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Multicenter International Registry of Unprotected Left Main Coronary Artery Percutaneous Coronary Intervention With Drug-Eluting Stents in Patients With Myocardial Infarction

Michael S. Lee,[1]* MD, Dario Sillano,[2] MD, Azeem Latib,[3] MD, Alaide Chieffo,[3] MD, Giuseppe Biondi Zoccai,[2] MD, Ravi Bhatia,[1] Imad Sheiban,[2] MD, Antonio Colombo,[3] MD, and Jonathan Tobis,[1] MD

Background: Patients who present with myocardial infarction (MI) and unprotected left main coronary artery (ULMCA) disease represent an extremely high-risk subset of patients. ULMCA percutaneous coronary intervention (PCI) with drug-eluting stents (DES) in MI patients has not been extensively studied. Methods: In this retrospective multicenter international registry, we evaluated the clinical outcomes of 62 consecutive patients with MI who underwent ULMCA PCI with DES (23 ST-elevation MI [STEMI] and 39 non-ST-elevation MI [NSTEMI]) from 2002 to 2006. Results: The mean age was 70 ± 12 years. Cardiogenic shock was present in 24%. The mean EuroSCORE was 10 ± 8. Angiographic success was achieved in all patients. Overall in-hospital major adverse cardiac event (MACE) rate was 10%, mortality was 8%, all due to cardiac deaths from cardiogenic shock, and one patient suffered a periprocedural MI. At 586 ± 431 days, 18 patients (29%) experienced MACE, 12 patients (19%) died (the mortality rate was 47% in patients with cardiogenic shock), and target vessel revascularization was performed in four patients, all of whom had distal bifurcation involvement (two patients underwent repeat PCI and two patients underwent bypass surgery). There was no additional MI. Two patients had probable stent thrombosis and one had possible stent thrombosis. Diabetes [hazard ratio (HR) 4.22, 95% confidence interval (CI) (1.07–17.36), $P = 0.04$), left ventricular ejection fraction [HR 0.94, 95% CI (0.90–0.98), $P = 0.005$), and intubation [HR 7.00, 95% CI (1.62–30.21), $P = 0.009$) were significantly associated with increased mortality. Conclusions: Patients with MI and ULMCA disease represent a very high-risk subgroup of patients who are critically ill. PCI with DES appears to be technically feasible, associated with acceptable long-term outcomes, and a reasonable alternative to surgical revascularization for MI patients with ULMCA disease. Randomized trials are needed to determine the ideal revascularization strategy for these patients.

Key words: drug-eluting stents; left main coronary artery; myocardial infarction

[1]Department of Medicine/Cardiology, University of California, Los Angeles Medical Center, Los Angeles, California
[2]Department of Medicine/Cardiology, San Giovanni Battista Hospital, Turin, Italy
[3]Department of Medicine/Cardiology, San Raffaele Hospital, Milan, Italy

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*Correspondence to: Dr. Michael S. Lee, UCLA Medical Center, Adult Cardiac Catheterization Laboratory, 10833 Le Conte Avenue, Rm BL-394 CHS, Los Angeles, CA 90095-171715.
E-mail: mslee@mednet.ucla.edu

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INTRODUCTION

The standard of care for patients with unprotected left main coronary artery (ULMCA) disease is coronary artery bypass surgery [1]. Patients who present with myocardial infarction (MI) and have ULMCA disease represent a very high-risk group of patients who are critically ill with prohibitive operative risk because it may be associated with cardiogenic shock, malignant ventricular arrhythmias, and sudden death. Although elective PCI with DES in patients with ULMCA disease was safe and associated with improved clinical outcomes compared with bare metal stents, patients with MI were excluded from most studies [2,3].

Randomized trials of DES in MI have either excluded patients with ULMCA disease [4,5] or provided very little [6] or no data in patients with ULMCA [7]. There is limited data on ULMCA PCI with DES in MI patients. In this study, we report a multicenter international experience with ULMCA PCI with DES in patients with MI.

