Stenting of Unprotected Left Main Coronary Artery Stenoses: Immediate and Late Outcomes

SEUNG-JUNG PARK, MD, PhD, FACC, SEONG-WOOK PARK, MD, PhD, MYEONG-KI HONG, MD, SANG-SIG CHEONG, MD, CHEOL WHAN LEE, MD, JAE-JOONG KIM, MD, MUN K. HONG, MD, FACC,* GARY S. MINTZ, MD, FACC,* MARTIN B. LEON, MD, FACC*

Seoul, Korea and Washington, D.C.

Objectives. **We examined the immediate and long-term outcomes after stenting of unprotected left main coronary artery (LMCA) stenoses in patients with normal left ventricular (LV) function.**

Background. **Left main coronary artery disease is regarded as an absolute contraindication for coronary angioplasty. Recently, several reports on protected or unprotected LMCA stenting, or both, suggested the possibility of percutaneous intervention for this prohibited area.**

Methods. **Forty-two consecutive patients with unprotected LMCA stenoses and normal LV function were treated with stents. The post-stent antithrombotic regimens were aspirin and ticlopidine; 14 patients also received warfarin. Patients were followed very closely with monthly telephone interviews and follow-up angiography at 6 months.**

Results. **The procedural success rate was 100%, with no episodes of subacute thrombosis regardless of anticoagulation regimen. Six-month follow-up angiography was performed in 32 of 34 eligible patients. Angiographic restenosis occurred in seven patients (22%, 95% confidence interval 7% to 37%); five patients subsequently underwent elective coronary artery bypass graft surgery (CABG), and two patients were treated with rotational atherectomy plus adjunct balloon angioplasty. The only death occurred 2 days after elective CABG for treatment of in-stent restenosis. The other patients (without angiographic follow-up) remain asymptomatic.**

Conclusions. **Stenting of unprotected LMCA stenoses may be a safe and effective alternative to CABG in carefully selected patients with normal LV function. Further studies in larger patient populations are needed to assess late outcome.**

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Significant left main coronary artery (LMCA) disease is of critical prognostic importance (1–3). Medical therapy of patients with LMCA disease is associated with a poor prognosis (4,5). Initial studies of balloon angioplasty of unprotected LMCA stenoses reported varying degrees of procedural success (6–9), but uniformly poor long-term results (7–9). Therefore, coronary artery bypass graft surgery (CABG) has been the standard treatment for significant LMCA disease (10,11).

Stenting of unprotected LMCA stenoses has been attempted as a therapeutic option in selected patients with prohibitive surgical risk, usually as a result of noncardiac comorbidities (12–14). A few cases of stenting of unprotected LMCA stenoses have also been reported in bailout situations (15–17). Thus far, elective stenting in patients with unprotected LMCA stenoses has been regarded as a contraindication, mostly due to the potential fatal outcome from subacute stent thrombosis. However, in the past few years there have been significant improvements in both stent implantation techniques (18) and post-stent antithrombotic regimens (19).

The objective of the current study was to determine whether stenting of unprotected LMCA stenoses in selected patients with normal left ventricular (LV) function is safe, and thus may provide an alternative treatment to CABG.

Methods

Study patients. From November 1995 to February 1997, 42 consecutive patients with significant unprotected LMCA stenoses who declined CABG were treated with stent implantation. One patient had a limited life expectancy owing to chronic myelogenous leukemia; the other 41 patients were good surgical candidates but did not want to undergo CABG. During the same period, 64 patients with significant LMCA stenoses underwent CABG because of depressed LV function, combined severe multiple stenosis of major epicardial arteries or significant stenosis of the distal LMCA with involvement of the proximal portion of the left anterior descending or left

From the Department of Internal Medicine, College of Medicine, University of Ulsan and Cardiovascular Center, Asan Medical Center, Seoul, Korea; and *Washington Hospital Center, Washington, D.C.

