Previous Percutaneous Coronary Intervention Does Not Increase Adverse Events After Coronary Artery Bypass Surgery

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Background. **Adverse effects of previous percutaneous coronary intervention (PCI) on clinical outcomes after coronary artery bypass grafting (CABG) are unclear. This study aimed to evaluate the effect of previous PCI on early outcomes after subsequent CABG by using data from the Japanese national database.**

Methods. **This study analyzed data from 48,051 consecutive patients that were retrieved from the Japan Adult Cardiovascular Surgery Database. These patients underwent primary, isolated, elective CABG between January 2008 and December 2013. Early mortality and morbidity rates in patients with previous PCI (n = 12,457, 25.9%) were compared with those in patients with no PCI (n = 35,594, 74.1%) by using multivariate logistic regression analysis and propensity score analysis.**

Results. **Operative mortality rates (no PCI, 1.2%; previous PCI, 1.2%; P = 0.970) and morbidity rates (no PCI, 7.4%; previous PCI, 7.2%; $p = 0.436$) were similar between the two groups. In risk-adjusted multivariate logistic-regression analysis, previous PCI (odds ratio [OR], 1.00; 95% confidence interval [CI], 0.82 to 1.22; $p = 0.995$) and morbidity (OR, 0.97; 95% CI, 0.89 to 1.05; $p = 0.391$) were not significant risk factors of operative mortality. Inverse probability of treatment weighting using the propensity score confirmed these results.**

Conclusions. **This study shows that a previous PCI procedure does not increase postoperative adverse events after subsequent CABG. In the setting of repeat coronary revascularization, the most appropriate method of revascularization should be selected by the heart team, without being affected by a history of a previous PCI procedure.**

(Ann Thorac Surg 2017;104:56–61)

After its introduction in the SYNTAX (SYNergy Between PCI With TAXUS and Cardiac Surgery) trial, the heart team approach has been widely adopted, and it improves efficiency and quality of coronary revascularization [1]. However, even in the era of the heart team, repeat revascularization after primary coronary revascularization poses challenging decision making. An unsolved problem in this decision making is whether previous percutaneous coronary intervention (PCI) increases early mortality and morbidity rates after subsequent coronary artery bypass grafting (CABG).

Many previous studies have evaluated the effect of previous PCI on outcomes after subsequent CABG [2–13]. A meta-analysis of these studies that compared patients who had CABG with and without previous PCI reported that a history of previous PCI increases early mortality rates after subsequent CABG [14]. In the current European Society of Cardiology/European Association for Cardio-Thoracic Surgery guidelines on myocardial revascularization, repeat PCI is recommended as the first-line treatment of recurrent ischemia after PCI (class IC recommendation) [15]. However, several studies have reported that a previous PCI procedure is not associated with increased mortality rates after subsequent CABG [7–10, 13]. Therefore, the prognostic effect of previous PCI on subsequent CABG remains controversial. To establish an effective treatment strategy for elective repeat revascularization after PCI, the effect of previous PCI on outcomes after subsequent CABG should be investigated in a large cohort of patients.

The Supplemental Table can be viewed in the online version of this article [http://dx.doi.org/10.1016/j.athoracsur.2016.10.028] on http://www.annalsthoracicsurgery.org.

Accepted for publication Oct 10, 2016.

Presented at the Poster Session of the Fifty-second Annual Meeting of the Society of Thoracic Surgeons, Phoenix, AZ, Jan 23–27, 2016.

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Published by Elsevier Inc.

0003-4975/$36.00
http://dx.doi.org/10.1016/j.athoracsur.2016.10.028

Abbreviations and Acronyms

CABG	= coronary artery bypass grafting
CI	= confidence interval
JACVSD	= Japan Adult Cardiovascular Surgery Database
MACE	= major adverse cardiac events
OR	= odds ratio
PCI	= percutaneous coronary intervention

This study aimed to assess whether a history of previous PCI increases postoperative mortality and morbidity rates after elective subsequent CABG. We used a large dataset from the Japan Adult Cardiovascular Surgery Database (JACVSD).

