Drug-Eluting Stent for Unprotected Left Main Coronary Artery Disease: Early and Mid-Term Outcomes

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Background: *PCI is increasingly performed in patients with ULMCA disease. The efficacy and safety of drug-eluting stents in ULMCA disease have been reported.*
Objective: *To evaluate the early and mid-term clinical outcome of the Percutaneous Coronary Intervention (PCI) with Drug-Eluting stent (DES) in unprotected left main coronary artery (ULMCA) disease patients.*
Material and Method: *PCI with DES was performed with 90 consecutive patients having ULMCA disease between January 2006 and June 2009.*
Results: *At a median follow-up of 22.8 $\pm$ 12.2 months, major adverse cardiac or cerebrovascular events (MACCE) occurred in 11 (12.2%) patients. There were seven (7.8%) deaths including two (2.2%) cardiac deaths and five (5.6%) non-cardiac deaths. There was one MI (1.1%), and four (4.4%) target vessel revascularization. Restenosis in the left main occurred only in two patients (2.2%) and definite stent thrombosis occurred in two patients (2.2%).*
Conclusion: *The present study demonstrates that PCI with Drug-Eluting stent implantation in unprotected left main coronary artery disease is a safe form of treatment and has favorable outcomes.*

Keywords: *Left main, Drug Eluting stent*

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Significant unprotected left main coronary artery (ULMCA) disease occurred in 5% to 10% of patients who underwent coronary angiography[1]. This represents a high-risk of coronary artery disease because it can jeopardize the integrity of the entire myocardium of the left ventricle. Previous studies showed that coronary artery bypass graft surgery (CABG) significantly improved long-term survival compared with medical therapy[2-4]. Several trials comparing PCI with CABG, where bare-metal stents were used, in patients with multivessel disease, showed similar survival rates, but higher revascularization rates among patients with the bare-metal stent[5-7]. However, recent improvements in PCI techniques and DES had reduced the risk of in-stent restenosis and several studies have demonstrated the safety and feasibility of ULMCA intervention using DES[8-14]. The non-randomized MAIN-COMPARE trial involving 2,240 patients with ULMCA disease compared outcomes between PCI and CABG, showed no significant differences in composite end points, being freedom from death, myocardial infarction, or stroke (DES 88.5% vs. CABG 92.0%, p = 0.16)[13]. The purpose of this retrospective study was to assess the safety and efficacy outcomes of DES implantation in patients with ULMCA disease.

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Material and Method

Ninety consecutive patients with significant stenosis (> 50% diameter stenosis) of ULMCA disease were treated between January 2006 and June 2009 in Sappasitthiprasong Hospital with implantation of a DES for ULMCA disease on *de novo* lesions and details were recorded and analyzed.

The decision to perform PCI instead of surgery (CABG) was considered when one of two conditions was present: (1) suitable anatomy for stenting and high risk for surgery because of the presence of co-morbidity or (2) suitable anatomy for stenting and preference by the patient for a percutaneous approach. Subjects with protected left main vessel disease, defined as the presence of at least one patent arterial or venous graft to the left coronary artery, were excluded. Written informed consent was obtained by all patients. Coronary intervention and DES implantation was performed according to the practice of fully covering the diseased segment[15].

The choice of devices, techniques, and drug therapy (including glycoprotein IIb/IIIa inhibitors) was left entirely to the discretion of the operator. Angiographic success was defined as residual stenosis < 30% and Thrombolysis In Myocardial Infarction flow grade 3. All patients were advised to continue lifelong aspirin medication and 75 mg clopidogrel for 6-12 months, or more. Angiographic follow-up was recommended, irrespective of symptoms or signs of ischemia 6 months after PCI.

End point definitions and clinical follow-up

The primary end point was the occurrence of major adverse cardiac and cerebrovascular (MACCE) events, defined as (1) all causes of death, (2) myocardial infarction (MI), (3) target vessel revascularization (TVR) and (4) cerebrovascular event (stroke).

Death was considered either cardiac or non-cardiac. A death that could not be classified was considered cardiac. Periprocedural myocardial infarction was defined as the elevation of creatine kinase MB (CKMB) or troponin to a level three times more than the upper normal limit. Spontaneous myocardial infarction was defined as the elevation of creatine kinase MB (CKMB) or troponin more than the upper normal limit. Target vessel revascularization was defined as a repeated intervention (surgical or percutaneous) to treat a luminal stenosis within the stent or in the 5 mm distal or proximal segments adjacent to the stent, including the ostium of the left anterior descending artery (LAD) and/or circumflex artery (LCX) (in a case of stenting at the bifurcation). Procedural success is defined as revascularization with less than 30% residual stenosis by angiography after procedure and the patients being released from the hospital without any of the following events: death, MI or CABG.

