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Comparison of Drug-Eluting Stents and Coronary Artery Bypass Grafting for the Treatment of Multivessel Coronary Artery Disease in Patients With Chronic Kidney Disease

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Background: Chronic kidney disease (CKD) is a strong predictor of mortality after percutaneous coronary intervention (PCI) or coronary artery bypass grafting (CABG), but the relative efficacy of the 2 revascularization strategies in this context remains unknown.

Methods and Results: The 1,069 patients with CKD undergoing revascularization for multivessel coronary disease were evaluated. Of them, 532 patients were treated for 2-vessel disease (97 CABG, 435 PCI) and 537 for 3-vessel disease (248 CABG, 289 PCI). CKD was defined as estimated glomerular filtration rate <60 ml/min. No differences between the PCI and CABG groups in the 2-vessel population were observed in the composite of death, myocardial infarction (MI) or cerebrovascular events (10.6% vs 8.2%, P=0.493) and repeat revascularization (6.7% vs 3.1%, P=0.181) during the 2-year follow-up. In the 3-vessel population, patients undergoing PCI showed similar rate for the composite endpoint (6.7% vs 3.1%, P=0.181), but had a higher incidence of repeat revascularization (12.5% vs 4.4%, P=0.001) compared with the CABG group. After multivariate adjustment, revascularization strategy was not an independent predictor of the composite endpoint.

Conclusions: Compared with PCI with a drug-eluting stent, CABG showed a similar incidence of death, MI or cerebrovascular events in patients with multivessel disease and CKD, but was associated with decreased repeat revascularization in the 3-vessel population. (*Circ J* 2009; **73:** 1228 – 1234)

Key Words: Coronary artery bypass grafting; Coronary heart disease; Drug-eluting stent (DES); Kidney; Survival

Percutaneous coronary intervention (PCI) and coronary artery bypass grafting (CABG) are optional treatments for patients with multivessel coronary artery disease (CAD). Multiple studies comparing CABG with PCI for the treatment of multivessel CAD demonstrate similar mortality rates, but increased incidences of repeat revascularization after PCI![1–12] In contrast, several large clinical registries reported that, compared with coronary stenting, CABG was associated with long-term survival benefits![3–15] Importantly, in some meta-analyses and registries, CABG demonstrated greater benefit in mortality and myocardial infarction (MI) in high-risk patient subsets, such as those with diabetes or left ventricular (LV) dysfunction![4–17]

Chronic kidney disease (CKD) is common in patients with coronary heart disease, estimated to affect approximately 25% of patients requiring coronary revascularization![18–25] It has been reported that the presence of CKD is associated with a higher risk of mortality among patients with CAD?[26–28] Multiple studies have also shown that CKD is a potent independent predictor of death and subsequent cardiac events in patients undergoing revascularization![18–22] However, the data on whether CABG or PCI offers a better clinical outcome among CKD patients requiring coronary revascularization are very limited. Although several observational studies have compared the outcomes of participants with CKD and multivessel CAD who were assigned to CABG or PCI, those patients were not examined in the setting of the current practice of coronary implantation with a drug-eluting stent (DES) versus CABG?[23,24] Therefore, in the present registry study, we compared the long-term outcomes of PCI with DES versus CABG in patients with multivessel CAD and CKD at a single high-volume center.

Methods

Study Population

Using the comprehensive revascularization database from Beijing Anzhen Hospital, whereby charts from patients undergoing a coronary intervention were reviewed by dedicated, independent investigators unaware of the objectives or purpose of the study, we evaluated 1,069 consecutive patients with multivessel CAD and CKD who underwent DES implantation or CABG between January 2004 and June 2006. We defined 2- and 3-vessel disease as the presence of 2 or 3 major epicardial coronary arteries with ≥70% diameter stenosis, determined visually by the cardiologist performing the first angiographic procedure. The method of revascularization was at the physician's and/or patient's

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discretion. The study design was reviewed and approved by the institutional research Ethics Committee, and all patients provided informed consent and the board guidelines. We excluded patients with unprotected left main CAD, acute MI with ST-segment elevation, cardiogenic shock, congenital or valvular heart disease, and those who had prior coronary stent implantation or prior CABG.