Patients and Methods

Japan Adult Cardiovascular Surgery Database

The JACVSD was established in 2000 to enable evaluation of surgical outcomes after cardiovascular procedures in hospitals throughout Japan. As of 2013, the JACVSD had collected clinical information from more than 516 hospitals across Japan. The JACVSD data collection form has more than 300 variables (definitions are available online at http://www.jacvsd.umin.jp), which are nearly identical to those of The Society of Thoracic Surgeons National Database. The methods of data collection of the JACVSD have been previously described [16]. Data collection was approved by the institutional review board at each participating hospital. The Data Utilization Committee of the JACVSD approved the use of data for the present study. Data collection achieved a high level of completion, with less than 3% of entries missing for overall preoperative risk factors used in risk models. In the present study population, no preoperative variable had a rate of missing data higher than 1%. The accuracy of submitted data is maintained by regular auditing of data in which monthly visits are made to participating hospitals to check the reported data against clinical records. Data validity is further confirmed by an independent comparison of specific hospitals' volume of cardiac operations entered in the JACVSD with that reported in the annual survey of the Japanese Association for Thoracic Surgery.

Study Population

The data of patients included in the JACVSD from January 1, 2008 to December 31, 2013 were analyzed. Patients who underwent primary, isolated, elective CABG were included. Exclusion criteria were urgent, emergency, or salvage status, redo operation, and acute myocardial infarction within the preceding 2 weeks. These criteria were defined mainly to exclude patients who underwent urgent or emergency CABG after failed PCI. Records with missing data on age (or out of range), sex, or 30-day status (see "Study Endpoints" for an explanation) were excluded. With the exception of body surface area and preoperative creatinine values, all missing or out-of-range values were imputed using the variable-specific median value. After this data cleaning was performed, 48,051 patients were included in the present study. Patients were classified as either with previous PCI (previous-PCI group) or without previous PCI (no previous-PCI group) before CABG surgical procedures. In the JACVSD, a previous PCI procedure is defined as a PCI procedure before the index CABG operation. Data of details of the PCI procedure, such as stent placement, type of stent used, and the dates of the procedure, are not defined.

Study Endpoints

The primary endpoints were operative mortality and composite outcome consisting of operative mortality and major morbidity. Operative mortality was defined as death occurring within 30 days after operation and death during the index hospitalization. Major morbidity was defined as any of the following postoperative complications: stroke, reoperation for bleeding, mechanical ventilation required for more than 24 hours postoperatively, renal failure with newly required dialysis, or deep sternal wound infection, which occurred in the hospital or within 30 days after the operation.

Statistical Analysis

Continuous variables are expressed as mean $\pm$ standard deviation, and the unpaired t test or Wilcoxon rank sum test was used for comparisons. Categorical variables are expressed as percentages and were compared using the χ^2 test. The effect of previous PCI procedures on early mortality and morbidity was evaluated by two risk-adjustment methods. First, a risk-adjusted prognostic effect of previous PCI was estimated within a multivariate logistic regression model that included the clinically relevant covariates (listed in Table 1) and the use of bilateral internal thoracic arteries.

Second, inverse probability of treatment weighting was also performed to validate the estimated prognostic effect [17]. The propensity score with previous PCI as an outcome was calculated in a multivariate logistic regression model including the preoperative variables (Table 1) as covariates. The area under the receiver operating characteristic curve was 0.693 (95% confidence interval [CI], 0.688 to 0.699; $p < 0.001$). The inverse probability weights calculated by using the propensity score were applied to a logistic regression model to obtain the propensity-weighted odds ratio (OR) of previous PCI procedures. In addition, risk-adjusted ORs of previous PCI were also calculated in subgroups defined by preoperative risk factors. In all logistic regression models for the OR of previous PCI procedures, the annual isolated CABG case volumes of hospitals were included as a covariate to minimize the effect of institutional surgical volume. All reported p values are two sided, and $p < 0.05$ was considered statistically significant. Statistical analysis was performed using SPSS 20.0 software (IBM Corp, Armonk, NY).

Table 1. Patient Characteristics[a]

