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Articles

Contemporary Percutaneous Treatment of Unprotected Left Main Coronary Stenoses

Initial Results From a Multicenter Registry Analysis 1994–1996

Stephen G. Ellis, MD; Hideo Tamai, MD; Masakiyo Nobuyoshi, MD; Kunihiko Kosuga, MD; Antonio Colombo, MD; David R. Holmes, MD; Carlos Macaya, MD; Cindy L. Grines, MD; Patrick L. Whitlow, MD; Harvey J. White, MD; Jeffrey Moses, MD; Paul S. Teirstein, MD; Patrick W. Serruys, MD; John A. Bittl, MD; Michael R. Mooney, MD; Thomas M. Shimshak, MD; Peter C. Block, MD; ; Raimund Erbel, MD

From The Cleveland (Ohio) Clinic Foundation.

Correspondence to Stephen G. Ellis, MD, The Cleveland Clinic Foundation, 9500 Euclid Ave, F-25, Cleveland, OH 44195. E-mail elliss@cesmtp.ccf.org

Abstract

Background Coronary artery bypass surgery (CABG) has been considered the therapy of choice for patients with unprotected left main (ULMT) coronary stenoses. Selected single-center reports suggest that the results of percutaneous intervention may now approach those of CABG.

Methods and Results To assess the results of percutaneous ULMT treatment from a wide variety of experienced interventional centers, we requested data on consecutive patients treated after January 1, 1994, from 25 centers. One hundred seven patients were identified who were treated either electively (n=91) or for acute myocardial infarction (n=16). Of patients treated electively, 25% were considered inoperable, and 27% were considered high risk for bypass surgery. Primary treatment included stents (50%), directional atherectomy (24%), and balloon angioplasty (20%). Follow-up was 98.8% complete at 15±8 months. Results varied considerably, depending on presentation and treatment. For patients with acute myocardial infarction, technical success was achieved in 75%, and survival to hospital discharge was 31%. For elective patients, technical success was achieved in 98.9%, and in-hospital survival was strongly correlated with left ventricular ejection fraction (P=.003). Longer-term event (death, infarction, or bypass surgery) -free survival was correlated with ejection fraction (P<.001) and was inversely related to presentation with progressive or rest angina (P<.001). Surgical candidates with ejection fractions ≥40% had an in-hospital survival of 98% and a 9-month event-free survival of 86±5%, whereas patients with ejection fractions <40% had 67% and 22±12% in-hospital and 9-month event-free survivals, respectively. Nine hospital survivors (10.6%) experienced cardiac death within 6 months of hospital discharge.

Conclusions While results for selected patients appear promising, until early post–hospital discharge cardiac death can be better understood and minimized, percutaneous revascularization of ULMT stenosis should not be considered an alternative to bypass surgery for most patients. When percutaneous revascularization of ULMT is required, directional atherectomy and stenting appear to be the preferred techniques, and follow-up angiography 6 to 8 weeks after treatment is probably advisable.

Key Words: angioplasty • bypass • coronary disease • arteries • stents

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The favorable Veterans Administration surgical trial[1] and poor initial angioplasty[2] results in patients with left main (LMT) stenoses have made coronary artery bypass surgery (CABG) the accepted therapy of choice for patients with LMT stenosis and no patent bypass grafts to either the left anterior descending or left circumflex coronary systems (unprotected LMT).[3] Recent advances in percutaneous technologies and improved results have made several centers reconsider the role of percutaneous treatment of patients with unprotected LMT stenosis.[4–6] Initial results from small single-center reports have been favorable in most instances.[7–11]

Whether such a percutaneous approach can be considered an acceptable alternative to CABG remains unknown. To evaluate this, a multicenter registry was developed to study the initial and long-term outcome of the various subgroups of patients who might be considered for percutaneous treatment of unprotected LMT stenoses.

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Methods

Patient Population

In March 1996, the Coordinating Center for this study was established, and it requested data from consecutive unprotected LMT patients treated beginning January 1994 from 25 high-volume clinical sites. In all, 16 sites contributed patients to this study, 8 stated that they had not performed percutaneous intervention on any patient meeting entry criteria for the study, and 1 chose to report its data separately.[7] To minimize a potential overwhelming contribution by any single center, centers that could contribute >30 patients were requested to submit data only for 30 consecutive patients beginning with the most recent patient eligible.