Preoperative serum creatinine levels were obtained from all patients, and renal function was assessed by estimated glomerular filtration rate (eGFR) calculated using the modified Modification of Diet in Renal Disease (MDRD) equation, which was modified from the original MDRD equation by adding a racial factor based on the Chinese population, and showed significant performance improvement in bias, precision, and accuracy compared with the original MDRD equations in Chinese patients[29] eGFR ($ml \cdot min^{-1} \cdot 1.73\,m^{-2}$) = $186 \times (\text{serum creatinine level [mg/dl]})^{-1.154} \times (\text{age [years]})^{-0.203} \times 0.742$ (if female) $\times 1.227$. Participants with eGFR <60 ml/min were defined as having CKD in this study, consistent with CKD stage 3–5 of the National Kidney Foundation classification.[30]

Revascularization Procedure

PCI All patients underwent PCI according to current clinical guidelines;[31,32] with the interventional strategy at the discretion of the operator. All patients received a DES, comprising sirolimus-eluting stents, paclitaxel-eluting stents or zotarolimus-eluting stents. Weight-adjusted intra-procedural unfractionated heparin (with a goal-activated clotting time 250–300 s) was administered during the procedure and was routinely discontinued at the end of the procedure. A loading dose of 600 mg clopidogrel was given to all patients prior to PCI, followed by a maintenance dose of 75 mg daily for 9–12 months unless severe bleeding complications occurred. In addition, all patients received 300 mg aspirin daily, begun on the day of the procedure.

CABG Surgical revascularization was performed using standard bypass techniques. Mammary artery conduits were preferentially used for revascularization of the left anterior descending artery (LAD) whenever possible. Complete revascularization was performed when possible with arterial conduits or saphenous vein grafts. For those patients taking aspirin or clopidogrel, surgery was delayed at least 5 days. After the procedure, patients were administered 100 mg aspirin per day indefinitely.

Clinical Outcomes and Definitions

The primary endpoint was a composite of all-cause death, non-fatal MI or cerebrovascular events (CVE). The second endpoint was repeat revascularization. MI was defined as any typical rise and fall of cardiac biomarkers in the setting of clinical signs or symptoms consistent with cardiac ischemia, following the American College of Cardiology definition.[33] Repeat revascularization included target vessel and nontarget vessel revascularization, regardless of whether the procedure was angiographically or clinically driven. CVE were divided into 3 categories: stroke, transient ischemic attack, and reversible ischemic neurological deficit, as determined by a neurologist.

Patients were contacted by telephone and interviewed about adverse events. Follow-up interviews and medical event classification were performed by independent investigators who were unaware of the objectives or purpose of the study. For those patients having reached at least 1 of the endpoints, a medical chart review was initiated to determine whether the event met the definitions described.

Statistical Analysis

Continuous variables are presented as mean ± SD, and were compared using Student's t-test. Categorical variables are presented as frequencies and percentages. Because of the nonrandomized nature of this study, separate analysis was undertaken for the 2- and 3-vessel disease populations. Differences in baseline characteristics between groups were compared with chi-square tests, or exact tests if expected cell frequencies were small. Event-free survival estimates were created using Kaplan-Meier methods and compared with the log-rank test with respect to revascularization strategy. Predictors of long-term clinical outcomes were identified using Cox proportional hazards regression and multivariate analysis. The candidate variables were: revascularization strategy, age, gender, smoking status, history of prior MI, diagnosis of diabetes mellitus, hypertension, hypercholesterolemia, and LV dysfunction with ejection fraction <30%, acute coronary syndrome, proximal LAD disease and chronic total occlusion lesion.