METHODS

Patients

Data were collected and analyzed on 62 consecutive patients with MI who underwent ULMCA PCI with DES from October 2002 to December 2006 at UCLA Medical Center, in Los Angeles, California, San Raffaele Hospital in Milan, Italy, and San Giovanni Battista Hospital in Turin, Italy. A total of 50 patients underwent PCI with sirolimus-eluting stents (Cypher, Cordis, Miami Lakes, FL) and 12 patients with paclitaxel-eluting stents (Taxus, Boston Scientific, Minneapolis, MN).

Percutaneous Coronary Intervention

Description of the technique for ULMCA PCI has been previously reported [3,8,9]. All patients in our study who presented to the emergency room and were diagnosed with MI were directly referred for cardiac catheterization. Patients subsequently underwent emergent PCI if the ULMCA was the infarct-related artery or if they had cardiogenic shock.

PCI was performed rather than bypass surgery because the interventional cardiologist deemed it necessary to perform emergent PCI because the patient presented in extremis, patients were refused by cardiac surgeons, or patients refused bypass surgery. The type of stent, and the use of intra-aortic balloon counterpulsation, intravascular ultrasound (Boston Scientific), and choice of anticoagulation regimen was left to the discretion of the operator. Patients were treated with aspirin and clopidogrel for at least one year. Cardiac enzymes (creatine kinase and CK-MB) were routinely drawn post-PCI.

Endpoint Definitions

Angiographic success was defined as the combination of a post-PCI stenosis $\leq$20% and thrombolysis in myocardial infarction (TIMI) grade 3 flow. The primary endpoint was major adverse cardiac events (MACE) as defined by death, myocardial infarction (MI), and target vessel revascularization during the entire follow up. ST-elevation MI (STEMI) was defined as chest pain persisting $>$30 minutes associated with ST-elevation $>$1 mm in $\geq$2 consecutive leads on the electrocardiogram. Non-STEMI (NSTEMI) was defined as ischemic symptoms and an increase in either creatine kinase, with the isoenzyme-MB that was three times the upper limit of normal or abnormal troponin levels. Target vessel revascularization was defined as revascularization to treat a luminal stenosis within the stent or within 5-mm distal and proximal segments adjacent to the stent, including the ostium of the left anterior descending artery and/or left circumflex artery. Binary restenosis was defined as stenosis $\geq$50%.

The left main coronary artery was considered unprotected if there were no patent coronary artery bypass graft to the left anterior descending or left circumflex arteries.

Patients were risk stratified by the European system for cardiac operative risk evaluation (EuroSCORE), with a score $\geq$6 identifying high-risk patients [10].

The Academic Research Consortium definition of stent thrombosis was used [11]. Definite/confirmed stent thrombosis is defined as acute coronary syndrome and angiographic confirmation of stent thrombus or occlusion or pathologic confirmation of acute stent thrombosis. Probable stent thrombosis is defined as any unexplained death within 30 days or as target vessel MI without angiographic confirmation of thrombosis or other identified culprit lesion. Possible stent thrombosis is defined as unexplained death after 30 days.

Follow Up

Patient data were retrospectively collected on a dedicated database. Surveillance angiography was recommended between 4 and 9 months or earlier if clinically indicated to detect early restenosis. Follow-up data were obtained from outpatient clinic visits or telephone conversation with referring physicians.

