In-Hospital and Mid-Term Outcomes of Stent Implantation in Patients with Protected and Unprotected Left Main Coronary Artery Disease; King Chulalongkorn Memorial Hospital Experiences

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Background: *Left Main Coronary Artery (LMCA) disease is now uniformly treated with coronary artery by pass grafting (CABG). However, some patients with LMCA disease did not receive CABG because of high operative risks as well as those who refused CABG. Recent studies demonstrated the feasibility of stenting for LM stenosis, although data remain limited.*

Objective: *To evaluate in-hospital and mid-term outcomes of using bare metal stent (BMS) and drug eluting stent (DES) in protected and unprotected left main coronary artery disease at King Chulalongkorn Memorial Hospital.*

Material and Method: *Retrospective, single-center study. The authors reviewed the outcomes of patients who underwent percutaneous coronary intervention on left main coronary artery lesions in our hospital from July 2000 to August 2007. In-hospital data and clinical follow-up outcomes were analyzed and determined as in-hospital and mid-term mortality, major adverse cardiac event (MACE).*

Results: *In eight years the authors reviewed 64 consecutive protected and unprotected LMCA patients who underwent PCI with stent placement. Altogether left main coronary artery stents were successfully deployed in all patients. DES usage was 64%. Bifurcation technique for distal left main coronary artery was executed in 32 patients (50%), included single stent in 62 (97%), two stents in 2(3%). Final kissing ballon inflation was done in 14 (21.9%). In-hospital mortality was 4.7% (three patients), two patients died from cardiac origin. The total in-hospital major adverse cardiac event (MACE) was 4.7%. Clinical follow-up of 6 months was completed in 100% of patients. Fifty percent of patients had angiographic follow-up and in-stent restenosis rate was 9.7%. No further death was noted and MACE at 6 months was 9.4%. Moreover, overall mean and median follow-up period were 31 $\pm$ 25 months (range, 6-93 months) and 26 months respectively.*

Conclusion: *Stent Implantation was technically feasible and safely applied for the treatment of protected and unprotected left main coronary artery lesions in patients, with acceptable in-hospital and mid-term outcomes. More randomized and controlled clinical trials are needed to confirm the long-term effects of stents for LMCA disease.*

Keywords: *Coronary artery disease, Coronary stenosis, Drug-eluting stents, Prostheses and implants, Prosthesis implantation, Stents*

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The prevalence of significant involvement of the left main segment in patients with atherosclerotic coronary artery disease varies from 2.5 to 10%[1]. Coronary artery bypass grafting (CABG) has been considered the standard treatment for significant left main coronary disease (LMCA) since the late 1970's[2-4]. However, some patients with LMCA disease do not receive CABG because of high operative risks or refuse CABG. The use of Percutaneous Coronary Intervention (PCI) in the treatment of LMCA disease resulted in discouraging outcomes prior to stent era. But more recent advances in procedural techniques, devices, medication, patient selection and the operators' experience has improved outcomes, made PCI an attractive alternative to CABG[5-12]. The authors therefore analyzed in-hospital and mid-term outcomes in patients who underwent left main coronary artery stenting at King Chulalongkorn Memorial Hospital.

Material and Method

Study population

From July 2000 to August 2007, the authors reviewed outcomes of the patients who underwent percutaneous coronary intervention with stent implantation on protected and unprotected left main coronary artery lesions in our hospital. Eligible patients had angina pectoris with LMCA disease or documented myocardial ischemia and angiographic evidence of > 50% diameter stenosis of the LMCA that did not received CABG because of non-cardiac comorbidity which caused high operative risks, in an emergency situation, for life-saving or refused to go to CABG. The authors routinely used aspirin indefinitely and ticlopidine or clopidogrel for at least 1 month if BMS was used and for at least 6 months if DES was used.

Data collection and follow-up

Chart, Procedural note and Cine-angiogram data for all patients were reviewed. Clinical follow-up was performed by clinic visits or by telephone interviews, for the occurrence of major adverse cardiac events (MACE), including cardiac death, myocardial infarction (MI) and target lesion revascularization (TLR). All patients were followed-up for at least 6 months.

