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PCI

Percutaneous Coronary Intervention versus Coronary Artery Bypass Grafting in Patients with Diabetic Nephropathy and Left Main Coronary Artery Disease

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Background: Patients with diabetic nephropathy and unprotected left main (LM) coronary artery disease suffer from high cardiovascular morbidity and mortality. Although surgical revascularization is currently recommended in this special patient population, the optimal revascularization method for this distinct patient group has remained unclear.

Methods: We collected 99 consecutive patients with unprotected LM disease and diabetic nephropathy, including 46 patients who had undergone percutaneous coronary intervention (PCI), and 53 who had coronary artery bypass grafting (CABG), with a mean age of 72 ± 10; with 80.8% male. Diabetic nephropathy was defined as overt proteinuria (proteinuria > 500 mg/day) and estimated glomerular filtration rate (eGFR) by the modified Modification of Diet in Renal Disease (MDRD) equation of less than 60 mL/min/1.73 m^2. The baseline characteristics, angiographic results and long-term clinical outcomes were retrospectively analyzed.

Results: The baseline characteristic of all patients were similar except for smokers, low density lipoprotein (LDL) level and extension of coronary artery disease involvement. The median follow-up period was 3.8 years. There were 73 patients (74%) considered as high risk with additive European System for Cardiac Operative Risk Evaluation (EuroSCORE) ≥ 6. During follow-up period, the long term rate of all-cause death (PCI vs. CABG: 45.7% vs. 58.5%, p = 0.20) and all-cause death/myocardial infarction (MI)/stroke (PCI vs. CABG: 52.2% vs. 60.4%, p = 0.41) were comparable between the PCI and CABG group, whereas the repeat revascularization rate was significantly higher in the PCI group (PCI vs. CABG: 32.6% vs. 9.4%, p < 0.01). eGFR remained an independent predictor for all-cause death [hazard ratio: 0.97, 95% confidence interval: 0.96 to 0.99; p = 0.002] in multivariate logistic regression.

Conclusions: In the real-world practice of high-risk patients with unprotected LM disease and diabetic nephropathy, we found that PCI was a comparable alternative to CABG in terms of long-term risks of all-cause death/MI/stroke, with significantly higher repeat revascularization rate. Given the small patient number and retrospective nature, our findings should be validated by larger-scale randomized studies.

Key Words: Chronic kidney disease • Coronary artery bypass grafting • Diabetes mellitus • Diabetic nephropathy • Left main coronary artery disease • Percutaneous coronary intervention

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INTRODUCTION

The disease burden of diabetes mellitus (DM) is increasing worldwide. Compared with non-diabetic patients, patients with DM tend to have coronary artery disease,[1] a greater extent of coronary ischemia,[2] with an increased likelihood of myocardial infarction[3] and silent myocardial ischemia.[4] Furthermore, post-revascularize-

tion morbidity and mortality are also higher in diabetic patients after coronary artery bypass grafting (CABG) and percutaneous coronary intervention (PCI).[5,6] Regarding the revascularization strategies for patients with diabetes mellitus and multi-vessel coronary artery disease, many trials have shown better outcomes in patients undergoing CABG. The BARI 2D trial showed fewer major adverse cardiovascular events (MACE) in the CABG stratum compared with the PCI stratum.[7] The FREEDOM trial found the benefit of CABG was driven by reductions in rates of both myocardial infarction and death from any cause.[8] On the other hand, several trials also demonstrated that PCI with stenting is a good alternative procedure besides CABG for left main coronary artery disease (LMCAD). In hospitals without on-site cardiac surgery, left main(LM) PCI was also found to be safe and effective in one observational study.[9] In the PRECOMBAT trial, the subgroup analysis in diabetic patients showed no difference in patients who underwent PCI compared with CABG.[10] Patients with diabetic nephropathy is a special higher risk population among diabetic patients. An observational study had demonstrated increasing mortality in patients with diabetic nephropathy who underwent PCI.[11] However, there is still no single trial that has elucidated the clinical outcomes of patient with diabetic nephropathy and LMCAD.

The aim of this study was to compare the long-term clinical outcomes of patients with diabetic nephropathy and LMCAD undergoing PCI or CABG.