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Address for correspondence: Dr. Seung-Jung Park, Department of Internal Medicine, College of Medicine, University of Ulsan, Cardiovascular Center, Asan Medical Center, 388-1 Pungnap-dong, Songpa-gu, Seoul, Korea. E-mail: sjpark@www.amc.seoul.kr.

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Abbreviations and Acronyms

CABG	=	coronary artery bypass graft surgery
DS	=	diameter stenosis
IVUS	=	intravascular ultrasound
LMCA	=	left main coronary artery
LV	=	left ventricular
MLD	=	minimal lumen diameter
QCA	=	quantitative coronary angiography

circumflex coronary artery. The inclusion criteria were 1) clinical symptoms or objective evidence of myocardial ischemia during an exercise test or thallium single-photon emission computed tomographic imaging; and 2) angiographic evidence of ≥50% diameter stenosis of the LMCA by quantitative coronary angiographic (QCA) analysis. The criteria for exclusion were 1) contraindication to aspirin or ticlopidine; and 2) reduced LV function (ejection fraction ≤40%). In addition to significant LMCA stenoses, significant narrowing of the right coronary artery was observed in six patients. Stenting of the right coronary artery was performed at the same time as LMCA stenting in four patients.

All patients gave written, informed consent to participate in the study. The study was carried out according to the principles of the Declaration of Helsinki and was approved by our Institutional Review Board on clinical study.

Stent implantation procedure. Stent implantation was performed electively in 38 patients and in bailout situations in the other four patients. An intraaortic balloon pump was prepared for emergency cardiopulmonary support, if needed, but was not inserted prophylactively. Predilation before stent implantation was performed with undersized, conventional angioplasty balloons. The stents were then deployed by inflating the stent delivery balloon at nominal pressure. After implantation of the stent, the stented segment was further dilated with high pressure balloon inflation to achieve angiographic optimization. The balloon inflations were brief (<30 s) and multiple (≥3) to avoid prolonged ischemia and ischemia-related complications. No perfusion balloon catheters were used during predilation, stent implantation or post-stent high pressure dilation. The Palmaz-Schatz (Johnson & Johnson Interventional Systems, Inc.), NIR (Medinol, Inc.) and Multi-Link (Guidant, Inc.) tubular design stents were selected for lesions at the ostium or shaft of the LMCA. The Gianturco-Roubin II (Cook, Inc.), Microstent (Arterial Vascular Engineering, Inc.) and Cordis (Cordis, Inc.) coil design stents were used for lesions involving the distal bifurcation.

The size of stent was ≥3.5 mm in 88% of the lesions. The lesions at the ostium or shaft without involvement of the distal bifurcation comprised 79% of the lesions. The stents used to treat LMCA stenoses were the Palmaz-Schatz stent in 25 patients, the NIR stent in 6 patients, the Cordis stent in 5 patients, the Multi-Link stent in 3 patients, the Gianturco-Roubin II stent in 2 patients and the Microstent in 1 patient. A debulking procedure before LMCA stenting was performed in six patients (directional atherectomy in one patient and rotational atherectomy in five patients).

During the procedure, patients received a 10,000-U bolus of heparin with a repeat bolus of 5,000 U every 30 min to maintain an activated clotting time >250 s. All patients were kept in the coronary care unit for 24 h after stenting.

Anticoagulation/antiplatelet regimen. All patients received aspirin and ticlopidine. Ticlopidine therapy (250 mg twice a day) was started at least 3 days before the elective procedure and continued for 1 month. All patients received aspirin (200 mg/day). In the first 14 patients, anticoagulation therapy using warfarin sodium was begun on the day of the procedure and continued for 1 month. Heparin infusion was maintained until the prothrombin time was in the therapeutic range (International Normalized Ratio 2.0 to 3.0). In the last 28 patients, heparin infusion was discontinued 12 h after stent implantation, and warfarin was not used.

