

Clinical outcomes of transradial unprotected left main coronary artery stenting in the elderly

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ABSTRACT

الأهداف: تقييم نتائج طويلة المدى لمرضى كبار السن الذين خضعوا إلى رأب الوعائي التاجي (PCI) مع الدعامة الناضحة بالدواء لمرض الشريان التاجي الأيسر الغير محمي عن طريق التدخل بالجلد.

الطريقة: اجريت هذه الدراسة في مستشفى تشنهوانغداو الأول، بجامعة خبي الطبية في مقاطعة خبي، الصين في الفترة الزمنية ما بين أكتوبر 2006م إلى ديسمبر 2009م. خضع 79 شخص من كبار السن تزيد أعمارهم عن 70 ≥ الذين يعانون من مرض الشريان التاجي الأيسر الغير محمي (ULMCA) إلى عملية الدعامة الناضحة بالدواء حيث تم تقييمهم. وسجلت الأحداث الرئيسية السلبية للقلب (MACE) منها: الموت، واحتشاء عضلة القلب الغير مميتة، وسكتة دماغية أو إعادة التوعي لأفة المستهدفة بعد ثلاث سنوات من المتابعة.

النتائج: أظهرت النتائج بعد ثلاث سنوات من المتابعة أن معدل المرضى الناجين من الأحداث الرئيسية السلبية للقلب كان بنسبة 72.2%. و معدل الوفيات نتيجة تعرضهم للأزمات القلبية بنسبة 7.6% وتعرض 5.1% من المرضى الى احتشاء عضلة القلب و تعرض 13.9% من المرضى الى اعادة توعي لأفة مستهدفة. ويعتبر العمر و انشعاب القاصيات الرئيسية اليسارية مؤشرات لحدوث MACE.

الخلاصة: من الممكن اجراء الرأب الوعائي التاجي (PCI) بواسطة التصوير الجيد للأوعية والتدخل بالجلد للحصول على نتائج سريرية لمرضى كبار السن. ويشير الباقيين على قيد الحياة على مدى الطويل بأن PCI الذي اجري على مرضى ULMCA بعمر 70 ≥ عام آمن وفعال.

Objectives: To evaluate the long-term results in elderly patients undergoing percutaneous coronary intervention (PCI) with drug-eluting stents for unprotected left main coronary artery disease by transradial approach.

Methods: This study took place in Qinhuangdao First Hospital, Hebei Medical University, Hebei, China between October 2006 and December 2009. Seventy-nine elderly patients with unprotected left main coronary artery (ULMCA) stenosis, aged ≥ 70 years,

that underwent drug-eluting stent were evaluated. The occurrence of major adverse cardiac events (MACE) (death, non-fatal myocardial infarction, stroke or target lesion revascularizations) was recorded after 3 years of follow-up.

Results: After 3 years follow-up, the MACE free survival rate was 72.2%. Cardiac deaths occurred in 7.6% of patients. Myocardial infarction occurred in 5.1%, and target lesion revascularization in 13.9% of patients. Age and left main distal bifurcation were favorable predictors of MACE.

Conclusion: Percutaneous coronary intervention can be performed with good angiographic and clinical results through a transradial approach in the elderly. The long term survival suggests that PCI in ULMCA patients ≥ 70 years is safe and efficacious.

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Coronary artery bypass graft (CABG) is the most suitable revascularization strategy to treat patients with unprotected left main coronary disease (ULMCA);^{1,2} however, it is more complex in elderly patients with ULMCA. These patients generally have diffuse and multi coronary vessel disease with diabetes, heart failure, stroke, and peripheral vascular disease.³ These characteristics predict an increased risk of adverse surgical outcome. The appropriate management of these patients is still controversial as there are no randomized controlled trials for the elderly. In recent years, some non-randomized studies⁴⁻⁷ demonstrated the safety and feasibility of ULMCA intervention using drug-eluting stents. However, there are limited outcomes

on percutaneous treatment of ULMCA disease in the elderly. Thus, the purpose of this study was to review a single center experience with left main stenting in the elderly.

Methods. *Study population.* This retrospective study took place in Qinhuangdao First Hospital, Hebei Medical University, Hebei, China between October 2006 to December 2009. Seventy-nine elderly patients with ULMCA stenosis, aged >70 years, that underwent drug-eluting stent were evaluated.

The inclusion criteria includes patients age >70 years, complaining of typical chest pain, and ULMCA stenosis treated with drug eluting stent (DES) by transradial approach. The exclusion criteria includes patients with acute myocardial infarction (MI), prior CABG, and carcinoma. All patients had confirmed myocardial ischemia related to ULMCA disease. Unprotected left main coronary artery was defined⁸ as at least 50% stenosis by visual assessment in the left main vessel without bypass grafts to left anterior descending artery or left circumflex artery. We used the European System for Cardiac Operative Risk Evaluation (EuroSCORE) to identify high preoperative risk patients with symptomatic left main disease. Patients with a EuroSCORE >6 were defined as high risk. The ethics committee of Qinhuangdao First Hospital approved the study. This study was carried out in compliance with the Helsinki Declaration.