METHODS

This study included 99 consecutive patients with DM nephropathy and unprotected LM coronary artery stenosis (> 50% narrowing) undergoing PCI or CABG at Taipei Veterans General Hospital from January 2004 to December 2010. Unprotected LM disease was defined as significant LM coronary artery stenosis without patent coronary artery bypass grafts to the left anterior descending or left circumflex arteries. Diabetic nephropathy was defined as overt proteinuria (proteinuria > 500 mg/day) and estimated glomerular filtration rate (eGFR) by the modified Modification of Diet in Renal Disease (MDRD) equation of less than 60 mL/min/1.73 m^2. Patients with acute coronary syndrome with cardiogenic shock and acute ST segment elevation myocardial infarction with totally occluded LM coronary artery as the culprit lesion were excluded. Patients who underwent concomitant valvular or aortic surgery were also excluded. The decision to perform PCI or CABG depended on the patient's or physician's preference, or surgical/interventional risk profile. The surgical risk of the patient was evaluated according to the European System for Cardiac Operative Risk Evaluation (EuroSCORE),[12] which was computed by 2 experienced cardiologists unaware of the clinical course of patients. The patients with EuroSCORE ≥ 6 were considered to be high surgical risk.

In the CABG group, CABG was performed using the standard bypass procedure. On-pump beating heart surgery was performed on patients with high risk for cardiac arrest such as emergency cases, low cardiac output, or pre-operation critical conditions with intra-arterial balloon pump or extracorporeal membrane oxygenator. The left internal mammary artery was harvested to bypass the left anterior descending coronary artery in all possible cases. In patients less than 60 years old, the radial artery graft would be considered. Aspirin or and/or clopidogrel would be prescribed as soon as possible after the surgery for life-long use. Complete revascularization was attempted whenever possible using arterial conduits or saphenous vein grafts.

In the PCI group, PCI and ventriculography were performed by the standard procedure as described before.[13] Pre-dilatation with balloon catheter was performed in all cases. For most LM lesions with distal bifurcation involved, stenting across the bifurcation toward the left anterior descending artery (cross-over technique) was attempted, followed by provisional stenting of left circumflex artery (T-stenting or culottes stenting) if there was residual stenosis or dissection over the orifice of the left circumflex artery. Post-dilation with kissing balloon technique was attempted except techniques difficulty or small non-dominant left circumflex artery. Debulking by means of rotablator was used only in highly calcified lesions, and the use of intravascular ultrasound and glycoprotein IIb/IIIa receptor antagonist were at the discretion of the interventional operators. After the procedure, all patients received aspirin (100 mg/d) indefinitely and clopidogrel (300 mg loading dose, then 75 mg per day) or ticlopidine (500 mg loading dose,

then 250 mg twice a day) for at least 1 month [bare metal stent (BMS)] or 12 months [drug-eluting stent (DES)]. Medications for treatment of angina pectoris (calcium channel blockers, beta-blockers and nitrates) were continued.

All patients were followed-up completely, without any case loss of follow up. For all patients undergoing PCI or CABG, follow-up angiography was performed only when there were ischemic symptoms or signs and/or non-invasive evidence of ischemia. The clinical follow-up data were collected by scheduled monthly clinic evaluations or direct telephone contact for all-cause death and the first-ever major adverse cardiovascular cerebrovascular event (MACCE), which was defined as all-cause death, myocardial infarction (MI), stroke and clinical-driven repeat revascularization. MI was defined as the presence of significant new Q waves in at least 2 electrocardiographic leads or of symptoms compatible with myocardial infarction associated with an increase in creatine kinase-MB fraction $\geq$ 3 times the upper limit of the reference range. Repeat revascularization was defined as any repeated percutaneous intervention of lesion performed for > 50% angiographic re-narrowing of the treated lesions 5 mm proximal to 5 mm distal to the stent/de novo new lesions, repeat bypass surgery, or repeat revascularization of graft lesions/de novo lesions after CABG. Stroke with neurological deficit was diagnosed by a neurologist on the basis of imaging study. The study protocol was approved by the Institutional Review Board at Taipei-Veterans General Hospital, and informed written consent was obtained from each participant.