Definitions

Protected LMCA was defined as LMCA disease which left anterior descending artery or left circumflex artery got at least one functioning arterial or venous graft on one of its major branches. High operative risk was defined as the European system of cardiac operative risk assessment (Euro SCORE) $\geq$ 6[13]. Angiographic success was defined as a residual stenosis of < 20% by visual estimation in the presence of Thrombolysis in Myocardial Infarction (TIMI) 3 flow. Procedural success was defined as angiographic success with no major procedural or in-hospital complications (*i.e.* death, Q-wave MI or emergency PCI or bypass surgery). Mid-term outcomes were defined as the outcome of at least 6 months follow-up: angiographic in-stent restenosis was defined as $\geq$ 50% diameter stenosis of a target lesion in follow-up coronary angiography. Target lesion revascularization (TLR) was defined as any re-intervention (surgical or percutaneous) performed on the treated segment. A major adverse cardiac event (MACE) was defined as the occurrence of all causes of death, nonfatal MI or TLR during follow-up. Deaths were classified as either cardiac or non-cardiac. Deaths that could not be classified were considered cardiac. MI was diagnosed when cardiac enzymes (creatine kinase-MB) were elevated more than three times the normal with chest pain lasting $\geq$ 30 min, or with the appearance of new electrocardiographic changes.

Statistical analysis

Data was expressed as mean $\pm$ SD for continuous variables and as frequencies for categorical variables. Survival and MACE-free survival distribution were estimated according to the Kaplan-Meier method. Statistical significance was defined as $p < 0.05$. All statistical analyses were performed using SPSS statistical software (version 13, SPSS Inc., Chicago, Illinois).

Results

Clinical, angiographic and procedural baseline characteristic

Baseline clinical characteristics are shown in Table 1. The 64 patients in the present study were aged from 25 to 92 years; mean age 68.1 $\pm$ 13.4 years, and most of them were male. Thirty-three (51.6%) patients had diabetes and eighteen (28.1%) patients had renal insufficiency. Four (6.3%) patients presented with AMI and 29 (45.3%) patients had unstable angina or NSTEMI. Mean left ventricular ejection fraction was 48.3 $\pm$ 16.7% and 34.1% of patients had LVEF less than 40%. Almost twenty percent of patients were complicated with congestive heart failure and 6.3% had cardiogenic shock.

Table 1. Baseline clinical characteristics of patients treated with stent for protected and unprotected left main coronary artery disease

	n = 64
Male (%)	50 (78.1)
Age (yr) mean ± SD (min-max)	68.1 ± 13.4 (25-92)
Cardiovascular risk factors	
Hypertension (%)	70.3
Diabetes mellitus (%)	51.6
Hyperlipidemia (%)	73.4
Smoking (%)	26.6
Family history of CAD (%)	3.1
Obesity (%)	12.5
Previous MI (%)	14.1
Previous CABG (%)	34.4
Renal insufficiency (%) Cr ≥ 1.5	28.1
STEMI (%)	6.3
UA/NSTEMI (%)	45.3
Mean LVEF ± SD (min-max)	48.3 ± 16.7 (13-80)
LVEF < 40%	34.1
Congestive heart failure (%)	18.8
Cardiogenic shock (%)	6.3

CAD = coronary artery disease; MI = myocardial infarction; CABG = coronary artery bypass graft surgery; Cr = creatinine; STEMI = ST-elevation myocardial infarction; UA = unstable angina; NSTEMI = non ST- elevation myocardial infarction; LVEF = left ventricular ejection fraction

Angiographic and procedural characteristics are shown in Table 2.The majority of lesions were located in distal part of LMCA. Unprotected left main coronary artery disease was found in nearly fifty-five percent. Sixty-one (95.3%) had combined coronary artery disease other than LMCA disease. Almost half of the patients had triple vessel disease and 39 patients (60.9%) underwent PCI for other coronary lesions. Intravascular ultrasound guidance was used in 7.8% of patients. Twenty four (37.5%) patients underwent direct stenting. The bifurcation technique strategy for distal LMCA lesion was treated by one stenting across the origin of circumflex artery (n = 62, 96.9%) or two stenting (n = 2, 3.1%). Almost two-thirds of the patients were treated with drug-eluting stent (DES). With DES widely usage, the ratio of DES implanted in LMCA lesions prominently increased in our center. Twenty-five percent of patients used DES in 2002, 50% of patients used DES in 2003 and approximately 80% after year 2005, Left main coronary artery stents were successful deployed in all patients without death during procedure.

