

Original Article

Clinical comparison of percutaneous coronary intervention with domestic drug-eluting stents versus off pump coronary artery bypass grafting in unprotected left main coronary artery disease

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Abstract: Objective: The aim of our study was to compare the clinical outcomes of percutaneous coronary intervention (PCI) with domestic drug-eluting stents (DES) and off pump coronary artery bypass grafting (CABG) for the treatment of unprotected left main coronary artery (ULMCA) disease. Methods: A total of 227 patients with ULMCA disease and underwent revascularization was included. One hundred and six patients were treated with PCI with domestic DES implantation and 121 patients with off pump CABG. Clinical outcomes with respect to the major adverse cardiovascular and cerebrovascular events (MACCE) including death any cause, non-fatal myocardial infarction (MI), stroke, and target vessel revascularization (TVR) during hospitalization and at 12-month follow-up were recorded. Results: There was no significant difference between the domestic DES and off pump CABG groups in the risk of death, non-fatal MI, stroke, and TVR during hospitalization and at 12-month follow-up. Overall in-hospital MACCE in PCI versus CABG was 0.94% versus 5.78% ($P < 0.05$). The overall MACCE at 12-month follow up in PCI versus CABG was in 3.77% versus 3.31% ($P > 0.05$). Conclusions: Domestic DES is feasible and safety in the treatment of ULMCA lesions. When compared with off-pump CABG, domestic DES achieved similar completeness of revascularization, similar in-hospital and 12-month follow-up outcomes. A longer follow-up is needed.

Keywords: Unprotected left main coronary artery, percutaneous coronary intervention, coronary artery bypass grafting, drug-eluting stents

Introduction

Unprotected left main coronary artery (ULMCA) disease occurs in 5% to 7% of patients undergoing coronary angiography [1]. About 75-90% patients with ULMCA disease had multivessel disease. Coronary artery bypass grafting (CABG) has been considered as a standard therapy for patients with ULMCA disease according to current guidelines [2, 3]. Advances in percutaneous intervention techniques and stent technology including the introduction of drug-eluting stents (DES) have renewed interest for the percutaneous treatment of ULMCA disease. Previous reports have shown that the implantation of DES for unprotected LMCA lesions is a feasible and safe approach [4, 5]. With the improvement of manufacturing technology of domestic stents and interventional

techniques, domestic DESs have been widely used in clinical practice. Recently, the long-term efficacy and safety in a large scale clinical trial of domestic DES [6] has demonstrated that there was no statistically different with respect to the incidences of clinical events and cumulative survival rates between domestic DESs and imported DES.

The recent data comparing efficacy and safety of PCIs using DES and CABG showed comparable results in terms of safety and a lower need for repeat revascularization for CABG. [7-9] Chieffo et al. reported that the different incidence of complications between on-pump and off-pump CABG with an in-hospital incidence of MACCE 2 times higher for on-pump surgery [7]. Puskas et al. reported that off-pump CABG achieved similar completeness of revascular-

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ization, similar in-hospital and 30-day outcomes, shorter length of stay, reduced transfusion requirement, and less myocardial injury, when compared with conventional CABG [10]. Similar study was shown in a report by Damien et al [11]. This finding is quite important in planning any future trial in which the use of off-pump revascularization should be encouraged. To our knowledge, however, there has been no report studying the safety of DESs versus off pump CABG for treating patients with unprotected left main lesions.

The aim of the present study was to evaluate and compare the in-hospital and midterm safety and efficacy of selected patients treated with PCI with domestic DES vs off pump CABG for ULMCA disease.

Materials and methods

This study was conducted in accordance with the Declaration of Helsinki and approved by the ethics committee of the Cangzhou Central Hospital. Written informed consent was obtained from all subjects.

Patients

A total of 227 patients with ULMCA disease underwent revascularization in Cangzhou Center Hospital from January 2009 to January 2013 was included. The patients consisted of 87 females and 140 males with a median age 61.31 ± 10.23 years.

