

Treatment Options for Patients With Left Main Coronary Artery Disease

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Coronary artery bypass grafting (CABG) is the gold standard for the treatment of left main disease, whereas percutaneous coronary intervention is a viable option for patients who are candidates for revascularization but ineligible for CABG. CABG is limited by extended hospital stay followed by rehabilitation and mediocre long-term patency of saphenous vein grafts. Drug-eluting stents decrease the restenosis rates compared with bare metal stents and provide comparable clinical outcomes with those of CABG. Patients with isolated left main disease limited to the ostium or midbody are most likely to have good clinical outcomes with low restenosis and stent thrombosis rates. The results of the ongoing EXCEL trial, which compares left main percutaneous coronary intervention with drug-eluting stents and CABG, will provide insight regarding the ideal revascularization strategy for these patients.

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Observational and randomized studies have reported that when compared with medical treatment, coronary artery bypass graft (CABG) surgery is safer and more effective for most patients with significant unprotected left main coronary artery (ULMCA) disease.¹⁻³ Previously, ULMCA disease was considered a contraindication to percutaneous coronary intervention (PCI) due to the frequent need for repeat revascularization as well as the disappointing 1-year mortality rates.^{4,5} Even with the introduction of bare metal

stents (BMS) in the early 1990s, data with longer-term follow-up continued to show high rates of restenosis and the need for repeat revascularization.⁶ Therefore, the 2005 American College of Cardiology (ACC)/American Heart Association (AHA)/Society of Cardiovascular Angiography and Interventions (SCAI) PCI guidelines continued to recommend CABG as the standard treatment of patients with ULMCA disease and indicated PCI as class III, Level of Evidence C recommendation for patients eligible for CABG and Class IIa, Level of Evidence B recommendation for patients who are not eligible for CABG.⁷ These guidelines confined ULMCA PCI to surgically high-risk patients and those with protected LMCA disease.

The introduction of drug-eluting stents (DES), together with the advancement of stenting techniques and adjuvant pharmacotherapy such as clopidogrel and statins, has significantly reduced the risk of restenosis and repeat revascularization for complex coronary lesions such as ULMCA disease.⁸⁻¹⁰ Therefore, despite the 2005 guideline recommendations, PCI of ULMCA has been increasing in frequency.¹¹ Additionally, several studies indicated that the advantage of CABG over DES consists primarily of fewer repeat revascularizations with no significant mortality differences even after 3 years of follow-up.¹² The 2009 ACC/AHA/SCAI focused updates specifically addressed the findings of Synergy Between PCI with TAXUS and Cardiac Surgery (SYNTAX), a randomized clinical trial comparing CABG and PCI for patients with three-vessel and/or ULMCA disease, and modified the recommendation for PCI of the ULMCA from Class III to Class IIb.¹³ Despite the rapidly expanding and extensive use of DES as therapy for ULMCA disease, concern

still remains regarding the long-term safety of DES because little evaluation has been done and no randomized trial has compared DES with CABG in a large population. We present a case of a patient with severe ULMCA disease and review the current status of percutaneous versus surgical treatment, focusing on recent advances and the current recommendations established by the ACC/AHA/SCAI for patients with ULMCA disease.

Case Presentation

A 56-year-old man with a past medical history of moderately severe chronic obstructive pulmonary disease (COPD) underwent cardiac catheterization due to new onset of angina and an abnormal stress test result with ischemia in the anterior wall. The coronary angiogram demonstrated a severe stenosis of the ostium of the ULMCA but no significant coronary disease in other epicardial coronary arteries (Figure 1). Intravascular ultrasound (IVUS) was performed to confirm the severe stenosis of the LMCA and demonstrated a minimal lumen area of 4.4 mm² (lower limit of normal for

minimal luminal area > 6 mm²). Left ventricular (LV) angiography demonstrated an LV ejection fraction (LVEF) of 60%. The patient was referred for cardiac surgical consultation. Despite being told that CABG is the standard of care for the treatment of ULMCA disease, the patient refused CABG. The patient was then referred for ULMCA PCI.

The patient was preloaded with clopidogrel, 600 mg, and aspirin, 325 mg, prior to the PCI. After predilatation, a 3.5 × 12 mm TAXUS[®] Express[®] stent (Boston Scientific Corporation, Natick, MA), was positioned precisely at the ostium of the ULMCA in the left anterior oblique-cranial view and implanted in the ULMCA at 16 atmospheres proximal to the distal bifurcation (Figure 2). The stent was postdilated with a 4.0 × 8 mm noncompliant balloon, and IVUS was performed, which demonstrated excellent stent apposition, expansion, and no dissection (Figure 3).

