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Interventional Cardiology

Unprotected Left Main Coronary Artery Stenting

Correlates of Midterm Survival and Impact of Patient Selection

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OBJECTIVES The study served to present the in-hospital and six-month clinical outcome and also the long-term survival data of a consecutive series of patients undergoing stenting for unprotected left main coronary artery (LMCA) disease.

BACKGROUND Revascularization with coronary bypass surgery has been generally recommended for treatment of left main coronary stenosis. Improvements in angioplasty and coronary stent techniques and equipment may result in the wider applicability of a percutaneous approach.

METHODS A total of 92 consecutive patients underwent unprotected LMCA stenting between March 1994 and December 1998. For the initial 39 patients (group I) angioplasty was performed only when surgical revascularization was contraindicated. The remaining 53 patients (group II) also included patients in whom surgery was feasible. Patients were followed for 7.3 ± 5.8 months (median 239 days; range 49 to 1,477 days).

RESULTS Compared to group I, group II patients had higher left ventricular ejection fraction (60 ± 12% vs. 51 ± 16%, $p < 0.01$), less severe LMCA stenosis (68 ± 12% vs. 80 ± 10%, $p < 0.001$), lower surgical risk score (13 ± 7 vs. 20 ± 7, $p < 0.001$), and had angioplasty more often performed via the radial approach (88% vs. 23%, $p < 0.001$) with smaller guiding catheters (6F: 49% vs. 15%; 8F: 2% vs. 77%, $p < 0.001$). The procedural success rate was 100%. In-hospital mortality was 4% (4 deaths, 3 cardiac). During follow-up there were six deaths, 13 patients required repeat percutaneous transluminal coronary angioplasty (4 LMCA), and two required coronary artery bypass graft surgery. Estimated survival (±SEE) was 89 ± 6.3% at 500 days and 85 ± 12% at 1,000 days post-stenting. Overall mortality was 3.8% in group II and 20.5% in group I ($p < 0.02$).

CONCLUSIONS Coronary stenting can be performed safely in high-risk individuals with acceptable intermediate-term outcome. It may be feasible to broaden the application of this technique in selected patients needing revascularization for left main coronary disease. (J Am Coll Cardiol 2001;37:832–8) © 2001 by the American College of Cardiology

Left main coronary artery (LMCA) disease is found in 3% to 5% of patients undergoing cardiac catheterization (1,2) for ischemic chest pain, congestive heart failure (CHF) or cardiogenic shock. Whereas medical therapy of patients with LMCA disease is associated with a poor prognosis (3–5), revascularization by coronary artery bypass grafting (CABG) has been shown to improve survival (6–12) and is generally the preferred therapeutic option.

Early studies reporting the results of balloon angioplasty for unprotected LMCA stenosis have shown poor long-term results (13–15). However, adjunctive LMCA stenting has more recently been proposed for selected patients with prohibitive surgical risk (16–22).

Current techniques of stent deployment using high balloon pressures with or without ultrasound guidance together with the combined use of platelet adenosine diphosphate receptor antagonists and aspirin have been associated with a dramatic reduction in the risk of subacute stent thrombosis (23–26). This study evaluated our experience to date with LMCA stenting and compared the outcome in two consecutive patient groups: an initial group who were judged unsuitable candidates for CABG surgery, and a more recent group that also included patients without absolute contraindications for CABG surgery who had coronary anatomy that appeared suitable for percutaneous transluminal coronary angioplasty (PTCA).

METHODS

Study Patients

Between March 1994 and December 1998, out of a total of 6,006 interventional coronary procedures performed at Clinique Pasteur, 92 patients underwent balloon angioplasty and stent implantation for significant unprotected (i.e., without functioning bypass grafts to branches of the left coronary artery) LMCA stenosis. Before PTCA, the potential risk of CABG surgery was evaluated for each patient by considering the patient's age, the presence of diabetes mellitus, chronic obstructive pulmonary disease, peripheral vascular disease, cardiogenic shock, prior heart surgery, or poor ventricular function and the possibility of incomplete

