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Original Article

Long-term Clinical Outcomes Following Elective Stent Implantation for Unprotected Left Main Coronary Artery Disease

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Background/Purpose: Percutaneous coronary intervention (PCI) has been increasingly adopted for unprotected left main coronary artery (LMCA) disease. The aim of this study was to evaluate the predictors of long-term clinical outcomes in patients after elective stent implantation for unprotected LMCA disease.
Methods: A total of 122 patients with medically refractory angina who received coronary stenting for unprotected LMCA disease between August 1997 and December 2008 were included.
Results: During the follow-up period of 45 ± 35 months (range: 1–137 months), the incidence of repeated PCI and/or coronary artery bypass grafting (CABG), and cardiovascular and total mortality were 28% (34 patients), 20% (24 patients), and 25% (31 patients), respectively. Multivariate analysis revealed that young age [$p = 0.02$; hazard ratio (HR): 2.19, 95% confidence interval (CI): 1.11–4.30] and bare-metal stent (BMS) use ($p = 0.02$; HR: 5.35, 95% CI: 1.27–22.57) were the independent predictors of repeated PCI and/or CABG. Only lower left ventricular ejection fraction (LVEF) could predict both cardiovascular mortality ($p = 0.003$; HR: 4.25, 95% CI: 1.63–11.08) and total mortality ($p = 0.002$; HR: 3.95, 95% CI: 1.65–9.45). Lower LVEF ($p = 0.001$; HR: 0.31, 95% CI: 0.16–0.61) and small stent size ($p = 0.01$; HR: 5.95, 95% CI: 1.43–24.80) could predict the composite endpoint, including target vessel revascularization and total mortality.
Conclusion: We showed that young age and BMS implantation could predict repeated PCI and/or CABG after stent implantation for unprotected LMCA disease. Only lower LVEF could predict both cardiovascular and total mortality. Lower LVEF and small stent size but not BMS implantation could predict composite target vessel revascularization/total mortality.

Key Words: coronary artery disease, left main coronary artery, percutaneous coronary intervention, stent

Unprotected left main coronary artery (LMCA) disease is considered to be a class II A or II B indication for percutaneous coronary intervention (PCI), according to current guidelines if coronary artery bypass grafting (CABG) is not a viable option.[1,2] Several studies have revealed that PCI for unprotected LMCA disease can be considered in selected patients.[3–8] Recently, drug-eluting stent

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(DES) placement has been recommended if PCI is undertaken in unprotected LMCA disease.[9–13] However, the predictors of long-term clinical outcomes in this patient population have not been well established.[9–14] Therefore, the purpose of our study was to investigate the predictors of long-term clinical outcomes in patients after elective stent implantation for unprotected LMCA disease.

Methods

Study population

From August 1997 to December 2008, 136 patients with medically refractory angina received elective coronary stenting at our institute for unprotected LMCA disease with angiographic evidence of > 50% diameter stenosis. Follow-up was absent in 14 patients, thus a total of 122 patients were included. The decision for stent implantation instead of surgical revascularization was considered when one of these two conditions was present; those who presented as highly symptomatic but inoperable because of comorbidity or those who refused CABG with a preference for PCI. Informed consent forms on the treatment choice between LMCA stenting or CABG was obtained from all patients before the procedure.[3,6]

Stent implantation

All patients were treated with the percutaneous trans-femoral approach via an angiography sheath and the standard angioplasty technique.[3,6] Each patient received intravenous heparin (100 U/kg), and, if necessary, an additional bolus of heparin was administered to maintain activated clotting time at > 5 minutes. Quantitative angiographic analysis was performed to demonstrate the stenosis in its most severe and non-foreshortened projection. With the use of a contrast-filled guiding catheter as the calibration standard, reference and lesion minimal lumen diameter were determined. Successful immediate outcome of stent implantation for LMCA disease was defined as < 30% residual stenosis. Myocardial infarction (MI) was diagnosed by a rise in the creatine kinase level to more than twice the upper normal limit, with an increased creatine kinase MB fraction. Post-stenting medications included aspirin (100 mg/day) and clopidogrel (75 mg/day). Therapy was continued for 3 months in patients who received a bare-metal stent (BMS) and 12 months in those who received a DES, and aspirin was continued indefinitely. The choice between BMS and DES was left to the patients' preference because our insurance system does not cover the fee for DES. Clinical follow-up was obtained by clinical visits, telephone conversation, and chart review.[3,6]

