Long-Term Clinical Outcomes After Unprotected Left Main Trunk Percutaneous Revascularization in 279 Patients

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Background—Percutaneous coronary revascularization (PCI) has been increasingly applied to unprotected left main trunk (LMT) lesions, with varied long-term success. This study attempts to define the predictors of outcome in this population.

Methods and Results—Two hundred seventy-nine consecutive patients who had LMT PCI at 1 of 25 sites between 1993 and 1998 were studied. Forty-six percent of these patients were deemed inoperable or at high surgical risk. Thirty-eight patients (13.7%) died in hospital, and the rest were followed up for a mean of 19 months. The 1-year incidence was 24.2% for all-cause mortality, 20.2% for cardiac mortality, 9.8% for myocardial infarction, and 9.4% for CABG. Independent correlates of all-cause mortality were left ventricular ejection fraction ≤30%, mitral regurgitation grade 3 or 4, presentation with myocardial infarction and shock, creatinine ≥2.0 mg/dL, and severe lesion calcification. For the 32% of patients <65 years old with left ventricular ejection fraction >30% and without shock, the prevalence of these adverse risk factors was low. No periprocedural deaths were observed in this low-risk subset, and the 1-year mortality was only 3.4%.

Conclusions—Patients undergoing unprotected LMT PCI have frequent serious comorbidities and consequently have high event rates. PCI may be an alternative to CABG for a select proportion of elective patients and may also be appropriate for highly symptomatic inoperable patients. Meticulous follow-up of hospital survivors is required because of the rather high mortality during the first few months after treatment. **(*Circulation*. 2001;104:1609-1614.)**

Key Words: angioplasty ■ coronary disease ■ revascularization ■ stents

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Coronary artery bypass graft surgery (CABG) has been the standard of care for left main trunk (LMT) disease ever since the Veterans Administration Cooperative Study established its superiority over medical therapy with regard to survival.[1] Percutaneous coronary revascularization (PCI) was shown in randomized clinical trials in the 1990s to be equivalent to CABG in terms of rates of survival and infarct-free survival in a growing number of patients with coronary artery disease.[2–5] Although the early experience of PCI for unprotected LMT (ULMT) showed satisfactory short-term technical success rates, follow-up revealed high attrition rates, leading to recommendations proscribing this practice for CABG-eligible patients.[6,7] The advent of better PCI equipment, stents, and ablative devices in the mid-1990s, along with reports of good intermediate-term outcomes in selected patients, have ushered in a renewed interest in the practice of ULMT percutaneous revascularization.[8–12]

Randomized clinical trials to address this issue are unlikely to be performed because of logistic considerations of prohibitive sample size and cost requirements. Therefore, a multicenter registry was established to evaluate outcomes after ULMT PCI.[13] The purpose of the present analysis is to describe long-term outcomes and define the predictors of outcome for this cohort of patients.

Methods

Study Population

Patient and procedural data were obtained from 25 high-volume clinical sites.[13] The entry criteria were consecutive patients undergoing PCI to an ULMT from July 1993 to July 1998. A maximum enrollment of 50 patients per site was implemented to avoid domination of contributions from any single center.

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TABLE 1. Baseline Demographics

	All (n=279), %	Low-Risk Subset (n=89), %
Age, y (mean)	66.1±12.9	54.2±9.2
Male	65.3	68.5
Hypertension	45.4	32.6
Diabetes mellitus	21.2	20.2
Current smoker	19.5	25.8
Peripheral vascular disease	10.3	7.9
Creatinine ≥2 mg/dL	5.8	2.2
Chronic obstructive pulmonary disease	8.7	2.2
History of prior CABG	9.4	5.6
Clinical presentation		
Acute MI	14.7	1.1
Cardiogenic shock	13.7	0
Infarction within 2–14 days	8.0	1.1
Rest angina	20.5	12.4
Progressive angina	14.0	16.9
New-onset angina	9.4	12.4
CABG eligibility		
Not operable*	16.6	4.5
High risk†	28.9	7.9
Low risk/patient preference for PCI	46.6	78.7
Other‡	7.9	8.9

*31.9% age ≥75 years, 28.3% cardiogenic shock, 27.7% LVEF ≤30%, 26.1% prior CABG, 19% severe chronic obstructive pulmonary disease, 6.4% dialysis, 6.4% malignancy, 2.1% limited life expectancy, 10.6% miscellaneous (eg, no suitable bypass conduits) (often multiple high-risk features).