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Abbreviations and Acronyms

CABG	=	coronary artery bypass graft
CHF	=	congestive heart failure
LMCA	=	left main coronary artery
LVEF	=	left ventricular ejection fraction
MI	=	myocardial infarction
MLD	=	minimum lumen diameter
PTCA	=	percutaneous transluminal coronary angioplasty
RCA	=	right coronary artery

and/or emergent revascularization. The Parsonnet surgical risk score (27) was calculated for each patient. All patients treated until October 1996 were judged to be unsuitable candidates for CABG surgery (group I, n = 39) by our institution's cardiothoracic surgeons in consultation with the patient's attending cardiologist, because of unacceptable operative risk considering the factors outlined above. After we reviewed the results of this initial cohort, we decided to broaden the selection criteria to include some patients who were otherwise reasonable candidates for surgery (group II, n = 53).

During the latter period, angioplasty was avoided in patients with bifurcation LMCA stenoses or heavily calcified lesions when CABG surgery was possible.

Stent Implantation Procedure

All patients except those presenting with acute myocardial infarction (MI) were pretreated with aspirin (250 mg/day) and ticlopidine (500 mg/day) for at least 72 h. Intravenous (IV) heparin 100 U/kg was administered at the commencement of the procedure, with further bolus doses to maintain the activated clotting time at above 200 s. All patients had neuroleptanalgesia administered by a cardiac anesthesiologist. Endotracheal intubation was required in two patients with cardiogenic shock, and intraaortic balloon counterpulsation was used in two patients. Systolic blood pressure was maintained at above 110 mm Hg using pressor agents if needed.

Arterial access was obtained via a transfemoral (using 7F or 8F guiding catheters in 37 patients, 40%) or transradial approach (using 6F or 7F guiding catheters in 55 patients, 60%). Predilation was performed with short (<40 s) and repeated balloon inflations in order to limit the duration of myocardial ischemia. In all cases, an inflation pressure of >15 atmospheres (atm) was used to obtain a satisfactory lumen in order to facilitate stent placement. Plaque debulking using a Rotablator™ device (Boston Scientific, Maple Grove, Minnesota) was used in seven patients with heavily calcified plaques to facilitate balloon expansion and stent deployment. Perfusion balloon catheters were not used during predilation or during stent implantation. Stent deployment was performed using high pressures (>15 atm) with a rapid-exchange, semicompliant balloon catheter. Tubular design stents were selected for ostial and mid-LMCA stenoses. Coil design stents were used for distal LMCA stenoses that involved the bifurcation into the left anterior descending coronary artery and left circumflex coronary artery.

Patients undergoing transfemoral catheterization had the arterial sheath either removed immediately with hemostasis achieved by the Perclose (Perclose, Menlo Park, California) or Angioseal (Sherwood Medical/Quinton Instrument, Bothell, Washington) device, or after 6 h, using the Femostop device (Radi Medical Systems AB, Uppsala, Sweden). The sheath was always removed immediately when the transradial approach was used. All patients were monitored in the intensive care unit for the first 24 h after the procedure.

Angiographic Analysis

Minimum lumen diameter (MLD) and vessel reference diameter were measured using an on-line quantitative coronary angiography system (DCI/ACA, Phillips, the Netherlands). Intracoronary nitrates were injected before each angiographic assessment. The diameters of normal segments proximal and distal to the treated area were averaged to determine the reference diameter, except for ostial or bifurcation lesions where the adjacent normal segment was used. Lesions were considered significant if the percentage diameter stenosis was >50%.

Definitions

Angiographic success was defined as a reduction in percent diameter stenosis to <30%. *Procedural success* required, in addition to angiographic success, the absence of any major cardiac events as defined in the following text during the period of hospitalization. *Major cardiac events* included recurrent angina requiring repeat catheterization, Q- or non-Q-wave myocardial infarction (MI), the need for urgent or semiurgent bypass surgery, and death. *Myocardial infarction* was defined clinically as the occurrence of symptoms or typical electrocardiographic changes following the stent procedure. Cardiac enzymes were not measured routinely unless there was clinical suspicion of an ischemic event.