Variable	No Previous PCI (N = 35,594)	Previous PCI (N = 12,457)	*p* Value
Age (y)	68.5 ± 9.6	67.9 ± 9.5	<0.001
Sex, male	27,738 (77.9)	10,079 (80.9)	<0.001
Body mass index (kg/m^2)	23.7 ± 3.5	23.9 ± 3.5	<0.001
Smoking history (within 1 month)	6,178 (17.4)	1,847 (14.8)	<0.001
Diabetes	15,655 (44.0)	5,776 (46.4)	<0.001
Hyperlipidemia	21,847 (61.4)	8,519 (68.4)	<0.001
Hypertension	27,575 (77.5)	10,041 (80.6)	<0.001
Preoperative renal dysfunction	5,161 (14.5)	2,131 (17.1)	<0.001
Preoperative dialysis	2,579 (7.2)	1,301 (10.4)	<0.001
Serum creatinine (mg/dL)	1.49 ± 2.06	1.74 ± 2.44	<0.001
Cerebrovascular disease	4,474 (12.6)	1,383 (11.1)	<0.001
Chronic lung disease	3,710 (10.4)	1,445 (11.6)	<0.001
Hepatic dysfunction	400 (1.1)	113 (0.9)	0.043
Peripheral vascular disease	5,774 (16.2)	1,702 (13.7)	<0.001
Previous myocardial infarction	9,124 (25.6)	6,428 (51.6)	<0.001
Congestive heart failure	4,337 (12.2)	1,326 (10.6)	<0.001
Unstable angina	8,044 (22.6)	2,692 (21.6)	0.023
Preoperative shock	144 (0.4)	75 (0.6)	0.005
Preoperative atrial fibrillation	1,194 (3.4)	463 (3.7)	0.056
NYHA functional class IV	794 (2.2)	299 (2.4)	0.275
LVEF <30%	1,775 (5.0)	510 (4.1)	<0.001
Preoperative IABP	1,674 (4.7)	535 (4.3)	0.061
Left main disease ≥50%	13,239 (37.2)	4,730 (38.0)	0.123
Triple-vessel disease	26,176 (73.5)	7,989 (64.1)	<0.001
Aortic stenosis ≥grade 1	978 (2.7)	304 (2.4)	0.067
Aortic insufficiency ≥grade 2	2,467 (6.9)	954 (7.7)	0.007
Mitral insufficiency ≥grade 2	5,367 (15.1)	1,921 (15.4)	0.359
Tricuspid insufficiency ≥grade 2	2,985 (8.4)	1,014 (8.1)	0.392
Aspirin	11,701 (32.9)	4,823 (38.7)	<0.001
Other antiplatelet agents	2,051 (5.8)	1,362 (10.9)	<0.001
β-Blockers	11,422 (32.1)	4,910 (39.4)	<0.001
Statins	14,819 (41.6)	6,089 (48.9)	<0.001
ACE inhibitors	3,484 (9.8)	1,643 (13.2)	<0.001
ARB	10,268 (28.8)	3,867 (31.0)	<0.001
Steroids	430 (1.2)	167 (1.3)	0.250
Intended OPCAB	23,320 (65.5)	8,403 (67.5)	<0.001

[a] Data are number (%) or mean ± SD.

ACE = angiotensin-converting enzyme; ARB = angiotensin receptor blocker; IABP = intraaortic balloon pump counterpulsation; LVEF = left ventricular ejection fraction; NYHA = New York Heart Association; OPCAB = off-pump coronary artery bypass; PCI = percutaneous coronary intervention.

Table 2. Intraoperative Characteristics[a]

Variable	No Previous PCI (N = 35,594)	Previous PCI (N = 12,457)	*p* Value
Conversion from OPCAB to ONCAB	671 (1.9)	251 (2.0)	0.363
ONCAB with cross-clamping	6794 (19.1)	2281 (18.3)	0.057
Operative duration (min)	325.3 ± 101.2	315.5 ± 102.3	<0.001
CPB time (min)	141.1 ± 53.4	138.5 ± 55.4	0.007
Distal anastomoses (n)	3.17 ± 1.20	2.96 ± 1.17	<0.001
ITA use			
Left	33,428 (93.9)	11,603 (93.1)	0.002
Right	13,046 (36.7)	4459 (35.8)	0.087
Bilateral	12,238 (34.4)	4140 (33.2)	0.020
None	1370 (3.8)	542 (4.4)	0.014
Radial artery use	5430 (15.3)	1788 (14.4)	0.015

[a] Data are number (%) or mean ± SD.

CPB = cardiopulmonary bypass; ITA = internal thoracic artery; ONCAB = on-pump coronary artery bypass; OPCAB = off-pump coronary artery bypass; PCI = percutaneous coronary intervention.

Results

Of 48,051 consecutive patients who underwent primary, isolated, elective CABG, 12,457 (25.9%) had previous PCI and 35,594 (74.1%) had no previous PCI. There were significant differences in patients' characteristics between the groups (Table 1). The no previous-PCI group had a higher prevalence of triple-vessel disease than did the previous-PCI group. The previous-PCI group had a much higher prevalence of previous myocardial infarction, preoperative renal dysfunction, and preoperative hemodialysis than did the no previous-PCI group. The previous-PCI group took more aggressive medication therapy preoperatively, including antiplatelet agents, β-blockers, angiotensin-converting enzyme inhibitors or angiotensin receptor blockers, and statins, than did the no previous-PCI group.

Table 2 shows operative data. The no previous-PCI group had more distal anastomoses than the previous-PCI group. The operative duration and cardiopulmonary bypass time were slightly longer in the no previous-PCI group than in the previous-PCI group.

