

Coronary Revascularization in Patients With Liver Cirrhosis

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Background. Liver cirrhosis is a major risk factor for cardiac surgery using cardiopulmonary bypass. However, percutaneous coronary intervention (PCI) or off-pump coronary artery bypass graft surgery (OPCABG) may be a less invasive alternative strategy.

Methods. Among the 9,877 patients undergoing first PCI or CABG enrolled in the CREDO-Kyoto Registry (a registry of first-time PCI and CABG patients in Japan), 332 patients diagnosed with liver cirrhosis were entered into the study (age 67.1 ± 9.4 years; 246 male). Liver cirrhosis was diagnosed by liver biopsy or signs of portal hypertension with characteristic morphologic liver and spleen changes.

Results. A total of 233 patients received PCI, 58 conventional on-pump CABG (CCABG), and 41 OPCABG. Median follow-up was 3.3 years. The PCI group included less complex coronary lesions such as triple vessel and left main disease ($p < 0.01$ each). Propensity score adjusted in-hospital mortality after CCABG or OPCABG

was higher than that after PCI; however, the differences were not significant (odds ratio [95% confidence interval]: 6.84 [0.52 to 90.8], $p = 0.14$ for CCABG versus PCI; and 1.86 [0.08 to 45.8], $p = 0.71$ for OPCABG versus PCI). Adjusted overall mortality after CCABG or CABG was lower than that after PCI, but the differences were not significant (0.66 [0.31 to 1.40], $p = 0.28$; and 0.64 [0.28 to 1.49], $p = 0.31$, respectively). Approximately two thirds of patients died of noncardiovascular morbidities (malignancies, including hepatocarcinoma, or hepatic decompression).

Conclusions. Because overall noncardiovascular mortality is high among patients with liver cirrhosis, complete revascularization may not be associated with better survival outcomes. Further study is warranted to determine the impact of a coronary revascularization strategy for liver cirrhosis patients.

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Liver cirrhosis (LC) is one of the major causes of morbidity and mortality and is regarded as an increased risk factor for hepatic decompression after surgery [1]. It has also been shown to be a major risk factor for cardiac surgery particularly when using cardiopulmonary bypass [2, 3]. However, to date, only a few studies based on a small number of patients with mixed surgical procedures have been performed [2–9]. In addition, most of these reports included only in-hospital or short follow-up periods. The prognosis of patients with LC is generally poor owing to noncardiovascular disorders such as hepatic decompression. Thus, to determine an effective revascularization strategy for patients with LC, it is important to investigate not only cardiovascular but also noncardiovascular outcomes with a longer follow-up period.

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Off-pump coronary artery bypass graft surgery (OPCABG) has been developed to reduce the risk of cardiopulmonary bypass [10]. Furthermore, percutaneous coronary intervention (PCI) may be a less invasive alternative strategy for patients with LC, particularly for those with less complex coronary lesions. The Coronary Revascularization Demonstrating Outcome Study in Kyoto (CREDO-Kyoto) is a multicenter registry from 30 institutions in Japan enrolling consecutive patients undergoing their first PCI or CABG [11]. In the present study, we show the current state of coronary revascularization strategies for LC patients in Japan, and analyze the outcomes of each revascularization strategy using the data from the registry.

Patients and Methods

Study Population

This study was approved by the Institutional Review Board or Ethics Committee of all participating institutions. Because the study subjects were retrospectively

enrolled, written informed consent was not obtained, in concordance with the guidelines for epidemiologic studies issued by the Ministry of Health, Labor, and Welfare of Japan. However, 73 patients were excluded because of their refusal to participate in the study when contacted for follow-up [11].

Between January 2000 and December 2002, 9,877 patients were identified as having undergone either CABG or PCI without prior history of coronary revascularization. Among these, 332 patients who were diagnosed with LC were the subjects of the present study.

Data Collection and Definitions

Demographic, angiographic, and procedural data were collected from hospital charts or databases in each center by independent clinical research coordinators according to prespecified definitions. Follow-up data were obtained from hospital charts or by contacting patients or referring physicians.