Follow-up

Follow-up status, including death (cardiac or noncardiac), reported MI and need for repeat revascularization, was obtained for all patients at approximately six months after the PTCA procedure. Symptomatic status was not determined and not considered helpful in this group of patients with a high prevalence of multisite dilation. Long-term survival data were obtained in all patients from clinic visits or telephone interview with the patient's physician.

Statistical Analysis

Clinical and angiographic data on all patients were prospectively recorded on standard forms and stored in a computerized information system (AS/400, IBM). Continuous data

Table 1. Baseline Clinical and Angiographic Characteristics

Characteristics	n = 92	(%)
Age (yrs)	74.3 ± 8.1	
Male gender	74	(80)
Hypertension	41	(45)
Diabetes mellitus	20	(22)
Hypercholesterolemia	26	(28)
Smoker	37	(40)
Unstable angina	58	(63)
Recent MI	7	(8)
Acute MI	4	(4)
Parsonnet score	15 ± 6.9	
LVEF (%)	56.1 ± 14.7	
Three-vessel disease	66	(72)
RCA stenosis	45	(49)
Mean LMCA stenosis (%)	72.8 ± 13.0	

LMCA = left main coronary artery; LVEF = left ventricular ejection fraction; MI = myocardial infarction; RCA = right coronary artery.

are reported as mean ± SD and were compared using the Student *t* test, except for percentage diameter stenosis following stenting, which is expressed as mean (range) and was compared using the Mann-Whitney *U* test. Survival was calculated by the Kaplan-Meier method and expressed in the text as percentage ± SE. A comparison of overall survival between groups I and II was attempted using the log-rank test; however, follow-up duration was markedly shorter in group II with few events, and the data are not presented. Categorical variables were compared using chi-square analysis or the Fisher exact test where appropriate. A multivariate model of predictors of adverse outcome did not have sufficient power to discriminate the small number of events, and the data are not presented. A p value of <0.05 was considered significant.

RESULTS

Patient Characteristics

The baseline clinical characteristics of the 92 patients are shown in Table 1. Seventy-four patients were men, with a mean age of 74 years (range 47 to 90 years). Most patients presented with unstable angina and four underwent stent implantation during the acute phase of MI. The average Parsonnet score was 15 ± 6.9 (range, 0 to 27). The baseline angiographic and procedural details are displayed in Table 1.

Table 2 outlines the differences between group I and group II. Patients of group I had a higher Parsonnet score (20 ± 7 vs. 14 ± 8, $p < 0.001$), lower left ventricular ejection fraction (LVEF) (51 ± 16 vs. 60 ± 12, $p < 0.01$), more severe LMCA stenoses (80 ± 10% vs. 68 ± 12%, $p < 0.001$), more bifurcation stenoses (15% vs. 0%, $p < 0.005$) and angioplasty more often performed via the femoral approach (77% vs. 12%, $p < 0.001$) with the use of larger guiding catheter (8F guiding catheter: 77% vs. 2%; 6F: 15% vs. 49%; $p < 0.001$). Eighty-eight percent of group II patients had LMCA stent implantation performed via the transradial approach. This reflects a progressive trend at our institution where a transradial approach is currently attempted in all elective PTCA cases.

Table 2. Baseline Clinical, Angiographic and Procedural Characteristics

Characteristics	Group I (n = 39)	Group II (n = 53)	p Value
Age (yrs)	75 ± 9	74 ± 8	NS
Male gender (%)	82	79	NS
Unstable angina (%)	77	62	< 0.1
Parsonnet score	20 ± 7	13 ± 7	< 0.001
LVEF (%)	51 ± 16	60 ± 12	< 0.01
RCA stenosis (%)	67	63	NS
Mean LMCA stenosis (%)	80 ± 10%	68 ± 12%	< 0.001
Bifurcation stenosis (%)	15	0	< 0.005
Arterial access			
Femoral	79%	12%	
Radial	21%	88%	< 0.001
Guide catheter size			
8F	77%	2%	
7F	8%	49%	
6F	15%	49%	< 0.001

LMCA = left main coronary artery; LVEF = left ventricular ejection fraction; RCA = right coronary artery.