Table 2. Angiographic and procedural characteristics of lesions treated with stent for protected and unprotected LMCA disease

	n = 64
Left main lesion location (%)	
Ostial	6.3
Mid-stem	32.2
Distal	50.0
All part	3.1
Others	9.4
eg; Ostial LAD or circumflex	
Number of vessel (vss) disease (%)	
Only left main disease	4.7
1 vss disease	17.2
2 vss disease	26.5
3 vss disease	51.6
Unprotected Left Main (%)	53.1
Mean diameter stenosis; pre ± SD (%) (min-max)	79.00 ± 13.96 (30-100)
Mean stent diameter ± SD, mm (min-max)	3.35 ± 0.39 (2.5-4)
Stent diameter < 3 mm	5 (7.8%)
Mean stent length ± SD, mm (min-max)	14.81 ± 5.44 (8-30)
High pressure inflation ≥ 16 atm, n (%)	27 (42.19%)
Direct stenting (%)	37.5
Mean stent number per patient ± SD, mm (min-max)	1.22 ± 0.52 (1-3)
Bifurcation technique	
Single stent (%)	96.9
Two stents (%)	3.1
Final kissing (%)	21.9
Bare/DES usage (%)	35.9/64.1
PCI at other sites (%)	60.9
IVUS guidance (%)	7.8
Procedural success, n (%)	61 (95.3)

DES = drug-eluting stent; PCI = percutaneous coronary intervention; IVUS = intravascular ultrasound

In-hospital and mid-term outcomes

In-hospital and 6 month outcomes are shown in Table 3. Two patients who were hospitalized for STEMI and NSTEMI died. Both causes of death were cardiogenic shock that presented previously admitted to the catheterization laboratory. The other one patient died from pneumonia. None of the other patients experienced any clinical events during hospitalization. In-hospital major adverse cardiac event (MACE) was 4.7% and the procedural success rate was 95.3%.

Table 3. In-hospital and 6-month outcomes of patients treated with stent for protected and unprotected left main coronary artery disease

In-hospital outcomes	
All cause death, n (%)	3 (4.7)
MACE, n (%)	3 (4.7)
Cardiac death, n (%)	2 (3.1)
MI, n (%)	0 (0)
TLR, n (%)	0 (0)
6-month outcomes	
All cause death, n (%)	3 (4.7)
MACE, n (%)	6 (9.4)
Cardiac death, n (%)	2 (3.1)
MI, n (%)	2 (3.1)
TLR, n (%) [BMS:DES]	3 (4.7) [1:2]
In-stent restenosis , n (%)	3 (9.7)

MACE = major adverse cardiac events (all cause death, non-fatal MI or target lesion revascularization); MI = myocardial infarction; TLR = target lesion revascularization; BMS = bare-metal stent; DES = drug-eluting stent

Minimum clinical follow-up of 6 months was completed in 100% of patients. The mean and median follow-up duration were 31 $\pm$ 25 months (range, 6-93 months) and 26 months respectively. Angiographic follow-up was performed in 31 patients (51%), and the 6 month-in-stent restenosis rate was 9.7%. At to 6 months follow-up, no patient died and MACE was found in 6 (9.4%) patients due to in-stent restenosis.

All cause death-free and MACE-free survival rate at clinical follow-up are shown in Fig. 1, 2. A total of 8 patients (12.5%) died and two which were cardiac causes. Of the six non-cardiac deaths, two each were due to pneumonia and stroke, and one each to sepsis and unknown cause. Most deaths occurred within 24 months after the procedure. After Cox regression univariate analysis was used to assess independent factors predicting all cause death and MACE and renal insufficiency (Cr $\geq$ 1.5) were independent factors that predicted all causes of death and MACE at OR = 3.13 (p = 0.008) and OR = 2.65 (p = 0.023) respectively. Cardiogenic shock was an independent factor that predicted all causes of death at RR = 2.12 (p = 0.044) and LVEF less than 40 was the independent factor that predicted MACE at OR = 1.73 (p = 0.056).

Discussion

An analysis of several published studies[9,10,12,14,15] on elective LMCA interventions by stenting in most of the lesions illustrated that in-hospital cardiac mortality rate for elective procedures ranged from 0-4%, but it increased to 13.7% when emergency PCI for AMI patients was included[6]. In the same studies, the long-term outcome of a follow-up time between 7.3 to 25.5 months presented a cardiac mortality rate from 0.7% to 5.7%, an incidence of MI from 0% to 2.6%, and a need for revascularization from 6.8% to 16.4%.Therefore, it was suggested that PCI could have favorable clinical efficacy in treating some unprotected LMCA lesions, and it could be an alternative method to CABG on the basis of better case selection. The present study showed that the in-hospital outcome of patients treated by PCI with

