Is Diabetic Nephropathy a Predicted Risk Factor? — Kaplan-Meier and Multivariate Analysis of Confounding Risk Factors in Off-Pump Coronary Artery Bypass Grafting for Chronic Dialysis Patients —

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Background: The purpose of this study was to investigate the preoperative risk factors of performing off-pump coronary artery bypass grafting (OPCAB) in patients on chronic dialysis.

Methods and Results: The 41 consecutive patients on chronic dialysis who underwent OPCAB from February 2000 to April 2006 at the National Cardiovascular Center were studied retrospectively. Of them, 29 had diabetic nephropathy (DN group) and the remaining 12 did not (NDN group). There were significant differences in the duration of dialysis before surgery (9.1 ± 7.5 years in NDN vs 4.2 ± 5.5 years in DN, $P=0.028$) and low cardiac function (left ventricular ejection fraction $<30\%$), which was recognized only in the DN group (7/29, $P=0.048$). The early mortality rate was 6.9% (2/29) in the DN group and 16.7% (2/12) in the NDN group ($P=0.349$). The actuarial survival rates in the DN group were 85% at 1 year, 45% at 3 years, and 30% at 5 years, whereas in the NDN group they were 71%, 49%, and 49%, respectively ($P=0.789$). Arteriosclerosis obliterans (ASO) and age (>65 years) were independent risk factors of late death.

Conclusions: For patients on chronic dialysis ASO and aging were predicted risk factors for OPCAB, whereas diabetic nephropathy was not. (Circ J 2009; 73: 2056–2060)

Key Words: Diabetic nephropathy; Dialysis; Off-pump coronary artery bypass grafting

It is still controversial whether off-pump coronary artery bypass grafting (OPCAB) is more effective than conventional on-pump coronary artery bypass grafting (CABG) in the population of poor prognosis patients. OPCAB is the most common strategy of CABG for low-risk patients in Japan,¹ but often there are patients with severe complications who require CABG and for whom either on-pump or off-pump surgery might be reasonable. A recent prospective study showed that chronic renal disease is independently associated with adverse long-term outcomes in a broad cohort of Japanese patients,² making chronic dialysis one of the most high-risk preoperative comorbidities in Japan. These days, the number of patients on chronic dialysis is increasing in parallel with the increase in diabetes, which is known as the leading cause of chronic renal failure requiring dialysis. In general, natural prognoses for patients on chronic dialysis are worse for those with diabetic nephropathy than for non-diabetic nephropathy patients. According to The United Kingdom Prospective Diabetes Study (2003), the largest-scale prospective study of diabetic nephropathy, when serum creatinine levels

increase over 2.0 mg/dl, renal failure becomes end-stage, which requires dialysis within approximately 2.5 years and at which point the patient is likely to die within 3 years,³ with the major cause of death being cardiovascular disease.^{4,5}

We mainly perform OPCAB in chronic dialysis patients and their intraoperative management has been established with an acceptable clinical outcome. In the present study, we investigated the preoperative and intraoperative confounding factors for chronic dialysis patients who underwent OPCAB and we assessed the impact of diabetic nephropathy and other possible risk factors on midterm survival after OPCAB in this population.

Methods

Patients

Among 1,050 consecutive patients undergoing OPCAB at the Department of Cardiovascular Surgery, National Cardiovascular Center, between February 2000 and April 2006, there were 41 patients on chronic dialysis (3.9%).

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Table 1. Patient Demographics

	DN (n=29)	NDN (n=12)	P value
Duration of dialysis (years)	4.2±5.5	9.1±7.5	0.02
Age (years)	65.7±8.8	67.9±7.6	NS
M/F	23/6	11/1	NS
Hyperlipidemia	7 (24%)	3 (25%)	NS
Hypertension	12 (41%)	6 (50%)	NS
Arteriosclerosis obliterans	9 (36%)	2 (17%)	NS
History of AAA	0	4 (33.3%)	0.04
Calcified ascending aorta	5 (17%)	3 (25%)	NS
COPD	0	0	NS
History of cerebrovascular disease	5 (20.8%)	3 (23.1%)	NS
Extent of disease			
1VD	0	0	
2VD	6 (20.6%)	0	0.05
3VD	15 (51.7%)	12 (100%)	0.05
Left main trunk disease	3 (10.3%)	1 (8.3%)	NS
Mean no. of diseased vessels	2.8±0.4	2.7±0.6	NS
LVEF <30%	7 (24.1%)	0	0.04
Valvular disease			
Mitral (>Grade 3)	1 (3.4%)	0	NS
Aortic (>Grade 3)	0	0	NS
History of PCI	4 (13.7%)	2 (16.7%)	NS
Previous MI	11 (37.9%)	4 (33.3%)	NS
Unstable angina pectoris	7 (24.1%)	4 (33.3%)	NS
Acute MI	2 (7.0%)	1 (8.3%)	NS
Preoperative IABP	3 (10.3%)	1 (8.3%)	NS

DN, diabetic nephropathy; NDN, non-diabetic nephropathy; AAA, abdominal aortic aneurysm; COPD, chronic obstructive pulmonary disease; VD, vessel disease; LVEF, left ventricular ejection fraction; PCI, percutaneous catheter intervention; MI, myocardial infarction; IABP, intra-aortic balloon pumping.