Angiographic analysis. Two experienced angiographers not involved in the stent procedure analyzed the angiographic results. Percent diameter stenosis (DS), minimal lumen diameter (MLD) and reference diameter using an on-line QCA system (ANCOR version 2.0, Siemens) were measured before predilation, after stenting plus adjunct balloon angioplasty and at follow-up using a matched view showing the MLD. Angiographic measurements were made during diastole after intracoronary nitroglycerin administration using the guiding catheter for magnification calibration. Single matched views with the worst DS were compared. Angiographic restenosis was defined as diameter stenosis ≥50% at follow-up.

Quantitative IVUS analysis. We tried to obtain intravascular ultrasound (IVUS) images in every patient with stenting of LMCA stenoses. The IVUS machine, however, was not available at an early stage of the study. Intravascular ultrasound was not performed in patients with tight stenosis of the LMCA because of hemodynamic compromise during the passage of the IVUS catheter across the lesions. Therefore, IVUS was performed in 12 selected patients before predilation and after stenting plus adjunct balloon angioplasty at a later stage of the study. Intravascular ultrasound imaging was performed after the administration of 0.2 mg of intracoronary nitroglycerin. The IVUS system (Cardiovascular Imaging System, Inc.) uses a 30-MHz transducer mounted on the end of a flexible shaft that rotates at 1,800 rpm (within either a 2.9F long monorail/common distal lumen imaging sheath or within a 3.2F short monorail imaging sheath) (20). Imaging was performed using a motorized transducer pullback device, which withdraws the transducer at a rate of 0.5 mm/s within the stationary imaging sheath. Quantitative IVUS analysis was performed using computer planimetry as previously described (20).

Clinical and angiographic follow-up. Clinical follow-up was obtained by monthly telephone interviews. All patients were requested to visit outpatient clinics at 1, 3 and 6 months and to have follow-up angiograms at 6 months.

Statistical analysis. All data are expressed as the mean value ± SD.

Table 1. Baseline Clinical Characteristics of 42 Study Patients

Age (yr)	54.3 ± 7.1
Male gender	62%
Cardiac risk factors	
Hypertension	38%
Diabetes mellitus	29%
Hypercholesterolemia	12%
Current smoker	41%
Myocardial infarction	
Previous	5%
Acute	2%
Unstable angina	69%
No. of diseased coronary arteries	
LMCA only	86%
LMCA and RCA	14%
LVEF (%)	56 ± 12

Data presented are mean value ± SD or percent of patients. LMCA = left main coronary artery; LVEF = left ventricular ejection fraction; RCA = right coronary artery.

Results

In-hospital outcome. The baseline clinical characteristics of the 42 patients are shown in Table 1. The angiographic and procedural characteristics of 42 lesions are shown in Table 2. The procedural success rate was 100%. Figures 1 and 2 show examples of successful stenting of the LMCA. Although an intraaortic balloon pump was prepared for emergency cardiopulmonary support, no patients required this therapy. Major in-hospital complications including stent thrombosis, myocardial infarction, emergency CABG or death did not occur regardless of stent type or anticoagulation therapy.

Results of QCA. The QCA measurements before predilation, after stenting plus adjunct balloon angioplasty and at follow-up are shown in Table 3. The mean reference vessel diameter was 4.0 mm. The DS decreased from 73% before the intervention to −5% after the intervention. The MLD increased from 1.1 mm before the intervention to 4.2 mm after the intervention. At follow-up, the DS was 26% and the MLD was 2.8 mm.

Table 2. Angiographic and Procedural Characteristics of 42 Lesions

Lesion location	
Aorto-ostial	45%
Confined to shaft	33%
Involving distal bifurcation	21%
Final diameter of stent	
3.0–3.5 mm	12%
3.5–4.0 mm	50%
≥4.0 mm	38%
Type of stent	
Palmaz-Schatz	60%
NIR	14%
Cordis	12%
Multi-Link	7%
Gianturco-Roubin II	5%
Microstent	2%
Multiple stents	5%
Procedural success	100%

Data presented are percent of lesions.