All statistical analyses were 2-tailed, and a value of $P < 0.05$ was considered statistically significant. Analysis was performed with SPSS software, version 13.0 for windows (SPSS, Inc, Chicago, IL, USA).

Results

Patient Sample Characteristics

Of 6,487 patients undergoing either revascularization with DES (4,824 patients) or CABG (1,663 patients) for multivessel CAD during the study period, 1,069 patients (16.5%) had CKD and were available for follow-up analysis. Among them, 724 underwent PCI with DES and 345 underwent CABG. In the DES group, a total of 2,353 DES were implanted, with the mean number of stents used per patient being 3.3±1.3. Of these, 1,984 (84%) were sirolimus-eluting stents (Cypher Select, Cordis, Bridgewater, NJ, USA; Firebird, Microport, Shanghai, China; Excel, JW Medical, Weihai, China; or Partner, Lepu Medical Technology, Beijing, China), 164 (7%) were paclitaxel-eluting stents (Taxus, Boston Scientific, Natick, MA, USA), and 205 (9%) were zotarolimus-eluting stents (Endeavor, Medtronic, Minneapolis, MN, USA). The mean total length of stents implanted per patient was 64.2±29.8 mm, and the average reference-vessel diameter was 2.9±0.4 mm. In the CABG group, 284 patients (82%) underwent off-pump surgery. Of the 173 patients with a proximal LAD lesion, 168 (97%) underwent revascularization of the LAD with a mammary artery conduit.

Baseline clinical and angiographic characteristics according to revascularization strategy are shown in **Table 1**. A total of 532 patients were treated for 2-vessel disease (97 CABG, 435 DES) and 537 for 3-vessel disease (248 CABG, 289 DES). In the 3-vessel cohort, patients undergoing PCI with DES were more likely to have acute coronary syndrome compared with those who underwent CABG. In both the 2- and 3-vessel populations, patients receiving CABG had a strikingly higher prevalence of proximal LAD disease and chronic total occlusion.

Clinical Outcomes

Complete follow-up data for major clinical events were obtained in 96% of the overall cohort: 39.0% (n=282) of patients implanted with DES and 13.9% (n=41) of patients

Table 1. Baseline Clinical and Angiographic Characteristics of Patients

	2-vessel disease		P value	3-vessel disease		P value
	DES (n=435)	CABG (n=97)		DES (n=289)	CABG (n=248)	
Clinical characteristic						
Age, years mean±SD	60.4±11.3	58.0±10.5	0.060	61.2±11.1	59.6±10.5	0.090
Female, n (%)	139 (32.1)	33 (34.0)	0.715	99 (34.3)	72 (29.0)	0.195
Current smoker, n (%)	187 (43.0)	36 (37.1)	0.289	138 (47.8)	108 (43.5)	0.330
Hypertension, n (%)	258 (59.3)	57 (58.8)	0.921	171 (59.2)	146 (58.9)	0.944
Diabetes, n (%)	104 (23.9)	29 (29.9)	0.218	85 (29.4)	90 (36.3)	0.090
Hypercholesterolemia, n (%)	87 (20.0)	21 (21.6)	0.715	77 (26.6)	62 (25.0)	0.665
LV dysfunction (EF <30%), n (%)	20 (4.6)	4 (4.1)	0.839	14 (4.8)	10 (4.0)	0.650
Previous MI, n (%)	74 (17.0)	18 (18.6)	0.716	56 (19.4)	54 (21.8)	0.493
NSTE-ACS, n (%)	167 (38.4)	30 (30.9)	0.169	115 (39.8)	78 (31.5)	0.045
Previous stroke, n (%)	44 (10.1)	9 (9.3)	0.804	28 (9.7)	29 (11.7)	0.452
Angiographic characteristic						
Proximal LAD disease, n (%)	155 (35.6)	59 (60.8)	0.000	76 (26.3)	114 (46.0)	0.000
CTO lesions, n (%)	34 (7.8)	26 (26.8)	0.000	29 (10.0)	61 (24.6)	0.000
Concomitant medication, n (%)						
Statins	356 (81.8)	76 (78.4)	0.426	242 (83.7)	200 (80.6)	0.349
β-blocker	304 (69.9)	66 (68.0)	0.721	208 (72.0)	166 (66.9)	0.206
ACEI or ARB	241 (55.4)	56 (57.7)	0.676	155 (53.6)	147 (59.3)	0.189