Statistical analysis

All continuous variables were presented as mean $\pm$ standard deviation, and categorical variables as numbers and percentages. The differences of continuous data between PCI and CABG groups were compared by two-sample *t*-test. Categorical data between 2 groups were compared using either the Chi-square test or Fisher's exact test. Multivariable Cox regression analysis was performed to determine independent predictors of long-term clinical outcomes. The hazard ratio (HR) and 95% confidence intervals (CI) were calculated. Cox regression models were developed to perform the unadjusted univariate analyses and adjusted multivariate analyses. A p-value of less than 0.05 was considered to be statistically significant. The SPSS 17.0 (SPSS Inc., Chicago, Illinois, US) software package was used for statistical analysis.

RESULTS

Patient characteristics

From January 2004 to December 2010, we collected 99 consecutive patients with unprotected LM coronary artery stenosis, of whom 46 were treated with PCI and 53 treated with CABG. The mean age of the population was 72 $\pm$ 10 years with male (80.8%) predominance. More than half of the patients presented as non-ST segment elevation acute coronary syndrome (66 patients, 67%). Furthermore, 32 patients (33%) presented with left ventricular ejection fraction (LVEF) < 40%. In particular, 73 patients (74%) were considered as high risk in the presence of the additive EuroSCORE $\geq$ 6. These features suggested that the study patients belonged to a higher risk population. The baseline characteristics of the PCI and CABG groups are summarized in Table 1. There were no significant differences in atherosclerotic risk factors between the PCI and CABG group, except a higher prevalence of smoking history and higher low density lipoprotein (LDL) cholesterol level in patients undergoing CABG. In contrast, the patients undergoing CABG had more complex coronary anatomy, including more 3-vessel disease and greater involvement of the right coronary artery (Table 1).

In the PCI group, DES was used in 30 patients (65%). The majority of patients with distal bifurcation involvement were treated with a single stent with cross-over technique (n = 40, 87%) of all patients with bifurcation lesions. Intravascular ultrasound and rotablation were applied in 7 (15.2%) and 4 (8.7%) patients, respectively. In the CABG group, 36 (67.9%) patients received at least one arterial conduit, and the others received vein grafts due to poor quality of left internal mammary artery or urgent surgery. The mean number of grafts was 0.68 $\pm$ 0.5 artery and 2.46 $\pm$ 0.8 venous grafts.

30-day and long-term outcomes

Within the 30-day period after index procedure, the risk of death and MACCE were comparable between the PCI and CABG groups. Table 2 summarizes 30 days and

Table 1. Baseline characteristic of patients treated with PCI and CABG

	PCI (n = 46)	CABG (n = 53)	p value
Age (years)	72.9 ± 8.9	71.5 ± 11.1	0.48
Gender (male, %)	41 (89.1%)	39 (73.6%)	0.07
Hypertension (%)	42 (91.3%)	47 (88.7%)	0.75
Hypercholesterolemia (%)	112 (54%)	135 (50%)	0.41
Smoking (%)	19 (41.3%)	36 (67.9%)	0.009
PAOD (%)	12 (26.1%)	18 (36%)	0.38
CVA	7 (15.2%)	9 (18%)	0.79
Clinical presentation as ACS (%)	30 (65.2%)	36 (67.9%)	0.78
Cholesterol (mg/dL)	150.28 ± 35.06	165.75 ± 49.02	0.08
HDL (mg/dL)	38.93 ± 18.49	38.24 ± 7.67	0.81
LDL (mg/dL)	91.11 ± 27.97	105.63 ± 39.48	0.04
HbA1C (%)	7.69 ± 1.64	7.46 ± 1.61	0.47
LVEF (%)	46.3 ± 13.1	45.65 ± 13.0	0.82
eGFR (ml/min per 1.73 m^2)	33.3 ± 18.8	31.25 ± 16.9	0.57
CKD by eGFR			0.29
Stage 3	28 (60.9%)	29 (54.7%)	
Stage 4	5 (10.9%)	12 (22.6%)	
Stage 5	13(28.3%)	12 (22.6%)	
EuroSCORE	10.2 ± 5.5	9.1 ± 4.2	0.28
EuroSCORE ≥ 6 (%)	33 (71.7%)	40 (75.5%)	0.67
Angiograhic and procedure characteristics			
LM bifurcation involved	32 (69.6%)	38 (79.2%)	0.35
RCA involved	23 (50%)	49 (92.5%)	< 0.001
Extent of diseased vessel n (%)			0.001
LM only	5 (10.9%)	1 (1.9%)	
LM plus 1-vessel disease	8 (17.4%)	2 (3.8%)	
LM plus 2-vessel disease	13 (28.3%)	6 (11.3%)	
LM plus 3-vessel disease	20 (43.5%)	44 (83%)	
Use of DES	30 (65.2%)	-	-