Guidance of IVUS. Because of IVUS findings of incomplete stent expansion, four patients underwent additional angioplasty with higher pressures or a larger sized balloon. In one patient, despite angiographic optimization, IVUS detected significant residual plaque burden at the ostium of the LMCA, which was not covered by the stent; therefore, an additional half-stent was implanted.

Late clinical outcomes and angiographic restenosis rate. Clinical follow-up with monthly telephone interviews and outpatient clinic visits revealed recurrence in 7 of 42 patients (17%, 95% confidence interval [CI] 5 to 28). The mean duration of clinical follow-up was 10.2 ± 4.7 months (range 3 to 17) in patients without restenosis. Restenosis occurred within 2 months (mean 1.8 ± 0.3) after LMCA stenting. The clinical manifestation was unstable angina in all patients with restenosis. Myocardial infarction did not occur during follow-up in all patients.

Angiographic follow-up data were obtained for 32 of the 34 eligible patients who underwent LMCA stenting. Two patients who refused angiographic follow-up were asymptomatic. Follow-up angiography for the remaining eight patients is scheduled to be performed 6 months after the intervention.

Angiographic restenosis occurred in seven patients (22%, 95% CI 7 to 37). The distal bifurcation was involved in all patients, including those whose initial lesion only involved the ostium. Elective CABG was performed in five patients, and rotational atherectomy plus adjunct balloon angioplasty was performed in two patients. Among these patients, one death (in a middle-aged woman with Takayasu's arteritis) occurred 2 days after elective CABG.

Discussion

This clinical study shows that stenting of unprotected LMCA stenoses may be as safe and effective in *carefully selected patients* with normal LV function. The procedure was successful in all patients, and there were no episodes of subacute stent thrombosis. Despite the large final MLD, restenosis occurred in 22% (95% CI 7 to 37) of patients (uniformly involving the distal LMCA). However, there were no incidences of sudden death or nonfatal myocardial infarction during the follow-up period.

Previous studies with balloon angioplasty and advantages of stents. Balloon angioplasty of unprotected LMCA stenoses has been associated with varying degrees of procedural success, but generally poor long-term prognosis (6–9). Previously reported *unprotected* LMCA stent procedures have been done in conditions of prohibitive surgical risk or in bailout situations (12–17). Other investigators have reported primarily *protected* LMCA stenting (21–23).

The current study indicates that stenting of LMCA stenoses improves both the immediate procedural success and the long-term clinical outcomes compared with balloon angioplasty, in part because of the low subacute stent thrombosis