Data Collection and Statistical Analysis

Data collected on dedicated case report forms and procedural cineangiograms were forwarded to the coordinating center for data entry, cross-checking, and analysis. Angiographic analysis was performed by core laboratory physicians who were blinded to clinical outcome using electronic calipers, catheter calibration, and standard definitions.[12]

The following data elements were obtained.

Baseline Angiographic Data
This information included left ventricular ejection fraction (LVEF), lesion length (shoulder to shoulder), location of stenosis (≥30% narrowing—ostial, proximal, or distal), "normal" reference dimension (in millimeters), number of diseased vessels, occluded right coronary artery, and pretreatment percent stenosis.

Baseline Clinical Data
Data were collected on age, aortic insufficiency, chronic obstructive pulmonary disease, creatinine ≥2 mg%, current smoker, diabetes, sex, hyperlipidemia, hypertension, jeopardy score,[13] malignancy, mitral insufficiency, peripheral vascular disease (symptomatic), presentation (acute myocardial infarction from LMT stenosis or occlusion, cardiogenic shock, stable angina, or unstable angina), prior bypass surgery (and years since that operation), and recent infarction (within 2 weeks).

Stated Primary Reason for Percutaneous Therapy
The stated reasons included high risk for CABG, limited life expectancy, patient preference in the absence of high surgical risk (common practice at several Asian centers), and refusal by surgeons for CABG.

Treatment
Data were collected on the use of abciximab, aspirin, ß-blockers, blood product transfusion, calcium channel blockers, cardiopulmonary support (as an adjunct to revascularization), intra-aortic balloon pump, intubation, nitrates, other coronary sites treated, peripheral vascular repair, procedure date, percutaneous therapy (pretreatment, primary and bailout [separately]: balloon angioplasty, directional atherectomy, rotational atherectomy, or stent), specific technical modifications (eg, use of intravascular ultrasound or a perfusion balloon for angioplasty), ticlopidine, vasopressors during the revascularization, and warfarin.

In-Hospital Outcome
This information included bypass surgery (and elective or emergency), death (and cause of death-cardiac or noncardiac), dialysis, length of stay, maximum posttreatment creatine kinase, myocardial infarction (and Q-wave or non–Q-wave infarction), and posttreatment percent stenosis.

Follow-up
We collected follow-up information on CABG, death (and cause of death), myocardial infarction, repeated percutaneous intervention, and restenosis.

Questions and Hypothesis

We prospectively sought to determine procedural, in-hospital, and long-term outcome in the entire cohort and in patients presenting or treated with acute myocardial infarction, directional atherectomy as primary therapy, differing stenosis location, LVEF ≥40% or <40%, other devices as primary therapy, stable angina, stents as primary therapy, surgically accepted, surgically high risk, surgically refused, unstable angina.

Data are presented as percent incidence, mean±SD, or median and interquartile range as appropriate. Between-group comparisons were performed by use of Student's *t* and χ^2 tests and by Cox and logistic regression analyses. Statistical significance was assumed at a value of $P<.05$.

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Results

Patients

Data on 107 patients (0.2% of all procedures performed at these 16 hospitals during this time period) were obtained. The patients described in this report varied widely in condition, ranging from those with stable angina and elective intervention (44%) to those who were deemed inoperable (27%) or presented with acute myocardial infarction and cardiogenic shock (15%). For the 23 patients without acute infarction who were deemed inoperable, the primary reasons listed by the clinical site were poor left ventricular function (n=6), advanced cancer (n=3), poor target vessels (n=3), advanced age (n=2), recent failed CABG (n=2), severe obstructive pulmonary disease (n=2), heparin allergy (n=1), multiple prior CABG (n=1), sepsis (n=1), and not stated (n=2). For the 25 patients at high surgical risk, the primary reasons were advanced age (n=10), poor left ventricular function (n=8), multiple prior CABG (n=2), inoperable severe carotid artery stenosis (n=1), multiple comorbidities (n=1), recent failed CABG (n=1), recent transient cerebrovascular attack (n=1), and recent stroke (n=1). Baseline patient characteristics are given in Tables 1 and 2.

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Table 1. Baseline Clinical Characteristics

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Table 2. Baseline Angiographic Characteristics

Treatment and In-Hospital Outcomes

The primary treatments used were the Palmaz-Schatz stent (n=45), directional atherectomy (n=27), balloon angioplasty (n=21), Rotablator (n=5), the Gianturco-Roubin I stent (n=2), the Palmaz "Biliary" stent (n=2), the ACS stent (n=1), the Cordis stent (n=1), the Gianturco-Roubin II stent (n=1), and the NIR stent (n=1). In 11 instances of stenting, preliminary debulking was performed (Rotablator [n=10] or directional atherectomy [n=1]). Hemodynamic support devices were used in 68% of the patients (intra-aortic balloon pump in 62 patients, cardiopulmonary support in 11). All patients were pretreated with aspirin, and 26 were also treated with ticlopidine. Only 2 received abciximab.