We included patients with angina or documented myocardial ischemia and $\geq 50\%$ diameter stenosis of the left main lesions on angiography. The left main coronary artery was defined as unprotected if there were no CABGs to the left anterior descending artery and left circumflex artery. The exclusion criteria were: 1) ULMCA disease caused by other than coronary artery atherosclerotic lesions; 2) ST elevation myocardial infarction patients due to acute left main occlusion; 3) patients with additional serious liver and renal insufficiency; 4) patients with additional diseases of the blood system; 5) patients with concomitant infection, tumors and diseases of the immune system; 6) patients had concomitant acute cerebral stroke events such as cerebral hemorrhage and cerebral infarction; 7) patients with concomitant serious communicable diseases; and 8) contraindication to surgical treatment.

Of the 227 patients, 106 patients underwent PCI with domestic DES and 121 patients underwent CABG for ULMCA disease. Patients were jointly evaluated by cardiac surgery and interventional cardiology consultants. The final decision of the method of revascularization using PCI or CABG was made after comprehensive review of all relevant factors. To be selected for PCI, a patient had to have one of the following characteristics: very high risk for CABG, patient had good left ventricular function and left main ostial and midshaft lesions, patient refusal to undergo CABG with a preference for PCI, or patient deemed unsuitable for CABG by the cardiac surgeon. To be selected for CABG, a patient had to have one of the following characteristics: patient had complexed coronary artery lesions; patient had concomitant complete occlusion of 2 or more major vessels; patients had multiple diffuse vascular lesions; patient had concomitant serious left ventricular dysfunction; patient had serious peripheral vascular disease which cannot undergo intraaortic balloon pump implantation; and patient refusal to undergo PCI with DES.

Surgical procedures

PCI: Percutaneous coronary intervention was performed via the transradial approach or using the standard percutaneous transfemoral approach due to extensive peripheral vascular disease or radial artery malformation. Lesions at the ostium or in the shaft of the ULMCA without distal bifurcation involvement were generally treated with a single stent. Where there was involvement of the distal bifurcation of the ULMCA, several techniques were used including a single stent deployed across the ostium of one branch (usually the circumflex), single stent combined with kissing balloon inflation or use of 2 stents using a "T", Culotte, crush, or kissing stent technique. DES type and length and the choice of anticoagulant agent were made by the operator. Pre-dilation with balloons was performed before stent implantation. High pressure stent deployment was performed using an initial inflation of 16 atm. Post-dilation with additional high-pressure balloons was performed for optimal stent apposition. Post-dilation with kissing balloon inflations was used if indicated. Intravascular ultrasound (IVUS) was used according to the physician's discretion. Antiplatelet therapy was started 12-24 hours before PCI with aspirin (300 mg) and a

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Table 1. Baseline clinical characteristics in two groups

	Domestic DES group (n=106)	Off pump CABG group (n=121)	P value
Age (year)	61.67±9.23	60.96±6.8	0.506
Weight (Kg)	70.75±10.94	68.17±10.14	0.066
Height (cm)	166.81±6.64	165.29±6.95	0.094
BMI (kg/m ²)	25.25±3.39	24.68±2.94	0.171
Male (%)	72 (67.9%)	68 (56.2%)	0.069
Hypertension (%)	71 (66.9%)	79 (65.2%)	0.788
Diabetes (%)	23 (21.7%)	26 (21.5%)	0.969
Hyperlipidemia (%)	47 (44.34%)	66 (54.55%)	0.125
Smoking	34 (32.1%)	37 (30.5%)	0.808
Previous MI (%)	14 (13.2%)	24 (19.8%)	0.182
Previous stroke	17 (16.0%)	14 (11.6%)	0.328
Previous PCI	16 (15.1%)	12 (9.91%)	0.237
Previous CABG	1 (0.94%)	0	0.284
Clinical presentation			
Stable angina (%)	0	0	NS
Unstable angina (%)	85 (80.2%)	102 (84.3%)	0.418
Other (%)	21 (19.8%)	19 (15.7%)	0.418
SYNTAX score	26.25±4.97	32.45±6.06	>0.05

CABG, coronary artery bypass grafting; MI, myocardial infarction; PCI, percutaneous coronary intervention.

loading dose of 300 mg of clopidogrel. Aspirin was continued indefinitely and clopidogrel recommended for a minimum of 6 months. Routine coronary angiography was recommended within 6 months after procedures.