Procedure. Coronary angiography and percutaneous coronary intervention (PCI) were performed in all patients by the transradial approach. A single anterior wall puncture technique was used with a 2.5 cm, 21 gauge needle (Cordis Corporation, Miami, USA). Then the a 0.018 inches stainless-steel guide wire was inserted through the needle and a 6 Fr sheath was used. Seven Fr sheaths were used for complex interventions. The angiographic findings were analyzed by quantitative coronary angiography (QCA) system (GE QCA, Centricity AI 1000-GE Mnet Version 4.1.15.07, Waukesha, USA). The outer diameter of the contrast-filled catheter as the calibration standard, the minimal lumen diameter, and lesion length were measured in diastolic frames from orthogonal projections.⁹ Complete revascularization⁴ was defined as complete

and successful treatment of all diseased vessels with reference diameter of >2.0 mm, serving a portion of viable myocardium. Procedural PCI success was defined as residual stenosis of less than 25% associated with thrombolysis in myocardial infarction (TIMI) flow grade III without death, MI, or emergency bypass surgery prior to hospital discharge. The stents used were sirolimus-eluting Firebird stents (Microport, Shanghai, China). Patients were loaded with 300 mg clopidogrel before the procedure and remained on a 75 mg dosage daily for at least one year. The patients were given aspirin 300 mg daily during the first month and 100 mg daily after the first month.

Follow up. Clinical follow up was performed at one month, 6 months, 12 months, and subsequently annually. The mean follow up time was 38.34±7.24 months. Angiographic follow up was performed between 9 and 12 months. The primary endpoint was major adverse cardiac event (MACE). Major adverse cardiac event was defined as death, non-fatal MI, stroke and target vessel revascularization (TVR). Stent thrombosis was defined according to the established criteria.¹⁰ Target lesion revascularization⁵ was defined as a new intervention (percutaneous or surgical) on a previously implanted stent or within 5 mm of that stent. Deaths were classified as either cardiac or non-cardiac. Deaths that could not be classified were considered cardiac according to the Academic Research Consortium definitions.⁵ Myocardial infarction was diagnosed by an elevation of serum creatine kinase or troponin 3 times the upper limit of normal, together with chest pain lasting more than 30 minutes.

All data relating to procedures and in-hospital outcomes were collected. Information regarding clinical status was collected at clinic visits and by telephone interview.

Statistics analysis. Continuous variables were expressed as mean±standard deviation of the mean, or as percentages. The Kaplan-Meier method was used for survival analysis. Independent predictors of MACE were identified by multivariate cox regression model with the use of baseline clinical, angiographic, and procedural characteristics. A *p*-value less than 0.05 was considered to be significant. The analysis was performed using the Statistical Package for Social Sciences version 12 (SPSS Inc., Chicago, IL, USA).

Results. The baseline clinical data are presented in Table 1. The angiographic and procedural characteristics are shown in Table 2. All patients received sirolimus-eluting stents successfully. Angiographic follow-up was

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Table 1 - Clinical characteristics of 79 elderly patients with unprotected left main coronary artery stenosis.

Clinical characteristics	Number (%)
Age (years) (mean±SD)	75.97±5.09
Gender (male/female)	51/28
Smoker	31 (39.2)
Diabetes	32 (40.5)
Hypertension	37 (46.8)
Hypercholesterol	25 (31.6)
Prior stroke	9 (11.4)
Prior myocardial infarction	17 (21.5)
Renal failure	3 (3.8)
Left ventricle function (mean±SD)	55.53±5.62
EuroSCORE (mean±SD)	7.02±1.09
EuroSCORE >6	54 (68.4)
Clinical presentation	
Stable angina	18 (22.8)
Unstable angina	49 (62.0)
NSTEMI	12 (15.2)
EuroSCORE - European System for Cardiac Operative Risk Evaluation, NSTEMI - non-ST elevation myocardial infarction	

available in 35 patients (44%). One patient died of acute stent thrombosis in the hospital. Two patients had late thrombosis. All patients received complete clinical follow-up for 3 years. Overall, cardiac and non-cardiac death occurred in 6 patients (7.6%), 3 died of MI, one died of acute stent thrombosis, one died of cardiac arrhythmia, and the last one died of stroke. Major adverse cardiac events occurred in 22 patients (27.8%) are shown in Table 3. Event-free survival was 72.2%. Target lesion revascularization occurred in 11 patients, revascularization with PCI was performed in 9 patients, and revascularization with CABG was performed in 2 patients.

On multivariate Cox regression analysis, age, and left main distal bifurcation were favorable predictors for MACE (Table 4).