The incidence of stent thrombosis was evaluated in accordance with the Academic Research Consortium Definitions of Stent Thrombosis[16].

Statistical analysis

The frequencies and percentages of the categorical data are presented. The continuous variables are reported as a mean $\pm$ standard deviation and categorical variables are described with frequencies and percentages.

Results

Baseline and procedural characteristics

Baseline clinical characteristics of the present study population are shown in Table 1, lesion characteristics are shown in Table 2 and procedural characteristics are shown in Table 3.

Between January 2006 and June 2009, 90 patients with ULMCA disease were treated in Sappasitthiprasong Hospital with PCI and DES. The mean age of patients was 65.3 $\pm$ 9.9 years and 76% were male. Thirty-eight patients (42.2%) had diabetes and 19 patients (21.1%) had renal insufficiency. Twenty-two patients (24.4%) presented with acute myocardial infarction and 20 patients (22.2%) had ST elevation MI. The mean left ventricular ejection fraction

Table 1. Clinical characteristics of study population (n = 90 patients)

Age, years	65.26 $\pm$ 9.96
Male, n (%)	69 (76.7)
Cardiovascular risk factors	
Hypertension, n (%)	48 (53.3)
Diabetes mellitus, n (%)	38 (42.2)
Hypercholesterolemia, n (%)	66 (73.3)
Smoking, n (%)	38 (42.2)
Renal insufficiency (Cr $\geq$ 1.5), n (%)	19 (21.1)
PVD, n (%)	3 (3.3)
Mean LVEF (%)	50.17 $\pm$ 19.06
LVEF $\leq$ 40% (%)	22 (24.4)
Cardiogenic shock, n (%)	9 (10)
Stable angina, n (%)	59 (65.6)
Unstable angina, n (%)	9 (10)
NSTEMI, n (%)	2 (2.2)
STEMI, n (%)	20 (22.2)

Table 2. Lesion characteristics of study population (n = 90 patients)

Lesion location of LM	n (%)
Ostium	16 (17.8)
Body	2 (2.2)
Ostium and body	3 (3.3)
Distal	69 (76.7)
Number of vessel disease	
Only LM disease	3 (3.3)
LM plus 1-vessel disease	11 (12.2)
LM plus 2-vessel disease	34 (37.8)
LM plus 3-vessel disease	42 (46.7)
RCA disease	60 (66.7)
RCA concomitant treatment	46 (51.1)
Stent diameter, mm	3.63 ± 0.37
Total stent length for vessel, mm	20.33 ± 6.46
SYNTAX score	
0-22	29 (32.2)
23-32	51 (56.7)
≥ 33	10 (11.1)

Table 3. Procedural characteristics of study population (n = 90 patients)

Procedural characteristics	n (%)
Bifurcation stenting	69 (76.7)
Bifurcation technique	
Provisional T	44 (63.8)
Crush	22 (31.9)
Culotte	3 (4.3)
Kissing Balloon	46 (51.1)
Cutting Balloon	0
Rotational Atherectomy	8 (8.9)
IVUS	18 (20.0)
IIb/IIIa inhibitor	16 (17.8)
IABP	10 (11.1)

IVUS = intravascular ultrasonography
IABP = intra aortic balloon pump

was 50.17 ± 19.06% and nine patients (10%) had cardiogenic shock. The majority of lesions were located at distal LM, 69 patients (76.7%). The stenosis was located at the ostium in 16 patients (17.8%), in the body of LMCA in two patients (2.2%), and at both the ostium and the body of LMCA in three patients (3.3%).

Fourty two patients (46.7%) had LM plus three vessel disease and 34 patients (37.8%) had LM plus two vessel disease. Sixty patients (66.7%) were found to have right coronary artery disease and 46 (51.1%) of them had concomitant right coronary artery disease treatment. The majority of patients, 51 (56.7%), had an intermediate SYNTAX score. One-third of the patients had a low syntax score and only 10 patients (11.1%) had a high SYNTAX score.

Of the patients treated with drug-eluting stents, 36 (40%) received Sirolimus-eluting stent, 42 (46.7%) received Paclitaxel-eluting stent, seven (7.8%) received Everolimus-eluting stent, three (3.3%) received Rapamycin-eluting stent, and two (2.2%) received Zotarolimus-eluting stent. The mean (± SD) stent diameter was 3.63 ± 0.37 mm and the mean total length of the stent was 20.33 ± 6.46 mm.

Rotation atherectomy was used for lesion preparation in eight patients (8.9%). An Intra aortic balloon pump was used in 10 patients (11.1%). Sixteen patients (17.8%) were administered with glycoprotein IIb/IIIa inhibitors. Intravascular Ultrasound (IVUS) guidance was used in 18 patients (20%)

In-hospital and intermediate-term MACCE

In-hospital MACCE did not occur in the present study and intermediate-term clinical outcomes are illustrated in Tables 4 and 5.

