Previous coronary stents do not increase early and long-term adverse outcomes in patients undergoing off-pump coronary artery bypass grafting: A propensity-matched comparison

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Objective: The aim of our study was to compare the early and long-term outcomes of patients undergoing off-pump coronary artery bypass grafting (CABG) with and without previous coronary stents.

Methods: Between September 2004 and September 2011, 269 patients with previous stents underwent first-time isolated off-pump CABG. These patients were compared with 897 patients without previous stent. A propensity score-matching analysis was performed to compare early and late outcomes between the groups. Mean follow-up time was 43.4 months after surgery.

Results: Patients with previous stents were more likely to be men (85.9% in the stent group vs 79.4% in the no-stent group; $P = .022$) and more likely to have prior myocardial infarction (60.2% vs 36.8%; $P < .001$). Mean number of anastomoses was lower in patients with previous stents than in patients without previous stents (4.0 vs 4.2; $P = .037$). There was no difference in the use of bilateral internal thoracic artery graft between the groups (88.8% vs 89.1%; $P > .999$). After propensity adjustment for preoperative characteristics, both operative death (0.7% vs 1.5%; $P = .414$) and the major complications rates (7.8% vs 7.5%; $P = .869$) were similar between the groups. The actuarial survival rate at 7 years was not different between the groups ($87.2\% \pm 3.2\%$ vs $84.8\% \pm 2.9\%$; $P = .470$). Furthermore, freedom from major adverse cardiac and cerebrovascular events at 7 years were similar between the groups ($78.9\% \pm 3.8\%$ vs $77.6\% \pm 3.3\%$; $P = .811$).

Conclusions: Previous coronary stents do not increase early and long-term morbidity or mortality in patients undergoing off-pump CABG. (J Thorac Cardiovasc Surg 2014;148:1843-9)

The use of stents during percutaneous coronary intervention (PCI) for the treatment of coronary artery disease has been increasing. However, restenosis is still a major problem after stent implantation. Therefore, the number of patients undergoing coronary artery bypass grafting (CABG) in whom previous PCI procedures have been performed is also increasing. Several investigators have demonstrated that previous PCI with stent is a risk factor of CABG.¹⁻⁴ Massoudy and colleagues³ showed in a multicenter analysis that a history of multiple PCIs was an independent predictor for in-hospital deaths and major adverse cardiac events.³ In another multicenter study, Mannacio and colleagues⁴ demonstrated that a history of PCI before CABG increased risk for both operative death and perioperative complications and decreased survival at 5 years' follow-up. Possible reasons for the worse outcome after CABG in patients with

previous stent compared with those without stent include local and systemic inflammatory reactions.^{5,6} Previous studies comparing outcomes in patients with and without previous PCI with stent included CABG using cardiopulmonary bypass, which accelerates systemic inflammatory responses.⁷ Thus we hypothesized that the elimination of cardiopulmonary bypass may diminish the difference in in-hospital and long-term outcomes among patients undergoing CABG with and without previous stent.

The aim of our study was to compare the early and long-term outcomes of patients undergoing off-pump CABG with and without previous coronary stents.

PATIENTS AND METHODS

Study Patients

Between September 2004 and September 2011, 1166 patients underwent first-time isolated off-pump CABG at the Sakakibara Heart Institute. Of those, 269 patients (23.1%; stent group) had at least 1 previous PCI with stent, whereas 897 patients (76.9%; no-stent group) underwent Off-pump CABG as the first-time intervention for the treatment of coronary artery disease. In the stent group, the mean number of PCI procedures with stent per patient was 1.7 ± 1.2 in the stent group (single PCI procedure with stent in 162 patients and multiple PCI procedures with stents in 107 patients). Furthermore, the median interval from the last PCI procedure to the CABG operation was 12 months (range, 1 day-254 months). The mean number of implanted stents was 1.8 ± 1.3 per patient. Implanted stent material included bare-metal stents in 174 patients, drug-eluting stents in 71 patients, and both in 24 patients.