Predictors of long-term cardiovascular outcomes

The outcomes analyzed for follow-up were target vessel revascularization (TVR), cardiovascular death, all-cause mortality, and composite TVR/total mortality. TVR was defined as any repeated revascularization (either PCI or CABG) to treat a luminal re-narrowing within the stent, or within 5-mm borders adjacent to the stent. Any death was considered cardiac unless proven otherwise. The analyzed variables included: age (≥ 65 years or < 65 years); sex; a history of prior MI or PCI; smoking; diabetes mellitus; hypertension; anemia (hemoglobin < 13 mg/dL in men, < 11 mg/dL in women); chronic renal insufficiency (serum creatinine ≥ 2 mg/dL); hypercholesterolemia (low-density lipoprotein ≥ 130 mg/dL); left ventricular ejection fraction (LVEF) (≥ 40% or < 40%); position of LMCA stenosis (proximal, middle or distal); stent size (≥ 4.0 mm or < 4.0 mm); and stent type (BMS or DES).

Statistical analysis

Continuous variables were shown as mean ± standard deviation, and categorical variables were presented as counts and percentages. Event-free survival at follow-up was evaluated according to the Kaplan-Meier method, and survival among groups was compared with the log-rank test. Multivariate analysis was performed with a Cox regression model to determine the independent predictors of the long-term outcomes. Variables

selected to be tested in the multivariate analysis were those with a p value < 0.1 in the univariate model. A p value < 0.05 was considered statistically significant, and confidence interval (CI) was 95%.

Results

Immediate and long-term outcomes of stent implantation

Basic clinical and angiographic characteristics of the 122 patients are shown in Table 1. The LMCA lesions were treated with BMSs (75%) or DESs (25%). The mean stent size was 3.3 ± 0.4 mm, and the mean length was 16 ± 6 mm. A total of 15% (18 patients), 16% (20 patients), and 69% (84 patients) had proximal, middle, and distal left main lesions, respectively. Among the 84 patients with distal left main lesion, 66 received simple crossover stenting. Out of the 66 patients who received simple crossover stenting, kissing balloon post-dilatation was performed in 44 patients. The remaining 18 patients received bifurcation stenting, of whom, four received T stenting, 10 Cullotte stenting, and four Crush stenting. Kissing balloon post-dilatation was performed in all 18 patients who received bifurcation stenting.

Table 1. Basic clinical and angiographic characteristics of total 122 patients

Age (yr)	70 ± 10
Sex, female	38 (31)
Prior MI	27 (22)
Prior PCI	60 (49)
Smoking	51 (42)
Diabetes mellitus	49 (40)
Hypertension	91 (75)
Anemia	42 (34)
Chronic renal insufficiency	14 (12)
Hypercholesterolemia	67 (55)
LVEF $\leq 40\%$	16 (13)
Position of LMCA stenosis	
Proximal	18 (15)
Middle	20 (16)
Distal	84 (69)
Mean stent size (mm)	3.3 ± 0.4
Mean stent length (mm)	16 ± 6
Bare-metal stent	92 (75)
Pure LMCA disease	24 (20)
LMCA plus 1-vessel disease	29 (24)
LMCA plus 2-vessel disease	48 (39)
LMCA plus 3-vessel disease	21 (17)

**Data presented as n (%) or mean ± standard deviation. LMCA = left main coronary artery; LVEF = left ventricular ejection fraction; MI = myocardial infarction; PCI = percutaneous coronary intervention.*

Patients with pure LMCA lesions, LMCA plus one-vessel disease, LMCA plus two-vessel disease, and LMCA plus three-vessel disease were 20% (24 patients), 24% (29 patients), 39% (48 patients), and 17% (21 patients), respectively. Ninety-eight patients (80%) received PCI in other coronary arteries at the time of LMCA stenting, in which right coronary artery stenting was performed in 47 patients, whereas PCI of three vessels in addition to LMCA stenting was achieved in 21 patients. Immediate success was achieved in all of the patients without major complications.