DES, drug-eluting stent; CABG, coronary artery bypass grafting; LV, left ventricular; EF, ejection fraction; MI, myocardial infarction; NSTE-ASC, non-ST segment elevation acute coronary syndrome; LAD, left anterior descending; CTO, chronic total occlusion; ACEI, angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker.

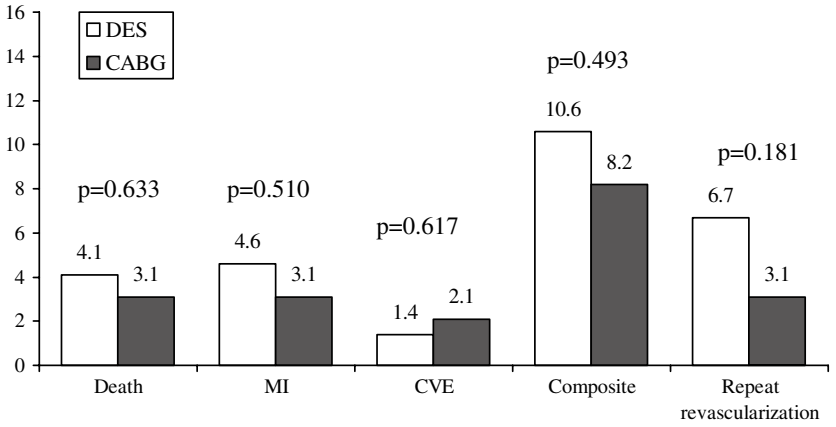

Figure 1. Two-year clinical outcomes after implantation with DES compared with CABG for patients with 2-vessel disease. CABG, coronary artery bypass grafting; CVE, cerebrovascular event; DES, drug-eluting stent; MI, myocardial infarction.

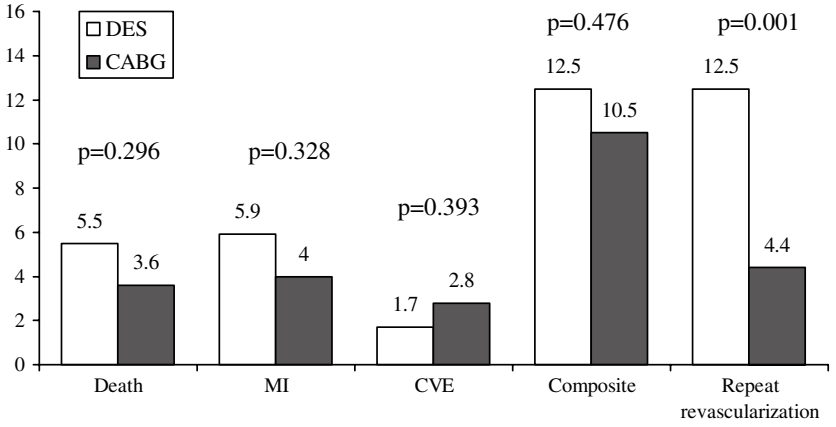

Figure 2. Two-year clinical outcomes after implantation with DES compared with CABG for patients with 3-vessel disease. CABG, coronary artery bypass grafting; CVE, cerebrovascular event; DES, drug-eluting stent; MI, myocardial infarction.

undergoing CABG had follow-up angiography. The 2-year clinical outcomes for the overall 2- and 3-vessel coronary disease populations are shown in **Figures 1** and **2**. In the 2-vessel population, the incidence of the primary endpoint was very similar in patients receiving DES or CABG (10.6% vs 8.2%, P=0.493), and there was no significant difference between the 2 treatment groups in the frequency of the individual outcomes of death, nonfatal MI or CVE. In the 2-vessel population, patients treated with DES also showed similar rates of repeat revascularization compared with