Discussion. The main finding of this study is that ULMCA stenting by the transradial approach in the elderly has good angiographic and clinical results. The PCI is an option in the elderly who refuse CABG. The number of elderly people is increasing very fast in China. They represent a larger portion of patients admitted to the hospital with ULMCA. Coronary artery bypass graft surgery therapy is considered the standard treatment for patients with ULMCA stenosis¹¹ as CABG offers a well-documented survival benefit over medical therapy. Unfortunately, octogenarians are generally poor candidates for surgery¹² due to high risk.

Table 2 - Angiographic and procedural characteristics of 79 elderly patients with unprotected left main coronary artery stenosis.

Characteristics	Number (%)
Left main	11 (13.9)
LM + 1VD	12 (15.2)
LM + 2VD	24 (30.1)
LM + 3VD	33 (41.8)
Lesion location	
Ostial/shaft	34 (43.0)
Distal	45 (56.9)
QCA findings	
Mean reference diameter (mm)	3.54±0.47
Minimal luman diameter (mm)	2.12±0.33
Complete revascularization	21 (26.6)
Approach	
Single stent	48 (60.8)
Two stents	31 (39.2)
Stenting technique for bifurcation disease	
Crossing over LAD or LCX	14 (31.1)
T stenting	22 (48.9)
Culotte stenting	6 (13.3)
Mini crash	3 (6.7)
Mean stent diameter (mm)	3.56±0.33
Total stent length (mm)	18.74±5.31
Angiographic follow up	35 (44.0)
LM - left main, 1VD - one vessel disease, 2VD - 2 vessel disease, 3VD - 3 vessel disease, LAD - left anterior descending, LCX - left circumflex, QCA - quantitative coronary angiography	

Table 3 - Major adverse cardiac events (MACE) during follow up among 79 elderly patients with unprotected left main coronary artery stenosis.

Event	Hospital	One year	2 years	3 years
Death	1	3	5	6
MI	0	2	3	5
TLR	0	6	8	11
MACE	1	11	15	22
MI - myocardial infarction, TLR - target vessel revascularization				

Table 4 - Predictors of major adverse cardiac events (MACE) among 79 elderly patients with unprotected left main coronary artery stenosis.

Variables	Coefficient	Odds ratio (95% CI)	P-value
Age	0.157	1.044 - 1.311	0.007
Distal bifurcation	2.939	6.180 - 62.546	0.001
CI - confidence intervals			

For these patients, PCI maybe an alternative therapy. However, it remains unclear whether PCI offers superior efficacy and safety to CABG. The recently published Syntax research trial¹³ is a prospective randomized controlled trial comparing CABG and PCI to treat LM or multivessel disease. This study indicated that patients with LM disease who had revascularization with PCI had safety and efficacy outcomes comparable with CABG

at one year. A non-randomized trial,¹⁴ which compared PCI and CABG for LM disease found that the one-year risk of MACE was significantly lower in PCI than in CABG treated subjects. Shimizu's investigation⁶ found that MACE free survival rate was better in CABG group than in the PCI group. These studies, despite their different outcomes were not focused on the elderly, therefore, they cannot represent the population of octogenarians.

In the present study, we evaluated procedural outcomes, clinical, and angiographic follow up. In agreement with previous studies, DES stenting performed in ULMCA patients aged ≥ 70 years achieves a successful angiographic result in most cases, and is associated with a low rate of death during hospitalization. During 3 years follow up, there was comparatively low incidence of death (7.6%), TLR (13.9%), and MACE (27.8%). Our results from a single center experience indicate that PCI with DES in ULMCA is a safe strategy for the elderly.

In our study, most patients had multivessel coronary disease, but the incidence of complete revascularization was lower (26.6%) than the other studies. Fernandez et al¹⁵ reported that incidence of complete revascularization was 56.4% in non-diabetic patients and 46.9% in diabetic patients with ULMCA. In our study, most patients required a single stent instead of 2 stents, as we choose a relatively simple strategy to treat LM disease in the elderly. Elderly patients have complex coronary anatomy, including calcification, tortuosity, and small vessel disease; therefore, PCI is undoubtedly more challenging than in young patients. Whereas the incidence of contrast nephropathy, access difficulty, vascular complications are also increased. In order to avoid these complication, we prefer simple strategy of single stent.

In the elderly, peripheral vascular disease is more prevalent, making access difficult, and increasing the incidence of bleeding. Previous studies¹⁶ demonstrated that the transradial approach has fewer access site complications and bleeding compared with the transfemoral approach. In the present study, all patients received procedural success by the transradial approach. Our findings show that the transradial approach is safe in the elderly undergoing ULMCA stenting.

Study limitations. This is not a randomized study. The major limitations of this study were the retrospective nature and the small sample size.

In conclusion, PCI can be performed with good angiographic and clinical result through a transradial

approach in elderly patients. The long term survival suggests that PCI in ULMCA patients ≥ 70 years is safe and efficacious.

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