ACS, acute coronary syndrome; CABG, coronary artery bypass grafting; CKD, chronic kidney disease; CVA, cerebrovascular accident; DES, drug-eluting stent; eGFR, glomerular filtration rate estimated by modified MDRD study equation; EuroSCORE, the European System for Cardiac Operative Risk Evaluation; HDL, high density lipoprotein; LDL, low density lipoprotein; LM, left main; LVEF, left ventricular ejection fraction; PAOD, peripheral artery occlusive disease; PCI, percutaneous coronary intervention; RCA, right coronary artery disease.

long-term clinical outcomes after treatment with PCI or CABG.

As for long-term outcomes, the median follow-up period was 4.3 years (25-75% range: 2.7 to 6.5 years). During the follow-up period, there were 52 all-cause deaths (52.5%), and 65 cumulative MACCE (65.6%), which also included 9 non-fatal MI (9.1%), 4 stroke (3.8%), and 20 repeat revascularization (20.2%) (Table 2). The long-term rate of all-cause death (p = 0.20), all-cause death/MI/stroke (p = 0.41) and MACCE (p = 0.73) were comparable between the PCI and CABG group, whereas the rate of repeat revascularization was significantly higher in the PCI group (p < 0.01, Table 2, Figure 1).

In patients with LM and 3-vessel disease, we also

Table 2. 30-day and cumulative long-term outcomes

	PCI (n = 46)	CABG (n = 53)	p value
30-day outcomes			
All-cause death	2 (4.3%)	4 (7.5%)	0.68
MACCE	2 (4.3%)	4 (7.5%)	0.68
Long-term outcomes			
All-cause death	21 (45.7%)	31 (58.5%)	0.20
Myocardial infarction	7 (15.2%)	4 (7.5%)	0.23
Repeat revascularization	15 (32.6%)	5 (9.4%)	< 0.01
Stroke	1 (2.2%)	3 (5.7%)	0.62
All-cause death/MI/stroke	24 (52.2%)	32 (60.4%)	0.41
MACCE	31 (67.4%)	34 (64.2%)	0.73

MACCE, major adverse cardiac and cerebrovascular event, including all-cause death, MI, stroke and repeat revascularization; MI, myocardial infarction.