At 3-year follow-up, the patient continues to do well with no angina and a recent nuclear stress test demonstrated no evidence of ischemia. The patient did not have any side effects from aspirin and clopidogrel;



Figure 1. This 56-year-old man had a significant ostial unprotected left main coronary artery stenosis.

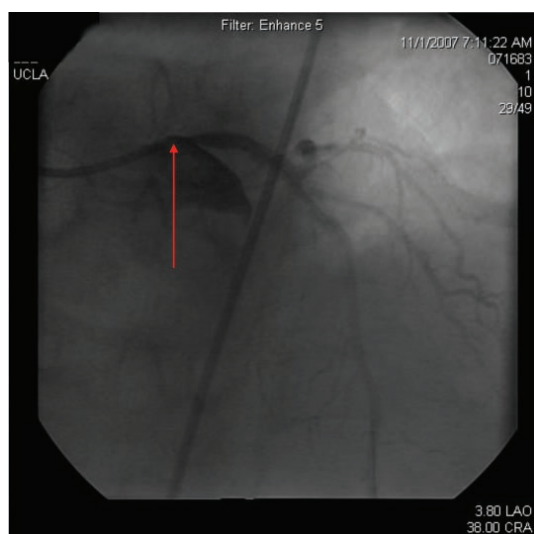


Figure 2. The stent is being positioned in the anteroposterior cranial view. The proximal stent marker (red arrow) is positioned in between the superior and inferior border of the ostial unprotected left main coronary artery.

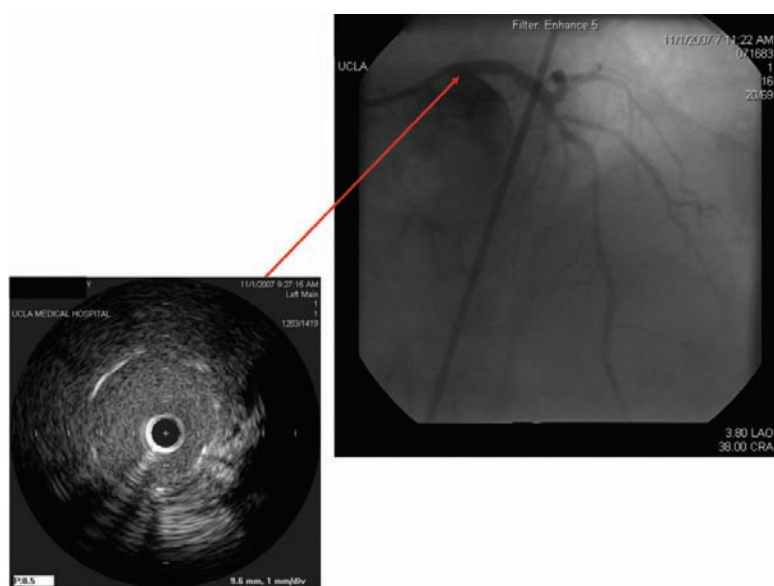


Figure 3. Final angiographic images demonstrate excellent angiographic results. Intravenous ultrasound demonstrates excellent stent apposition and confirms coverage of the ostial unprotected left main coronary artery with stent struts visible in the aorto-ostial junction.

therefore, dual antiplatelet therapy has been continued indefinitely.

Percutaneous Coronary Intervention

Pre-DES Era

The clinical outcomes of patients treated with PCI correspond with baseline clinical characteristics such as LVEF and various comorbidities. The Unprotected Left Main Trunk

(68.8% received BMS and 15.1% were treated with balloon angioplasty alone). Of these patients, 46% were deemed inoperable or at high surgical risk. These high-risk patients demonstrated an in-hospital mortality rate of 13.7% and a 1-year incidence of all-cause mortality of 24.2% attributed to LVEF < 30%, mitral regurgitation grade 3 or 4, presentation with acute myocardial infarction (MI) and shock, creatinine \geq 2.0 mg/dL, and severe lesion calcification. Among the 32% low-risk patients (age < 65 years, LVEF > 30%, and without shock), 1-year mortality was 3.4% with a lack of periprocedural deaths.¹⁴ A series conducted in elective, low-risk patients supported these findings, revealing favorable short- or midterm outcomes of PCI with BMS for ULMCA disease.¹⁵⁻¹⁷ The development of restenosis and repeat revascularization, however, remained a major and potentially fatal complication of LMCA stenting with BMS and has limited its more widespread use.^{4,5}