In-Hospital Outcome

Sixty-three patients underwent multisite dilation, including 13 who underwent dilation of the right coronary artery at the time of the LMCA dilation. Two patients received two stents (GRII + Palmaz-Schatz stent in 1; two Palmaz-Schatz stents in 1) (Table 3). Angiographic success was achieved in all patients, and the mean final stent diameter was 3.9 ± 0.51 mm. In-hospital major adverse cardiac events included four procedure-related deaths (4%): two from ventricular arrhythmias, one from heart failure, and one from gastrointestinal bleeding (Table 4). No MI was

Table 3. Summary of Procedures

Procedures	Patients	(%)
Target Vessel		
LMCA alone	29	32
LMCA + LAD	21	23
LMCA + LCX	15	26
LMCA + LAD + LCX	14	15
LMCA + RCA	7	8
LMCA + LAD + RCA	5	5
LMCA + LAD + LCX + RCA	1	1
Stents utilized		
Gianturco-Roubin GRII (Cook) (GR)*	26	28
GFX (AVE)	21	22
Palmaz-Schatz (Johnson & Johnson) (PS)*	16	17
Cross-Flex (Cordis)	15	16
Nir (Scimed, Boston Scientific)	6	6
Enforcer (Cardio-Vascular Dynamics)	4	4
Multilink (Advanced Cardiovascular Systems)	3	3
Wiktor (Bard)	2	2
XT (Bard)	1	1
Total	94	

*PS × 2: 1 patient received 2 Palmaz-Schatz stents; PS + GR: 1 patient received 1 Palmaz-Schatz and 1 Gianturco-Roubin stent.

LAD = left anterior descending coronary artery; LCX = left circumflex coronary artery; LMCA = left main coronary artery; RCA = right coronary artery.

Table 4. In-Hospital and Six-Month Complications

Complications	Overall (n = 92)	Group I (n = 39)	Group II (n = 53)	p Value Group I vs. Group II
In-hospital outcome				
Non-Q-wave MI	0	0	0	
Q-wave MI	0	0	0	
Repeat PTCA	0	0	0	
CABG	0	0	0	
Death	4 (4.3%)	3 (7.6%)	1 (1.8%)	NS
Noncardiac	1	1	0	
Cardiac	3	2	1	
VF/arrhythmia		1	1	
Sudden death		0	0	
CHF		1	0	
Follow-up	(n = 88)	(n = 36)	(n = 52)	
Non-fatal MI	0	0	0	
Re-PTCA	4	1	3	
LMCA				
Re-PTCA (other)	9	5	4	
CABG	2	1	1	
Death	6 (6.8%)	5 (13.8%)	1 (1.9%)	NS
Noncardiac	1	1	0	
Cardiac	5	4	1	
VF/arrhythmia		1	1	
Sudden death		1	0	
CHF		2	0	
Total mortality	10 (10.8%)	8 (20.5%)	2 (3.8%)	$p < 0.02$

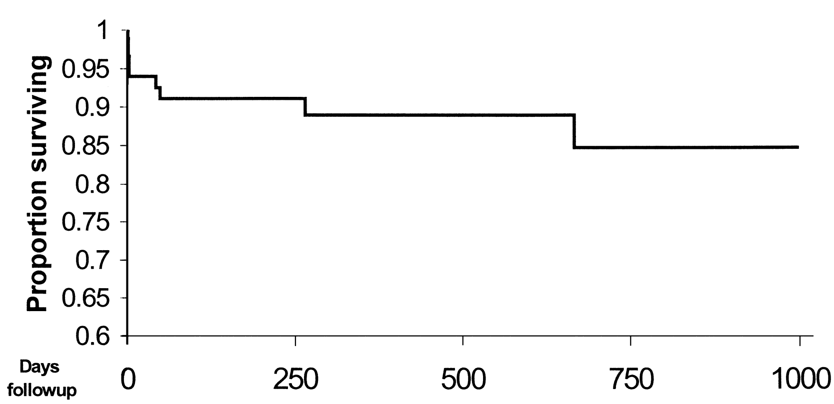
CABG = coronary artery bypass graft; CHF = congestive heart failure; LMCA = left main coronary artery; MI = myocardial infarction; PTCA = percutaneous transluminal coronary angioplasty; VF = ventricular fibrillation.

observed. No patients needed emergency bypass surgery; no patients had recurrent angina during hospitalization.