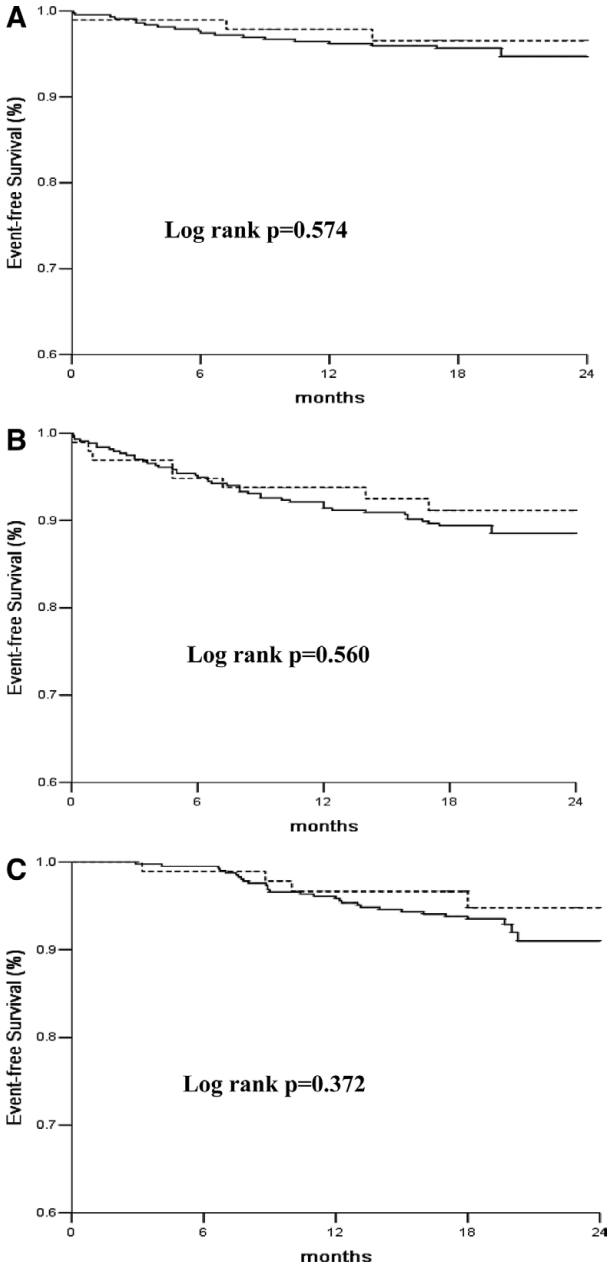

Figure 3. Two-year Kaplan-Meier survival curves for (**A**) all-cause death, (**B**) composite endpoint and (**C**) repeat revascularization in patients with 2-vessel disease undergoing drug-eluting stent implantation (solid line) or coronary artery bypass grafting (dotted line).