Statistical Analysis

Continuous variables were presented as mean values $\pm$ SD and were compared with Student t test. Categor-

TABLE I. Baseline Clinical Characteristics

Clinical presentation	
STEMI (%)	37
NSTEMI (%)	63
Age (years ± SD)	70 ± 12
Male (%)	86
Hypertension (%)	82
Hypercholesterolemia (%)	66
Diabetes mellitus (%)	28
Chronic renal insufficiency (Cr ≥ 1.5 mg/dl) (%)	16
Smoking (%)	32
Ejection fraction (%)	46 ± 15
Ejection fraction >40% (%)	65
Previous PCI	16
Previous MI	65
Mean Euroscore (%)	10 ± 8
Euroscore ≥ 6 (%)	58
Cardiogenic shock (%)	24
Peak CK (U/l)	1,280 ± 1,714

CK, creatine kinase; Cr, creatinine; MI, myocardial infarction; NSTEMI, non-ST-elevation myocardial infarction; PCI, percutaneous coronary intervention; STEMI, ST-elevation myocardial infarction.

ical variables were presented as frequency (%) and were compared with Fisher exact test. Survival curves were generated by the Kaplan-Meier method. Multivariable Cox proportional hazards models were created with the use of baseline clinical and angiographic characteristics and procedure-related variables to identify independent predictors of mortality. Statistical analysis was performed with SAS, version 9.1 (SAS Institute, Cary, NC).

The data was available to all authors who take full responsibility for the integrity of the data. The manuscript has been read and approved by all the authors.

RESULTS

Baseline Clinical Data

Baseline demographic data are presented in Table I. Sixty-two patients underwent PCI for MI (STEMI, $n = 23$ and NSTEMI, $n = 39$) at our centers. The mean age of patients was 70 ± 12 years with the majority of patients being male (86%). The overall proportion of patients with diabetes mellitus was 28% and chronic renal insufficiency (creatinine ≥ 1.5 mg/dL) was 16%. Previous MI occurred in 65%. The mean ejection fraction was 46 ± 15%, and 65% had ejection fraction >40%. The mean EuroSCORE was 10 ± 8, and 58% of patients had EuroSCORE ≥ 6. Cardiogenic shock was present in 15 patients (24%). The mean peak creatine kinase level was 1,280 ± 1,714 U/l.

Angiographic and Procedural Data

The angiographic and procedural data are presented in Table II. The LMCA was the infarct-related artery in 33%. When the LMCA was the infarct-related artery, 80% had thrombolysis in myocardial infarction (TIMI) grade 3 flow, 5% had TIMI grade 2 flow, 10% had TIMI grade 1 flow, and 5% had TIMI grade 0 flow. Distal bifurcation disease was present in 71% and there was significant calcification of the ULMCA in 21%. The majority of PCI were performed with sirolimus-eluting stents (81%). A mean of 1.6 ± 0.8 stents per patient were used, and the mean total stent length was 27 ± 16 mm. The right coronary artery was significantly diseased in 44% of patients and treated in 29%. The right coronary artery was treated if the patient was hemodynamically unstable and it was felt that revascularization of the right coronary artery would improve hemodynamics. Glycoprotein IIb/IIIa antagonists were used in 35%, and intra-aortic balloon pump was used in 24%.

TABLE II. Angiographic and Procedural Characteristics

LMCA as infarct-related artery (%)	33
Location of LMCA disease	
Ostial/Body (%)	29
Distal (%)	71
Calcification of LM (%)	21
Type of DES	
Cypher stent (%)	86
Taxus stent (%)	14
No. of implanted stents/patient (mean ± SD)	1.6 ± 0.8
Total stent length (mm)	27 ± 16
Significant right coronary artery disease (%)	44
Treatment of right coronary artery (%)	29
Glycoprotein IIb/IIIa antagonist (%)	35
Intra-aortic balloon pump (%)	24
Intravascular ultrasound (%)	6

DES, drug-eluting stent; LMCA, left main coronary artery.

TABLE III. In-Hospital Outcomes

Angiographic success (%)	100
MACE (%)	10
Death (%)	8
MI (%)	2
Target vessel revascularization (%)	0

MACE, major adverse cardiac events; MI, myocardial infarction.

In-Hospital Outcomes

The in-hospital outcomes are presented in Table III. Angiographic success was achieved in 100%. The overall incidence of MACE was 10%. The mortality rate was 8%, all of which was due to cardiogenic shock. One patient suffered a periprocedural MI. There was no case of target vessel revascularization.