A diagnosis of LC was made either by liver biopsy or signs of portal hypertension with characteristic morphologic changes in the liver and spleen confirmed by ultrasonography, computed tomography, and magnetic resonance imaging [5]. Other diagnostic criteria, such as varices, thrombocytopenia, ascites, encephalopathy, and

biological abnormalities, were also employed. Left ventricular ejection fraction (LVEF) was measured either by contrast left ventriculography or by echocardiography. Chronic kidney disease was regarded as present when creatinine clearance estimated by the Cockcroft-Gould formula was less than 60 mL/min. Anemia was defined as a blood hemoglobin level less than 12 g/dL, as previously described [11].

Endpoints

An independent clinical events committee adjudicated events. Death was regarded as cardiovascular in origin unless obvious noncardiovascular causes could be identified. (Any death during the index hospitalization was regarded as cardiovascular death.) Myocardial infarction was adjudicated according to the definition in the Arterial Revascularization Therapy Study [12]. Within 1 week of the index procedure, only Q-wave myocardial infarctions were adjudicated as myocardial infarctions. Stroke at follow-up was defined as symptomatic stroke. The primary endpoint was death from any cause. Secondary endpoints were cardiovascular death, myocardial infarction, stroke, and the need for any revascularization procedures (PCI or CABG) during the follow-up period.

Table 1. Baseline Characteristics

	PCI n = 233	%	CCABG n = 58	%	OPCABG n = 41	%	p Value ^a
Age, years	67.0 ± 9.9		66.4 ± 8.4		68.4 ± 7.2		0.58
Male	171	73	46	79	29	71	0.57
Body mass index	23.5 ± 3.3		22.8 ± 2.9		22.6 ± 3.2		0.10
Emergency procedure	21	9	2	3	1	2	0.15
Ejection fraction	63.6 ± 11.6		58.8 ± 17.2		61.0 ± 14.8		0.05
Prior myocardial infarction	57	24	21	36	13	32	0.14
Heart failure	28	12	22	38	16	39	< 0.01
Atrial fibrillation	25	11	8	14	2	5	0.36
Stroke history	38	16	14	24	15	37	< 0.01
Peripheral vascular disease	17	7	10	17	13	32	< 0.01
Chronic pulmonary disease	3	1	1	2	3	7	0.045
Hypertension	166	71	35	60	31	76	0.19
Diabetes mellitus	99	42	32	55	25	61	0.04
Hyperlipidemia	80	34	24	41	19	46	0.27
Chronic kidney disease	73	31	22	38	15	37	0.56
Hemodialysis	21	9	6	10	4	10	0.95
Malignancy	35	15	6	10	5	12	0.62
Anemia	63	27	21	36	15	37	0.25
Current smoker	77	33	21	36	12	29	0.74
Coronary characteristics							
Number of diseased vessels	1.8 ± 0.8		2.3 ± 0.9		2.5 ± 0.8		< 0.01
Triple vessel disease	52	22	32	55	28	68	< 0.01
Left main disease	10	4	17	29	10	24	< 0.01
Proximal LAD disease	155	67	50	86	36	88	< 0.01
Total occlusion	66	28	20	34	19	46	0.06

^a The p value is for comparison among percutaneous coronary intervention (PCI), conventional on-pump coronary artery bypass graft surgery (CCABG), and off-pump coronary artery bypass graft surgery (OPCABG).

LAD = left anterior descending artery.

Statistical Analyses

All continuous variables are expressed as the mean $\pm$ SD. Differences in baseline characteristics across the three groups were examined by analysis of variance of a χ^2 test. We used Kaplan-Meier estimates to plot survival curves in each group. The log rank test was used to identify significant differences in unadjusted survival curves.

