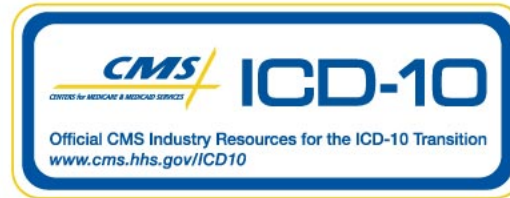


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**Unprotected left main coronary artery stenting: immediate and medium- term outcomes of 140 elective procedures**

Marc Silvestri, Paul Barragan, Joël Sainsous, Gilles Bayet, Jean-Baptiste Simeoni, Pierre-Olivier Roquebert, Gilles Macaluso, Jean-Louis Bouvier, and Bertrand Comet  
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# Unprotected Left Main Coronary Artery Stenting: Immediate and Medium-Term Outcomes of 140 Elective Procedures

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- OBJECTIVES** We sought to evaluate immediate and late outcomes after stenting for left main coronary artery (LMCA) stenosis.
- BACKGROUND** Conventional percutaneous transluminal coronary angioplasty (PTCA), for which coronary artery bypass grafting (CABG) has been the gold standard therapy for years, has yielded poor results in unprotected LMCA lesions. The development of coronary stents, together with their dramatic patency improvement provided by new antiplatelet regimens and their validation against restenosis, warrants a reappraisal of angioplasty in LMCA stenosis.
- METHODS** From January 1993 to September 1998, 140 consecutive unselected patients with unprotected LMCA stenosis underwent elective stenting. Group I included 47 high-CABG-risk patients, and group II included 93 low-CABG-risk patients. Ticlopidine without aspirin was routinely started at least 72 h before the procedure and continued for one month. Patients were reevaluated monthly. A follow-up angiography was requested after six months.
- RESULTS** The procedure success rate was 100%. One-month mortality was 9% (4/47) in group I and 0% in group II. A follow-up angiography was obtained in 82% of cases, and target lesion revascularization was required in 17.4%. One-year actuarial survival was 89% in the first 29 group I patients and 97.5% in the first 63 group II patients.
- CONCLUSIONS** Stenting of unprotected LMCA stenosis provided excellent immediate results, particularly in good CABG candidates. Medium-term results were good, with a restenosis rate of 23%, similar to that seen after stenting at other coronary sites. Stenting deserves to be considered a safe and effective alternative to CABG in institutions performing large numbers of PTCAs. (*J Am Coll Cardiol* 2000;35:1543-50) © 2000 by the American College of Cardiology
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In the early days of percutaneous transluminal coronary angioplasty (PTCA), Andréas Gruentzig used the procedure to treat unprotected left main coronary artery (LMCA) stenoses in a few patients (1,2). This practice was promptly stopped, however, because of its poor results and because of the publication of several surgical series (3-5) demonstrating

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longer survival times after surgical revascularization compared with nonsurgical treatment in patients with LMCA disease.

Subsequently, a number of interventional cardiology groups (6-9) also reported disappointing outcomes after

balloon angioplasty alone in LMCA stenosis: there was substantial perioperative mortality, restenosis rates were high, and long-term survival rates were unsatisfactory. Thus, coronary artery surgery remained the gold standard procedure. However, the explosive growth of coronary stenting in the 1990s, fueled in part by the dramatic reduction in thrombotic complications provided by ticlopidine therapy (10-13) and by evidence that stenting reduced postangioplasty restenosis rates (14,15), prompted new attempts at LMCA dilation, often on a case-by-case basis (16-19). Since 1993, we offer angioplasty with stenting to all patients with LMCA stenoses. We have evaluated the results of this optimized angioplasty procedure.

## **METHODS**

**Patients.** From January 1993 to November 1998, 8,042 patients were treated at our institution by angioplasty procedures performed by six operators. Among them, 140

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**Abbreviations and Acronyms**

CABG	= coronary artery bypass grafting
CASS	= Coronary Artery Surgery Study
IVUS	= intravascular ultrasound
LAD	= left anterior descending
LMCA	= left main coronary artery
LVEF	= left ventricular ejection fraction
MI	= myocardial infarction
MLD	= minimal lumen diameter
PTCA	= percutaneous transluminal coronary angioplasty

(1.7%) had a greater than 50% stenosis of an unprotected (i.e., nonbypassed) LMCA, which was treated by dilation with implantation of one or more stents. Before the procedure, informed consent was obtained from all these patients in accordance with the Declaration of Helsinki. Patients who presented with cardiogenic shock or progressive myocardial infarction (MI) were excluded from the study. Also excluded were patients who were unable to receive ticlopidine for at least three days before the procedure because of irregular observance of treatment or severe side effects.