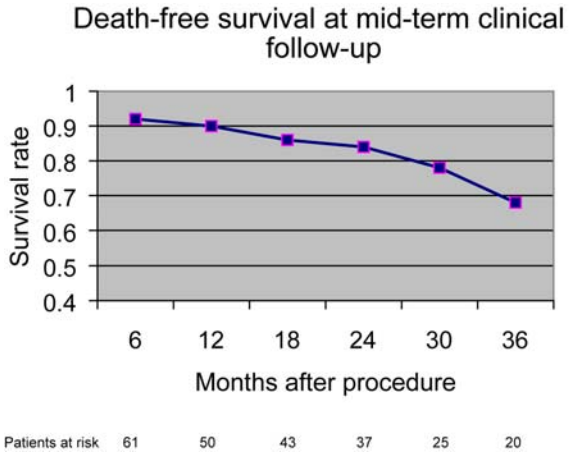

Fig. 1 All cause death-free survival rate at mid-term clinical follow-up

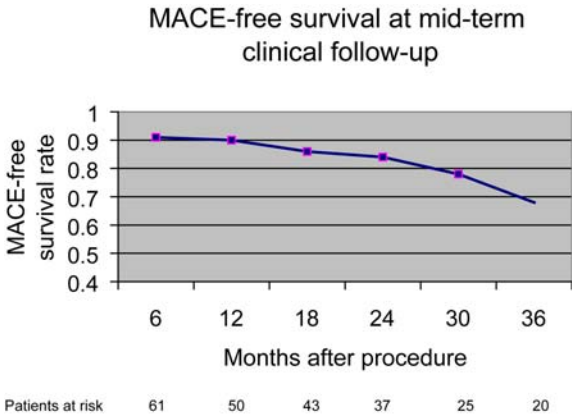

Fig. 2 MACE-free survival rate at mid-term clinical follow-up

stent implantation for LMCA lesions was satisfactory. The procedural success rate of procedure was 95.3%. Three patients (4.7%) died after the procedure, most of them from cardiac events and the incidence of total in-hospital MACE was 4.7%. During the mid-term follow-up period, 8 (12.5%) patients died, two of them from cardiac causes and the total MACE was 18.75%. Obviously the present study is characterized by more complicated patients; *e.g.* high percentage of diabetes, renal insufficiency, acute coronary syndrome (ACS), poor LVEF and cardiogenic shock[9,10,12,14,15]. All of which were considered to be potential factors leading to occurrence of restenosis and even cardiac deaths. Compared to the studies[5,7,8,16,17] where at least 60% of the cases were treated for distal disease and mainly with a two-stent technique, the presented our patients only 3.1% of the patients were treated with two-stent technique. Park SJ et al[5,10,18] reported that in the bare metal stent era, IVUS guidance could optimize the immediate procedural results, and in patients treated with DES and concomitant IVUS guidance, a restenosis rate of 7% was observed. But in the presented patients, intravascular ultrasound guidance was done in only 7.8%.This limitation was due to healthcare reimbursement. The long-term outcomes of clinical and angiographic follow-up for this group of patients seem to be similar to other previous reports[6, 9,10]. Rate of in-stent restenosis might not be accurate due to a low rate of angiographic follow-up (51%). It is generally believed that operators' experience and technique are correlated with the incidence of MACE and restenosis of PCI. Therefore, when PCI for LMCA is necessary, it is recommended to be performed by experienced centers and operators[19]. Since 2005, the PCI volume was increasing in our center, the authors experience had enriched and skill had elevated in terms of PCI technique for LMCA lesions.

Study limitations

One major limitation is that the present study is a retrospective summary for our single-center experience that one technique may be different and influence on the outcomes, therefore the results may not be very typically compared with those obtained from a multi-center study. Moreover, the number of patients analyzed is small, primarily because of the low occurrence of this anatomical subset of lesions in the general population. Another limitation is the duration of clinical follow-up. Duration of dual antiplatelet therapy was heterogeneous at the time of data collection. Furthermore, rate of in-stent restenosis may not be accurate due to the low rate of angiographic follow-up (51%). Continuous long-term follow-up of the patients and the results of randomized trials when compared with CABG are indispensable to clarify the equivalence of LMCA stenting are needed.