Propensity scores, which represented the probabilities that a patient would undergo PCI, conventional on-pump CABG (CCABG), or OPCABG, were calculated for each patient. The propensity scores were estimated separately using multivariable logistic regression analyses. Confounding factors in the logistic regression included age, sex, body mass index, emergency procedure, prior myocardial infarction, congestive heart failure, stroke, peripheral arterial disease, atrial fibrillation, chronic obstructive pulmonary disease, malignancy, hypertension, diabetes mellitus, hemodialysis, chronic kidney disease, anemia, current smoker status, LVEF, total occlusion, proximal left anterior descending artery (LAD) disease, triple vessel disease, and left main disease. Outcomes after PCI, CCABG, or OPCABG were compared using the Cox proportional hazard models stratified by the quartiles of propensity scores. Propensity score adjusted hazard ratios, 95% confidence intervals, and *p* values are reported. The *p* values for multiple comparisons among the three groups were adjusted by the Bonferroni correction. All reported *p* values were two-sided.

To determine the baseline predictive factors for mortality, other than revascularization modality, we used the same potential variables above. Those variables for which *p* values were less than 0.05 in univariate analysis were included in the multivariate Cox proportional hazard model.

All analyses were conducted by a statistician using SAS software version 9.2 (SAS Institute, Cary, NC) and S-Plus version 7.0 (Insightful Corp, Seattle, WA), and all reported *p* values were two-sided. The authors had full access to the data and take responsibility for its integrity. All authors have read and agree to the contents of the manuscript as written.

Results

Baseline Characteristics

Among the 332 patients diagnosed with LC, 233 patients (70.1%) were treated with PCI, 58 (14.51%) with CCABG, and 41 (12.4%) with OPCABG. Baseline characteristics of the patients in the three groups are shown in Table 1. Age, ratio of emergency procedure, and ejection fraction did not differ among the groups. Comorbidities such as malignancy and hemodialysis also did not differ among the groups. The PCI group generally included less high risk patients, such as those with diabetes and left ventricular dysfunction. The numbers of diseased vessels were lower in the PCI group. The PCI group included less complex patients, such as those with left main and proximal LAD disease. In the PCI group, bare-metal stents were used in 79% of patients. None of the patients received drug-eluting stents.

Operative outcomes are shown in Table 2. The number of diseased vessels and anastomotic sites did not differ between CCABG and OPCABG patients. More left and bilateral internal thoracic artery grafts were used in the OPCABG group. Concomitant operations were more common in the CCABG group.

In-Hospital and Follow-Up Outcomes

Clinical follow-up was 100% during the entire study period. The median follow-up period was 1,214 days for

Table 2. Operative Outcomes

	CCABG n = 58	%	OPCABG n = 41	%	<i>p</i> Value
Number of diseased vessels	2.3 $\pm$ 0.9		2.5 $\pm$ 0.8		0.20
Number of anastomotic sites	3.0 $\pm$ 1.1		3.3 $\pm$ 1.6		0.21
Preoperative IABP use	1	1.7	1	2.4	0.91
Emergency	2	3.4	1	2.4	0.77
Type of bypass graft					
Left internal thoracic artery	51	87.9	40	97.6	0.08
Bilateral internal thoracic artery	8	13.8	18	43.9	< 0.01
Right gastroepiploic artery	8	13.8	6	14.6	0.91
Radial artery	19	32.8	12	29.3	0.71
Saphenous vein	40	69.0	22	53.7	0.12
Concomitant surgery					
Aortic valve	5	8.6	0	0.0	
Mitral valve	5	8.6	0	0.0	
Thoracic aortic	2	3.4	0	0.0	
Abdominal/peripheral vascular	0	0.0	4	9.8	
Others	4	6.9	0	0.0	
Concomitant surgery total	16	27.6	4	9.8	0.03

CCABG = conventional on-pump coronary artery bypass graft surgery; IABP = intraaortic balloon pump;

OPCABG = off-pump coronary artery bypass graft surgery.

the PCI group and 1,168 days for the CABG group. Regarding in-hospital outcomes, 1 patient in the PCI group, 4 in the CCABG group, and 1 in the OPCABG group died in the hospital (Table 3). Bleeding complications, such as postprocedure tamponade were more common in the CCABG group. During follow-up, 21 patients died of cardiovascular events, and 40 patients died of noncardiovascular events. Approximately two thirds of patients died of noncardiovascular events. Of the 40 patients who died of noncardiovascular events, 26 patients (65%) died of malignancy, including hepatocarcinoma or hepatic failure, during the follow-up period.