These patients' preoperative characteristics are shown in **Table 1**: 29 (70.7%) had diabetic nephropathy (DN group) and 12 (29.3%) did not (NDN group). The causes of renal failure in the NDN group were chronic glomerulonephritis (n=4), nephrosclerosis (n=6) and unknown (n=2). There were no significant preoperative differences between the DN and NDN groups except for duration of dialysis and cardiac function. At the time of operation, the duration of dialysis was longer in the NDN group (9.1±7.5 years) than in the DN group (4.2±5.5 years) (P=0.028). Poor cardiac function (left ventricular ejection fraction (LVEF) <30%) was recognized only in the DN group (P=0.048).

Urgent operation was performed for 7 patients because of unstable angina or acute myocardial infarction with unstable hemodynamic conditions, and the remaining 34 patients underwent elective surgery in a stable condition.

Institutional approval for this study was obtained, and each patient gave informed consent to serve as a subject.

Surgical Technique

At the National Cardiovascular Center, OPCAB with extensive use of an arterial conduit has been performed since 2000. In our recent series, total arterial revascularization by OPCAB achieved excellent patency in the early postoperative period and showed good clinical results, and for this reason we prefer to perform it. Our standard technique is composite grafting of the radial artery (RA) in combination with 1 or both internal thoracic arteries (ITA).⁶ In dialysis patients, however, the RA either needs to be reserved for shunt formation for dialysis or has already been used, so bilateral ITA composite grafting is often used for complete revascularization. The advantage of this method is that it

Table 2. Surgical Results

	DN (n=29)	NDN (n=12)	P value
Mean no. of bypass grafts	3.0±0.8	3.4±1.1	NS
Urgent	5 (17.2%)	2 (16.7%)	NS
All arterial grafts	22 (75.8%)	6 (50.0%)	0.146
Bilateral ITA use	22 (75.8%)	3 (25.0%)	<0.0001
Composite grafting	19 (65.5%)	2 (16.6%)	0.006
All in-situ	7 (24.1%)	3 (25.0%)	NS
GEA use	1 (3.4%)	0	NS
Single ITA + GEA	0	2 (16.6%)	0.08
Single ITA + RA	2 (6.8%)	0	NS
Operation time (h)	309±81	307±35	NS
Graft patency	100% (88/88)	94% (30/32)	NS
Hospitalization (days)	37±47	36±48	NS

GEA, gastroepiploic artery; RA, radial artery. Other abbreviations see in Table 1.

avoids neurologic complications, because we use the aorta no-touch technique (ie, no side clamping of the diseased aorta). In high-risk patients, such as elderly patients, obese female patients and patients with chronic obstructive pulmonary disease (COPD), we occasionally use a single ITA plus either the saphenous vein (SV) or gastroepiploic artery (GEA) if they are in acceptable condition (**Table 2**).

Definitions

Early mortality was defined as any death occurring within 30 days after the operation or during the initial hospital stay, and late mortality was any death occurring after that. Development of congestive heart failure (CHF), fatal or non-fatal myocardial infarction, requirement for a cardiac intervention (redo-CABG, percutaneous transluminal coronary angiography etc) or sudden, unexplained death were all considered as cardiac events.

Patient Follow-up

Follow-up information was obtained from each patient's hospital record, interviews at the time of outpatient visits, telephone calls and from referring physicians.

Statistical Analysis

Comparison between groups was performed using the unpaired Student's t-test and the χ^2 test for categorical variables. Actuarial survival and cardiac event-free survival was calculated by the Kaplan-Meier method. Cox proportional hazard models were used to determine the influence of patients' characteristics and operative data on late survival. Hazard ratios, 95% confidence intervals, and levels of statistical significance (P value) were calculated. All results were expressed as mean±standard deviation and P<0.05 was considered statistically significant.