Procedural success rate was 100%. The median follow-up was 22.8 ± 12.2 months. Complete follow-ups for major clinical events were obtained in 98.9% of the overall cohort. During the follow-up period, seven patients (7.8%) died, of whom two (2.2%) died of a cardiac cause and five (5.6%) died of a non-cardiac cause. One patient (1.1%) had myocardial infarction. No patients had a stroke. Target-vessel revascularization by repeating PCI was performed in

Table 4. MACCE at mid-term clinical follow-up

MACCE	n (%)
Total death	7 (7.8)
Cardiac death	2 (2.2)
Non cardiac death	5 (5.6)
MI	1 (1.1)
Stroke	0
TVR	4 (4.4)
Total MACCE	11 (12.2)
Stent thrombosis	2 (2.2)

Note: 1 patient had 2 MACCEs (MI and TVR)
No MACCE occurred in hospital
MI = Myocardial infarction
TVR = Target vessel revascularization

Table 5. Characteristics of MACCE (n = 11 patients)

LM	Clinical	Lesion location	SYNTAX score	LVEF	Stent type	Technique	MACCE	Time of MACCE
LM 1	NSTEMI	Distal	35	36	Cypher	Provisional T	Cardiac death (CHF)	7 months
LM 2	Stable angina	Ostium	13	49	Cypher	Provisional T	Cardiac death (CHF)	1 month
LM 3	Stable angina	Ostium	11	42	Taxus	Provisional T	Non-cardiac death (ARF with hyper K)	17 months
LM 4	Stable angina	Distal	34	31	Cypher	Provisional T	Non-cardiac death (sepsis)	10 months
LM 5	Stable angina	Distal	21	45	Cypher	Provisional T	Non-cardiac death (Leptospirosis with ARF)	14 months
LM 6	Unstable angina	Distal	31	14	Cypher	Crush	Non-cardiac death (sepsis)	10 months
LM 7	Stable angina	Distal	32	36	Cypher	Provisional T	Non-cardiac death (sepsis)	21 months
LM 8	Stable angina	Distal	27	67	Taxus	Provisional T	In-stent restenosis	6 months
LM 9	Stable angina	Ostium	19	30	Endeavor	Provisional T	In-stent restenosis	6 months
LM 10	STEMI	Distal	37	30	Taxus	Culotte	TVR (late stent thrombosis)	6 months
LM 11	NSTEMI	Distal	27	30	Taxus	Provisional T	MI and TVR (very late stent thrombosis)	14 months

four patients (4.4%) and one of them had myocardial infarction. In two of the four patients, the intervention was performed because of the occurrence of definite stent thrombosis. The other two patients (2.2%) had in-stent restenosis.

Discussion

This present study demonstrates that PCI with DES in ULMCA cases that were relatively unselected is safe and effective. The MACCE rate at 22.8 $\pm$ 12.2 months was 12.2% (11 patients) and the restenosis rate was 2.2% (2 patients).

The American College of Cardiology/ American Heart Association (ACC/AHA/SCAI) 2005 guidelines have recommended against UPLM percutaneous revascularization as an optional therapy in individuals eligible for CABG (class III) and support the indication with a still uncertain benefit (class IIb) only in circumstance of excessive surgical risk[17]. More recently, following advances in technique, and the reduction in restenosis rates provided by drug-eluting stents (DES), there has been many observational and non-randomized comparative trials of DES in ULMCA revascularization and bypass surgery[13,18]. These studies have reported similar rates of combined safety outcomes including death, myocardial infarction and stroke, in line with contemporary randomized studies[12,18].

In the present study, 85% of patients had multivessel disease, half of them had RCA concomitant treatment, a little over 3/4 (76.7%) had a distally localized lesion, and 1/3 of them underwent double stent implantation with "crush" (31.9%) and "culotte" (4.3%) technique. MACCE occurred in eight patients (8.9%) in the left main distal lesion group and in three patients (3.3%) in the non-distal left main group. The SYNTAX score was used in the present study. The SYNTAX score was designed to predict outcomes related to anatomical lesion complexity[19]. The authors found that the rate of MACCE was highest in the high SYNTAX score group, which was similar in the SYNTAX trial. MACCE occurred 13.8% (4 from 29 patients) with a low SYNTAX score (0-22), 7.8% (4 from 51 patients) with an intermediate SYNTAX score (23-32) and 30% (3 from 10 patients) with a high SYNTAX score (> 33).