Survival Analyses

KAPLAN-MEIER ANALYSIS. Unadjusted freedom from all-cause death values of all patients at 30 days, 1 year, and 3 years were 98.5%, 93.9%, and 81.1%, respectively (Fig 1A). Freedom from all-cause death values did not differ between PCI and CABG groups ($p = 0.34$, Table 1). Freedom from all-cause and cardiovascular death values did not differ among PCI, CCABG, and OPCABG groups ($p = 0.61$ in Fig 1C, and $p = 0.48$ in Fig 1D).

PROPENSITY SCORE ANALYSIS. Propensity score adjusted in-hospital mortality did not differ between PCI and CABG groups (Table 4). There were also no significant differences in adjusted in-hospital mortality among PCI, CCABG, and OPCABG groups. Similarly, adjusted overall mortality did not differ between PCI and CABG groups (Table 4). There were no significant differences in adjusted overall mortality among the three groups.

RISK FACTORS FOR MORTALITY. The strongest predictive variable for overall all-cause death was comorbid malignancy (Table 5). Significant predictive variables for cardiovascular death were hemodialysis, heart failure, stroke history, anemia, triple vessel disease, and left main disease (Table 5).

Comment

Main Findings

In the present study, we show the current state of coronary revascularization strategies for LC patients in Japan, and analyze the outcomes of each revascularization strategy. We obtained the following findings: (1)

Table 3. In-Hospital and Follow-Up Outcomes

	PCI		CCABG		OPCABG		Total	
	(n =233)		(n = 58)		(n = 41)		(n = 332)	
In-hospital outcomes								
Death								
Myocardial infarction	1	0.4%	1	1.7%	0	0.0%	2	0.6%
Renal failure	0	0.0%	1	1.7%	0	0.0%	1	0.3%
Sepsis	0	0.0%	1	1.7%	1	2.4%	2	0.6%
Bleeding	0	0.0%	1	1.7%	0	0.0%	1	0.3%
Death total	1	0.4%	4	6.9%	1	2.4%	6	1.8%
Events								
Stroke	0	0.0%	1	1.7%	2	4.9%	3	0.9%
Myocardial infarction	9	3.9%	0	0.0%	2	4.9%	11	3.3%
Bleeding	1	0.4%	5	8.6%	2	4.9%	8	2.4%
Follow-up outcomes								
Death								
Cardiovascular	16	6.9%	3	5.6%	2	5.0%	21	6.4%
Noncardiovascular								
Hepatic failure	0	0.0%	1	1.9%	1	2.5%	2	0.6%
Hepatocarcinoma	7	3.0%	2	3.7%	2	5.0%	11	3.4%
Other carcinomas	11	4.7%	0	0.0%	2	5.0%	13	4.0%
Renal failure	2	0.9%	1	1.9%	0	0.0%	3	0.9%
Pneumonia	0	0.0%	1	1.9%	1	2.5%	2	0.6%
Sepsis	3	1.3%	0	0.0%	0	0.0%	3	0.9%
Gastrointestinal	2	0.9%	1	1.9%	0	0.0%	3	0.9%
Unknown	2	0.9%	0	0.0%	1	2.5%	3	0.9%
Noncardiovascular total	27	11.6%	6	11.1%	7	17.5%	40	12.3%
Death total	43	18.5%	9	16.7%	9	22.5%	61	18.7%
Events								
Stroke	9	3.9%	4	7.4%	1	2.5%	14	4.3%
Myocardial infarction	10	4.3%	2	3.7%	0	0.0%	12	3.7%
Revascularization	95	40.9%	7	13.0%	5	12.5%	107	32.8%

CCABG = conventional on-pump coronary artery bypass graft surgery; PCI = percutaneous coronary intervention.