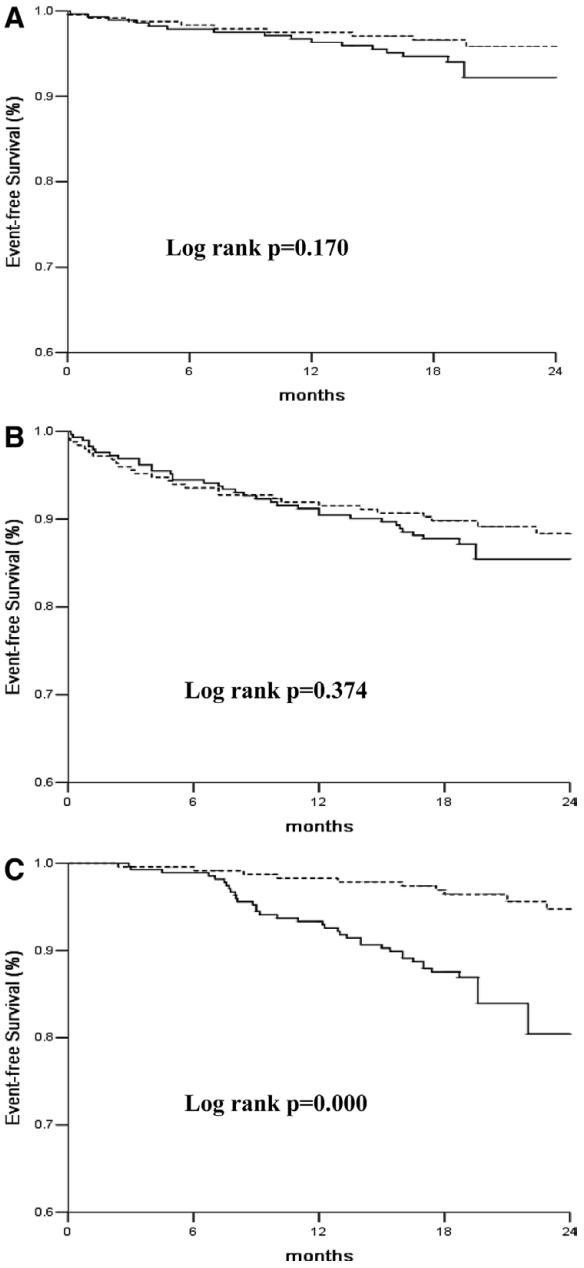

Figure 4. Two-year Kaplan-Meier survival curves for (**A**) all-cause death, (**B**) composite endpoint and (**C**) repeat revascularization in patients with 3-vessel disease undergoing drug-eluting stent implantation (solid line) or coronary artery bypass grafting (dotted line).

those undergoing CABG (6.7% vs 3.1%, P=0.181).

In the 3-vessel population, there was also no significant difference between the DES and CABG groups in the frequency of the composite endpoint (12.5% vs 10.5%, P=0.476) or in the individual outcomes of death, nonfatal MI or CVE. However, patients receiving a DES had a significantly higher rate of repeat revascularization as compared with patients who underwent CABG during the 2-year follow-up (12.5% vs 4.4%, P=0.001).

Figures 3 and **4** depict the Kaplan-Meier event-free survival curves for the 2- and 3-vessel populations. There were no significant differences in cumulative death (**Figures 3A**, **4A**) and the composite endpoint of death, MI and CVE (**Figures 3B**,**4B**) between CABG and DES in either the 2- or 3-vessel cohort during the 2 years of follow-up. In patients with 2-vessel disease, the 2 treatments showed similar survival rates free from repeat revascularization (log-rank P=0.372). In contrast, in the 3-vessel cohort CABG was associated with a significantly higher survival rate free from repeat revascularization, as compared with PCI with DES, during the 2-year follow-up (log rank P=0.000).

Multivariate Analyses

As presented in **Tables 2** and **3**, multivariate Cox regression analysis of long-term outcome showed that the choice of revascularization strategy were not an independent predictor of the cumulative composite endpoint or death in either the 2- or 3-vessel populations during the 2 years of

Table 2. Multivariate Predictors of Composite Endpoint, All-Cause Death and Repeat Revascularization for Patients With 2-Vessel Disease During 2-Year Follow-up

	Hazard ratio (95%CI)	P value
Composite endpoint		
Revascularization strategy (DES/CABG)	1.46 (0.66–3.22)	0.345
Age (continuous)	1.04 (1.02–1.07)	0.001
Diabetes	2.08 (1.05–4.13)	0.036
LV dysfunction (EF <30%)	5.40 (1.75–16.66)	0.003
Acute coronary syndrome	2.26 (1.15–4.44)	0.018
All-cause death		
Revascularization strategy (DES/CABG)	1.76 (0.48–6.46)	0.397
Age (continuous)	1.06 (1.02–1.11)	0.006
LV dysfunction (EF <30%)	8.91 (1.72–46.29)	0.009
Diabetes	3.33 (1.28–8.66)	0.045
Repeat revascularization		
Revascularization strategy (DES/CABG)	1.45 (0.49–4.26)	0.498
Diabetes	2.17 (1.33–3.62)	0.003
Current smoker	1.96 (1.12–3.97)	0.015

CI, confidence interval. Other abbreviations see in Table 1.