Conclusion

Stent Implantation was technically feasible and safely applied for the treatment of protected and unprotected left main coronary artery lesions, with acceptable in-hospital and mid-term outcomes

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การศึกษาผลการรักษาขณะที่อยู่ในโรงพยาบาลและระยะกลางในผู้ป่วยหลอดเลือดขั้วหัวใจตีบด้วยการใส่ขดลวดในโรงพยาบาลจุฬาลงกรณ์

จิราณัติ ชลธีศุภชัย, วสันต์ อุทัยเฉลิม, สุพจน์ ศรีมหาโชตะ, วศิน พุทธารี, จักรพันธ์ ชัยพรหมประสิทธิ์, สมนพร บุณยะรัตเวช สองเมือง, ถาวร สุทธิไชยากุล

ภูมิหลัง: *ปัจจุบันการผ่าตัดต่อทางเบี่ยงหลอดเลือดหัวใจถือเป็นการรักษามาตรฐานในผู้ป่วยหลอดเลือดขั้วหัวใจตีบ แต่ในผู้ป่วยส่วนหนึ่งไม่สามารถผ่าตัดได้เนื่องจากมีข้อจำกัดต่อการผ่าตัด มีความเสี่ยงจากโรคร่วม หรือ ผู้ป่วยปฏิเสธการผ่าตัด การศึกษาในปัจจุบันแสดงถึงผลการรักษาผู้ป่วยหลอดเลือดขั้วหัวใจตีบด้วยการใส่ขดลวดค้ำยันผ่านสายสวนสามารถกระทำได้และได้ผลดี แม้ในปัจจุบันข้อมูลจะยังมีจำกัดอยู่ก็ตาม*

วัตถุประสงค์: *เพื่อเป็นการศึกษาถึงผลการรักษาระยะสั้นและระยะกลางผู้ป่วยหลอดเลือดขั้วหัวใจตีบด้วยการใส่ขดลวดค้ำยันผ่านสายสวน ในโรงพยาบาลจุฬาลงกรณ์*

วัสดุและวิธีการ: *เป็นการศึกษากลุ่มผู้ป่วยหลอดเลือดขั้วหัวใจตีบที่ได้รับการรักษาด้วยการใส่ขดลวดค้ำยันผ่านสายสวน ในโรงพยาบาลจุฬาลงกรณ์ตั้งแต่กรกฎาคม พ.ศ. 2543 ถึง สิงหาคม พ.ศ. 2550 ผลที่ได้จะดูถึงอัตราการเสียชีวิตจากโรคหลอดเลือด อัตราการเกิดกล้ามเนื้อหัวใจตายซ้ำและอัตราการตีบหรือตันซ้ำขณะอยู่ในโรงพยาบาลและขณะตรวจติดตามการรักษา*

ผลการศึกษา: *มีผู้ป่วยหลอดเลือดขั้วหัวใจตีบที่ได้รับการรักษาด้วยการใส่ขดลวดค้ำยันผ่านสายสวน ในโรงพยาบาลจุฬาลงกรณ์ในช่วงเวลาดังกล่าวทั้งสิ้น 64 ราย โดยผู้ป่วยได้รับขดลวดเคลือบยา 64% ผู้ป่วยที่ได้รับการรักษามีอัตราการเสียชีวิตในโรงพยาบาล 4.7% และอัตราการเกิด MACE ในโรงพยาบาล 4.7% มีผู้ป่วยมาตรวจติดตามการรักษาที่ 6 เดือนครบ 100% ผู้ป่วยจำนวนครึ่งหนึ่งได้รับการฉีดสีหัวใจเพื่อประเมินซ้ำ พบอัตราการตีบ และหรือ ตันซ้ำหลังใส่ขดลวดค้ำยันผ่านสายสวนคิดเป็น 4.7% ไม่พบมีผู้ป่วยเสียชีวิตเพิ่ม และอัตราการเกิด MACE ที่ 6 เดือน เท่ากับ 9.4% นอกจากนี้ได้มีการตรวจติดตามผู้ป่วยต่อจนถึงปัจจุบันซึ่งมีค่าเฉลี่ยและค่ากลางที่ 31 $\pm$ 25 และ 26 เดือนตามลำดับ*

สรุป: *การรักษาผู้ป่วยหลอดเลือดขั้วหัวใจตีบที่ได้รับการรักษาด้วยการใส่ขดลวดค้ำยันผ่านสายสวนสามารถทำได้และมีความปลอดภัย โดยมีผลการรักษาระยะสั้นและระยะกลางอยู่ในระดับที่น่าพอใจใกล้เคียงกับรายงานจากต่างประเทศ ทั้งนี้คงต้องรอผลการศึกษาแบบสุ่มเพื่อยืนยันถึงผลการรักษาในระยะยาวต่อไป*