†54.3% age ≥75 years, 19.8% cardiogenic shock, 8.6% prior CABG, 8.6% LVEF ≤30%, 74% severe chronic obstructive pulmonary disease, 4.9% limited life expectancy, 1.2% malignancy, 1.2% dialysis (often multiple features).

‡Other reasons CABG not performed, ie, limited life expectancy due to cancer.

Data Collection

Data collection and analysis have been described previously (see also Tables 1 to 3).[13]

Statistical Analysis

Kaplan-Meier survival analysis was used to determine the specific and composite 1-year event rates for both hospital survivors and the entire cohort.[14] Variables with a univariate value of $P \leq 0.10$ and relevant clinical predictors known from other studies (age, sex, diabetes) were entered into the initial Cox proportional hazards model.[15] A 1-step classification and regression tree (CART) method (S plus V4.5, MathSoft, Inc) was used adjunctively to identify low-risk clusters of patients. This low-risk subgroup comprised 32% of the entire study population. It consisted of patients <65 years of age who had a left ventricular ejection fraction (LVEF) >30% and were not in acute myocardial infarction (AMI) with cardiogenic shock. The SAS system version 6.12 was used for all computations.[16]

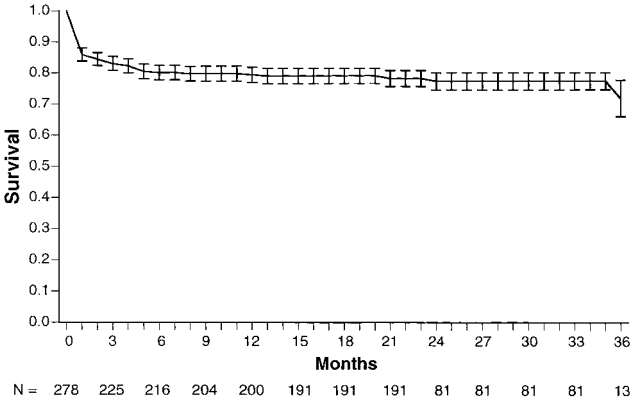

Figure 2. Cardiac survival in complete cohort.

Results

Patients

Baseline characteristics of the entire study population are summarized in Tables 1 and 2. The regional contributions were as follows: Europe 31.3%, Japan 33.5%, Korea 13.7%, South America 1.1%, and the United States 20.5%. As expected, the low-risk cohort of patients had a smaller proportion of unfavorable characteristics (eg, renal insufficiency, acute MI, severe mitral regurgitation [MR]) compared with the entire cohort. These patients were also much more commonly from Japan and South Korea, where there are strong social prohibitions against surgery. Complete data regarding right coronary artery (RCA) patency were unavailable in 132 patients, primarily because of study centers having only the films of the intervention itself.

Thirty-eight patients (13.7%) died in hospital, most of whom had presented with AMI. The 1-year follow-up rate was 97.1%, with a mean follow-up of 19 months. Two

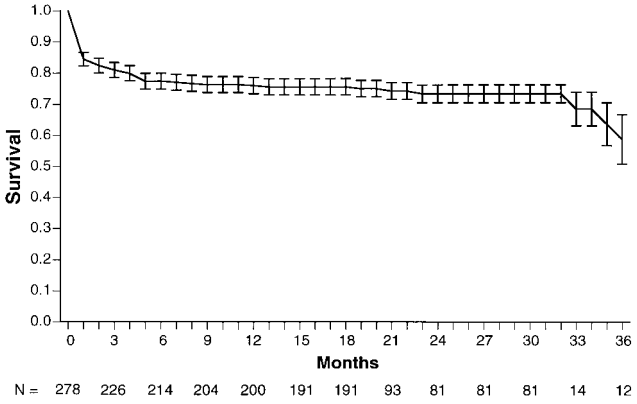

Figure 1. Overall survival in complete cohort.