Results

Perioperative Data

Intraoperative data are shown in **Table 2**. There were no cases of conversion from OPCAB to CABG in either group. Complete revascularization was accomplished in all cases. Revascularization using only arterial grafts was more frequently performed in the DN group than in the NDN group (P=0.146). Bilateral ITAs were more often used in the DN group (P<0.001), as were composite grafts using only the left ITA (P=0.006).

Table 3. Postoperative Morbidity

	DN (n=29)	NDN (n=12)	P value
Postoperative morbidity	18 (62.0%)	7 (58.3%)	NS
GI complication	2 (6.9%)	2 (16.7%)	NS
Infection	7 (29.2%)	3 (23.1%)	NS
Superficial wound	4 (13.8%)	1 (8.3%)	NS
Deep sternum	1 (3.4%)	0	NS
Respiratory	2 (6.9%)	0	NS
Stroke	2 (6.9%)	1 (8.3%)	NS

GI, gastrointestinal. Other abbreviations see in Table 1.

Figure 1. Freedom from any cardiac events after surgery between diabetic nephropathy (DN) and non-diabetic nephropathy (NDN) patients on dialysis.**Table 4. Postoperative Mortality**

	DN (n=29)	NDN (n=12)	P value
Hospital death	2 (6.9%)	2 (16.6%)	NS
Mediastinitis	2 (100%)	0	
GI complication	0	2 (100%)	
Late death	11 (37.9%)	3 (10.3%)	NS
Heart failure	4 (36.3%)	1 (33.3%)	
MI	1 (9.0%)	1 (33.3%)	
Respiratory complication	1 (9.0%)	0	
GI complication	1 (9.0%)	0	
SIRS	1 (9.0%)	0	
Unknown	3 (27.2%)	1 (33.3%)	

SIRS, systemic inflammatory response syndrome. Other abbreviations see in Tables 1,3.

Postoperative coronary angiography was performed within 1 month after surgery in 33 patients (80.5%: 23 patients in the DN group, 10 patients in the NDN group). All grafts (88/88) were patent in the DN group compared with 94% (30/32) in the NDN group. Graft occlusion occurred in 2 patients in the NDN group: GEA-PL and RITA-D1. Neither patient had experienced any cardiac events after graft occlusion.

Morbidities and Mortalities

Operative morbidities are shown in **Table 3**. No differences were found in the incidence of postoperative morbidities, including mediastinitis and superficial wound problems.

Figure 2. Survival after surgery between diabetic nephropathy (DN) and non-diabetic nephropathy (NDN) patients on dialysis.**Table 5. Preoperative and Intraoperative Confounding Factors for Cox Hazard Model**

Preoperative confounding factors	Intraoperative confounding factors
Duration of dialysis (years)	Bilateral ITA
Age	Functional complete revascularization
M/F	
Diabetes	
Hyperlipidemia	
Hypertension	
ASO	
History of AAA	
Calcified ascending aorta	
COPD	
History of cerebrovascular disease	
3VD	
Left main trunk disease	
LVEF <30%	
History of PCI	
Previous MI	
Unstable angina pectoris	
Acute myocardial infarction	
Preoperative IABP	

ASO, arteriosclerosis obliterans; ITA, internal thoracic artery. Other abbreviations see in Table 1.

Table 6. Cox Proportional Hazard Model for Death at Midterm Follow-up

	HR	95%CI	P value
Age	0.534	0.306–0.890	0.016
ASO	0.367	0.194–0.681	0.002
History of AAA	0.475	0.238–1.053	0.064
No. of diseased vessels	0.364	0.112–1.215	0.098

HR, hazard ratio; CI, confidence interval. Other abbreviations see in Tables 1, 5.

Mediastinitis occurred only in patients from the DN group who had had both ITAs harvested.

Freedom from cardiac event is shown in **Figure 1**. The actuarial freedom from postoperative cardiac events among the DN group was 92% at 1 year, 60% at 3 years and 28% at 5 years, whereas in the NDN group it was 60%, 45% and 43%, respectively. There were no statistical differences

between the 2 groups. The linearized rate of postoperative cardiac events was 18.03 events per 100 patient-years in the DN group and 18.23 events per 100 patient-years in the NDN group, which showed no significant difference between the 2 groups ($P>0.999$).

Early and late mortalities are shown in **Table 4**. Early death occurred in 2 patients in the DN group (6.9%; mediastinitis caused by methicillin-resistant *Staphylococcus aureus*) and in 2 patients in the NDN group (16.7%; gastrointestinal complications) ($P=0.349$).

There were 11 (37.9%) late deaths in the DN group and 3 (25.0%) in the NDN group ($P=0.439$). The most frequent cause of death in the DN group was heart failure associated with dialysis cardiomyopathy, which was caused by long-term dialysis.