The 140 study patients were divided in two groups. Group I was composed of the 47 patients categorized as poor surgical candidates because of a contraindication to cardiopulmonary bypass by one or more surgeons or of the presence of any of the following factors: age older than 75 years, history of heart surgery, left ventricular ejection fraction (LVEF) lower than 35%, renal failure, inadequate coronary distal runoff or severe respiratory failure. Group II included the 93 patients with no contraindications to surgery or factors associated with a decreased likelihood of successful coronary artery bypass grafting (CABG). Significant differences were found between the two groups for age, history of MI or CABG and left ventricular function (Table 1).

**Angioplasty procedure.** A total of 186 stents were implanted in the LMCAs of the 140 patients (mean, 1.33 stent per artery). The first patients underwent predilation by inflation for 10 to 15 s of a slightly undersized balloon done after the stent was prepared on another, semicompliant, optimally sized balloon to enable immediate stent implantation after the predilation. The stent was delivered by a

short inflation providing a satisfactory balloon profile; mean pressure used was  $12.6 \pm 2.6$  bars (range, 9–20 bars). Subsequently, we used precrimped stents without predilation whenever the anatomic conditions permitted in order to avoid the additional period of ischemia. Use of perfusion balloons was not necessary in any of our patients. Stent placement was checked by angiography without intravascular ultrasound (IVUS).

In patients with concomitant lesions of the left anterior descending (LAD) coronary artery or circumflex artery, treatment of the LMCA was given priority; however, in some cases with proximal tortuosity or a risk of impossibility of pulling back through the stented segment, distal lesions were treated after LMCA predilation.

Starting on June 1, 1997, distal lesions of the main artery and lesions of the origin of the LAD and circumflex arteries were routinely dilated at the end of the procedure using a double balloon; in some cases, the ostia of the LAD and circumflex arteries were stented.

Various types of stents were used: the Palmaz-Schatz stent (Johnson & Johnson Interventional Systems, Roden, the Netherlands) in 54% of cases (n = 100); the GFX stent (Arterial Vascular Engineering, Galway, Ireland) in 28% of cases, particularly for distal or bifurcation lesions; the Multilink Duet stent (Advanced Cardiovascular Systems) in 9% of cases; other tubular stents (Saint Côme, Biocompatible, Bestent) in 5% of cases; and coil stents (Gianturco-Roubin I, Cook Corporation, Bloomington, Indiana) in 4% of cases.

In most patients, the stents were implanted via the femoral route using a 6F, 7F or 8F guiding catheter (79%, 24% and 5% of cases, respectively). An extra backup catheter was used in most instances.

Debulking was required before stenting in nine cases (6%). Neither intraaortic counterpressure balloon support nor abciximab was used as preventive or curative therapy. In one of our first patients, preventive cardiopulmonary support was set up via the femoral route.

**Anticoagulation protocol.** All 140 patients were treated using the following protocol:

- Initiation of ticlopidine therapy three days before the angioplasty procedure, in a dose of 500 mg per day, without aspirin;
- Intravenous bolus of 7,500 to 10,000 IU of heparin at the beginning of the procedure;
- Ticlopidine alone, 500 mg/day for one month, without aspirin or coumadin, followed by aspirin in a dose of 250 mg per day;
- Monitoring in an intensive care unit for 24 h, then in a cardiology ward room for six days.

**Angiography evaluation.** Minimal lumen diameter (MLD) was calculated routinely before dilation and after stenting, after injection into the artery of 1 mg of molsidomide, using the On-line Quantitative Coronary Angiogra-

**Table 1.** Comparison of Group I and Group II Patients

	Group I n = 47	Group II n = 93	p Value
Age	75 ± 10	65 ± 10	< 0.001
Women	12 (25)	16 (17)	NS
Prior MI	17 (36)	8 (9)	< 0.005
Prior CABG	11 (23)	0	< 0.005
LVEF (%)	52 ± 18	66 ± 11	< 0.001

Data are n (%).