OPCABG = off-pump coronary artery bypass graft surgery;

PCI =

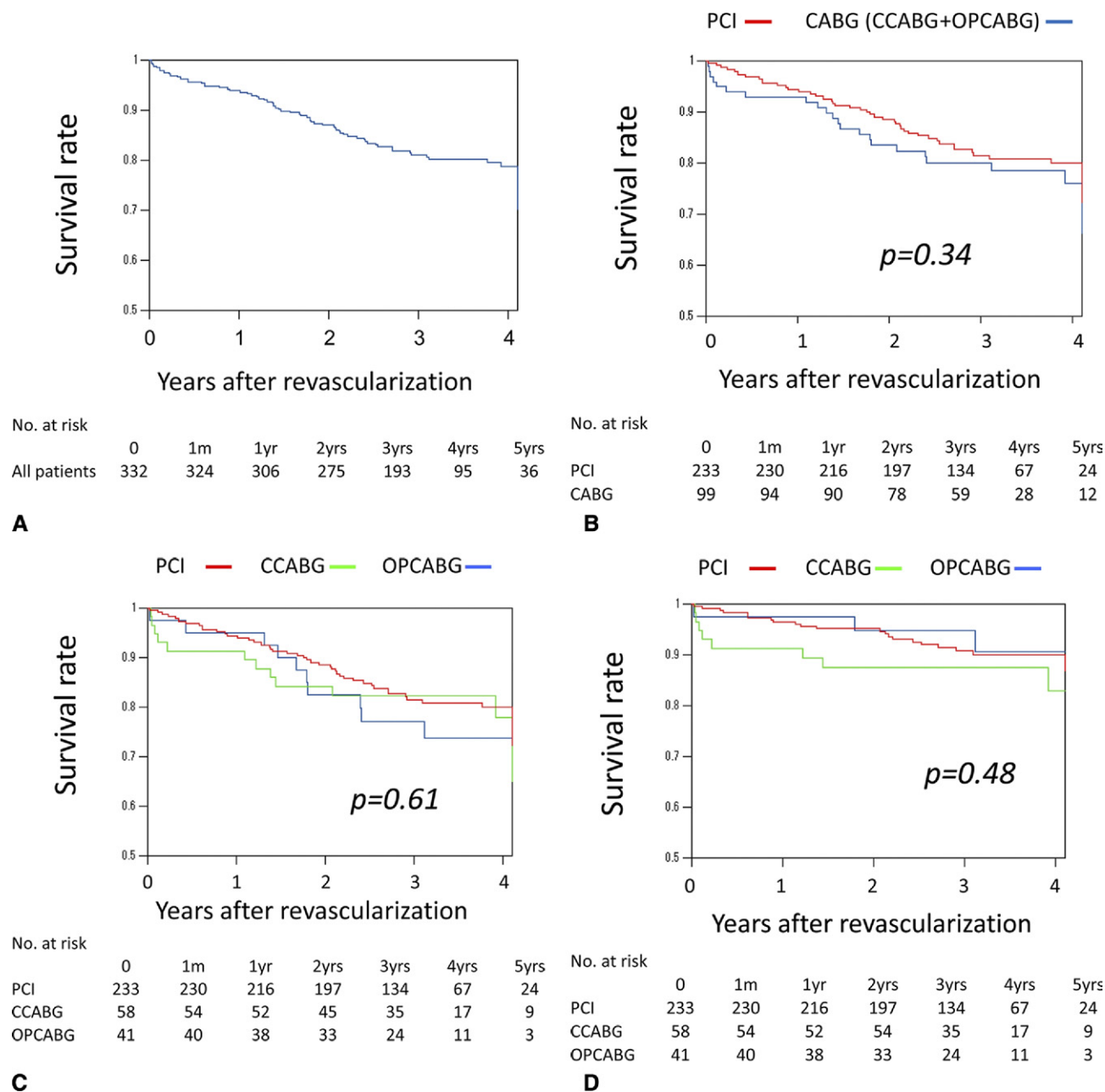


Fig 1. (A) Freedom from all-cause death (all patients). (B) Freedom from all-cause death, percutaneous coronary intervention (PCI [red line]) versus coronary artery bypass graft surgery (CABG [blue line]). (C) Freedom from all-cause death, PCI (red line) versus conventional on-pump CABG (CCAB [green line]) versus off-pump CABG (OPCAB [blue line]). (D) Freedom from cardiovascular death, PCI (red line) versus CCAB (green line) versus OPCAB (blue line).