Off-pump CABG: Off-pump CABG procedures were performed through a median sternotomy. The heparin infusion was commenced 1 mg/kg for a target ACT of 200-300 s and blood pressure of appropriate 12 kPa. To fully expose the targeted vessels, the CTS coronary stabilizer (CardioThoracic Systems, Inc, Cupertino, CA) and deep pericardial retraction sutures (DPRS) was placement. Local shunt was applied to construct a bloodless kissing region. After achieving a proximal (aortic incision) and distal (coronary artery lesions) segments anastomosis, protamine was used to neutralize heparin in vivo. In most patients, left internal mammary artery was anastomosed to the left anterior descending (LAD). Based on the lesions sites and target vessel condition, great saphenous vein was usually used as bypass vessels for posterior descending, posterior branch of left ventricle, obtuse marginal branch and/or diagonal branch. For young patients, in order to improved long-term vessel patency, radial

artery instead of saphenous vein may be used. Theoretically speaking, all lesions with >50% stenosis in vessels with a diameter of >2.0 mm should be treated with bypass surgery. Five days before procedures, aspirin and clopidogrel was discontinued. Percutaneous anticoagulant therapy was performed with 4000IU low molecular heparin once 12 hours. Aspirin was continued indefinitely and clopidogrel was continued for at least 12 months. Angiographic follow-up was scheduled if clinical presentation suggested ischemia chest pain.

Follow up and medical evaluation

The major adverse cardiovascular and cerebrovascular events (MACCE) of patients in DES and CABG group were recorded during the hospitalization period. Clinical follow-up via office visits or telephone contact was scheduled for all patients within 12 months after hospital discharge.

The primary clinical endpoint was the composite of MACCE, including death any cause, non-fatal myocardial infarction (MI), stroke, and target vessel revascularization (TVR). All deaths were considered as cardiac in origin unless non-cardiac reasons were indicated. Non-fatal MI was defined as ischemic symptoms associated with cardiac enzyme elevation ≥ 3 times the upper limit of the normal value and ST-T changes on electrocardiogram. Stroke, as indicated by neurologic deficits, was confirmed by a neurologist on the basis of imaging studies. In this study, stroke consisted of cerebral infarction, cerebral parenchymal haemorrhage, and transient ischemic attack. TVR in PCI group was defined as a repeat revascularization to treat a restenosis within the stent or within 5-mm proximal segments adjacent to the stent, or new lesions of the left anterior descending artery and/or left circumflex artery. TVR in CABG group was defined as any repeat revascularization of the treated vessel, including any segments of the left anterior descending artery and the left circumflex artery.

Statistical analysis

SPSS 13.0 (SPSS Inc, Chicago, IL) was used for was used for data analysis. Qualitative data

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Table 2. Coronary angiographic characteristics in two groups

	Domestic DES group (n=106)	Off pump CABG group (n=121)	P value
Extent of diseased vessel			
LM only	3 (2.83%)	0	0.062
LM plus single-vessel disease (%)	11 (10.38%)	8 (6.61%)	0.307
LM plus double-vessel disease (%)	29 (27.36%)	30 (24.79%)	0.66
LM plus triple-vessel disease (%)	63 (59.43%)	83 (68.6%)	0.151
Disease location			
Ostium (%)	2 (1.89%)	0	0.129
Shaft (%)	1 (0.94%)	0	0.284
Distal Bifurcation (%)	103 (97.17%)	121 (100%)	0.062
PCI technique			
Single stent crossing over LCX	78 (73.58%)		
Simultaneous kissing stenting (%)	1 (0.94%)		
T-stenting	2 (1.89%)		
Culotte-stenting	11 (10.38%)		
Crush-stenting	14 (13.21%)		
Final diameter of stent (mm)	3.81±0.32		
Total stent length (mm)	40.9±28.1		
Guidance with IVUS (%)	13 (12.26%)		

LM, left main.