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Abbreviations and Acronyms

CABG	= coronary artery bypass grafting
ITA	= internal thoracic artery
MACCE	= major adverse cardiac and cerebrovascular event
PCI	= percutaneous coronary intervention

The institutional review board of our institution approved this retrospective study and waived the need for written consent. All data were collected prospectively and reviewed retrospectively. Follow-up involved direct communication with the patient, the patient's family, the attending physician, or a combination of these.

The primary end point of our study was long-term all-cause mortality, including early deaths. The secondary end points were operative death, early major complications, and late major adverse cardiac and cerebrovascular event (MACCE).

Operative Method

Our operative technique for off-pump CABG has been described previously.⁸ All arterial grafts were harvested in a skeletonized fashion using an ultrasonic scalpel (Harmonic Scalpel, Ethicon Endosurgery, Cincinnati, Ohio). We bypassed all significantly diseased coronary vessels ($\geq 50\%$ diameter reduction) which were >1 mm in diameter. Deep pericardial stay sutures were not used, and a commercially available heart positioner and stabilizer were applied in all cases. We performed extensive reconstruction when the left anterior descending artery was diffusely diseased, and branches such as the septal and diagonal arteries were affected by severe atheromatous plaque. The detailed indications, techniques, and outcomes of extensive reconstruction of the left anterior descending artery have been described previously.⁹

During the operation, graft patency was assessed with a Doppler flow meter in all patients. Furthermore, intraoperative fluorescence imaging has been additionally used since April 2007.

We routinely prescribed low-dose aspirin to all patients postoperatively, continued indefinitely. Clopidogrel was given only in patients with a drug-eluting stent.

Definitions

Nonelective operations included both emergency and urgent cases, according to the definitions in the Society of Thoracic Surgeons database. Operative death was defined as death occurring during the same hospitalization, or after discharge but within 30 days after surgery. Low-output syndrome was defined as the postoperative need for intra-aortic balloon pumping, or any dose of adrenaline, or >5 $\mu\text{g/kg/min}$ dopamine or dobutamine. Perioperative myocardial infarction was defined as new Q waves on electrocardiography or a peak creatine kinase MB level of ≥ 5 times the upper limit of normal (25 IU/L). Respiratory failure was defined as a requirement for prolonged ventilation (>48 hours) or the occurrence of pneumonia. Postoperative stroke was defined as a new neurological deficit that was detected on computed tomography. In patients with preoperative stroke, postoperative stroke was defined as a worsening of the neurologic deficit with new radiologic findings. The major complications included low-output syndrome, perioperative myocardial infarction, respiratory failure, stroke, new requirement of hemodialysis, mediastinitis, and reexploration due to bleeding. MACCE was defined as death from any cause, stroke, myocardial infarction, or repeat revascularization.

Statistical Analysis

All statistical analyses were performed using the StatView 5.0 software package or the SAS program for Windows, release 9.2 (SAS Institute Inc,

Cary, NC). Continuous variables are reported as the mean $\pm$ standard deviation. Continuous variables were compared by Student *t* test, whereas discrete variables were compared by the χ^2 test or Fischer exact test.

Actuarial survival curves were estimated using the Kaplan-Meier method. The log-rank test was used to assess differences in survival between groups. Multivariate Cox proportional hazards analysis was performed to identify significant predictors of late mortality and late MACCE, using the clinical variables listed in Table 1 and the history of previous stent. Variables with $P < .1$ in univariate analyses were included in the multivariate model.

A propensity score of having previous stent was calculated for each patient using a logistic regression model that included all preoperative variables listed in Table 1. Patients were matched 1:1 on propensity scores with greedy matching techniques. Outcomes of interest between the matched groups were compared using the paired *t* test for continuous variables, and the McNemar test for discrete variables.