DES

With the advent of DES and effective reductions in restenosis, the rate of PCI for ULMCA disease has risen, whereas that of CABG surgery has declined, revealing a paradigm shift in the world of myocardial revascularization.¹¹ In a randomized comparison of paclitaxel-eluting stents (PES) versus BMS, 103 patients with

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Investigation Multicenter Assessment (ULTIMA) registry was a prospective, multicenter, international registry of 279 patients who underwent PCI of the ULMCA

ULMCA disease were randomly assigned to receive BMS (n = 50) or PES (n = 53) implantation.¹⁸ At 6 months, the PES group revealed a statistically significant reduction in

binary restenosis (6% vs 22%) and target-lesion revascularization (TLR) (2% vs 16%) when compared with the BMS group. The major adverse cardiac event (MACE)-free survival rate was 70% in BMS patients and 87% in PES patients demonstrating the short-term safety and efficacy of PCI of ULMCA with PES.

In addition to efficacy and short-term safety, concerns over the long-term safety of DES in ULMCA patients, particularly regarding the possibility of late or very late thrombosis, have hindered the widespread use of PCI with DES as an alternative therapy to CABG. A series of ULMCA DES studies have evaluated the long-term clinical outcomes after DES implantation for ULMCA disease. In a multicenter registry, 731 patients underwent elective ULMCA stenting with DES revealing a combined incidence of definite or probable thrombosis of 0.95% and cumulative rates of death, MI, and TLR of 6.2%, 1.5%, and 12.9%, respectively, at 30 months follow-up.¹⁹ The Drug Eluting Stent for Left Main (DELFT) registry, which included 358 patients who underwent PCI with DES and 3 years of follow-up, revealed the incidence of definite, probable, and possible stent thrombosis as 0.6%, 1.1%, and 4.4%, respectively.²⁰ MACE-free survival in the whole population was 73.5% and cardiac death occurred in 9.2% of patients; reinfarction, TLR, and target vessel revascularization (TVR) occurred in 8.6%, 5.8%, and 14.2% of patients, respectively. When comparing results between elective and emergent patients, the 3-year MACE-free survival (74.2% vs 68.2%), mortality (6.2% vs 21.4%), reinfarction (8.3% vs 10.0%), and TLR (2.8% vs 6.6%) rates were all superior for elective patients. The Intracoronary Stenting and Angiographic Results: Drug-Eluting Stents for Unprotected

Coronary Left Main Lesions (ISAR-LEFT-MAIN) trial reported on 607 patients treated with DES and observed a 2-year rate of definite or probable stent thrombosis of 0.5% to 1.0%.²¹

A PES was chosen for the PCI of the ULMCA. In the ISAR-LEFT MAIN trial, there were no differences in rates of angiographic restenosis at 6 to 9 months follow-up with ULMCA PCI with either sirolimus-eluting stents (SES) or PES (16.0% PES vs 19.4% SES; $P = .30$).²¹ Similarly, through 2 years, there was no difference in the rate of TLR (9.2% with PES vs 10.7% with SES; $P = .47$).

CABG Versus PCI for ULMCA Disease

To appropriately treat patients with ULMCA disease, the choice of PCI or CABG must be made. Certain characteristics of ULMCA lesions, as well as patient clinical presentations, are important to take into consideration when selecting PCI or CABG for revascularization. The application of the 2005 guidelines based on 20-year-old clinical trials comparing CABG versus medical treatment seemed inappropriate, especially given the fact that no adequately powered randomized studies between PCI and CABG have been completed.