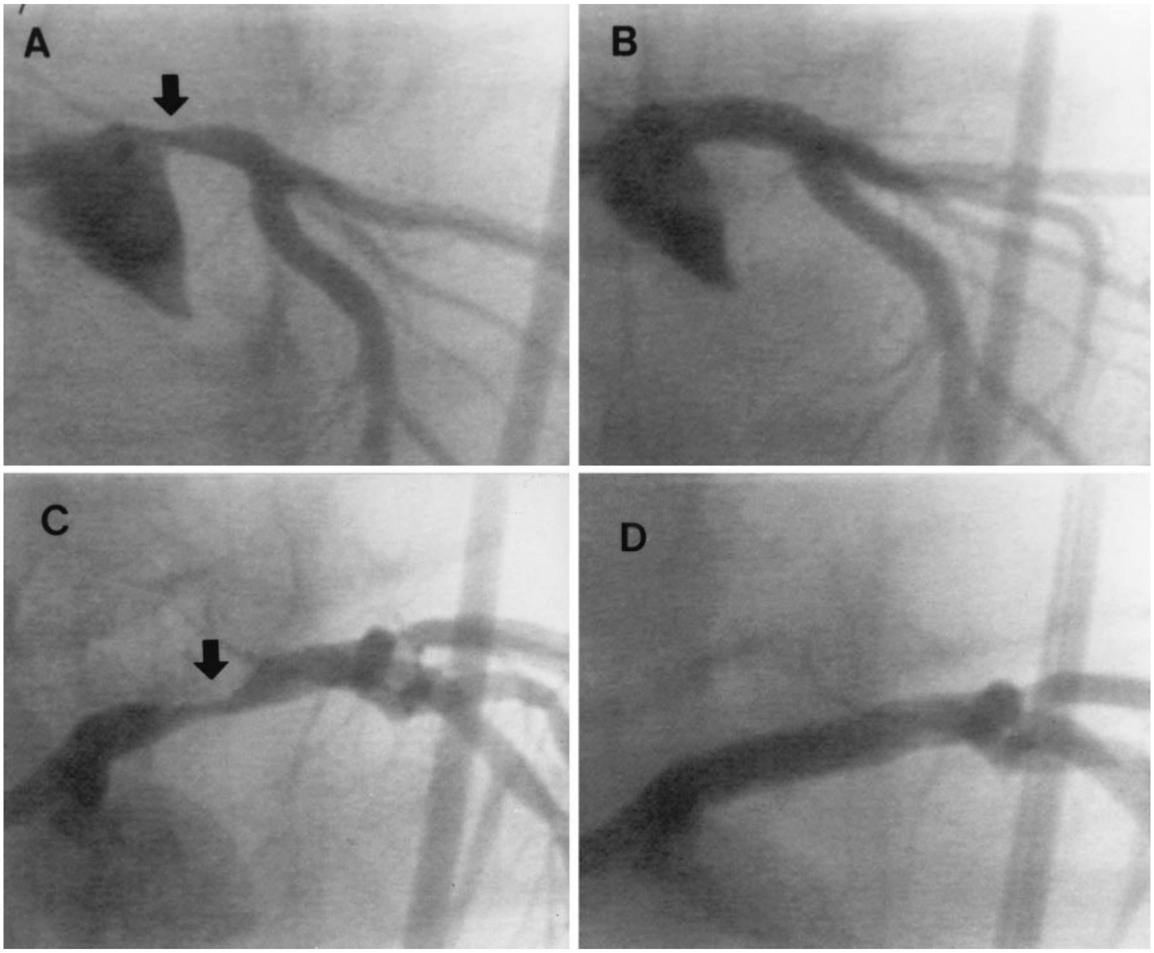

Figure 1. A, Left coronary angiogram showing a tight stenosis of the ostium of the LMCA **(arrow)**. **B,** No residual stenosis after stenting. **C,** Left coronary angiogram showing a tight stenosis of the shaft of the LMCA **(arrow)**. **D,** No residual stenosis after stenting.

rate using optimal stent implantation techniques (18) and new antiplatelet agents (19). Most of the procedures in the current study were elective; all patients had normal LV function; and balloon inflations were intentionally kept short in duration. These facts may explain the high procedural success rate. Regardless of anticoagulation therapy, major in-hospital complications did not occur in the current study. This finding suggests that antiplatelet therapy alone might be an effective post-stent antithrombotic regimen even in the LMCA.

Lesion-specific stent selection. The high concentration of elastic fibers in the aorto-ostial and proximal segments of the LMCA has been proposed as the possible mechanism of elastic recoil and high restenosis rate of conventional coronary angioplasty at these sites (7). For this reason, the slotted-tube stent, instead of the coil stent, was considered to be the stent of choice in case of ostial lesions of the LMCA. In contrast, for distal bifurcating lesions, coiled stents were used. For example, in one example of an angled lesion in the distal LMCA and proximal portion of the left circumflex artery, a coiled stent was placed from the LMCA into the left circumflex artery, and then another slotted-tube stent was placed in the proximal portion of left anterior descending coronary artery through the struts of coil stent (Fig. 2).