CABG = coronary artery bypass grafting; LVEF = left ventricular ejection fraction; MI = myocardial infarction.

phy System (DCI, Philips, the Netherlands). The guiding catheter was used as the calibration reference. A diameter stenosis of 50% or more was considered significant.

**Follow-up.** All patients were evaluated monthly by a cardiologist during the first six months after the angioplasty procedure. A repeat selective coronary angiogram was requested routinely after six months; if this investigation proved unfeasible, an exercise test or scintigraphy was performed.

**Statistical analysis.** The clinical and angiographic data were collected prospectively and stored in a computerized database via computers located in the catheterization laboratory (Summit Medical). Data are reported as means  $\pm$  standard deviations. Variables were compared using either the chi-square test or Fisher exact test. Statistical significance was defined as  $p < 0.05$ . The confidence intervals for our rates are 95%. Continuous variables were compared using variance analysis. The variables that were found to be significant by univariate analysis were entered into multivariate analysis using stepwise logistic regression analysis with the statistical computer package SPSS (SPSS, Inc., Chicago, Illinois). Kaplan Meier survival curves were constructed with Log Rank and Wilcoxon test. Statistical software were SAS and SPSS.

**RESULTS**

**Immediate results.** Baseline clinical characteristics of the 140 patients are summarized in Table 2. Mean age was  $70.2 \pm 9$  years (range, 36-86); 49% of patients had unstable angina. In 11% of patients, LMCA disease was diagnosed upon evaluation for silent ischemia.

Baseline angiographic and procedural data are displayed in Table 2. Nearly half the patients (47%) had three-vessel disease. The right coronary artery was occluded in 14% of patients and showed significant stenosis in 33%. The site of the LMCA lesion was the ostium in 10% of patients, the midportion of the artery in 38% and the distal portion in 52%. Mean number of lesions treated per patient was 1.8. Minimal lumen diameter increased from  $1.28 \pm 0.48$  mm before angioplasty to  $3.46 \pm 0.63$  mm after stenting, while mean diameter stenosis decreased from  $73 \pm 12\%$  to  $12 \pm 8\%$ . The procedural success rate was 100%.

**One-month follow-up data.** Major cardiac events recorded within the first month after the procedure in the two patient groups are shown in Table 3. In group I (poor surgical candidates), there were four procedure-related deaths (9% of group I). Two were sudden deaths that occurred within the first week and were ascribed to subacute stent thrombosis, although both events were so abrupt as to preclude angiography; both patients were in their 80s and had a poor distal coronary runoff, an LVEF of only 25% and contraindications to surgery. Another death occurred as a result of end stage congestive heart failure despite satisfactory revascularization as assessed by angiography. Finally,

**Table 2.** Baseline Clinical and Angiographic Characteristics (140 Study Patients)

Age (yrs)	70.2 $\pm$ 9
Male gender (%)	79%
Cardiac risk factors (% with the factor)	
Hypertension	44%
Diabetes mellitus	14%
Cigarette use	31%
High serum cholesterol	43%
Unstable angina	49%
Recent MI	6%
Silent ischemia	11%
CC <sub>4</sub>	15%
CC <sub>3</sub>	13%
CC <sub>2</sub>	6%
Three-vessel disease	47%
Complete revascularization	70%
RCA	
Occlusion	14%
Stenosis	33%
Normal	53%
Pre-PTCA	
Mean LMCA stenosis (%)	73 $\pm$ 12
Mean MLD (mm)	1.28 $\pm$ 0.48
Ref. diameter (mm)	3.67 $\pm$ 0.63
Poststenting	
Mean LMCA stenosis (%)	12 $\pm$ 8
Mean MLD (mm)	3.46 $\pm$ 0.53
Ref. diameter	3.77 $\pm$ 0.53

CC = Canadian classification; LMCA = left main coronary artery; MI = myocardial infarction; MLD = minimal lumen diameter; PTCA = percutaneous transluminal coronary angioplasty; RCA = right coronary artery.

one patient died of thrombosis of an aortobifemoral prosthesis three weeks after the angioplasty procedure. Other adverse events in group I consisted of non-Q wave MI in two patients (4% of group I). None of the group I patients required bypass grafting or blood transfusion, and none developed complications at the femoral catheterization site.

In group II (good candidates), the only complication was a false aneurysm, which was closed by external compression under ultrasound guidance.