During a follow-up period of 45 ± 35 months (range: 1–137 months), 34 patients (28%) underwent repeated coronary intervention for recurrent angina; 19 (16%) received PCI, 12 (10%) CABG, and three (2%) both PCI and CABG for restenosis of LMCA. In the three patients who received both PCI and CABG, the LMCA stenosis was located in the distal portion, and simple crossover stenting was performed at the first time of LMCA stenting. All three patients received repeated PCI within 6 months because of LMCA restenosis and/or ostial side branch restenosis. Unfortunately, all three patients needed to receive CABG soon because of LMCA restenosis and/or new stenosis of other coronary arteries.

Thirty-one patients (25%) died: 24 (20%) with cardiovascular disease and seven (5%) with non-cardiovascular disease. In the six deaths within 3 months after LMCA stenting, five were due to acute MI, and one of these had received a second PCI. The other patient died from congestive heart failure after CABG for unstable angina (Table 2).

Table 2. Clinical data of patients with mortality

Patient no.	Repeated PCI	CABG	Mortality reasons	Follow-up (d)
1	N	Y	Sepsis	606
2	Y	N	Acute myocardial infarction	387
3	N	N	Congestive heart failure	2400
4	N	Y	Acute myocardial infarction	3853
5	N	Y	Esophageal varices bleeding	3610
6	N	N	Acute myocardial infarction	27
7	Y	Y	Congestive heart failure	89
8	Y	N	Congestive heart failure	3087
9	N	N	Congestive heart failure	3424
10	N	N	Pneumonia	2210
11	N	N	Acute myocardial infarction	2876
12	Y	N	Acute myocardial infarction	2327
13	N	N	Traffic accident	1542
14	Y	Y	Acute myocardial infarction	2630
15	N	N	Acute myocardial infarction	204
16	Y	N	Congestive heart failure	628
17	N	N	Congestive heart failure	358
18	Y	N	Acute myocardial infarction	1889
19	Y	N	Acute myocardial infarction	58
20	N	N	Colon carcinoma	553
21	N	N	Congestive heart failure	111
22	Y	N	Acute myocardial infarction	796
23	N	N	Congestive heart failure	1469
24	N	N	Congestive heart failure	704
25	N	N	Congestive heart failure	1053
26	N	N	Acute myocardial infarction	68
27	N	N	Acute myocardial infarction	156
28	N	N	Pneumonia	370
29	N	Y	Sepsis	161
30	N	N	Acute myocardial infarction	24
31	N	N	Acute myocardial infarction	77

CABG = coronary artery bypass grafting; PCI = percutaneous coronary intervention; Y = yes; N = no.

The Figure shows the Kaplan-Meier curve for freedom from TVR, cardiovascular death, total death, and composite TVR/total mortality at follow-up.

Predictors of repeated PCI and/or CABG

Univariate analysis revealed that young age ($p = 0.003$), lower LVEF ($p = 0.08$), small stent size ($p = 0.01$), and BMS use ($p = 0.01$) were related to repeated PCI and/or CABG (Table 3). Multivariate analysis showed that young age [$p = 0.02$; hazard ratio (HR): 2.19, 95% CI: 1.11–4.30] and BMS use ($p = 0.02$; HR: 5.35, 95% CI: 1.27–22.57) were independent predictors of TVR.

Predictors of cardiovascular mortality

Univariate analysis revealed that anemia ($p < 0.001$), chronic renal insufficiency ($p < 0.001$), and lower LVEF ($p < 0.001$) were related to cardiovascular mortality (Table 3). Multivariate analysis showed that only lower LVEF could predict the presence of cardiovascular mortality ($p = 0.003$; HR: 4.25, 95% CI: 1.63–11.08).

Predictors of total mortality

Univariate analysis revealed that anemia ($p < 0.001$), chronic renal insufficiency ($p < 0.001$), lower LVEF ($p < 0.001$), and position of LMCA

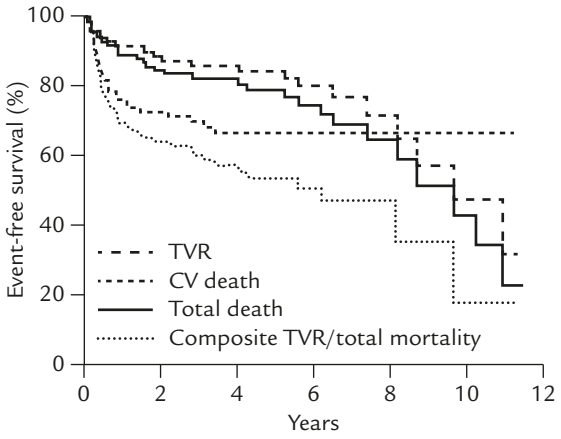

Figure. Kaplan-Meier curve showing freedom from target vessel revascularization, cardiovascular death, total death, and composite target vessel revascularization/total mortality at follow-up.