Rotational atherectomy before LMCA stenting was performed in five patients. The beneficial effects of the debulking procedure before LMCA stenting needs to be evaluated in larger numbers of patients. However, preliminary data support the concept of debulking before stenting (24,25).

Guidance of IVUS. Intravascular ultrasound may be an especially important adjunctive imaging modality for LMCA intervention. Despite its clinical significance, LMCA disease is often neither accurately nor precisely evaluated by coronary angiography (26,27). Unlike angiography, IVUS provides tomographic images that delineate the composition and topography of normal and atherosclerotic vascular structures.

In the current study, in one patient, despite angiographic optimization, IVUS revealed significant residual plaque burden at the ostium of the LMCA not covered by the stent. In general, IVUS had a critical role in our decision to implant additional stents in ostial lesions. There was a marked discrepancy between QCA analysis and IVUS findings. Based on these data, IVUS guidance may improve decisions

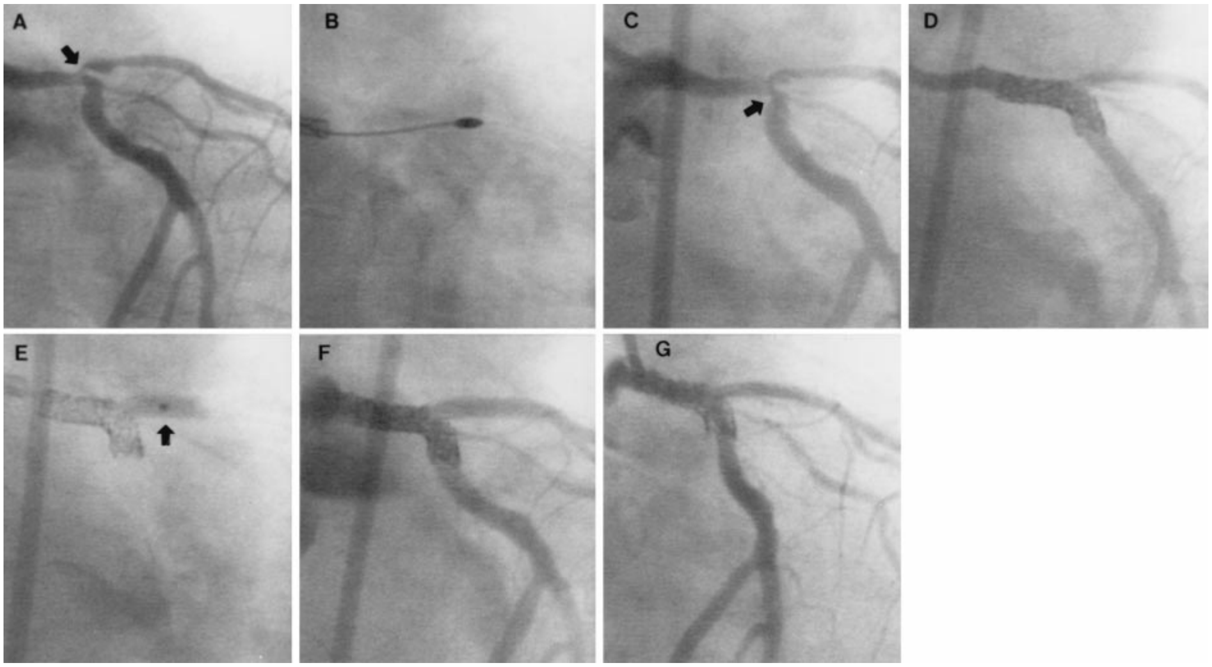

Figure 2. **A,** Left coronary angiogram showing narrowing of the distal part of LMCA with a tight stenosis of the ostium of left anterior descending coronary artery with severe calcification **(arrow). B,** Rotational atherectomy of the proximal left anterior descending coronary artery. **C,** Compromise of the ostium of left circumflex coronary artery after rotablation of the left anterior descending coronary artery **(arrow). D,** Cordis stent implantation from the LMCA to the proximal left circumflex coronary artery. **E and F,** Palmaz-Schatz stent implantation **(arrow)** at the ostium of the left anterior descending coronary artery through the struts of the Cordis coil stent. **G,** Left coronary angiogram 6 months later revealing a patent LMCA, proximal left anterior descending coronary artery and proximal left circumflex coronary artery.

regarding the size, length and type of stents and additional procedures.