**Table 3.** One-month Clinical Outcomes (n = 140 Patients)

	Group I n = 47	Group II n = 93	Total n = 140
Death, n (%)	4 (9%)	0	4 (3%)
Subacute thrombosis	2		
Terminal left ventricular failure	1		
Aortic prosthesis thrombosis	1		
Nonfatal MI	2 (4%)	0	2 (1%)
CABG	0	0	0
Groin complications	0	1	1 (0.7%)
Blood transfusion	0	0	0

CABG = coronary artery bypass grafting; MI = myocardial infarction.

**Table 4.** Outcome at Six Months (n = 115 Patients)

	Group I (n = 38)	Group II (n = 77)
Death	1 (2%)	2 (2.6%)
Cardiac	1	0
No cardiac	0	2 (1 cancer, 1 suicide)
Nonfatal MI	0	1 (0.8%)
TLR	4 (10.5%)	16 (21%)
Repeat LM/PTCA	3	5
CABG	1	11 (14%)

CABG = coronary artery bypass grafting; LM/PTCA = left main/percutaneous transluminal coronary angioplasty; MI = myocardial infarction; TLR = target lesion revascularization.

**Six-month follow-up data (Table 4).** As of this writing, 38 group I patients have been followed up for at least six months. There was one additional cardiac death in an 82-year-old woman with recurrent angina probably due to restenosis treated at another institution by pharmacotherapy without angiographic evaluation. Four group I patients developed restenosis of the target lesion requiring a repeat revascularization procedure, which consisted in angioplasty in three cases and surgery in one.

In Group II, 77 patients had a follow-up of at least six months. A repeat angiography was done in 82% of these 77 patients. There were two noncardiac deaths (one case each of cancer and suicide) and one nonfatal MI. Sixteen patients (16/77, 21%) required repeat revascularization of the LMCA, which was done by angioplasty in five cases and by surgery in 11 (11/77, 14%).

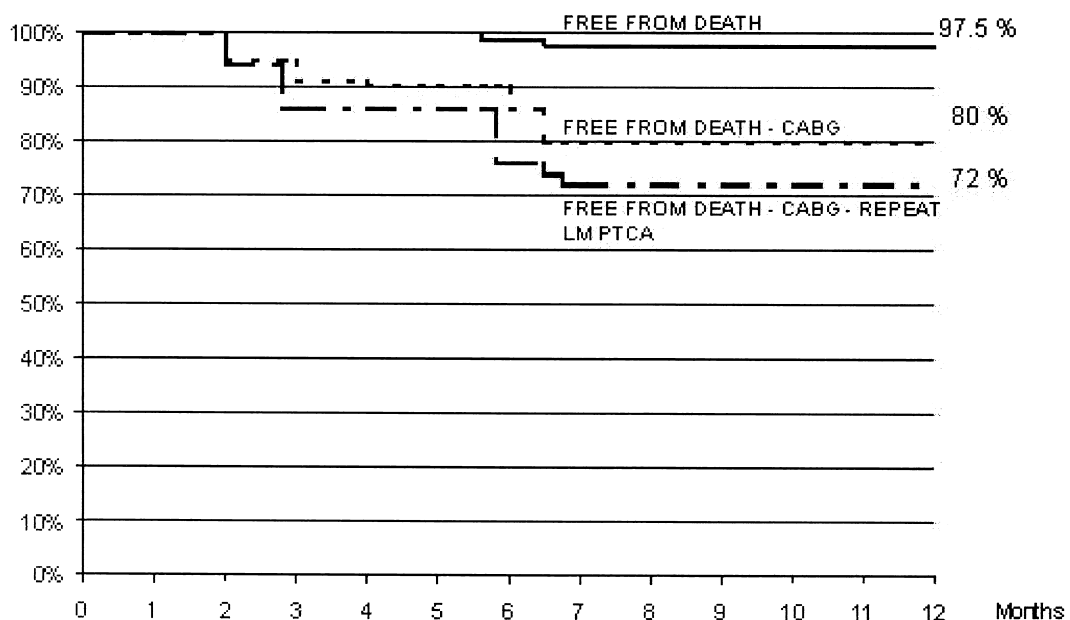
The overall repeat revascularization rate in the 115 patients with a follow-up of six months or more was 20/115

(17.4%). Six-month angiography (94 of 115 eligible patients) showed a 23% restenosis rate defined as more than 50% stenosis. No factors predictive of a need for a repeat revascularization procedure were identified. In particular, the site of the lesion on the LMCA had no influence on the repeat revascularization rate, which was 17% for ostial lesions, 23% for midportion lesions and 20% for distal lesions.