Postoperative outcomes are shown in Table 3. Unadjusted operative mortality rates were similar between the groups (previous-PCI 1.2% vs no previous-PCI 1.9%). There was no significant difference in composite outcome between the groups (previous-PCI 7.2% vs no previous-PCI 7.4%). Unadjusted ORs for previous PCI on operative mortality and composite outcome were 1.00 (95% CI, 0.83 to 1.20) and 0.97 (95% CI, 0.90 to 1.05), respectively (Table 4, Supplemental Table).

After risk adjustment in a multivariate logistic regression model, previous PCI was still not a significant risk factor for operative mortality and composite outcome. The risk-adjusted ORs for previous PCI on operative mortality and composite outcome were estimated as 1.00 (95% CI, 0.82 to 1.22; $p = 0.995$) and 0.97 (95% CI, 0.90 to 1.05; $p = 0.391$), respectively, and adjusted for the institutional CABG case volume (Table 4, Supplemental Table).

Inverse probability of treatment weighting analyses confirmed these results. In logistic regression analysis

Table 3. Postoperative Outcomes[a]

Outcomes	No Previous PCI (N = 35,594)	Previous PCI (N = 12,457)	*p* Value
Operative mortality	433 (1.2)	151 (1.2)	0.970
Composite outcome	2,650 (7.4)	901 (7.2)	0.436
Stroke	460 (1.3)	152 (1.2)	0.536
Reoperation for bleeding	443 (1.2)	164 (1.3)	0.536
Renal failure needing dialysis	491 (1.4)	133 (1.1)	0.008
Deep sternal wound infection	513 (1.4)	149 (1.2)	0.043
Prolonged ventilation (≥24 h)	1,248 (3.5)	451 (3.6)	0.552

[a] Data are number (%).

PCI = percutaneous coronary intervention.

that included previous PCI and the institutional CABG case volume, the ORs for previous PCI on operative mortality and composite outcome were estimated as 1.00 (95% CI, 0.83 to 1.22; $p = 0.990$) and 1.00 (95% CI, 0.92 to 1.08; $p = 0.945$), respectively (Table 4).

Risk-adjusted ORs were also calculated in subgroups stratified by preoperative risk factors. Previous PCI procedures were not associated with either operative mortality or composite outcome in any subgroup (Table 5).

Comment

In the present study, we assessed the effect of previous PCI on clinical outcomes after elective subsequent CABG by using the JACVSD. This study included a large of CABG-treated patients with previous PCI (n = 12,457). Although we used two risk-adjustment methods to minimize the effect of confounding factors, previous PCI was not significantly associated with increased operative mortality and morbidity after subsequent CABG. Additionally, subgroup analysis showed that previous PCI was not a significant risk factor for operative mortality and morbidity, even in high-risk patients. These results provide additional evidence for treatment strategies in the setting of elective repeat coronary revascularization.

Our finding that a previous PCI procedure was not associated with increased operative mortality and morbidity after subsequent CABG is similar to that reported in several previous studies [6–10]. Stevens and colleagues [7] reported that previous PCI that was performed 14 days or longer before CABG did not increase 30-day mortality and hospital morbidity rates in their propensity score-matching analysis including 3,236 patients. In their study, patients requiring primary PCI for acute myocardial infarction were excluded to avoid bias caused by poor outcomes of urgent or emergency CABG after unsuccessful PCI. Based on propensity score analysis using data from an Australian registry, Yap and colleagues [8] reported that previous PCI was not a predictor of operative mortality or major adverse cardiac events (MACE). A large study including 63,420 patients (2,942 patients with previous PCI) reported that previous PCI was not an independent risk factor of hospital mortality in multivariate logistic regression analysis or in propensity score adjustment [9]. Both these previous studies attempted to reduce the urgent or emergency bias by excluding from their analysis patients who underwent PCI and subsequent CABG during the same admission [8, 9]. More recently, Fukui and colleagues [10] reported that previous PCI did not increase operative mortality and morbidity in patients undergoing off-pump CABG. Because our study included a larger number of patients with previous PCI, we observed a large number of adverse events. This large number of events enabled performance of risk-adjusted analysis with strong statistical power. Furthermore, the present study tried to minimize the urgent or emergency bias by excluding patients with acute myocardial infarction and patients who underwent urgent, emergency, or salvage operations. Therefore, the present study provides further evidence for the clinical effect of previous PCI in subsequent CABG.