Table 3. Multivariate Predictors of Composite Endpoint, All-Cause Death and Repeat Revascularization for Patients With 3-Vessel Disease During 2-Year Follow-up

	Hazard ratio (95%CI)	P value
Composite endpoint		
Revascularization strategy (DES/CABG)	1.32 (0.77–2.23)	0.311
Age (continuous)	1.03 (1.01–1.06)	0.019
Diabetes	1.96 (1.16–3.30)	0.012
LV dysfunction (EF <30%)	5.61 (1.72–18.35)	0.004
All-cause death		
Revascularization strategy (DES/CABG)	1.79 (0.73–4.43)	0.206
Age (continuous)	1.05 (1.01–1.09)	0.026
LV dysfunction (EF <30%)	7.57 (1.16–49.28)	0.034
Diabetes	2.72 (1.13–6.55)	0.025
Repeat revascularization		
Revascularization strategy (DES/CABG)	3.89 (1.87–8.10)	0.000
Diabetes	2.04 (1.09–3.82)	0.027
Current smoker	1.98 (1.07–3.68)	0.031

Abbreviations see in Tables 1,2.

follow-up. In patients with 2-vessel disease, the choice of revascularization strategy was not an independent predictor of repeat revascularization (hazard ratio 1.45, 95% confidence interval 0.49–4.26, P=0.498). However, PCI with DES was independently associated with a higher risk of repeat revascularization in patients with 3-vessel disease compared with CABG (hazard ratio 3.89, 95% confidence interval 1.87–8.10, P=0.000).

Discussion

In this large observational study of consecutive patients with 2- or 3-vessel CAD and CKD, we found that patients undergoing PCI with multivessel DES implantation had similar rates of death, MI or CVE as those who underwent CABG. However, subjects receiving DES as treatment for 3-vessel disease had substantially higher rates of subsequent revascularization compared with those undergoing CABG in the 2-year follow-up.

Several observational studies have compared CABG and PCI, first with BMS and then with DES, in patients with multivessel CAD[12–15] The Arterial Revascularization Therapies Study (ARTS) II study, which compared outcomes of patients treated with sirolimus-eluting stents and that of the surgical arm of the ARTS trial, demonstrated that implantation with DES was associated with similar 1-year outcomes as CABG[3,4] In a large multicenter registry study from Korea, adjusted long-term mortality risk was equivalent in patients who underwent PCI with DES implantation or CABG, although the subsequent revascularization rate was considerably higher in the DES group[12] In contrast, another large single-center registry study showed that CABG resulted in improved major adverse cardiovascular and CVE in patients with multivessel disease compared with PCI with DES, primarily in those with diabetes[15] Also, in several studies and in a meta-analysis, CABG demonstrated benefit in death and MI in high-risk patient subgroups such as those with diabetes or with LV dysfunction[14,16,17]

Moderate or severe CKD is highly prevalent and represents an important high-risk subset of patients undergoing revascularization[18–25] CKD is significantly associated with increased mortality, MI, acute renal failure and restenosis after PCI[18–20] and also has an adverse prognosis after CABG, probably because of the longer postoperative mechanical ventilation time, higher postoperative bleeding rates, and increased length of hospital stay[21,22] Despite moderate or severe CKD having been confirmed as an independent predictor of mortality or morbidity after revascularization with PCI or CABG[18–22] limited data are available on the treatment effect of choice of revascularization strategy (PCI or

CABG) in this high-risk patient subset. In a large observational study based on 4,584 patients undergoing revascularization, CABG was found to be associated with significant survival benefit compared with PCI among patients with moderate and severe CKD not demonstrated among patients with normal renal function and mild CKD.[23] In contrast, the post hoc analysis from the ARTS trial showed that, among patients with multivessel CAD and CKD, treatment with CABG or PCI with multivessel stenting led to similar outcomes of death, MI or stroke.[24] Those 2 studies, however, have limited applicability to current practice, primarily because they were both based on patients undergoing PCI with BMS or balloon angioplasty.