Compared with PCI, CABG was applied to patients with more complex coronary lesions and more comorbidities, such as heart failure and diabetes. (2) Propensity score adjusted in-hospital mortality after PCI tended to be low compared with that of CCABG or OPCABG. (3) Adjusted in-hospital mortality after OPCABG tended to be low compared with that of CCABG. (4) Adjusted overall all-cause mortality after CABG tended to be low compared with that of PCI. (5) Adjusted overall mortality was similar for CCABG and OPCABG. (6) Overall mortality was high regardless of revascularization strategy because

of the high incidence of noncardiovascular death caused primarily by malignancy or hepatic decompression.

These results indicate that it is not possible to determine the optimal revascularization strategy for patients with LC from our registry because there were significant differences in the patient population for the three revascularization strategies, and noncardiovascular mortality was high. A randomized controlled trial may clarify the problem, but it is difficult to obtain matched patient populations because such patients are less common owing to varying degrees of severity of LC.

Table 4. Odds and Hazard Ratios for Death Comparing Each Revascularization Strategy By Propensity Score Stratification

	Propensity Score Adjusted		
	Odds Ratio	95% CI	p Value
In-hospital death			
CABG versus PCI	4.37	0.30 to 62.5	0.28
CCABG versus PCI	6.86	0.52 to 90.8	0.14
OPCABG versus PCI	1.86	0.08 to 45.8	0.71
CCABG versus OPCABG	3.70	0.33 to 40.7	0.29
Overall death			
CABG versus PCI	0.66	0.34 to 1.27	0.21
CCABG versus PCI	0.66	0.31 to 1.40	0.28
OPCABG versus PCI	0.64	0.28 to 1.49	0.31
CCABG versus OPCABG	1.03	0.43 to 2.44	0.95

CABG = coronary artery bypass graft surgery; CCABG = conventional on-pump coronary artery bypass graft surgery; CI = confidence interval; OPCABG = off-pump coronary artery bypass graft surgery; PCI = percutaneous coronary intervention.

Liver Cirrhosis and Cardiac Surgery

There have been several observational studies that investigated the outcomes of cardiac surgery in patients with LC [2-9]. Although these studies included a limited population with mixed surgical procedures, all these studies demonstrated that LC is a serious risk factor of cardiac surgery. The studies employed the Child-Turcotte-Pugh classification to evaluate the severity of LC [13, 14]. The operative mortality rate of class A patients was relatively low (0% to 10%) [2-9]. On the contrary, early studies reported higher mortality rates in class B patients, which ranged from 50% to 80% [2, 3]. Recent studies, with the exception of the report from Lin and colleagues [5], also reported relatively high mortality rates of 18% to 67% for group B patients as compared with class A patients [6-9]. However, all these studies involved in-hospital or short-term follow-up periods. The Model for End-Stage Liver Disease scoring system [15] has been validated for predicting survival in patients with end-stage liver disease. This score may be useful in predicting the prognosis of patients undergoing cardiac surgery [8, 9].

Benefit of Complete Revascularization for LC

Long-term survival outcomes in patients with LC were poor as compared with those of the whole population of the CREDO-Kyoto registry. Freedom from all-cause death values of the whole population at 30 days, 1 year, and 3 years were 99.4%, 96.6%, and 91.6% in the PCI group and 98.0%, 94.3%, and 89.3% in the CABG group, respectively; whereas, in the present study of patients with LC, freedom from all-cause death values at 30 days, 1 year, and 3 years were 99.6%, 99.4%, and 81.6% in the PCI group and 96.0%, 92.9%, and 80.1% in the CABG group, respectively. It is noteworthy that approximately two thirds of patients died of noncardiovascular morbidities such as malignancy, including hepatocarcinoma or hepatic failure, during follow-up. These results indicate

that late mortality rather than early mortality was higher in patients with LC because noncardiovascular causes such as malignancy lower the chance of survival. This finding might mean that complete revascularization may not contribute to improving long-term outcome.