Follow-Up

During follow-up (7.3 ± 5.8 months; median 239 days; range 49 to 1,477 days), there were six additional deaths (7%): one sudden death was presumed cardiac; one was due to ventricular arrhythmia; three patients died of CHF, and there was one noncardiac death from pulmonary cancer (this patient had been referred for LMCA stenting because of limited life expectancy). The Kaplan-Meier survival estimates depicted in Figure 1 show 500- and 1,000-day survival estimates of 89 ± 6.3% and 85 ± 12%, respectively. Of the 82 (89%) patients surviving at six months, four had symptomatic LMCA restenosis at three, four, five and six months, respectively, and were treated by repeat balloon angioplasty within the stent. Nine other patients had repeat PTCA to other vessels, and two patients had bypass surgery for restenosis (1 LMCA; 1 LAD).

Overall mortality data are summarized in Table 4. Total



	0	250	500	750	1000
Survival	1.0	0.911	0.890	0.848	0.848
SEE	0	0.042	0.063	0.085	0.120
No at risk	92	45	25	18	9

Figure 1. Kaplan-Meier survival curve.

Table 5. Univariate Analysis of the Predictors of Cardiac Death

Predictors	Cardiac Death (n = 8)	Others (n = 84)	p Value
Age (yrs)	75 ± 4	74 ± 8	NS
Male gender (%)	63	82	NS
Unstable angina (%)	88	68	NS
LVEF (%)	50 ± 14	58 ± 15	< 0.1
Three-vessel disease (%)	100	71	< 0.1
RCA stenosis (%)	75	39	NS
Reference vessel diameter (mm)	3.7 ± 0.6	3.8 ± 0.6	NS
Mean LMCA stenosis (%)	77 ± 11	72 ± 13	NS
Bifurcation stenosis (%)	13	6	NS
Post-stent stenosis (%)	3.7 (0–20)	1.3 (0–10)	< 0.05
Final stent diameter (mm)	3.5 ± 0.2	3.9 ± 0.5	<0.03
PTCA/other vessel (%)	88	63	NS

LMCA = left main coronary artery; LVEF = left ventricular ejection fraction; PTCA = percutaneous transluminal coronary angioplasty; RCA = right coronary artery.

mortality was significantly higher in group I (20.5%) compared to group II (3.8%) ($p < 0.02$).

Correlates of Cardiac Mortality

Univariate predictors of cardiac death are listed in Table 5. Only the final stent MLD or post-stent diameter stenoses were predictive of mortality. Lower LVEF and the presence of three-vessel coronary artery disease were more common in patients who developed cardiac death; however, these trends were not statistically significant.

DISCUSSION

Balloon Angioplasty for Unprotected LMCA Disease

Several studies have reported the results of balloon angioplasty (without stenting) of unprotected LMCA stenosis, with generally poor long-term prognosis.

O'Keefe et al. (13) reported the results of 127 LMCA balloon angioplasty procedures of which 33 were elective for unprotected LMCA stenosis and 9 were unprotected LMCA acute occlusions. In the elective subgroup the procedural mortality rate was 9.1% and late mortality reached 65% at a mean follow-up of 20 months. Repeat revascularization procedures (PTCA or CABG) were required in 42% of patients. In nine patients who had presented with acute occlusion, five died in-hospital; of the four who survived to discharge, two subsequently died and two others underwent bypass surgery.

Stenting of Unprotected LMCA Stenosis

Elective stenting of unprotected LMCA stenosis should theoretically provide the following advantages over balloon angioplasty alone: reduction of the risk of abrupt closure after balloon angioplasty, greater acute gain after the procedure with a larger MLD, and a lower restenosis rate at follow-up. The risk of subacute thrombosis after stent placement is estimated at about 1% with the current technique of stent implantation utilizing high pressure and/or intravascular ultrasound guidance, together with the use of combined aspirin and ticlopidine therapy. Both the high concentration of elastic fibers in the aorto-ostial and proximal segment of LMCA and subsequent marked elastic recoil have been proposed as possible causes of the high restenosis rates seen after conventional balloon angioplasty. In this situation, stent implantation should result in significant reduction in restenosis.