Long-Term Outcomes

At 586 ± 431 days, 18 patients (29%) experienced MACE. The 3-year cumulative survival rate was 82 ±

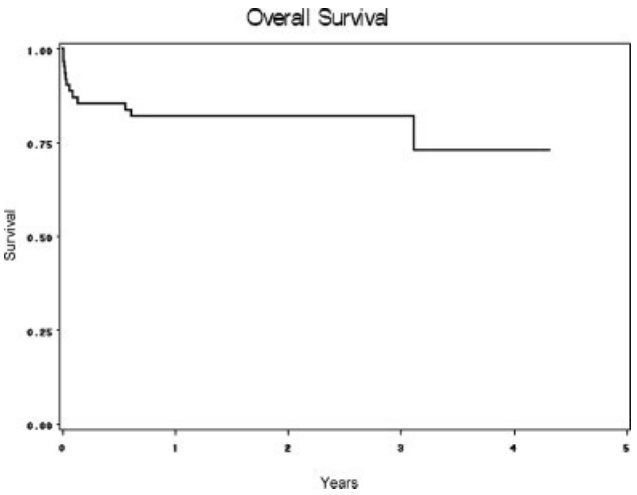

Fig. 1. Kaplan-Meier curves for survival proportion for all 62 patients with MI who underwent ULMCA PCI with DES.

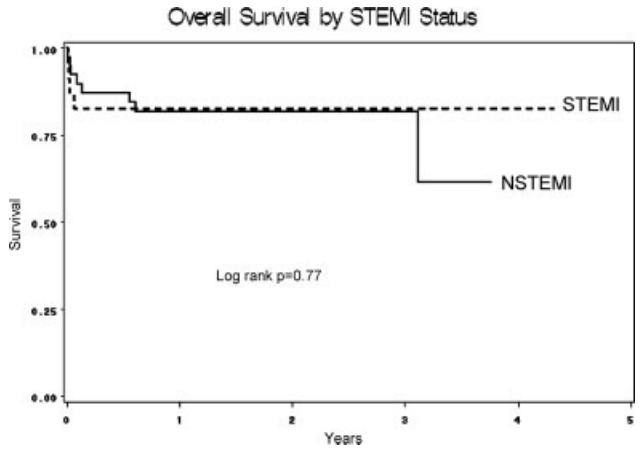

Fig. 2. Kaplan-Meier curves for survival proportion for STEMI and NSTEMI patients who underwent ULMCA PCI with DES.

5% (Fig. 1). There was no difference in mortality rate in STEMI and NSTEMI patients (log rank $P = 0.77$) (Fig. 2). Eleven of 12 patients (92%) who died were high-risk patients with EuroSCORE ≥ 6. There was no additional MI. Follow-up angiography was performed in 37 patients (60%). Binary restenosis of the ULCMA or side branches was detected in four patients, all of whom had distal bifurcation involvement, and subsequently underwent target vessel revascularization, (two underwent repeat PCI and two bypass surgery). Although there were no cases of definite stent thrombosis, two patients had probable stent thrombosis (sudden death within 30 days) and one had possible stent thrombosis.

Correlates for Survival

The following variables were entered into a stepwise multivariable Cox proportional hazard model for 30-day survival: age, sex, prior MI, hypertension, diabetes, renal failure, smoking, STEMI, prior PCI, left ventricular ejection fraction, use of glycoprotein IIb/IIIa antagonists, EuroSCORE, intubation, and cardiogenic shock (Table IV). Diabetes [hazard ratio (HR) 4.22, 95% confidence interval (CI) (1.07–17.36), $P = 0.04$), left ventricular ejection fraction [HR 0.94, 95% CI (0.90–0.98), $P = 0.005$), and intubation [HR 7.00, 95% CI (1.62–30.21), $P = 0.009$) were significantly associated with increased mortality.