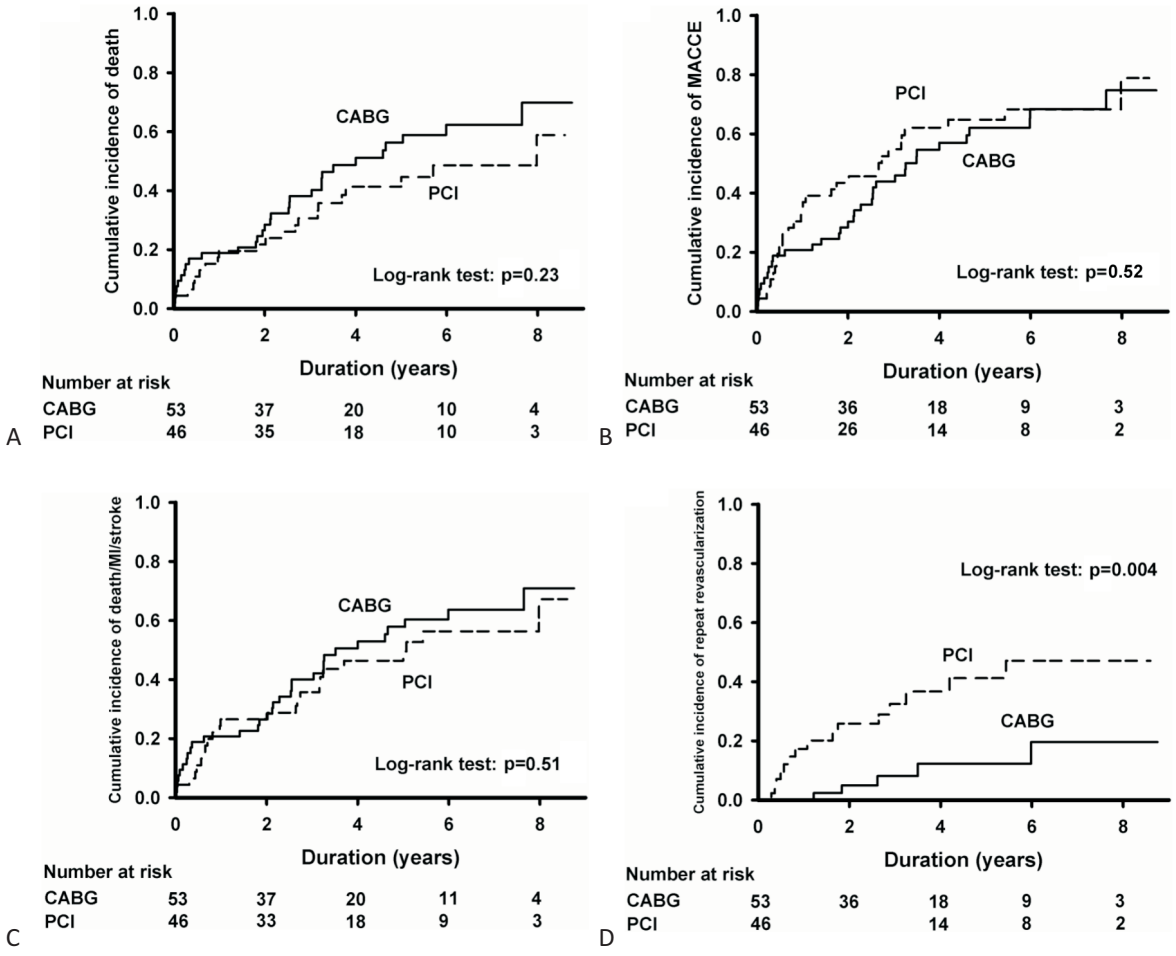

Figure 1. *Cumulative incidence of all-cause death (A), all-cause death/MI/stroke (B), MACCE (C), and repeat revascularization (D) in the PCI and CABG groups.*

demonstrated comparable long-term result of all-cause death (p = 0.51), all-cause death/MI/stroke (p = 0.78) and MACCE (p = 0.54) between the PCI and CABG group. Additionally, a slightly higher rate of repeat revascularization in the PCI group was also found (p = 0.05, Table 3). When we did further analysis in patients with chronic kidney disease (CKD) stage 5, we found statistical insignificance in the rate of repeat revascularization between the PCI and CABG group (p = 0.06). Nonetheless, the long-term rate of all-cause death (p = 0.47), all-cause death/MI/stroke (p = 0.42) and MACCE (p = 0.20) were still comparable between the PCI and CABG group (Table 3).

In the multivariate Cox regression analysis for long-term clinical outcomes, the EuroSCORE and the eGFR were identified as independent predictors for all-cause death (Table 4), whereas the treatment with CABG appeared to be an independent protective factor against repeat revascularization (Table 4).

DISCUSSION

In this retrospective, observational study, we found that (1) the long-term risk of death and MACCE between PCI and CABG in patients with diabetic nephropathy and LMCAD are not statistically significantly different; (2) target vessel revascularization (TVR) is significant higher in the PCI groups in patients with diabetic nephropathy and LMCAD; (3) the predictive factors of death in patients with diabetic nephropathy are eGFR and addictive EuroSCORE; (4) the predictive factor of MACCE in patient with diabetic nephropathy is eGFR. To our knowledge, this is the first study to compare the revascularization strategies in patients with LMCAD and diabetic nephropathy.