Table 3. In-hospital clinical outcomes of domestic DES and off pump CABG groups

	Domestic DES (n=106)	Off pump CABG (n=121)	P value
MACCE (%)	1 (0.94%)	7 (5.78%)	0.048*
Death (%)	0	4 (3.31%)	0.059
Cardiac death (%)	0	3 (2.48%)	0.102
Stroke (Cerebral infarction)	0	1 (0.83%)	0.348
Nonfatal MI (%)	1 (0.94%)	1 (0.83%)	0.925
TVR (%)	0	1 (0.83%)	0.348
Stroke (%)	0	1 (0.83%)	0.348

CABG, coronary artery bypass grafting; MACCE, major adverse cardiac and cerebrovascular event; MI, myocardial infarction; PCI, percutaneous coronary intervention; TVR, target vessel revascularization. *P<0.05.

were expressed as percentage and were compared using Chi-square test. Normally distributed continuous data are presented as means ± standard deviation (SD) and were compared using *t* tests. Non-normally distributed continuous data are presented as the median and interquartile range, and were compared using the *rank-sum* tests. Binary logistic regression analysis was used as multiple-factor analysis. Survival probabilities were calculated by the Kaplan-Meier method and comparisons were made using the log-rank test to identify poten-

tial prognostic factors. Differences were considered statistically significant when P<0.05.

Results

Baseline clinical characteristics

Two hundred twenty-seven patients with ULMCA disease were treated: 106 with PCI using domestic DES and 121 with off pump CABG. Baseline clinical and demographic characteristics are listed in **Table 1**. There were no significant differences with respect to the age, weight, height, BMI, percentage of male, prevalence of hypertension, diabetes, hyperlipidemia, and smoking, history of myocardial infarction (MI), stroke, PCI, CABG, stable angina, unstable angina and other factors between the two groups.

Angiographic characteristics

Coronary arteriography characteristics of patients were shown in **Table 2**. There were no statistically significant differences with respect to the extent of diseased vessel and disease location between domestic

DES and off pump CABG groups. One hundred and six patients (100 %) had domestic sirolimus-eluting stents used in the left main position. An average of 2.6±1.4 stents per patient, with an average total length of 49.9±33.7 mm were implanted in these procedures (not just in the left main position). A total of 103 of 106 PCI patients (97.17%) had disease involving the bifurcation of the left main coronary artery. When bifurcation disease was present, the following stenting techniques were used to deal with the bifurcation lesion: One stent placed

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Table 4. Follow-up outcomes in two groups

	Domestic DES (n=106)	Off pump CABG (n=121)	P value
Death (%)	0	2 (1.66%)	0.184
Cardiac death (%)	0	2 (1.66%)	0.184
Nonfatal MI (%)	0	1 (0.83%)	0.348
TVR (%)	4 (3.77%)	1 (0.83%)	0.131
Stroke (%)	0	0	NS
MACCE (%)	4 (3.77%)	4 (3.31%)	0.849

CABG, coronary artery bypass grafting; MACCE, major adverse cardiac and cerebrovascular event; MI, myocardial infarction; PCI, percutaneous coronary intervention; TVR, target vessel revascularization.

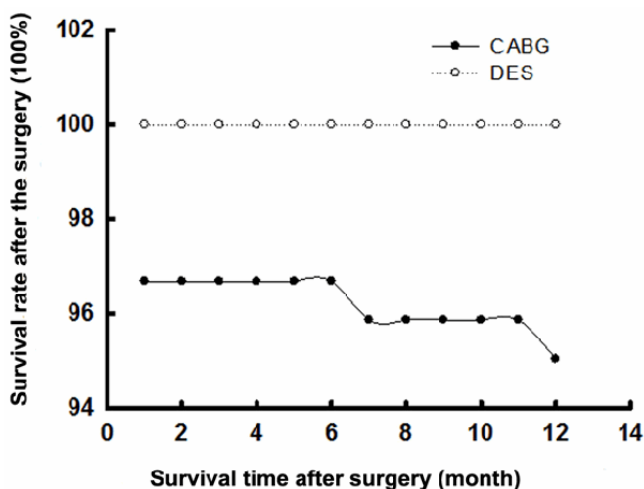


Figure 1. The survival rate of domestic DES and off pump CABG groups.

across the ostium of the circumflex into the proximal LAD, 78 (73.58%); double stents placed by the kissing stent technique in 1 (0.94%), Crush technique in 14 (13.21%), Culotte technique in 11 (10.38%), and T-stenting technique in 2 (1.89%). Intravascular ultrasound was used in 13 (12.26%).