Power analysis for log-rank test indicated that this study has adequate power to detect significant differences for the late death ($1-\beta$: 0.94; survival proportion of 7 years of the no-stent group: 0.84; hazard ratio [HR], 0.27) for an α value of 0.05.

RESULTS

Preoperative Characteristics and In-Hospital Outcomes

Preoperative characteristics of both groups are shown in Table 1. The stent group had higher proportions of men ($P = .022$) and prior myocardial infarction ($P < .001$). The mean number of diseased vessels was higher in the no-stent group than in the stent group ($P = .006$).

The intraoperative and postoperative data are listed in Table 2. The mean number of anastomoses per patient was significantly higher in the stent group than in the no-stent group ($P = .037$). The incidence of performing extensive reconstruction of the left anterior descending artery was higher in the stent group than in the no-stent group ($P = .003$).

The operative death rates did not differ between these groups ($P > .999$) and neither did the major complication ($P > .999$). The causes of death were mediastinitis in 1 patient and congestive heart failure in the other patient in the stent group and pneumonia in 6 patients, congestive heart failure in 1 patient, and a rupture of aortic aneurysm in 1 patient in the non-stent group.

Long-Term Outcomes

Follow-up was complete in 1158 of 1166 patients (99.3%). During the follow-up period (43.4 ± 24.5 months), there were 19 deaths in the stent group and 81 deaths in the no-stent group. The actuarial survival rate at 7 years was $87.3\% \pm 3.2\%$ in the stent group and $84.4\% \pm 3.8\%$ in the no-stent group ($P = .381$) (Figure 1, A). Univariate analyses identified that age, smaller body surface area, acute coronary syndrome, Canadian Cardiovascular Society class III or IV, lower ejection fraction, number of diseased vessel, higher creatinine level, a history of congestive heart failure, peripheral vascular disease, chronic obstructive pulmonary disease, nonelective surgery, and

TABLE 1. Preoperative characteristics

Characteristic	Non-matched pairs			Propensity-matched pairs		
	Stent (n = 269)	No-stent (n = 897)	P value	Stent (n = 268)	No-stent (n = 268)	P value
Age (y)	68.0 ± 9.4	68.2 ± 10.5	.786	68.0 ± 9.5	67.3 ± 11.0	.445
Female	38 (14.1)	185 (20.6)	.022	38 (14.2)	51 (19.0)	.128
Body surface area (m ²)	1.7 ± 0.2	1.7 ± 0.2	.882	1.7 ± 0.2	1.6 ± 0.2	.716
Acute coronary syndrome	94 (34.9)	312 (34.8)	>.999	93 (34.7)	104 (38.8)	.305
Ejection fraction (%)	55.8 ± 11.3	56.1 ± 11.8	.750	55.9 ± 11.3	56.0 ± 11.5	.862
Diseased vessel	2.7 ± 0.5	2.8 ± 0.4	.006	2.7 ± 0.5	2.7 ± 0.5	.718
Left main disease	91 (33.8)	316 (35.2)	.727	91 (34.0)	97 (36.2)	.587
Creatinine (mg/dL)	1.3 ± 1.8	1.1 ± 1.3	.100	1.3 ± 1.8	1.3 ± 1.9	.805
Congestive heart failure history	37 (13.8)	121 (13.5)	.992	36 (13.4)	32 (11.9)	.599
Prior myocardial infarction	162 (60.2)	330 (36.8)	<.001	161 (60.1)	148 (55.2)	.133
Hypertension	176 (65.4)	629 (70.1)	.166	175 (65.3)	171 (63.8)	.708
Diabetes mellitus	126 (46.8)	419 (46.7)	>.999	125 (46.6)	130 (48.5)	.641
Hyperlipidemia	170 (63.2)	572 (63.8)	.922	169 (63.1)	170 (63.4)	.929
Smoking history	166 (61.7)	535 (59.6)	.592	166 (61.9)	164 (61.2)	.862
Previous stroke	23 (8.6)	102 (11.4)	.230	23 (8.6)	31 (11.6)	.228
Peripheral vascular disease	25 (9.3)	68 (7.6)	.435	25 (9.3)	19 (7.1)	.366
Chronic obstructive pulmonary disease	8 (3.0)	34 (3.8)	.657	8 (3.0)	2 (0.7)	.058
Atrial fibrillation	8 (3.0)	49 (5.5)	.134	8 (3.0)	9 (3.4)	.808