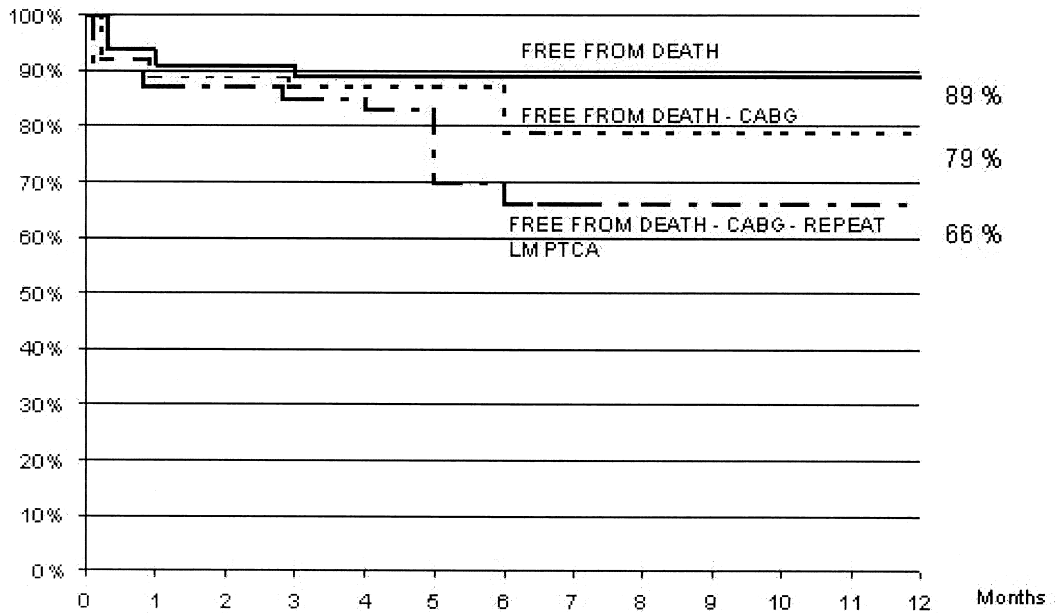
**One-year follow-up data.** One-year data were available for 29 group I patients, of whom 89% were alive and 66% were alive and free of repeat revascularization procedures (Fig. 1). In the 63 group II patients followed up for at least one year, the corresponding figures were 93% and 72% (Fig. 2).

## DISCUSSION

**Feasibility of LMCA angioplasty and six-month outcomes.** Because it compromises a large proportion of the myocardium, stenosis of an unprotected LMCA is the most severe type of coronary artery lesion and carries a high risk of short-term death in the absence of treatment (20,21). Interventional revascularization by balloon dilation, atherectomy or laser have provided disappointing results and, consequently, have been deemed inadvisable in this situation (8,22-24). The Coronary Artery Surgery Study (CASS) registry (3), which provides data on a vast patient population with long follow-ups, has demonstrated unequivocally that surgical revascularization improves both survival and quality of life. However, a number of new developments have created a need for reappraisal of the role of interventional treatment in LMCA stenosis. Thus, stenting provides for a reduction in immediate elastic recoil,



**Figure 1.** Unprotected left main stenting—63 good candidates: one-year event-free survival. CABG = coronary artery bypass grafting; LM = left main; PTCA = percutaneous transluminal coronary angioplasty.



**Figure 2.** Unprotected left main stenting—29 poor candidates: one-year event-free survival. CABG = coronary artery bypass grafting; LM = left main; PTCA = percutaneous transluminal coronary angioplasty.

which occurs almost consistently at the LMCA because of the presence of elastic fibers in the vessel wall (16). Stenting reduces the risk of procedure-related acute occlusion, which otherwise would be prohibitive at this anatomic site, and also decreases the risk of restenosis at other sites (14). Furthermore, the use of ticlopidine, with or without aspirin, has substantially decreased the rate of local complications, particularly of stent thrombosis after one month (10,12,13).

