergy Between PCI With TAXUS and Cardiac Surgery) trial,³⁰ PCI demonstrated 1-year clinical outcomes equivalent to those seen after standard bypass surgery. In particular, PCI-treated patients showed a trend towards lower MACCE rates in cases with anatomically simple LMCA disease (LMCA only and LMCA plus single-vessel disease), compared with CABG-treated patients. The rate of revascularization was significantly higher in PCI-treated patients, whereas the stroke risk was significantly greater in CABG-treated patients. However, due to the exploratory, hypothesis-generating nature of subgroup analysis, results from more specific LMCA-targeted trials are needed. The ongoing PRECOMBAT (PREmiere of COMparison of Bypass Surgery and Angioplasty Using Sirolimus-Eluting Stents in Patients With Unprotected Left Main Coronary Artery Disease) trial, which is a prospective, multicenter, randomized study to compare the safety and efficacy of SES and CABG for treatment of unprotected LMCA disease with a primary study end-point of 1-year MACCE (death, MI, stroke, and TVR), is expected to provide a more definitive evaluation of the two primary interventions.

Meta-analysis and systemic review

A recent meta-analysis, which considered results of 16 observational studies on 1,278 patients undergoing PCI with DES for unprotected LMCA disease, showed a low in-hospital mortality rate of 2.3% and a low mid-term mortality rate of 5.5% at a median of 10 months follow-up, as well as adjusted odds ratios for MACCE (death, MI, TVR, or stroke) of 0.46 (0.24-0.90), favoring PCI with DES over CABG.³¹ In contrast, another systemic review suggested that early (in-hospital, to 30 days) and longer-term (1-2 year) mortality rates were better after CABG (early, 2-4%, average 3%; late, 5-6%, average 5%) than PCI with BMS (early, 0-14%, average 6%; late, 3-31%, average 17%) or DES (early, 0-10%, average 2%; late, 0-14%, average 7%).³² However, these results should be interpreted with caution and regarded as only exploratory findings, given the limited number of patients, selection or publication bias in the literature reviewed, and caveats on internal validity of the included clinical studies.

CONCLUSIONS

Based on clinical trials comparing CABG and medical therapy, current guidelines recommend CABG as the treatment of choice for patients with asymptomatic ischemia, stable angina, or unstable angina/non-ST elevation myocardial infarction who have LMCA disease.¹ PCI can be selectively performed in patients who are candidates for revascularization but who are not suitable for CABG. However, evidences indicates that stenting yields mortality and morbidity rates that compare favorably with CABG, suggesting that a current guideline (class III recommendation of PCI for unprotected LMCA disease) may no longer be justified. A large clinical trial (the SYNTAX trial) showed that DES, compared with CABG, demonstrated acceptable outcomes in patients with LMCA disease. Also, data from large registries (the MAIN-COMPARE and the DELFT study) from routine clinical practice and from a DES clinical study (the ISAR-LEFT MAIN trial) may have prompted many interventional cardiologists to choose PCI with stenting as a good treatment option for patients with LMCA disease. These results may inform future guidelines and support the need for well-designed, adequately powered, prospective, randomized trials comparing the two revascularization strategies in patients with unprotected LMCA disease. In addition, the cumulative evidence from ongoing and future clinical trials will change the current clinical practice of revascularization for unprotected LMCA disease, which was introduced several decades ago and has continued without major revision to date.

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