Values are presented as mean ± standard deviation or n (%).

atrial fibrillation were associated with late mortality. Multivariate analysis (Table 3) revealed that age, smaller body surface area, lower ejection fraction, higher creatinine level, a history of congestive heart failure, peripheral vascular disease, chronic obstructive pulmonary disease, and atrial fibrillation were independent predictors of late mortality. Previous stent was not identified as an independent predictor of late mortality.

MACCE were observed in 36 patients in the stent group and 140 patients in the no-stent group. Freedom from MACCE at 7 years was 79.1% ± 3.7% in the stent group and 76.2% ± 2.2% in the no-stent group ($P = .438$) (Figure 1, B). Univariate analyses identified that age, smaller body surface area, acute coronary syndrome, Canadian Cardiovascular Society class III or IV, lower ejection fraction, number of diseased vessel, higher

TABLE 2. Operative and postoperative data

Variable	Non-matched pairs			Propensity-matched pairs		
	Stent (n = 269)	No-stent (n = 897)	P value	Stent (n = 268)	No-stent (n = 268)	P value
Anastomoses/patient	4.0 ± 1.3	4.2 ± 1.2	.037	4.0 ± 1.3	4.2 ± 1.2	.283
Bilateral internal thoracic artery use	239 (88.8)	799 (89.1)	>.999	238 (88.8)	235 (87.7)	.691
Extensive reconstruction of left anterior descending artery	78 (29.0)	182 (20.3)	.003	77 (28.7)	51 (19.0)	.012
Operation time (min)	278.6 ± 65.0	275.1 ± 61.1	.422	278.2 ± 64.8	269.2 ± 57.9	.010
Intraoperative red blood cell transfusion	92 (34.2)	305 (34.0)	>.999	92 (34.3)	92 (34.3)	>.999
Intubation (h)	11.5 ± 24.8	8.9 ± 8.3	.008	11.5 ± 24.9	9.1 ± 9.2	.091
Intensive care unit stay (d)	1.7 ± 3.1	1.9 ± 8.5	.665	1.7 ± 3.1	2.0 ± 8.3	.672
Operative death	2 (0.7)	8 (0.9)	>.999	2 (0.7)	4 (1.5)	.414
Major complication	21 (7.8)	69 (7.7)	>.999	21 (7.8)	20 (7.5)	.869
Low output syndrome	4 (1.5)	17 (1.9)	.798	4 (1.5)	8 (3.0)	.248
Perioperative myocardial infarction	2 (0.7)	7 (0.8)	>.999	2 (0.7)	2 (0.7)	>.999
Respiratory failure	10 (3.7)	22 (2.5)	.368	10 (3.7)	6 (2.2)	.314
Severe ventricular arrhythmia	1 (0.4)	9 (1.0)	.473	1 (0.4)	3 (1.1)	.314
Require hemodialysis	5 (1.9)	12 (1.3)	.737	5 (1.9)	8 (3.0)	.405
Stroke	5 (1.9)	12 (1.3)	.737	5 (1.9)	2 (0.7)	.257
Mediastinitis	1 (0.4)	9 (1.0)	.469	1 (0.4)	0	.317
Reexploration due to bleeding	2 (0.7)	10 (1.1)	.744	2 (0.7)	2 (0.7)	>.999
Atrial fibrillation	67 (24.9)	233 (26.0)	.814	67 (25.0)	74 (27.6)	.518

Values are presented as mean ± standard deviation or n (%).