Late clinical outcomes and angiographic restenosis rate. In the current study, meticulous clinical follow-up with monthly telephone interviews and outpatient clinic visits revealed clinical recurrence in 7 of 42 patients (17%, 95% CI 5 to 28). The restenosis occurred early (within 2 months) after LMCA stenting. The clinical manifestation was usually unstable angina. Therefore, we followed our patients carefully by telephone interview each month. High restenosis rates (≥50%) and adverse clinical events have been reported during follow-up in previous studies of balloon angioplasty or laser angioplasty of LMCA stenoses (7,28). However, other previous studies of stenting of LMCA stenoses (albeit in small numbers of patients) showed acceptable angiographic restenosis rates and clinical events during follow-up (21–23). In the current study, the angiographic restenosis rate (22%, 95% CI 7 to 37) was similar to that of the previous studies (21–23). Compared with restenosis rates after balloon angioplasty or laser angioplasty, low restenosis rates after stenting of LMCA stenoses may be attributed to larger post-stent lumen dimensions and to the effect of stents in resisting pathologic arterial remodeling and acute recoil.

Of the 32 patients who had angiographic follow-up, 24 had stent implantation at the ostial or proximal portion of the LMCA. Angiographic restenosis occurred in 4 of 24 patients in this subgroup. In all patients with restenosis of the LMCA in the current study, the site of restenosis involved the distal bifurcation. This may be explained in part by incomplete stent coverage of significant lesions at the distal LMCA or proximal left anterior descending coronary artery not be detected by angiography. Because the length of the entire LMCA can be less than the balloon length, injury during high pressure balloon inflation might occur in both the distal LMCA and proximal segment of the branch vessel (e.g., left anterior descending coronary artery).

There were some limitations in the current study. First, IVUS images were obtained in only 12 patients at a later stage

Table 3. Results of Quantitative Angiographic Analysis

Reference vessel diameter (mm)	4.0 ± 0.5
Balloon to artery ratio	1.06 ± 0.04
Diameter stenosis (%)	
Baseline	73 ± 9
Final	−5 ± 4
Follow-up	26 ± 21
Minimal lumen diameter (mm)	
Baseline	1.1 ± 0.3
Final	4.2 ± 0.5
Follow-up	2.8 ± 0.9
Acute gain (mm)	3.1 ± 0.2
Late loss (mm)	1.4 ± 0.6
Maximal balloon inflation pressure (atm)	15.7 ± 1.9

Data presented are mean value ± SD.

of the study. Second, angiographic follow-up data were not obtained in all study groups. However, the angiographic follow-up rate was 94% (32 of 34 eligible patients). Follow-up angiography for the remaining patients is scheduled to be performed 6 months after the intervention.

Conclusions and clinical implications. Patients most suitable for unprotected LMCA stenting may be those with isolated LMCA disease and normal LV function. The most suitable lesions are those limited to the LMCA shaft, especially the ostium or proximal portion of the LMCA, or both. Inflating the balloons in the distal LMCA might be avoided, if possible. If the lesions involve the bifurcation area, a maximal debulking procedure or stenting, or both, of the proximal portion of the left anterior descending coronary artery and left circumflex artery might be considered to reduce restenosis. Further clinical study with larger numbers of patients will be needed to evaluate the late outcomes after stenting of LMCA stenoses.

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