Choice of primary therapy appeared to depend on clinical presentation and, to a certain extent, clinical site (see Table 3). Balloon angioplasty was used more often in patients with acute infarction (adjusted odds ratio, 11.5; multivariate P=.002). Directional atherectomy was used less commonly in nonsurgical candidates (adjusted odds ratio, 0.07; P=.014) and slightly more commonly in patients with distal LMT involvement (adjusted odds ratio, 2.9; P=.08). Stent usage was not related to any variable studied. Stenting of distal LMT lesions almost always was accomplished with a single stent spanning the distal LMT and the proximal portion of the larger of the anterior descending or circumflex arteries. All stents were implanted at pressures ≥12 atm. Intravascular ultrasound use was recorded in 42.9% of elective cases.

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Table 3. Use of Specific Primary Device Treatments

Considering all patients, technical success (final stenosis <50% diameter stenosis and Thrombosis in Myocardial Infarction grade 3 flow) was achieved in all but 4 patients (96.2%). Stenoses were reduced from 70±16% to 15±19% (balloon angioplasty, 37±19%; directional atherectomy, 12±13%; and stents, 7±14%). Eleven of 16 patients (69%) presenting with acute infarction died in hospital. Excluding these patients, in-hospital outcomes were as follows: cardiac death, 11.0%; noncardiac death, 1.1%; Q-wave infarction, 4.5%, non–Q-wave infarction, 10.1%; bypass surgery, 1.1%; peripheral vascular surgery, 4.4%; blood product transfusion, 36.3%; and median length of stay, 8 days. Four deaths occurred in the catheterization laboratory, three of which occurred in patients with LVEF <40%. Two in-hospital deaths were not believed to be

cardiovascular: One was due to sepsis and the other to pneumonia. Outcomes varied dramatically, depending on several patient characteristics (Tables 4 and 5).

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Table 4. In-Hospital Outcomes for Selected Patient Subgroups

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Table 5. Correlates of In-Hospital Death[1]

Post–Hospital Discharge Outcome

Mean follow-up is currently 15±9 months. One patient was lost to follow-up after surviving 3 months. Excluding patients presenting with infarction, 1-, 6-, and 12-month survival and event (death, infarction, bypass surgery) -free survivals were 88.8±3.5%, 72.6±4.8%, and 70.9±5.0%, and 87.5±3.5%, 68.1±5.1%, and 68.1±5.1%, respectively. Three deaths were directly attributable to cancer. These results varied considerably by patient subgroup (Tables 6 and 7 and Figs 1 and 2).

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Table 6. Long-term Results

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Table 7. Independent Correlates of Event-Free Survival[1]

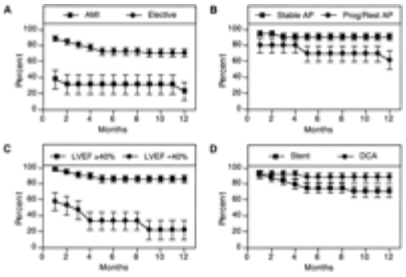

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Figure 1. Kaplan-Meier survival curves for selected patient subsets: A, patients presenting with acute myocardial infarction (AMI) or noninfarct (elective) patients; B, patients with stable angina pectoris (AP) and rest or progressive angina pectoris; C, patients with left ventricular ejection fraction (LVEF) ≥40% or <40%; and D, patients treated with stent or directional coronary atherectomy (DCA).

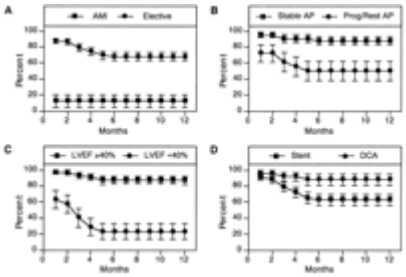

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Figure 2. Kaplan-Meier event-free survival curves for selected patient sets: A, patients presenting with acute myocardial infarction (AMI) or noninfarct (elective) patients; B, patients with stable angina pectoris (AP) and rest or progressive angina pectoris; C, patients with left ventricular ejection fraction (LVEF) ≥40% or <40%; and D, patients treated with stent or directional coronary atherectomy (DCA).