Numerous studies have assessed the midterm safety and efficacy of stenting in ULMCA disease. How-

ever, long-term advantages of PCI compared with CABG are not as readily apparent. Several nonrandomized studies, though small and observational, have looked into this issue. In a retrospective analysis, 249 patients with ULMCA stenosis were treated with PCI and DES implantation ($n = 107$) or CABG ($n = 142$).²² At 1 year, there was no statistical difference in the occurrence of death in PCI versus CABG (adjusted odds ratio [OR] = 0.331; $P = .167$). However, DES revealed a significantly lower incidence of the composite endpoint of death and MI (adjusted OR = 0.260; $P = .0005$). No difference was detected in the occurrence of major adverse cardiac and cerebrovascular events (MACCE) between the two groups (adjusted OR = 0.568; $P = .227$). However, patients who underwent CABG had lower rates of TVR (3.6% vs 19.6%; $P = .0001$). Other studies by Lee and colleagues²³ and a multicenter registry²⁴ supported these findings, demonstrating similar rates of death and MI between DES and CABG, but higher incidences of TLR in the DES group compared with the CABG group.

The Revascularization for Unprotected Left Main Coronary Artery Stenosis: Comparison of Percutaneous Coronary Angioplasty Versus Surgical Revascularization (MAIN-COMPARE) study reported on 2240 patients with ULMCA disease treated with either BMS ($n = 318$), DES ($n = 784$) or CABG ($n = 1138$)—providing the first long-term study comparing PCI with CABG.²⁵ Outcomes including death and composite outcome of death, MI, stroke, and

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TVR were compared between the stenting and CABG groups during the first 3 years after treatment. The rate of TVR was significantly lower in the CABG group than in the PCI group (hazard ratio [HR], 4.76; 95% confidence interval [CI], 2.80-8.11). The risks of death (HR, 1.18; 95% CI,

0.77-1.80) and the combined rates of death, MI, and stroke (HR, 1.10; 95% CI, 0.75-1.62) were similar in the PCI and CABG groups. Similar patterns were seen when comparing either BMS or DES with CABG.

Confirmation of the relative risks and benefits of PCI versus CABG for ULMCA disease depends on the results of randomized clinical trials comparing the two revascularization strategies. The Synergy between Percutaneous Coronary Intervention with Taxus and Cardiac Surgery (SYNTAX) trial compared the outcomes of PCI with PES versus CABG for ULMCA stenosis in left main subsets from the randomized study cohort (348 patients treated with CABG and 357 treated with PES).²⁶ In the SYNTAX trial, PCI was not shown to be noninferior to CABG in the overall cohort of patients; however, in the subset of patients with ULMCA disease, there was no difference in MACCE between CABG and PCI with PES (22.3% vs 26.8%; $P = .20$) at 3-year follow-up.²⁷ Based on the results of the SYNTAX trial, the 2009 PCI Focused Update Recommendations state that CABG is

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preferred in patients with complex coronary anatomies at the LMCA and concomitant diffuse multivessel disease,¹³ although in patients with ULMCA disease involving the ostium or shaft, PCI is a reasonable alternative and possibly a favorable substitute to reduce the risk of stroke associated with CABG.²⁸

Due to the hypothesis-generating nature of the SYNTAX posthoc analysis, results from a more specific randomized study are needed to provide answers for patients with ULMCA stenosis. The Premier of Randomized Comparison of Bypass

Patients who are good candidates for ULMCA PCI include those with isolated or concomitant single-vessel coronary artery disease, ostial or midbody disease, and preserved LV function who undergo elective PCI as opposed to emergent PCI.

Surgery versus Angioplasty using Sirolimus-Eluting Stent in Patients with Left Main Coronary Artery Disease (PRECOMBAT) trial, currently being performed in Korea, is a prospective, multicenter, randomized study comparing the safety and efficacy of SES and CABG for 600 ULMCA patients with the primary endpoint of MACCE at 2 years. The Evaluation of Xience Prime versus Coronary Artery Bypass Surgery for Effectiveness of Left Main Revascularization (EXCEL) trial will randomize 2500 selected patients with ULMCA disease to DES or CABG to determine the optimal revascularization

Patient Selection

The success of ULMCA PCI depends on the careful selection of patients. Patients who are good candidates for ULMCA PCI include those with isolated or concomitant single-vessel coronary artery disease, ostial or

midbody disease, and preserved LV function who undergo elective PCI as opposed to emergent PCI. Patients with ostial or midbody disease who underwent PCI of ULMCA had excellent clinical results with low rates of cardiac death (2.7%) and TLR (0.7%) at 2.5-year follow-up.²⁹ Severe calcification of the LMCA may require debulking with rotational atherectomy, which may increase the complexity of the PCI. Distal bifurcation disease requiring a two-stent technique may make the PCI more technically challenging. The patient we present here had many favorable features, including isolated ostial ULMCA disease and preserved LV function with no significant calcification of the ULMCA. Furthermore, the patient had moderately severe COPD and was the main care provider for his wife, who had a chronic medical condition. Therefore, the patient preferred to undergo PCI rather than CABG. The patient also agreed to continue dual antiplatelet therapy for at least 1 year to minimize the risk of stent thrombosis—a dreaded complication of ULMCA PCI.