FIGURE 1. A, Kaplan-Meier event-free survival analysis for all deaths in nonmatched patients. B, Kaplan-Meier event-free survival analysis for major adverse cardiac and cerebrovascular events in nonmatched patients.

creatinine level, a history of congestive heart failure, peripheral vascular disease, chronic obstructive pulmonary disease, nonelective surgery, and atrial fibrillation were associated with MACCE. Multivariate analysis (Table 3) revealed that lower ejection fraction, higher creatinine level, peripheral vascular disease, and atrial fibrillation were independent predictors of MACCE. Previous stent was not identified as an independent predictor of MACCE.

Propensity Score Matched-Pairs Analysis

Preoperative and perioperative data of the propensity-matched patients are listed in Tables 1 and 2. These matched pairs were well balanced for all known covariates (Table 1). The rate of patients undergoing extensive reconstruction of the left anterior descending artery were higher in the stent group than in the no-stent group

($P = .012$), which lead to the longer operation time in the stent group than the no-stent group ($P = .010$).

The operative death rates did not differ between these groups ($P = .414$) and neither did the major complication rates ($P = .869$).

The actuarial survival rate at 7 years was not different between the groups ($87.2\% \pm 3.2\%$ in the stent group and $84.8\% \pm 2.9\%$ in the no-stent group; $P = .470$) (Figure 2, A). Furthermore, freedom from MACCE at 7 years was not different between the groups ($78.9\% \pm 3.8\%$ in stent group and $77.6\% \pm 3.3\%$ in the no-stent group; $P = .811$) (Figure 2, B).

DISCUSSION

Our study demonstrates that previous PCI with stent does not increase early morbidity or mortality in patients undergoing off-pump CABG. Moreover, previous coronary stent

TABLE 3. Multivariate Cox proportional hazard analysis for late events

Outcome	Hazard ratio	P value	95% Confidence interval
Late death			
Age	1.084	<.001	1.052-1.116
Smaller body surface area	4.878	.002	1.821-13.158
Lower ejection fraction	1.016	.049	1.000-1.033
Creatinine	1.260	<.001	1.156-1.373
History of congestive heart failure	1.764	.025	1.074-2.899
Peripheral vascular disease	2.824	<.001	1.675-4.762
Chronic obstructive pulmonary disease	2.227	.010	1.212-4.082
Atrial fibrillation	2.041	.025	1.096-3.802
Late MACCE			
Lower ejection fraction	1.013	.049	1.000-1.027
Creatinine	1.119	.003	1.038-1.206
Peripheral vascular disease	1.848	.006	1.196-2.857
Atrial fibrillation	2.037	.006	1.229-3.367

MACCE, Major adverse cardiac and cerebrovascular event.

was not an independent predictor of late adverse outcome after off-pump CABG. Similar results have been reported by other investigators.¹⁰⁻¹² They demonstrated that there were no differences in mortality or morbidity between patients undergoing CABG with and without previous PCI.¹⁰⁻¹² Barakate and colleagues¹⁰ reported similar 30-day mortality rates (2.0%) for patients undergoing CABG with and without previous PCI. Van den Brule and colleagues¹¹ also described no significant differences in the rates of myocardial infarction, arrhythmia, reinterventions, neurologic complications, renal complications, pulmonary complications, or in-hospital mortality for patients undergoing CABG with and without previous PCI. Furthermore, they reported that a 1-year follow-up did not reveal any significant differences in the rates of cardiac-related mortality or recurrent ischemic events between their groups. More recently, Boening and colleagues¹² reported that coronary stenting in patients with diabetes did not predispose to a higher perioperative risk regarding mortality and morbidity after CABG. However, these studies were limited to demonstrate the early outcomes; moreover, CABG was performed with cardiopulmonary bypass in the majority of patients. In our study, we selected patients undergoing off-pump CABG to eliminate the inflammatory effect of cardiopulmonary bypass. Furthermore, long-term outcomes were compared between the groups to investigate the influence of having a stent on patients' prognoses.