stenosis ($p = 0.07$) were associated with total mortality (Table 3). Multivariate analysis showed that only lower LVEF could predict the presence of total mortality ($p = 0.002$; HR: 3.95, 95% CI: 1.65–9.45).

Predictors of composite TVR/total mortality

Univariate analysis revealed that anemia ($p = 0.02$), chronic renal insufficiency ($p = 0.099$), lower LVEF ($p < 0.001$), and small stent size ($p = 0.01$) were associated with composite TVR/total mortality (Table 3). Multivariate analysis showed that lower LVEF ($p = 0.001$; HR: 0.31, 95% CI: 0.16–0.61) and small stent size ($p = 0.01$; HR: 5.95, 95% CI: 1.43–24.80) could predict composite TVR/total mortality.

Discussion

Major findings

The present study showed that young age and BMS use could predict repeated PCI and/or CABG in patients after stent implantation for unprotected LMCA disease. Only lower LEVF could predict both cardiovascular and total mortality.

Comparisons with previous studies

Previous studies have shown that in-hospital mortality is around 0–3% after stent implantation in patients with unprotected LMCA disease.[6–10] In the present study, none of the patients had in-hospital mortality after stenting of unprotected LMCA stenosis. However, six of 24 cardiovascular deaths occurred within the first 3 months after stent implantation. This finding suggests that stent thrombosis plays an important role in early cardiovascular mortality. The present study suggests that PCI should only be considered in selected patients.

Predictors of repeated PCI and/or CABG

Price et al have reported that impaired renal function can predict TVR in patients who receive DES implantation for unprotected LMCA disease.[10] Previous studies have shown that the incidence of TVR after unprotected LMCA stenting was 17–31% in the BMS era and 2–14% in the DES era.[9–11,15–19] The present study also showed that patients in the DES group had significantly lower rates of TVR than those in the BMS group. Cameron et al have demonstrated that young age and female sex can predict recurrent angina within 1 year of CABG for coronary artery disease.[20] Our previous study has shown that young age and female sex can predict repeated revascularization after unprotected LMCA stenting.[6] The present study found that BMS use and young age could predict repeated PCI and/or CABG after stent implantation for unprotected LMCA disease. Furthermore, some previous studies have found that maximal balloon inflation pressure correlates with occurrence of angiographic restenosis in patients after unprotected LMCA stenting.[9,10] These findings suggest that small vessel size explains the higher incidence of restenosis after stent implantation for unprotected LMCA disease. The present study revealed that the patients who needed repeated PCI and/or CABG tended to have small stent size; however, the stent size was not a predictor of repeated PCI and/or CABG.

Predictors of cardiovascular mortality

Our previous study has shown that lower LVEF is associated with cardiovascular mortality after unprotected LMCA stenting.[6] Meliga et al have

Table 3. Univariate and multivariate analysis for repeated percutaneous coronary intervention and/or coronary artery bypass grafting, cardiovascular mortality, total mortality and composite target vessel revascularization/total mortality