TABLE 4. Cox Proportional Hazard Model Results

Variables	*P* value	Hazard ratio (95% CI)
Multivariable analysis		
Diabetes	0.04	4.31 (1.07−17.36)
Left ventricular ejection fraction	0.005	0.94 (0.900.98)
Intubation	0.009	6.99 (1.62−30.21)

DISCUSSION

The principal findings of this multicenter, international registry of PCI with DES for ULMCA disease is that similar to previous studies, ULMCA PCI with DES in MI patients is technically feasible and is associated with a high angiographic success rate and acceptable rate of MACE, including clinical target vessel revascularization and mortality. Diabetes, left ventricular ejection fraction, and intubation were significantly associated with increased mortality.

The American College of Cardiology/American Heart Association guidelines indicate that PCI is a class IA indication for the management of STEMI and NSTEMI [12,13]. Bypass surgery is also as a class IA indication if there is suitable coronary anatomy. The angiographic success rate was 100% in our study, which is consistent with other studies of ULMCA PCI with DES. Similar to previous studies of elective ULMCA PCI with DES which showed promising results [2,3,9], especially in nonbifurcation lesions [14], our patients who had nonbifurcation lesions had no restenosis and did not require target lesion revascularization. Although distal bifurcation disease is associated with increased clinical events, PCI is still a reasonable initial strategy in the setting of MI especially in patients who are hemodynamically unstable.

Occlusion of the ULMCA can lead to devastating consequences such as sudden death and cardiogenic shock. Previous studies of ULMCA PCI in the pre-DES era has shown that patients who presented with acute MI had poor results [15,16]. Chauhan et al. [17] reported an 83% in-hospital mortality rate in MI patients who underwent ULMCA PCI. The ULTIMA registry reported an in-hospital mortality rate of 55,

18% in-hospital bypass surgery rate, and a 12-month mortality rate of 43% in 40 MI patients (92% had cardiogenic shock) who underwent PCI with either primary angioplasty (57%) or primary stenting (43%) for ULCMA disease [18]. Quigley et al. [19] reported that eight of nine MI patients with severe ULMCA disease complicated by cardiogenic shock who underwent PCI or CABG died. De Luca et al. [20] reported an angiographic success rate of 67% and in-hospital mortality rate of 58% in the total population and 80% in patients with cardiogenic shock in 24 MI patients who underwent ULCMA PCI (stents were used in 58%). Lee et al. [21] reported an in-hospital mortality rate of 44% and probability of freedom from death at 3-year was 56% ± 12% in 18 patients who underwent ULMCA stenting for MI. The one-year mortality rate was 70% in patients with left main coronary disease that underwent PCI predominantly with balloon angioplasty in the SHOCK trial [22]. Although we report a lower mortality rate, it is difficult to make meaningful comparisons with other studies because of the small number of patients and different revascularization techniques from different eras.

Bypass surgery has been considered the gold standard for ULMCA disease based upon several studies conducted 2 decades ago demonstrating improved survival and registries that reported poor outcomes after balloon angioplasty [1,23,24]. The data on surgical treatment for MI patients with ULMCA disease is sparse. The in-hospital mortality rate for 13 patients with MI and ULMCA disease who underwent emergency bypass surgery was 46 and 53% for patients with cardiogenic shock [25]. Another study reported a 46% in-hospital mortality rate for patients who underwent bypass surgery for ULMCA MI [26]. An advantage of ULMCA PCI is that it can performed immediately to promptly restore coronary blood flow and improve hemodynamics much more expeditiously than bypass surgery and therefore may be the preferred treatment in MI patients with ULMCA disease. The delay with bypass surgery is confirmed by the SHOCK trial which reported a shorter median time from randomization to PCI compared with randomization to bypass surgery [22]. A disadvantage of ULMCA PCI in MI is potential distal embolization of thrombus into both the left anterior descending and left circumflex arteries especially if there is a large thrombus burden possibly leading to hemodynamic collapse. Bypass surgery may be preferred in this scenario especially if there is TIMI 3 flow and the patient is hemodynamically stable.