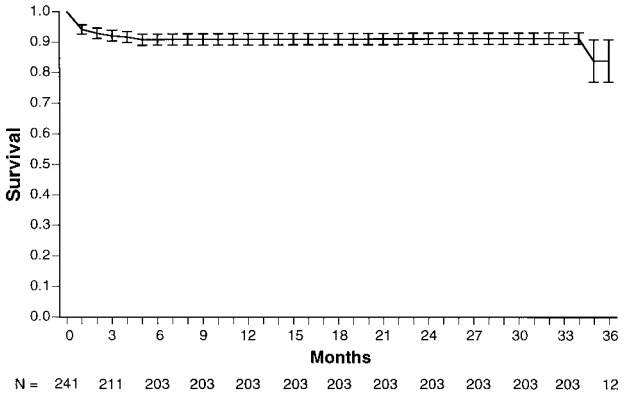

Figure 3. Freedom from infarction in complete cohort.

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TABLE 2. Baseline Angiographic Characteristics

	All (n=279), %	Low-Risk Subset (n=89), %
LVEF (mean)	51.3±16	58.5±10.6
LVEF <40%	28.0	2.9
MR grade 3 or 4	4.1	0
Three-vessel disease	32.5	22.0
Severe lesion calcification	8.9	3.4
LMT characteristics		
Reference diameter, mm (mean)	3.97±0.8	4.0±0.8
Lesion length, mm (mean)	4.64±2.9	4.96±3.0
Lesion location		
Ostial	44.0	55.3
Midshaft	26.9	29.9
Distal	58.3	49.4
% stenosis before, mean/median/ interquartile range	68.5/68.0/55–79	62.6/62.5/52–73
% stenosis after, mean/median/ interquartile range	12.6/10.0/1–23	7.2/5.0/0–16

patients were lost to follow-up because of emigration abroad, and 3 patients from one center could not be contacted for their 1-year follow-up.

Treatments Received

The treatment profile of these patients is outlined in Table 3. Of note, almost half of the study population had adjunctive intra-aortic counterpulsation. Ten patients (3.6%) received stenting for a bailout indication, and another 65.2% of patients received it as primary therapy. Approximately 15% of patients were treated with balloon angioplasty (PTCA) alone, and only 4.3% of patients received abciximab. Among the low-risk patients, there was less use of support devices, and only 4.5% received PTCA as sole device therapy for their ULMT stenoses. Twenty-one percent of patients had therapy to other coronary segments during the index procedure.

TABLE 3. In-Hospital Treatment

	All Patients (n=279), %	Low-Risk Subset (n=89), %
Aspirin	90.9	96.6
Ticlopidine	41.7	57.3
β-Blockers	28.4	28.4
Abciximab	4.3	1.1
Balloon only	15.1	4.5
Stent	68.8	76.4
Rotablator as 1° treatment	9.3	8.9
Directional coronary atherectomy	17.1	19.1
Ablation followed by stenting	11.2	11.2
Pulmonary artery catheter	16.8	3.9
Temporary pacer	31.6	20.5
Intra-aortic balloon counterpulsation	46.0	26.4
Prophylactic percutaneous cardiopulmonary support	5.9	0

TABLE 4. Correlates of All-Cause Mortality (In-Hospital and During Follow-Up)

Event	% of Study Population	Hazard Ratio	95% CI	P
LVEF ≤30%	14.3	4.21	2.27–7.81	0.001
MR grade 3 or 4	4.1	3.66	1.61–8.30	0.001
Cardiogenic shock	13.7	3.56	1.73–7.34	0.001
Creatinine ≥2 mg/dL	5.8	3.10	1.30–7.39	0.011
Severe lesion calcification	8.9	2.32	1.13–4.76	0.022

In-Hospital and Long-Term Outcomes

There were a total of 75 deaths, 61 of which were cardiac related (Figures 1 and 2). By multivariate analysis, covariates of all-cause mortality (in-hospital and long-term) were LVEF ≤30%, hazard ratio (HR) 4.2; MR grade 3 or 4, HR 3.7; clinical presentation of MI with cardiogenic shock, HR 3.6; serum creatinine ≥2.0 mg/dL, HR 3.1; and severe lesion calcification, HR 2.3 (Table 4). Except for lesion calcification, the predictors of cardiac death were similar, although different in magnitude: MR grade 3 or 4, HR 5.0; LVEF ≤30%, HR 4.9; MI with cardiogenic shock, HR 4.8; and serum creatinine ≥2.0 mg/dL, HR 3.2. The 1-year specific and composite outcomes for death, MI, or CABG are summarized in Table 5.