Clinical outcomes of patients during hospitalization period in two groups

Clinical outcomes of patients were shown in **Table 3**. During hospitalization, there were 4 cases of in-hospital death in the off pump CABG group and none in the PCI group. The patients consisted of 3 cases of cardiac death and 1 case of stroke death. Nonfatal MI in PCI versus off pump CABG was observed in 0.94% (1 case) versus 0.83% patients. There were 1 case of in-hospital TVR and stroke in the CABG group. Overall in-hospital MACCE in PCI versus CABG was 0.94% versus 5.78% ($P < 0.05$).

Follow-up outcomes of patients in DES and off pump CABG groups

At 12-month follow-up, the combined clinical end point was reached in 3.77% of patients after PCI and in 3.31% after CABG ($P > 0.05$) (**Table 4**). No patient treated with PCI died of cardiac cause or had a nonfatal MI or a stroke during follow-up; only 4 patients had a TVR. In the CABG group, there were 2 cases of death (all from cardiac cause), 1 case of nonfatal MI and 1 case of TVR. The survival rate of the two groups was shown in **Figure 1**.

Discussion

The main finding of this study is that there is no statistically significant difference with respect to the combined end point of death, stroke, nonfatal MI, and TVR during hospitalization and at 1 year follow up between PCI with domestic DES and off pump CABG for unprotected LMCA disease. This result is consistent with the previous comparisons of PCI to CABG [7]. The equivalence in death, MI, stroke and TVR suggests that the choice between the 2 treatment options can be defined by both the individual clinical presentation and the practical tradeoff between differences in recovery period.

Current guidelines recommend CABG for LMCA disease. Some retrospective studies evaluating CABG for this disease reported an in-hospital mortality rate varying from 1.7% to 7.0% and a 1-year mortality rate of 6% to 14% [12-15]. We reported 3.31% in-hospital mortality and 1.66% one-year mortality in patients with ULMCA disease. Our findings are slightly lower than with the published data for CABG for ULMCA disease. Currently, the treatment of LMCA disease by PCI is still debated. The advent of DES prompted a marked improvement in clinical outcomes after PCI of the ULMCA. In recent years, encouraging results have been reported with elective DES implantation in LMCA, with a 1-year mortality rate from 0% to 4% [4, 5, 16, 17]. Our study showed no death in patients with DES implantation in ULMCA.

In addition, we also compared the in-hospital and 12-month follow up MACCE of PCI with domestic DES and off pump CABG in ULMCA

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disease. We found that the incidence of in-hospital MACCE was lower in the DES group than in the CABG group (0.94% vs 5.78%, $P < 0.05$). This finding was consistent with previous studies. Sanmartin et al. [8] reported that the MACCEs at 30 days occurred in 2.1% vs 9.0% between after DES implant after surgery ($P = 0.03$), and 10.4% vs 11.4% for surgery at 1 year, respectively ($P > 0.50$). Pawel et al [18] found that PCI was associated with a lower 30-day risk of MACCE ($P = 0.03$) and shorter hospitalizations ($P = 0.0007$). In Lee et al.'s report [19], the 30-day MACCE rate for CABG and PCI was 17% and 2% ($P < 0.01$), respectively. At 12 months follow up, we found that comparable occurrence of MACCE between domestic DES and off pump CABG Groups. Several studies showed no significant differences in MACCE between PCI with DES and CABG in patients with ULMCA disease [7, 19-21].

The main limitation of this study is the nonrandomized observational design. Consequently, the choice of the treatment was left to the physician and/or patient. This limit was mainly due to the exploratory nature of the study. In addition, the definition of MI in this study was based on a surgical definition (the finding of ST-T change on electrocardiography, in association with a value for the creatine kinase MB fraction that was 3 times the upper limit of the normal range), which may have resulted in less severe cases of myocardial infarction being ignored. Finally, the 12-month follow-up period may have penalized the off pump CABG group because of the higher occurrence of in-hospital MACCE in this type of treatment. Further study with a longer follow-up will give us further information to evaluate the optimal treatment of LMCA.

In conclusion, we found comparable complications such as death, stroke, nonfatal MI, and TVR between PCI with domestic DES and off pump CABG for ULMCA disease. Further studies with a large, multicenter, randomized study with long-term follow-up are still needed to find an optimal treatment strategy for ULMCA disease.

Disclosure of conflict of interest

None.

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