Stent thrombosis is a possible lethal complication of DES that concerns patients who will undergo this procedure. The necessity for compliance with dual antiplatelet medication in DES-treated patients is indicated by increased rates of stent thrombosis occurring in the cases of premature drug withdrawal[20]. Several recent studies showed the occurrence of stent thrombosis rates of 0.5-2.7%. The 3-year rate of definite/probable stent thrombosis was 1.7% in The DELFT (Drug Eluting Stent for LeFT

main)[21]. The 2-year occurrence of definite stent thrombosis was 0.5% in the ISAR-LEFT MAIN trial (n = 607)[23] and the 1-year rate of stent thrombosis was 2.7% in the SYNTAX trial[12].

In the present study, there were two cases of definite stent thrombosis. In the first case, the patient presented with STEMI, with total thrombotic occlusion at distal LM and PCI was performed with Culotte technique. This patient developed late total thrombotic occlusion at distal LM 6 months after procedure. In the second case, the patient presented with NSTEMI with total thrombotic occlusion at distal LM, PCI was performed with two stents by provisional-T technique, and very late total thrombotic occlusion occurred at 14 months after procedure because he stopped both ASA and clopidrogrel one month before the event.

IVUS was used 20% for proper evaluation of both the distribution and severity of disease in this study. The impact of IVUS on clinical outcomes appeared to be beneficial when applied to the left main group[23,24]. However, IVUS study reporting has been inconsistent, with some studies reporting favorable outcomes despite only negligible use of IVUS[25].

The limitations of the present study: Firstly, this was an observational study with a small number of patients. Secondly, MACCE occurred highest in the high SYNTAX score group but only a few patients were in this group when compared with other groups. Thirdly, the authors could not compare the MACCE between the use of one stent and two stents for the distal left main group because the authors usually used two stents for very complex true bifurcation and the authors could not compare between non-distal left main and distal LM because of the difference between the two groups *i.e.* only 21 patients (23%) for non-distal LM group and 69 patients (76.7%) for distal LM group.

In conclusion, the present study demonstrates that PCI with Drug-Eluting stent implantation in unprotected left main coronary artery disease is a safe form of treatment with acceptable, low rates of early and mid-term major adverse cardiac or cerebrovascular events and restenosis.

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การใช้ขดลวดค้ำยันชนิดเคลือบยาในภาวะหลอดเลือดหัวใจเส้นหลักด้านซ้ายตีบตันในระยะแรกและระยะกลางของการรักษา

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ภูมิหลัง: วิธีการรักษาผู้ป่วยในกลุ่มโรคหลอดเลือดหัวใจเส้นหลักด้านซ้ายตีบตัน (ULMCA disease) ด้วย PCI เพิ่มจำนวนขึ้น ซึ่งรายงานนี้เป็นการศึกษาเพื่อการประเมินประสิทธิภาพ และความปลอดภัยในการใช้ขดลวดที่เคลือบยาต้านการตีบซ้ำในการรักษาผู้ป่วย ULMCA disease

วัตถุประสงค์: เพื่อประเมินประสิทธิภาพการรักษาผู้ป่วยในกลุ่มโรคหลอดเลือดหัวใจเส้นหลักด้านซ้ายตีบตัน (Unprotected left main coronary artery, ULMCA disease) ในระยะแรก และระยะกลางของการรักษาด้วยการขยายหลอดเลือดหัวใจด้วยบอลลูน และใส่ขดลวดค้ำยันชนิดเคลือบยาต้านการตีบซ้ำ (Percutaneous Coronary Intervention, PCI with Drug-Eluting stent, DES)

วัสดุและวิธีการ: ติดตามผลการรักษาด้วย PCI ร่วมกับ DES ในกลุ่มผู้ป่วย ULMCA disease จำนวน 90 ราย อย่างต่อเนื่อง ในระหว่างเดือน มกราคม พ.ศ. 2549 ถึงเดือนมิถุนายน พ.ศ. 2552

ผลการศึกษา: จากการติดตามผู้ป่วยภายหลังการรักษาด้วย PCI ร่วมกับ DES เป็นเวลา 22.8 $\pm$ 12.2 เดือน พบว่าผู้ป่วยมี major adverse cardiac or cerebrovascular events (MACCE) จำนวน 11 ราย (12.2%) มีผู้ป่วยที่เสียชีวิต 7 ราย (7.8%) cardiac deaths 2 ราย (2.2%) non cardiac deaths จำนวน 5 ราย (5.6%) MI 1 ราย (1.1%) target vessel revascularization 4 ราย (4.4%) ผู้ป่วยมีการตีบซ้ำในขดลวดเพียง 2 ราย (2.2%) และเกิด definite stent thrombosis 2 ราย (2.2%)

สรุป: จากการศึกษาแสดงให้เห็นว่าการรักษาด้วยวิธี PCI ร่วมกับ DES ในผู้ป่วย ULMCA disease มีความปลอดภัยและให้ผลการรักษาเป็นที่น่าพอใจ