In the low-risk subset of 89 patients selected by CART analysis, the 1-year actuarial incidence of death was 3.4%, and that of MI was 2.3%. Of note, there were no periprocedural deaths in this subgroup, and there were no additional deaths or MI beyond 4 months after discharge (up to 35 months). The corresponding revascularization rates were 11.4% for CABG, 20.4% for PCI, and 24.5% for either during the 1-year follow-up (Table 5).

Long-Term Outcome in Hospital Survivors

For the 240 patients who survived their index hospitalization, the rates for death, MI, and CABG at 1 year were 12.2%, 8.7%, and 8.7%, respectively. Most of these events, and MI in particular, occurred within the first 3 months after ULMT PCI (Table 6 and Figure 3). The correlates of postdischarge mortality are shown in Table 7. Excess deaths were observed predominantly in patients initially deemed inoperable. In addition, non–Q-wave MI complicating PCI and diminished LV function also foreshadowed late events for these survivors of initial hospitalization. Specific event rates for each of these high-risk subgroups are provided in Table 8.

Discussion

The first report of PTCA applied to ULMT disease was published by Gruntzig in 1978.[17] Other reports followed,[18–21] with the largest series published by O'Keefe et al[6] in 1989, demonstrating technical feasibility but a 64% 3-year mortality rate. Planned PCI for ULMT disease was subsequently reserved for patients who were ineligible for surgery. Increased operator experience, the availability of stents, ablative devices,[22–24] hemodynamic support devices, and encouraging results in protected LMT PCI and CABG-ineligible patients prompted a resurgence of this procedure despite an initial paucity of data.[5,9,10,25–27] The initial report from the ULTIMA registry characterizing the outcomes of 107 pa-

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TABLE 5. One-Year Actuarial Outcomes in the Entire Population and Selected Subgroups*

Population	Death,† %	Cardiac Death,† %	MI, %	CABG, %	Repeat PCI, %	Death/MI/CABG, %
All (n=278)	24.2	20.2	9.8	9.4	24.2	34.6
High-risk LVEF ≤30% (n=26)	78.7	73.7	40.1	0.0	67.7	83.7
MR grade 3 or 4 (n=10)	80.0	80.0	0.0	46.7	0.0	90.0
Cardiogenic shock (n=37)	67.6	65.3	0.0	45.8	14.1	78.4
Creatinine ≥2 mg/dL (n=16)	68.4	68.4	22.1	0.0	52.8	68.4
Severe calcification (n=21)	56.2	56.2	8.3	10.1	46.0	57.2
Intermediate risk (n=118)	24.4	20.4	14.2	7.8	27.1	33.9
Low risk (n=89) (<65 years, LVEF >30%, and not in cardiogenic shock)	3.4	3.4	2.3	11.4	20.4	16.9

*Includes in-hospital outcomes.

†All deaths considered cardiac unless clearly from other causes, eg, cancer.

tients, the largest series on ULMT PCI at that time, however, revealed a disturbingly high 6-month death rate of 10.6.[13] Many of these patients had been deemed high risk or ineligible for CABG, however. In addition, compared with earlier large surgical trials of CABG versus medical therapy or PCI, the patients in this registry were at higher risk because of greater age and the inclusion of higher-risk patient subsets of acute coronary syndromes and cardiogenic shock.[1,28,29]

For this heterogeneous group of patients, in-hospital mortality was 14.0% and overall 1-year mortality was 20.2%. The independent correlates of all-cause death during and after hospitalization were LVEF ≤30%, grade 3 or 4 MR, clinical presentation of MI with cardiogenic shock, serum creatinine ≥2.0 mg/dL, and severe lesion calcification. Decreasing LVEF was related to events in an inverse fashion but not linearly, with an apparent inflection point at the 30% LVEF cutoff level.