Patients who are better suited for ULMCA PCI are those who are poor surgical candidates. These include patients presenting with multiple comorbidities such as COPD, history of stroke, a heavily calcified aorta, poor distal targets, and the inability to

strategy for these patients. The primary endpoint is the composite incidence of death, MI, or stroke at a median follow-up duration of 3 years. The results from these studies are expected to provide more definitive answers regarding the two revascularization techniques for ULMCA disease.

receive a left internal mammary artery to left anterior descending artery graft. Patients with limited life expectancy such as the very elderly or patients with terminal malignancy might also be better candidates for ULMCA PCI.

The SYNTAX score is a risk model that is comprised of eight angiographic variables (lesion location, left main, three vessels, chronic total occlusion, tortuosity, bifurcation, thrombus, and calcification [www.syntaxscore.com]).³⁰ It is a valuable tool to predict the clinical outcomes in patients with ULMCA as well as multivessel disease. In particular, patients with low (≤ 22) and intermediate (23-32) SYNTAX scores may be good candidates for ULMCA PCI with DES because the mortality rate was lower when compared with CABG (2.7% vs 7.9%; $P = .02$) with similar rates of repeat revascularization (14.3% vs 11.4%; $P = .44$) at 2-year follow-up.³¹

Post-Revascularization Surveillance

The 2009 ACC/AHA/SCAI focused PCI guidelines no longer recommend follow-up angiography.¹³ In the Left Main Coronary Artery Stenting (LE MANS) substudy of the SYNTAX trial, binary restenosis occurred in only 2% (1/48) and 10% (10/97) of patients

with ostial/midbody and distal bifurcation disease, respectively, at 15-month follow-up angiography.³² The performance of routine surveillance angiography has not been proven a clinical benefit and may lead to unnecessary repeat procedures.

Coronary computed tomographic (CT) angiography may be an alternative to routine surveillance angiography in patients who have undergone ULMCA PCI. When compared with quantitative coronary angiography and IVUS, CT angiography has shown reliable accuracy for single stent cases but limited utility when two stents are used in distal bifurcation disease due to blooming artifact.³³ Despite the lack of consensus recommendations, noninvasive assessment of ischemia should be considered at 6 months and annually thereafter.

Conclusions

CABG has been the recommended treatment of patients with ULMCA stenosis, whereas PCI was reserved for patients who were candidates for revascularization but were ineligible for CABG. Although the results of CABG have improved in recent years, it is still limited by its association with prolonged hospital stay and rehabilitation, and mediocre long-term pa-

tency of saphenous vein grafts. Stenting was not a good alternative to CABG surgery during the BMS era due to high restenosis rates and poor long-term results. DES have dramatically reduced the restenosis rates, and the data indicate that they provide comparable clinical outcomes to those of CABG. Those with isolated ULMCA disease limited to the ostium or midbody may be a subset of patients who are most likely to have good clinical outcomes. The results of upcoming randomized clinical studies such as the EXCEL and PRECOMBAT trials, which will compare ULMCA PCI with DES and CABG, will provide insight regarding the ideal revascularization strategy for these patients. ■

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Main Points

- Coronary artery bypass grafting (CABG) is the gold standard for the treatment of unprotected left main coronary artery (ULMCA) stenosis whereas percutaneous coronary intervention (PCI) is reserved for patients who are candidates for revascularization but are ineligible for CABG.
- Although the results of CABG have improved in recent years, it is still limited by its association with prolonged hospital stay and rehabilitation, and mediocre long-term patency of saphenous vein grafts.
- Drug-eluting stents (DES) have dramatically reduced the restenosis rates, and the data indicate that they provide comparable clinical outcomes to those of CABG.
- Patients with isolated ULMCA disease limited to the ostium or midbody may be a subset of patients who are most likely to have good clinical outcomes.
- The results of the upcoming randomized clinical trial such as the EXCEL trial, which will compare ULMCA PCI with DES and CABG, will provide insight regarding the ideal revascularization strategy for these patients.

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