Typically, coronary artery disease involvement is more extensive in diabetic patients. The CABG group has more case numbers of LMCAD and 3-vessels disease compared with the PCI group (83% vs. 43.5%). The CARDia trial is the first randomized trial for the coronary revascularization treatments in diabetic patients though the non-inferiority margin is not met, this study did show multi-vessel PCI is comparable to CABG in diabetic patients.[14] In 452 patients with LMCAD, the one-year follow-up of the SYNTAX trial for pre-specified subgroup in patients with LMCAD showed comparable results between PCI and CABG, particularly in patients with a SYNTAX score less than 33.[15] Furthermore, a subgroup analysis suggested that there were no significant differences in composite death/cerebrovascular accident/MI between CABG and paclitaxel-eluting stents (PES) groups in diabetic patients. However, in comparison with non-diabetic patients, patients with diabetes had increase mortality in both the CABG and PES group.[16] In the above studies, increase in TVR rate was common adverse event in diabetic patients, even in patients who received PCI with DES. Although our TVR rate was also significant higher in the PCI group, the MACCE rate is still similar in both groups. Regarding the patients with LM and 3-vessel disease in our study, we also showed comparable results between CABG and PCI. Our result is similar to the present studies when comparing CABG and PCI. More comorbidities and higher risk profiles might lead to higher rate of death/MI, which might contribute to the non-signifi-

Table 3. Subgroup analysis for cumulative long-term outcomes

	PCI	CABG	p value
LM and 3-vessel disease (n)	n = 20	n = 44	
All-cause death	10 (50%)	26 (59.1%)	0.51
MACCE	14 (70%)	28 (63.6%)	0.54
All-cause death/MI/stroke	11 (55%)	27 (61.3%)	0.78
Repeat revascularization	6 (30%)	4 (9%)	0.05
CKD stage 5 (n)	n = 13	n = 12	
All-cause death	10 (76.9%)	7 (58.3%)	0.47
MACCE	12 (92.3%)	7 (58.3%)	0.20
All-cause death/MI/stroke	10 (76.9%)	7 (58.3%)	0.42
Repeat revascularization	6 (46.1%)	1 (8.3%)	0.06

CKD, chronic kidney disease; LM, left main; MACCE, major adverse cardiac and cerebrovascular event, including all-cause death, MI, stroke and repeat revascularization; MI, myocardial infarction.

Table 4. Cox regression analysis for (A) all-cause death and all-cause death/MI/stroke; (B) MACCE and repeat revascularization

(A)

Variables	All-cause death				All-cause death/MI/stroke			
	Univariate		Multivariate		Univariate		Multivariate	
	HR (95% CI)	p	HR (95% CI)	p	HR (95% CI)	p	HR (95% CI)	p
Age	1.02 (0.99-1.05)	0.16			1.03 (0.99-1.06)	0.09	1.03 (0.99-1.07)	0.07
ACS	0.92 (0.52-1.62)	0.76			1.07 (0.61-1.88)	0.81		
eGFR	0.97 (0.96-0.99)	< 0.001	0.97 (0.96-0.99)	0.002	0.98 (0.96-0.99)	0.001	0.97 (0.96-0.99)	0.001
HDL	1.02 (0.99-1.03)	0.07	1.00 (0.97-1.02)	0.70	1.01 (0.99-1.03)	0.10	1.00 (0.99-1.02)	0.70
LVEF	0.99 (0.97-1.01)	0.37			0.99 (0.98-1.02)	0.75		
EuroSCORE	1.10 (1.04-1.17)	0.001	1.09 (1.02-1.15)	0.001	1.08 (1.02-1.15)	0.006	1.04 (0.97-1.12)	0.23

(B)

Variables	MACCE				Repeat revascularization			
	Univariate		Multivariate		Univariate		Multivariate	
	HR (95% CI)	p	HR (95% CI)	p	HR (95% CI)	p	HR (95% CI)	p
Age	1.02 (0.99-1.05)	0.08	1.03 (0.99-1.06)	0.08	-	-	-	-
ACS	1.24 (0.73-2.12)	0.43			4.77 (1.11-20.6)	0.04	5.30 (1.23-22.9)	0.03
eGFR	0.98 (0.97-0.99)	0.01	0.98 (0.96-0.99)	0.08	0.99 (0.97-1.02)	0.62		
LVEF	0.99 (0.97-1.01)	0.26			-	-	-	-
EuroSCORE	1.07 (1.02-1.13)	0.01	1.04 (0.98-1.10)	0.22	-	-	-	-
PCI/CABG	-	-	-	-	3.91 (1.42-10.7)	0.008	4.25 (1.54-11.7)	0.005

Abbreviations are in Table 1.

cant difference in MACCE rate.