To our knowledge, this observational study is the first to compare the clinical outcomes of patients with multivessel CAD and CKD who underwent either CABG or PCI with DES. The availability of DES has been shown to significantly reduce clinical and angiographic restenosis in patients with preserved, as well as impaired, baseline renal function.[35–38] Despite that finding, in our study the use of DES did not offer an incremental benefit in the rates of death, MI or CVE, and was still associated with a higher risk of repeat revascularization in the 3-vessel population, as compared with CABG. However, the rate of follow-up angiography in the DES group was significantly higher than in the CABG group (39.0% vs 13.9%, P=0.000), so the rate of asymptomatic graft stenosis or occlusion may have been dramatically underestimated in the CABG group relative to the DES group.

The choice of revascularization strategy for the treatment of multivessel disease depends on several factors, including patient characteristics, LV function, severity of involved coronary disease, and the presence of comorbidities. There is increasing information that treatment with CABG offers greater survival benefit over PCI in specific high-risk patient subgroups.[14–17] In our study, however, we found that DES and CABG had equivalent rates of death, MI or CVE among patients with CKD and with either 2- or 3-vessel disease. Our results suggest that PCI with DES is an acceptable and less invasive alternative to CABG in this high-risk patient subset, but possibly at the expense of increased repeat revascularization within 2 years.

Study Limitations

First, this was a single-center nonrandomized, observational data, which may lead to several potential biases. For instance, in the 3-vessel population, the PCI group had a larger proportion of patients with acute coronary syndrome, whereas in both the 2- and 3-vessel populations, the CABG group had a strikingly higher prevalence of proximal LAD disease and chronic total occlusion lesions. Furthermore, the choice of revascularization was at the discretion of the treating physician or patient and that indication bias may affect the results of our study in that the indication for treatment may affect the outcome. Although this bias may not be entirely obviated, it was minimized by the adjustment of factors such as patient's characteristics, presence of comorbidities, severity of CAD and LV dysfunction by using multivariable Cox modeling. Despite this, future randomized prospective studies are urgently indicated. Second, the sample size of patients with CKD makes our analysis underpowered to detect significant differences in mortality between DES and CABG. Nonsignificant trends toward higher death and MI rates and lower CVE rate were seen in patient who received DES, especially in the 3-vessel population; these trends might have been significant with a larger cohort of patients. Thirdly, we relied on estimated GFR, which is an imprecise measure of renal function; however, the gold standard for measurement of GFR is labor-intensive and expensive.[39] Fourthly, the definition of CKD is not specific and ranges from stage 3 to 5 of the National Kidney Foundation classification. Because of the sample size limitation, we did not further analyze differences in clinical outcome among different stages of CKD. Finally, follow-up angiography was not mandatory and because of the lower rate of follow-up angiography in CABG group compared with the DES group, it is prudent to draw the conclusion that CABG is superior over DES on the need for repeat procedure.

In conclusion, this observational study is the first to compare the clinical outcomes of patients with multivessel CAD and CKD who underwent either CABG or PCI with DES. Our results suggest that patients undergoing PCI with multivessel DES implantation have comparable long-term rates of death, MI or CVE as those who undergo CABG. Despite the use of DES, patients with 3-vessel disease receiving DES had substantially higher rates of subsequent revascularization compared with those undergoing CABG at the 2-year follow-up. Conclusions regarding the comparison of these 2 treatment strategies for this high-risk patient subset await results from future prospective randomized trials.

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