The actuarial survival after operation in the DN group was 85% at 1 year, 45% at 3 years, and 30% at 5 years, compared with 71%, 49%, and 49%, respectively, in the NDN group (**Figure 2**). There was no significant difference between the 2 groups ($P=0.789$). Cox proportional hazard models were used to assess the effect of preoperative and intraoperative confounding factors (**Table 5**) on late death. As shown in **Table 6**, the significant predictors of late death were arteriosclerosis obliterans (ASO) ($P=0.002$) and age (>65 years) ($P=0.016$).

Discussion

In the current era, diabetes is the most common reason for dialysis. According to a recent overview of dialysis treatment in Japan, diabetic nephropathy constitutes the highest proportion (42.9%) of primary renal diseases in patients who began dialysis, which is approximately twice as much compared with 20 years ago.⁷ Cardiovascular disease is the major cause of death, accounting for more than 50% of cases.^{8–11} In addition to significantly developed cardiovascular disease prior to the initiation of dialysis, the tissue deposition of advanced glycosylation end-products may also have an influence on cardiovascular mortality once dialysis has begun.^{12–14} Based on these facts, adequate treatment for cardiovascular disease is the key to better prognosis for these patients.

Several recent reports on survival of patients with chronic dialysis after CABG^{4,15–26} have demonstrated the operation can be performed with an acceptable mortality and morbidity for dialysis patients.^{16,17,19,23,24,26} Herzog et al reported that dialysis patients have better long-term survival after CABG surgery than after percutaneous coronary intervention, especially diabetic patients.²³

In Japan, OPCAB is currently the most common strategy for patients with coronary artery disease. According to the registry of the Japanese Association for Thoracic Surgery in 2006, 64% of patients on chronic dialysis had undergone OPCAB and mortality for patients on dialysis was 8.5%, whereas hospital mortality was 6.4%.¹ In the present study, hospital mortality was 6.9% in the DN group and 16.7% in the NDN group, both of which were higher than the hospital mortality of patients without dialysis, which was 1.9%.

With regard to the preoperative characteristics, there were several differences between the DN and NDN groups. The period from initiation of dialysis to surgery in the DN group was significantly shorter than that of the NDN group ($P=0.02$). Preoperative left ventricular function in the DN group was significantly lower than in the NDN group ($P=0.04$).

The surgical strategy, including graft selection, may be an important predictor for outcome of these patients. We use an arterial composite graft to achieve complete revascularization and avoid side-clamping of the diseased ascending aorta (ie, the aorta no-touch technique). In general, the use of a total arterial graft with bilateral ITAs has an advantage for long-term graft patency.^{27–31} Recent reviews demonstrate that using the bilateral ITAs is effective for both diabetic and dialysis patients;^{29,30} however, their use in diabetic patients, especially those on chronic dialysis, has the potential risk of mediastinitis. We had only 1 case of deep sternal infection (2.4%), which was in the DN group (bilateral ITAs were used for this patient). A skeletonized technique is preferable for reducing the risk of mediastinitis or other sternal wound problems in patients with poor risks, such as diabetes and renal failure.^{29–31} Regarding graft selection in diabetic patients on dialysis, the RA is not available because of its use as a primary arteriovenous fistula for vascular access. The SV and GEA are also less available because of severe arteriosclerosis of the abdominal aorta or/and ASO. For these reasons we generally use the bilateral ITAs even in diabetic patients on dialysis.

Cox proportional hazard models were performed to assess the predicted factors for late death because there were several critical biases in both the preoperative and intraoperative conditions. As analyzed by the Kaplan-Meier method, diabetes was not a predicted risk factor in this population. Use of bilateral ITAs and complete revascularization were expected to be important factors for the survival, but, unexpectedly, the Cox model did not show any influence on midterm survival in this population. On the other hand, ASO and aging were the predicted risk factors in this population, which is a reasonable result because the presence of ASO suggests general progressive arteriosclerosis, not to mention aging.³²

We also analyzed the actuarial survival of the diabetic and non-diabetic patients when patients with low cardiac function (LVEF $<30\%$) are excluded. The result was that there was no significant difference between these patients ($P=0.935$).

Study Limitations

This was a retrospective study and had a relatively small number of patients. Longer follow-up and a larger number of patients will be necessary in order to obtain stronger evidence.

In conclusion, the midterm survival of both diabetic and non-diabetic nephropathy patients on chronic dialysis after OPCAB was acceptable. Multivariate analysis suggests that diabetes is not a predicted risk factor for OPCAB in chronic dialysis patients, whereas peripheral arterial disease and aging are.

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