These considerations prompted us to initiate this study in 1993. The first patients included had contraindications to surgery, were in a critical clinical condition or had extremely severe anatomic lesions (26 cases). These patients constituted group I (25). The promising results in these patients, together with the introduction of further technical improvements, led us to extend our study to good surgical candidates, who constituted group II (26). Our data support the feasibility of unprotected LMCA stenting because there were no intraprocedure or immediate postprocedure complications. There were four deaths in group I, including two sudden deaths within the first week, possibly due to acute thrombosis. This mortality rate (4/47) can be considered acceptable given the complex challenges raised by this high-surgical-risk group (advanced age, multiple lesions on other vessels, impaired left ventricular function). Furthermore, abciximab was not yet available at the time these patients were treated. The most striking finding from our study is, in our opinion, the absence of immediate or one-month mortality in group II, which is the largest cohort of good-surgical-risk patients published to date. Stent thrombosis is a real danger and the major limitation of LMCA stenting, as it can be responsible for fatal MI. In our

experience, no stent thrombosis was observed in the good candidate group. Although the patient cohort was not sufficient to reveal any statistically predictive risk factors, we believe that the large size of LMCA, optimal deployment of stents (with kissing balloon inflation for the bifurcation), perfect compliance with ticlopidine therapy and early detection of patients at high risk of thrombosis (inflammatory syndromes, cancer, etc.) ensure the lowest possible thrombosis rate. Although even a single clinical event could change the statistical results dramatically given the small sample size, our data strongly suggest that stenting improves outcomes after LMCA balloon angioplasty. Indeed, procedural mortality was 9.1% in a study by O’Keefe et al. (6) and 12% in a study by Eldar et al. (7). Our results are consistent with those reported by Park et al. (18), Wong et al. (27) and Tamura et al. (28), although in our series good left ventricular function was a selection criterion for group II patients.

Our local complication rate was also very low (0.7%) and similar to that seen in the general stent-supported angioplasty population. This can be ascribed to the use of ticlopidine and of 6F and 7F catheters. Stenting reduces the need for hemodynamic assistance (intraaortic counterpressure balloon, circulatory support), which is a well-established source of local morbidity (29); rapid stent delivery ensures an optimal result without prolonged ischemia.

After six months, there were no cardiac deaths in group II (good surgical candidates); the only two deaths were due to cancer and suicide, respectively. At this writing, only 77 group II patients have been followed for more than one year. However, earlier experience acquired with stenting suggests

**Table 5.** Factors Potentially Predictive of TLR Within Six Months

	TLR n = 20	No TLR n = 95	p Value
<b>Univariate Analysis</b>			
Age, yr (mean ± SD)	64 ± 10	70 ± 10	0.016
Male gender (%)	17	78	NS
Unstable angina	9	49	NS
Diabetes mellitus	1	14	NS
Pressure	12.8 ± 2.5	12.4 ± 2.8	NS
Ref. diameter	3.59 ± 0.67	3.67 ± 0.6	NS
LVEF (%)	64.7 ± 13	60.1 ± 16	NS
Distal LM	11	50	NS
<b>Multivariate Analysis</b>			
Age			NS

LM = left main; LVEF = left ventricular ejection fraction; TLR = target lesion revascularization.

that no cases of subacute thrombosis will occur, because beyond the first month restenosis is the main complication and acute events are uncommon. Even in group I, the only delayed death could have been avoided if a repeat selective coronary angiogram had been performed to investigate the recurrent clinical symptoms.

**Repeat revascularization procedures.** In our series, the overall rate of repeat revascularization procedures, i.e., repeat procedures on the stented LMCA, was 17.4%, a figure consistent with those reported for other large coronary arteries. Among group II patients with a follow-up of six months or more, 14% had surgery and 7% had a repeat angioplasty procedure with a good immediate outcome. Surgery was recommended to patients with restenosis; before the angioplasty procedure, patients were told of the possibility that surgery may subsequently be required. However, some patients chose to undergo a repeat angioplasty procedure because of the unpredictable nature of restenosis. After repeat LMCA angioplasty, 80% of patients remained free of symptoms, and 20% developed restenosis and were subsequently operated on. Ninety percent of patients immediately operated on for restenosis were free of symptoms, and one died after one year. The repeat revascularization rate was not influenced by the site of the lesion on the LMCA; thus, the trend toward a higher restenosis rate for distal lesions, which was found early in our experience, was not detectable in this larger sample of patients. This is, without doubt, ascribable in part to technical changes, particularly to the introduction of simultaneous double balloon dilation of the LAD and circumflex arteries at the end of the procedure (30). However, this technique requires considerable experience on the part of the operator. Also, it should be borne in mind that the small number of distal LMCA lesions followed up for six months or more (61/72) implies the possibility that statistical results may change as the number of patients increases. No factors significantly predictive of restenosis were identified by univariate or

multivariate analysis; in particular, diabetes mellitus, final diameter and inflation pressure had no influence on the restenosis rate (Table 5).