In contrast, there are several reports demonstrating that the previous PCI with stent is a risk factor for CABG. Hassan and colleagues² reported that the in-hospital mortality rates after CABG were higher in patients with prior PCI than in patients without prior PCI (3.6% vs 2.3%). Furthermore, prior PCI emerged as an independent predictor of

postoperative in-hospital mortality. Similarly, Thielmann and colleagues¹ described that multiple previous PCI procedures were strongly associated with in-hospital mortality (odds ratio, 2.24) and major adverse cardiac events (odds ratio, 2.28). More recently, Massoudy and colleagues³ showed in a large multicenter analysis (N = 37,140) that a history of multiple PCIs was an independent predictor for in-hospital death and major adverse cardiac events. Furthermore, Mannacio and colleagues⁴ demonstrated that a history of PCI before CABG decreased survival at 5 years' follow-up. Several negative influences of PCI with stent have been considered. Lazar¹³ suggested that stents not only may result in local vascular inflammation, but also may stimulate platelet and neutrophil adhesion along the entire vessel, with resulting decreased graft patency. Moreover, because of the physical presence of the stent, bypass grafts may need to be inserted more distally in vessels, which may compromise runoff and ultimately patency.¹⁰ In fact, Gomez and colleagues⁶ found that the coronary artery distal to the stent had chronic inflammation and an intimal acute inflammatory infiltrate with polymorphonuclear leukocytes. Moreover, the myocardium adjacent to the stent had significant chronic inflammatory infiltrate and fibrosis.

The use of cardiopulmonary bypass may amplify these inflammatory reactions both locally and systemically. Then the off-pump procedure may contribute to better outcomes than the on-pump procedure. In a previous study,¹⁴ we demonstrated that the in-hospital outcomes and the early patency rates of grafts were not different between patients with and without previous PCI who underwent off-pump CABG. However, in that study, the number of patients was small (N = 545), and there were no follow-up results. In our present study, we extended the follow-up to more than 7 years and further demonstrated that long-term survival and freedom from major complications were not affected by previous PCI with stent. Moreover, we adopted propensity score matched-pairs analysis to minimize the difference between the groups, which was not done in our previous study.

In our study, the percentage of use of bilateral internal thoracic artery (ITA) was higher than in other studies. Moreover, there was no difference regarding the use of bilateral ITA between the groups. It is well known that the use of bilateral ITA provides better survival benefit than single ITA.¹⁵ Furthermore, the combination of off-pump CABG with bilateral ITA grafting also yields favorable outcomes.¹⁶ We also demonstrated in a previous study¹⁷ that off-pump bilateral ITA grafting can be performed safely and effectively with favorable early and 1-year patency rates in patients with and without left main disease. In our study, the potential influence of bilateral ITA rather than off-pump CABG may have affected the outcome in both groups, although there was no

FIGURE 2. A, Kaplan-Meier event-free survival analysis for all deaths in matched patients. B, Kaplan-Meier event-free survival analysis for major adverse cardiac and cerebrovascular events in matched patients.

difference regarding the outcome between the groups. However, because nonuse of bilateral ITA was not associated with late mortality (HR, 1.457; 95% confidence interval, 0.859-2.472; $P = .163$) and MACCE (HR, 1.101; 95% confidence interval, 0.708-1.713; $P = .669$) by univariate analysis, further study is necessary to investigate the effect of bilateral ITA in patients with and without previous stents.

Our clinical study has some limitations. The number of patients was relatively small. Although propensity-matched comparison was used, it was still a retrospective observational study and unrecognized confounding factors may exist. We did not show any patency rates of grafts in our study because we did not have enough data on follow-up patency rates of these patients (stent group: 144 out of 268 [53.5%], no-stent group: 479 out of 897 [53.4%]).

CONCLUSIONS

Previous coronary stents do not increase early and long-term morbidity or mortality in patients undergoing off-pump CABG.

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