In a recent study of LMCA stenting in a population of 42 consecutive patients with unprotected LMCA stenosis and normal left ventricular (LV) function, Park et al. (28) presented excellent results with a procedural success rate of 100%, clinical recurrence at six-month follow-up of 17%, and angiographic restenosis of 22%. Only one patient died in that series, two days after elective bypass surgery for treatment of in-stent restenosis. That report describes a series of patients with low surgical risk. In our series, results in the subgroup of patients with "relatively" low surgical risk appear satisfactory, with one death from ventricular arrhythmia (3.6%). There were no other procedural or in-hospital complications. During follow-up, three patients required target lesion revascularization—two treated with repeat LMCA angioplasty and one with CABG surgery.

The current results are consistent with the series reported by Silvestri et al. (29) regarding the one-month mortality of a group of patients considered as good candidates for CABG (0 deaths out of 93 patients) compared with those considered poor candidates (4 deaths out of 47 patients).

Ellis et al. (30) reported the results of a multicenter registry of percutaneous treatment of unprotected LMCA stenosis in 107 patients from 25 centers. Ninety-one patients were treated electively and 16 patients were treated for MI. In the group of patients with acute MI, technical success was achieved in 75%, and survival to hospital discharge was 31%. In elective patients, technical success was achieved in 98.9%. The in-hospital mortality rate was 5.9% in patients considered good candidates for CABG and 30.4% in patients not candidates for CABG. In-hospital mortality was strongly correlated with LVEF ($p = 0.003$). Patients who had elective stenting and who were considered as good potential candidates for CABG had an in-hospital survival of 98% and a nine-month event-free survival of 86 ± 5% when LVEF was >40%, compared with 67% and 22 ± 12%, respectively, when LVEF was <40%. Long-term freedom from death, MI or CABG was strongly correlated with LVEF ($p < 0.001$) and was inversely related to presentation with progressive or rest angina ($p < 0.001$).

In our study, the small number of end points limited our ability to draw any statistically significant conclusions; however, the eight patients with cardiac death had a smaller final stent MLD than survivors, and they tended to have lower EF and a higher prevalence of three-vessel coronary disease.

"Debulking" Before Unprotected LMCA Stenting

In our series, plaque "debulking" by rotational atherectomy was used in only seven cases (7.6%), and the results are not presented separately. However, preliminary data support the concept of debulking before stenting in a general sense (31,32). In the context of LMCA angioplasty, the concept of "debulking" prior to stenting could be considered in some specific anatomical conditions—for example, using rotational atherectomy when the vessel is heavily calcified, or directional atherectomy if the lesion is eccentric or bifurcated.

Study Limitations

This series represents a retrospective analysis of patients who were carefully selected to undergo percutaneous revascularization for LMCA disease. These patients comprise a heterogeneous group that includes those with absolute and relative contraindications for bypass surgery on the one hand, and those with relatively favorable coronary anatomy on the other. Direct comparison with a similar population treated surgically is not possible; however, the Parsonnet surgical risk score provides an estimate of surgical mortality shown to be reasonably robust (33,34). The observed procedural mortality (±SEE) in the current series (4.3 ± 2.1%) compares favorably with that predicted (±SD) by the Parsonnet score (15 ± 6.9%). Further, cardiac enzyme measurements were not done unless there was a clinical suspicion of postprocedural ischemia, which may have led to a systematic underestimate of ischemic complications following PTCA/stenting. Nevertheless, as the patients were closely monitored during the early postprocedural period, we believe that any clinically important ischemic events would have been identified.

Conclusions. Our results suggest that, in selected patients, stenting of unprotected LMCA stenoses could be considered as a feasible alternative to CABG with an acceptable complication rate. Patients who are candidates for CABG appear to have a better outcome than those where CABG is contraindicated. Cardiac mortality was associated with a trend to more extensive coronary artery disease and lower preprocedural LVEF. Importantly, the only significant predictor of cardiac mortality was a low final stent lumen diameter. It remains to be demonstrated that lesion "debulking" by atherectomy will improve results, especially in cases of very eccentric, calcified or bifurcated lesions.

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