Importantly, nine hospital survivors (10.6%) died of cardiac or presumed cardiac cause within 6 months. Most had presented with unstable angina and had been treated with stents. All patients except one were discharged on aspirin and ticlopidine, and one was also taking warfarin at the time of death (Table 8♦).

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Table 8. Early Postdischarge Death (7 d-6 mo)

Overall event-free survival for patients not treated for initial myocardial infarction was significantly correlated with low ejection fraction, presentation with progressive or rest angina, and, to a lesser degree, use of treatments other than directional atherectomy (Tables 6♦ and 7♦).

Of patients eligible for >4-month angiography, 70% had known studies, of whom 22.0% had restenosis (stenosis ≥50%). In this small cohort, the only variable related to risk of restenosis was ostial LMT location (odds ratio, 4.67; *P*=.07).

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Discussion

Since 1976, when the Veterans Administration trial investigators reported a 5-year survival advantage of 80% versus 64% for bypass surgery compared with medical therapy for patients with unprotected LMT stenoses,[1] this anatomy has been considered to be an absolute indication for surgery at most centers. Current 30-day mortality after bypass surgery in patients with LMT involvement is about 2% to 3%.[14] Patients with renal dysfunction, prior bypass surgery, advanced age, and severe heart failure are at highest risk.[14]

Early reports of conventional percutaneous transluminal coronary angioplasty in this setting did little to dissuade clinicians from this conclusion. The report of O'Keefe et al[2] from the Mid-America Heart Institute in 1989 was both representative and sobering, reporting a 55% 6-month mortality in 26 such patients.

The techniques of stenting and directional and rotational atherectomy have matured greatly in nearly 10 years of clinical experience.[15] Since the early report of Macaya et al,[4] an increasing number of small-scale reports of generally successful outcomes with unprotected LMT stenting or atherectomy have been reported.[5–11] Several centers in Asia now offer these therapies as alternatives to CABG in selected patients.

This report, although still modest in scope, is the first to study >40 patients and to evaluate results in more than a few categories of patients. Short- and intermediate-term results varied greatly, depending on a number of factors. Excluding presentation with acute myocardial infarction, LVEF was the most important risk factor for in-hospital death. In elective cases, when LVEF was ≥40%, mortality was only 1.7% (n=59), whereas when LVEF was <30%, mortality was 31.8% (n=22), Three of the seven deaths in the latter group occurred in the catheterization laboratory, attesting to the intolerance of the impaired left ventricle to even short periods of near-global ischemia. Acceptable event-free survival over time was also related to high LVEF but also to the absence of

severe unstable angina at baseline and possibly to the use of directional atherectomy as the treatment modality (Table 6↑). These data should be contrasted with those from patients receiving thecontemporary therapy of "protected" LMT stenoses—those with patent bypass grafts to the anterior descending or circumflex territories—in whom survival is generally excellent.[16]

A disturbingly high incidence of cardiac or presumed cardiac death occurred during the first 6 months after treatment. This occurred primarily in patients with unstable angina, several of whom also had depressed left ventricular function, who were treated with stents, despite the use of aspirin, ticlopidine, and high-pressure inflations. Stent thrombosis, worsening heart failure, or arrhythmias without restenoses are plausible explanations for this finding. It is also possible that severe restenosis may precipitate rapidly worsening heart failure or electrical instability. It may be prudent to bring the patient back for angiographic restudy 6 to 8 weeks after treatment to attempt to detect early aggressive restenosis, although the benefit of such a course of action is, of course, yet unproven.

With limited data from selected hospital sites, it is difficult to define the role of percutaneous intervention for patients with unprotected LMT stenoses. Less experienced sites might not be able to replicate these results. The impressions from subset analyses of this experience need to be studied further, because the likelihood of some type I statistical error is fairly high. If the early postdischarge events could be minimized, a strategy of LMT directional atherectomy or stenting for patients with stable or new-onset angina and well-preserved left ventricular dysfunction, when practiced in highly experienced centers, would not appear to be totally unreasonable. Before such a practice could to be accepted, randomized controlled trials comparing long-term outcome against that with bypass surgery would need to be completed. Percutaneous intervention for inoperable patients with LMT stenoses may be reasonable for those individuals with intractable symptoms. All groups of patients might be expected to have improved outcomes with adjunctive use of abciximab or related drugs, which have been demonstrated to decrease the risk of infarction with directional atherectomy[17] and emergency stenting[18] and are under study in the setting of elective stenting.

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