The impact of CKD on the prognosis of patients with LMCAD has not been fully elucidated. Kazuhiro et al. reported 95 patients with LMCAD (22% with DM) and more than half of the patients received CABG for LMCAD. Although they didn't report the long-term result of both revascularization methods, they demonstrated that renal insufficiency was a risk factor for LMCAD, and might predict poor prognosis in these Japanese patients.[17] Our study also showed the same conclusion, that the eGFR is a clinical predictor of death and MACCE in patients with diabetic nephropathy. Moreover, a retrospective cohort study collected 59,576 patients with renal insufficiency which were divided into 3 groups: creatinine < 2.5 mg/dL (n = 58,329), creatinine ≥ 2.5 mg/dL (n = 840) and end stage renal disease (ESRD) (n = 407). The survival benefit was noted only in the ESRD group in patients who underwent CABG as compared with PCI.[18] Another retrospective study also confirmed this observation. The stenting group is even worse in patients with diabetes mellitus and ESRD under dialysis.[19] However, the subgroup analysis of patients with CKD stage 5 in our study did not show any difference between CABG and PCI with regard to all-cause death/MACCE/TVR. The possible reason might be related to small patient numbers in this subgroup. The ARTS trial showed that patients with mild to moderate CKD undergoing coronary revascularization had similar rates of MI, stroke or death whether they underwent PCI with stenting or CABG.[20] In our study population, PCI group has 71.8% of patients with CKD stage 3 to 4 and the CABG group has 77.3% of patients with CKD stage 3 to 4. That is one possible reason for the negative result in our study. According to the result of ARTs trial, there is increasing evidence showing that in dialysis patients, the DES, compared with BMS, are associated with reduced restenosis rates and a decreased requirement for repeat revascularization.[21] A previous study in our hospital also demonstrated that the use of DES in high-risk population undergoing unprotected LM PCI is more beneficial than the use of BMS in reducing MACE and cardiovascular death.[22] We used DES in 30 of 46 patients (65%) in the PCI group, which might be another reason for a comparative result with CABG group. Bae KS et al. reported one study relating to patients with coronary artery disease and DM nephropathy who underwent CABG and PCI, which demonstrated similar results as our study. However, the MACE rate was lower in the CABG group in the 3-year follow-up. Nevertheless, the PCI group used BMS to treat all the lesions which may influence the outcome.[23]

Except the specific patient population in our study, the average age of our patients was also older than most of the revascularization for LMCAD study (PCI: 72.93 ± 8.97 yrs, CABG: 71.47 ± 11.13 yrs). PCI might be suitable for elderly patients with chronic pulmonary disease, chronic renal insufficiency, peripheral vascular disease and other comorbidities which will increase the operative risk and reduce life expectancy.[24] One observational study compared CABG with PCI with DES in patient older than 75 years of age. They didn't demonstrate any difference in mortality between CABG and PCI with DES.[25] We may need more randomized studies to ascertain the better revascularization strategy for elderly patients with multiple comorbidities and LMCAD.

Limitations

There were several limitations to the present study. This study was a single-center, non-randomized, uncontrolled registry that requires validation by prospective randomized studies. According to the SYNTAX trial, SYNTAX score ≥ 33 showed better outcome in CABG group, we didn't calculate the SYNTAX score in our study. The rate of MACCE might be underestimated due to incomplete angiographic follow-up related potential bias. Another important limitation was that a significant heterogeneity in treatment, stenting strategy and surgical technique might exist because of the extended enrollment period from 2004-2010.

CONCLUSIONS

The overall survival rate and MACCE rate were similar in the CABG and PCI group, in patients with diabetic nephropathy and left main coronary artery disease. Renal function can be used as a predictor for death and MACCE.

DISCLOSURES

None.

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