Variable	Repeated PCI and/or CABG				Cardiovascular mortality				Total mortality				Composite TVR/total mortality			
	Univariate	Multivariate			Univariate	Multivariate			Univariate	Multivariate			Univariate	Multivariate		
	p	*p*	HR	95% CI	*p*	*p*	HR	95% CI	*p*	*p*	HR	95% CI	*p*	*p*	HR	95% CI
Young age	0.003	0.02	2.19	1.11–4.30	0.30	–	–	–	0.11	–	–	–	0.31	–	–	–
Female sex	0.35	–	–	–	0.35	–	–	–	0.47	–	–	–	0.19	–	–	–
Prior MI	0.41	–	–	–	0.61	–	–	–	0.85	–	–	–	0.21	–	–	–
Prior PCI	0.68	–	–	–	0.76	–	–	–	0.25	–	–	–	0.50	–	–	–
Smoking	0.95	–	–	–	0.31	–	–	–	0.26	–	–	–	0.67	–	–	–
Diabetes mellitus	0.84	–	–	–	0.89	–	–	–	0.78	–	–	–	0.96	–	–	–
Hypertension	0.88	–	–	–	0.30	–	–	–	0.59	–	–	–	0.69	–	–	–
Anemia	0.96	–	–	–	<0.001	0.15	–	–	<0.001	0.09	–	–	0.02	0.17	–	–
Chronic renal insufficiency	0.82	–	–	–	<0.001	0.21	–	–	<0.001	0.24	–	–	0.099	0.89	–	–
Hypercholesterolemia	0.37	–	–	–	0.36	–	–	–	0.29	–	–	–	0.77	–	–	–
Lower LVEF	0.08	0.15	–	–	<0.001	0.003	4.25	1.63–11.08	<0.001	0.002	3.95	1.65–9.45	<0.001	0.001	0.31	0.16–0.61
Position of LMCA stenosis	0.73	–	–	–	0.25	–	–	–	0.07	0.16	–	–	0.81	–	–	–
Small stent size	0.01	0.97	–	–	0.21	–	–	–	0.30	–	–	–	0.01	0.01	5.95	1.43–24.80
Bare-metal stent	0.01	0.02	5.35	1.27–22.57	0.23	–	–	–	0.52	–	–	–	0.16	–	–	–

CABG = coronary artery bypass grafting; CI = confidence interval; HR = hazard ratio; LMCA = left main coronary artery; LVEF = left ventricular ejection fraction; MI = myocardial infarction; PCI = percutaneous coronary intervention; TVR = target vessel revascularization.

reported that lower LVEF, old age, shock, and EuroSCORE (European System for Cardiac Operative Risk Evaluation) were associated with cardiovascular mortality.[13] Tamburino et al have shown that lower LVEF, diabetes mellitus, and reference vessel diameter are predictive of cardiovascular mortality after stent implantation for unprotected LMCA disease.[8] The present study showed that only lower LVEF could predict cardiovascular mortality after coronary stenting for unprotected LMCA disease.

Predictors of total mortality

Price et al have reported that impaired renal function is the only predictor of total mortality.[10] Palmerini et al have shown that lower LVEF, acute coronary syndrome and peripheral vascular disease can predict total mortality after stent implantation for unprotected LMCA disease.[12] Tamburino et al have demonstrated that lower LVEF, diabetes mellitus, and EuroSCORE were predictors of total mortality.[8] The present study and our previous study have shown that lower LVEF but not impaired renal function could predict total mortality after stent implantation for unprotected LMCA disease.[6]

Predictors of composite TVR/total mortality

Valgimigli et al have revealed that reference vessel diameter is predictive of major adverse cardiovascular events (MACEs) after stent implantation for unprotected LMCA disease.[15] Price et al have reported that chronic renal insufficiency is an independent predictor of MACEs.[10] Furthermore, some studies have found that DES implantation could predict lower MACE rate in patients who are receiving unprotected LMCA stenting.[8,9,15] The present study showed that lower LVEF and small stent size, but not BMS implantation, could predict composite TVR/total mortality.

Limitations

First, the number of patients was small. Second, angiographic follow-up was only performed in patients with clinical presentation or non-invasive evaluation, which suggested the presence of myocardial ischemia, which led to possible underestimation of the restenosis rate of LMCA stenting. Third, patients were treated in a time frame in which evolution of devices (such as intravascular ultrasonography and DES) and operator experience might have had an impact on outcomes. Finally, because we did not routinely perform echocardiography or right heart catheterization in each patient, we could not provide EuroSCORE and Parsonnet score for the study populations. Also, SYNTAX score could not be provided because of the extended time period in this study when SYNTAX score was not available. Despite these limitations, long-term clinical outcomes following stent implantation for unprotected LMCA disease are still relatively acceptable.

In conclusion, the present study showed that young age and BMS implantation could predict repeated PCI and/or CABG in patients after stent implantation for unprotected LMCA disease. Only lower LVEF could predict both cardiovascular and total mortality. Lower LVEF and small stent size, but not BMS implantation, could predict composite TVR/total mortality.

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