Distal bifurcation disease in the ULCMA appears to be associated with increased risk for adverse events [27]. Price et al. [28] reported a target lesion revascularization of 38% in 50 patients, of whom 94% had distal bifurcation disease. In our study, target vessel revascularization occurred in four patients, all of whom had distal bifurcation involvement, but restenosis did not occur in any of the 18 patients who did not have distal bifurcation involvement. Probable/possible stent thrombosis occurred in three patients. The stent thrombosis rate in previous DES STEMI trials was 1% to 3.4% [4,6]. In the PREMIER registry, 13.6% of patients who underwent PCI with DES for MI stopped thienopyridine therapy within 30 days of discharge, and the mortality rate at one year was 7.5% in these patients [29].

In the DES-era, urgent/emergent PCI has increased from 16.0 to 19.7% from 2002 to 2004 in the United States ($P < 0.0001$) [30]. PCI for acute coronary syndrome/cardiogenic shock also increased from 22.9 to 28.7% from 2002 to 2004, while CABG decreased from 77.1 to 71.3% in the same time period ($P < 0.0001$). This may reflect the increasing amount of data on urgent/emergent ULCMA PCI, increased operator experience and comfort level, hemodynamic support with intra-aortic balloon pump and ventricular assist devices, and improved techniques and pharmacotherapy.

The use of glycoprotein IIb/IIIa antagonists was only 35% in this registry. In STEMI and NSTEMI, glycoprotein IIb/IIIa antagonists have been shown to improve clinical outcomes although the ADMIRAL trial did not include patients who underwent PCI with ULCMA, and the PURSUIT trial did not report PCI of the ULMCA [31,32]. In the Platelet Glycoprotein IIb/IIIa in Unstable Angina: receptor suppression using integrilin therapy (PURSUIT) Trial, patients with non-ST-segment elevation acute coronary syndromes who developed cardiogenic shock had a lower 30-day mortality than those treated with placebo (adjusted odds ratio, 0.51; 95% CI, 0.28 to 0.94) [33]. Increased usage of glycoprotein IIb/IIIa antagonists may have decreased mortality in our patients undergoing ULMCA PCI with DES.

Limitations

This was a retrospective nonrandomized study with a relatively small sample size and a relatively short-term follow up. Comparison with surgical revascularization was not performed for this patient subgroup. Follow-up angiography was not performed in all patients. Therefore, the true restenosis rate is unknown. Intra-aortic balloon pumps were only used in 24% of cases. Increased use may have improved survival. Intravascular ultrasound was only used in 6%, which is lower than previous studies of ULMCA PCI with DES [2,8,27,28]. Although it would be ideal to use intravas-

cular ultrasound in all cases to ensure full stent expansion and apposition, this may not be feasible in all patients, especially in those who are hemodynamically unstable and in cardiogenic shock. Despite this, our study of consecutive unselected patients from three experienced centers provides insight into the use of DES in this high-risk group of patients.

CONCLUSION

Patients with MI and ULMCA disease represent a very high-risk subgroup of patients who are critically ill. PCI with DES appears to be technically feasible and a reasonable alternative to surgical revascularization for MI patients with ULMCA disease. The mortality rate was acceptable and compares favorably with historical surgical data in patients with ULMCA disease and MI. The ideal revascularization strategy for patients with myocardial infarction and ULMCA disease is unknown. Without data of randomized controlled trials, the decision to perform bypass surgery or PCI in MI patients with ULMCA disease may be difficult. The decision needs to be individualized taking into consideration all relevant factors including discussion with cardiologists, cardiac surgeons, and patients and family if possible. Ultimately, randomized, controlled trials are needed to further elucidate the optimal treatment strategy.

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