Multiple and diffuse lesions can often be associated with LMCA disease. In our work, we attempted 1.7 lesion/patient and had 11% repeat PTCA on other vessels. One must take this parameter into consideration in order to propose the most adequate therapeutic solution to the patient, which will impel to surgical decision if the number of lesions is really important.

**Selection of the stent according to the lesion.** Because the ostium and trunk of the LMCA contain an abundance of elastic fibers, we prefer tubular stents and stents that generate strong radial forces (31). Although it is less often used now in Europe, the Palmatz-Schatz stent proved satisfactory for LMCA stenting in our study. Use of coil stents has been recommended to treat bifurcation lesions. However, we rarely used coil stents, because they have been associated with a higher risk of restenosis than tubular stents (32). Furthermore, the mesh is easily cleared with some of the currently available tubular stent configurations. Here again, we advocate double balloon dilation at the end of the procedure. In France, the use of 6F guide catheters has proved satisfactory, particularly because of the absence of occlusion of the ostium and of the low rate of arterial catheter insertion-site complications.

**Debulking before stenting.** In our experience, rotational atherectomy was used in only 6% of cases, the indication being significant calcifications in the distal LMCA. No significant influence of this procedure on outcomes was found, but the number of patients in this subgroup is small. Debulking can reduce the risk of dissection, facilitate stent passage and optimize the initial diameter gain (33). However, it needs to be validated in a larger number of patients, with special attention to the risk of restenosis.

**Ultrasound guidance.** We used “simple” angiography without IVUS to guide stent implantation. Colombo et al. (34) advocated use of IVUS together with high inflation pressures, both to reduce the risk of early subacute stent thrombosis due to inadequate stent deployment and to decrease the restenosis rate. Our data do not support this strategy, probably because our patients received preventive ticlopidine therapy (as did 70% of the patients in the study by Colombo et al. [34]), a measure that likely contributed to the absence of subacute thrombosis in our group II patients. Furthermore, a study by Finet et al. (35) identified pitfalls in the interpretation of IVUS images. Last, although IVUS provides quantitative and qualitative information on coronary artery lesions (36), no large study of its performance for evaluating the LMCA has been reported to date. Our data demonstrate the feasibility of stent-supported LMCA angioplasty performed under angiographic guidance alone. Use of IVUS for selecting the most appropriate stent or improving stent apposition could be considered of addi-

tional benefit only if it were shown to reduce the restenosis rate, which is not the case for the time being.

**Comparison with surgery.** Only a randomized design could provide a valid comparison of surgery versus stenting in the treatment of LMCA stenosis. The undertaking of such a study would require a large sample size and several years of follow-up, but it may deserve to be considered in view of the good results obtained in our group II patients, who were good candidates for surgery. There is conclusive evidence that surgery provides longer survival and greater functional improvement than conservative therapy. However, the surgical mortality rate in the CASS registry was 4.6%, which is noticeably higher than the mortality rate in our study. Also, the disadvantages of surgery are frequently underestimated; they include a long hospital stay, delayed wound healing, transfusion-related morbidity, restrictive ventilatory defects, a need for a period of convalescence and adverse consequences on work ability. Stenting shares the well-known advantages of angioplasty, including an absence of mortality in our study and in that by Park et al. (18) and femoral hematoma as the only nonfatal complication. However, it also shares the main disadvantage of angioplasty, namely a 23% overall risk of restenosis in our study. However, stenting can be followed by surgery if needed and obviates the need for surgery in most cases (82% in our study).

**Conclusions.** Our data show that stent-supported angioplasty of the LMCA is feasible and is associated with acceptable morbidity and mortality rates, particularly in patients considered good candidates for surgery. It follows that stent-supported angioplasty is a reasonable alternative to CABG in the treatment of LMCA stenosis as long as the operator is experienced in the technique and the risk of restenosis is accepted.

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