Coronary Revascularization and LC

Regardless of recent decreases in overall perioperative mortality, postoperative morbidities remain a major issue in this population. It is well known that cardiopulmonary bypass triggers production and release of numerous vasoactive substances and cytotoxic mediators that affect coagulopathy, the immune system, vascular resistance, vascular permeability, fluid balance, and major organ functions [7]. Therefore, OPCABG may be advantageous in avoiding such perioperative complications. Hayashida and associates [6] reported that no patient with the Child-Turcotte-Pugh classification class B undergoing OPCABG died in the hospital. Filsoofi and coworkers [8] also reported that no mortality occurred among patients who underwent OPCABG.

Based on these findings, we suggest the following

Table 5. Predictive Variables^a for All-Cause Death and Cardiovascular Death

	Multivariate Hazard Ratio	95% CI	p Value
All-cause death			
Malignancy	3.26	1.86 to 5.75	< 0.01
Left main disease	2.11	1.09 to 4.08	0.03
Hemodialysis	2.03	0.99 to 4.18	0.05
Diabetes mellitus	1.88	1.11 to 3.19	0.02
Triple vessel disease	1.60	0.96 to 2.68	0.07
Age, per years old	1.03	0.99 to 1.06	0.12
Anemia	1.49	0.83 to 2.69	0.18
Stroke history	1.38	0.78 to 2.43	0.27
Chronic total occlusion	1.36	0.81 to 2.29	0.25
Heart failure	1.12	0.61 to 2.07	0.71
Cardiovascular death			
Hemodialysis	4.65	3.12 to 6.94	< 0.01
Heart failure	1.56	1.14 to 2.12	< 0.01
Stroke history	1.55	1.12 to 2.15	< 0.01
Anemia	1.55	1.12 to 2.15	< 0.01
Triple vessel disease	1.49	1.05 to 2.13	0.03
Left main disease	1.47	1.05 to 2.06	0.02
Peripheral artery disease	1.27	0.91 to 1.78	0.17
Diabetes mellitus	1.02	0.76 to 1.37	0.90

^a These variables were selected from the following potential variables (univariate $p < 0.05$): age, sex, body mass index, emergency procedure, prior myocardial infarction, congestive heart failure, stroke, peripheral arterial disease, atrial fibrillation, chronic obstructive pulmonary disease, malignancy, hypertension, diabetes mellitus, hemodialysis, chronic kidney disease, anemia, current smoker status, left ventricular ejection fraction, total occlusion, proximal left anterior descending artery disease, triple vessel disease, and left main disease.

CI = confidence interval.

revascularization strategy: because long-term outcomes are largely influenced by noncardiovascular events in LC patients, PCI, rather than complete revascularization (by CCABG or OPCABG), should be recommended for patients with complex coronary lesions accompanied by malignancies or severe hepatic decompression as well as for patients with less complex coronary lesions. If CABG is indicated, CCABG or OPCABG should be selected based on the balance between the patient's general condition and the need for complete revascularization, because complete revascularization may not be associated with better survival outcomes. However, further study is warranted to determine the impact of a coronary revascularization strategy for LC patients.

Study Limitations

There are several important limitations to the present study, the most important being that the CREDO-Kyoto registry lacks the preoperative data of hepatic function, such as bilirubin and aspartate aminotransferase. The severity of liver disease could not be determined by the Child-Turcotte-Pugh classification or the Model for End-Stage Liver Disease score. These data may influence the outcomes of multivariate analyses. Second, several biases may exist, such as indications regarding the revascularization strategies and level of expertise in the procedures for each institution and physician involved in the registry. Finally, since our study is nonrandomized, these potential confounders may influence our results.

In conclusion, because overall noncardiovascular mortality (eg, malignancy or hepatic decompression) is high among patients with LC, complete revascularization may not necessarily be associated with better survival outcomes. The revascularization modality should be selected after consideration of the balance between the patient's general condition and the severity of coronary lesions. Further study is warranted to determine the impact of the different coronary revascularization strategies on long-term outcomes for patients with LC.

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