On the basis of this analysis, the 32% of patients identified by 3 clinical features—age <65 years, LVEF >30%, and absence of cardiogenic shock from AMI—composed a low-risk group and had a 3.4% 1-year mortality (Table 5). At 1 year, 9 in 10 had been spared CABG. Similar data were recently reported by Silvestri et al,[30] who defined a low-risk group with age <75 years, no prior CABG, LVEF ≥35%, and the absence of renal failure, poor coronary runoff, or severe respiratory failure, whose 1-year mortality was 7% and need for revascularization 28%. For purposes of comparison, recent data from the Society of Thoracic Surgery[31] indicate an in-hospital mortality for patients with left main disease of 3.9%, and data from The Cleveland Clinic Foundation show an in-hospital mortality of 2.3%, with a 1-year mortality of 11.3%.[8] One-year mortality after bypass for a low-risk group similar to that identified in this analysis of (age <65 years, New York Heart Association congestive heart failure class ≤2 [LVEF was not routinely obtained in this surgical series]) was 5.7%.[8]

The limitations of this study are those inherent to registries requiring long-term patient follow-up. There was a low rate of use of platelet glycoprotein IIb/IIIa receptor antagonists in this registry, and it remains to be seen whether these agents can deliver the improved outcomes observed in the non-LMT stenosis trials.[32–34] Even though multivariate analysis of the available data revealed no significant effect of concomitant RCA occlusion, missing data elements for this field preclude any definitive conclusion that this feature is not contributory to outcome. Data about collateral flow were not recorded. An analysis using a worst-case scenario in which missing elements were assumed to represent an occluded RCA, however, showed only a trend for significance and did not appreciably alter our conclusions (data not shown). Definitions of several patient characteristics, such as "not a candidate for bypass surgery," are subjective and certainly varied between institutions. Finally, although generally supported by the experiences of Kosuga et al,[9] Park et al,[10] Silvestri et al,[30] Chanhan et al,[35] and others, the low-risk group identified in this study requires prospective confirmation.

Judicious patient selection remains critical for both the interventionalist and cardiac surgeon, and further studies are needed to define which patients are truly inoperable, who among these patients still may benefit from PCI, and those in whom revascularization attempts will be futile. Unfortunately, patients who are good candidates for surgery are typically the same ones who will do well with other invasive procedures, and poor surgical risks often mean poor global risks. It is fair to say that CABG is still the first choice for the majority of patients with ULMT disease, but PCI is a viable option in select circumstances: those presenting with AMI,[36]

TABLE 6. Overall Patient Outcomes (Including In-Hospital Events)

	All-Cause Death, %	Cardiac Death, %	MI, %	CABG, %	Death or MI,* %	Death/MI/CABG,* %
3 mo	5.8	3.8	6.4	5.0	10.0	15.0
1 y	12.2	9.1	8.7	8.7	16.4	24.3

*Some patients experienced more than one type of event.

TABLE 7. Independent Correlates of Postdischarge Mortality

Event	n	Hazard Ratio	95% CI	*P*
IH NQMI	21	5.70	2.61–12.42	0.0001
Not CABG candidate	29	4.72	2.21–10.05	0.0001
LVEF ≤30%	22	3.48	1.72–7.03	0.0005

IH indicates in-hospital; NQMI, non–Q-wave MI.

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TABLE 8. One-Year Actuarial Outcomes for High-Risk Patient Subsets Among Hospital Survivors

Subpopulation	Death, %	Cardiac Death, %	MI, %	CABG, %	Death or MI,* %	Death/MI/CABG,* %
All (n=240)	12.15	9.14	8.68	8.73	16.37	24.26
IH NQMI (n=21)	9.52	9.52	47.62	19.33	47.62	66.67
Non-CABG candidate (n=29)	37.93	32.37	20.9	3.45	41.48	44.83
LVEF ≤30% (n=22)	45.83	38.89	42.27	0.0	56.96	59.60

IH NQMI indicates in-hospital non–Q-wave MI.

*Some patients may have concurrently experienced more than one type of event.

the highly symptomatic but inoperable patient, and perhaps the low-risk patient group described here.

Finally, on the basis of the 2% per month death rate among hospital survivors noted over the first 6 months after hospital discharge, probably partly a result of restenosis, we strongly urge routine surveillance angiography at 2 and 4 months after treatment.

Appendix

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