In contrast, several studies have reported that a previous PCI procedure is a significant risk factor for subsequent CABG [2–4, 11, 12]. Bonaros and colleagues [11] compared 306 patients with elective PCI within 24 months before CABG and 452 age-, sex-, and risk-matched patients

Table 4. Effect of Previous Percutaneous Coronary Intervention on Outcomes After Subsequent Coronary Artery Bypass Grafting

	OR (95% CI)		
Variable	Unadjusted	Risk Adjustment (Multivariate Logistic Regression)	IPTW
Operative mortality	1.00 (0.83–1.20)	1.00 (0.82–1.22)	1.00 (0.83–1.22)
Composite outcome	0.97 (0.90–1.05)	0.97 (0.89–1.05)	1.00 (0.92–1.08)
Stroke	0.94 (0.79–1.13)	1.03 (0.85–1.26)	1.04 (0.86–1.26)
Reoperation for bleeding	1.06 (0.88–1.27)	1.13 (0.94–1.36)	1.14 (0.94–1.37)
Renal failure needing dialysis	0.77 (0.64–0.94)[a]	0.72 (0.58–0.88)[a]	0.84 (0.69–1.02)
Deep sternal wound infection	0.83 (0.69–0.99)[a]	0.82 (0.68–0.99)[a]	0.83 (0.69–1.00)
Prolonged ventilation (≥24 h)	1.03 (0.93–1.15)	1.02 (0.91–1.15)	1.05 (0.94–1.18)

[a] $p < 0.05$.

CI = confidence interval; IPTW = inverse probability of treatment weighting; OR = odds ratio.

Table 5. Adjusted Odds Ratios for Operative Mortality and Composite Outcome in Subgroups

	Operative Mortality		Composite Outcome	
Subgroup (Number Included in Analysis)	OR (95% CI)	*p* Value	OR (95% CI)	*p* Value
Age ≥75 years (n = 12,106)	0.81 (0.58–1.13)	0.214	0.92 (0.79–1.08)	0.311
Diabetes (n = 25,408)	1.05 (0.81–1.37)	0.726	0.97 (0.87–1.07)	0.530
Previous MI (n = 15,552)	1.11 (0.84–1.46)	0.482	0.90 (0.80–1.02)	0.094
No previous MI (n = 32,395)	0.94 (0.70–1.25)	0.660	1.02 (0.92–1.15)	0.672
Preoperative renal dysfunction (n = 7,292)	1.03 (0.77–1.38)	0.843	0.94 (0.81–1.10)	0.454
LVEF <30% (n = 2,285)	1.36 (0.75–2.46)	0.317	0.87 (0.63–1.21)	0.414
Triple-vessel disease (n = 34,165)	1.06 (0.84–1.33)	0.636	1.00 (0.91–1.10)	0.968
Male (n = 37,817)	1.08 (0.86–1.35)	0.509	0.96 (0.88–1.05)	0.391
Female (n = 10,233)	0.75 (0.48–1.18)	0.211	0.98 (0.82–1.17)	0.852

CI = confidence interval; LVEF = left ventricular ejection fraction; MI = myocardial infarction; OR = odds ratio.

without previous PCI. These investigators reported that patients with previous PCI had significantly worse mortality and morbidity rates. Although this was a case-control study, patients with previous PCI had a higher rate of a history of myocardial infarction and showed a significantly lower preoperative ejection fraction than did patients without PCI [11]. These worse preoperative characteristics in patients with previous PCI could affect their worse outcome. Mannacio and colleagues [12] studied 1,021 patients with previous PCI and 6,834 patients without previous PCI. These investigators reported that previous PCI was significantly associated with an increased risk for hospital mortality and MACE in an analysis of 852 propensity-score matched pairs [12]. Additionally, within their previous-PCI group, 41% of patients had a history of multiple previous PCIs. Subgroup analysis of the previous-PCI group showed a significantly higher incidence of cardiac death and MACE in patients with multiple previous PCIs than in patients with a single previous PCI [12]. Consequently, the adverse effect of previous PCI in their study was strongly affected by the worse outcome in patients with multiple previous PCIs.

Previous studies have focused on the adverse effect of multiple previous PCIs [2, 3]. Thielmann and colleagues [2] evaluated the association between previous single or multiple PCIs before CABG and postoperative in-hospital patients' outcomes. These investigators reported that a history of multiple repeated PCIs was an independent predictor of hospital death (OR, 2.24; 95% CI, 1.52 to 3.21) and MACE (OR, 2.28; 95% CI, 1.38 to 3.59), but a history of single PCI was not [2]. Massoudy and colleagues [3] confirmed similar results in a large, multicenter study in Germany. In their study, multiple previous PCIs significantly increased hospital mortality (OR, 2.02; 95% CI, 1.36 to 2.99) and MACE (OR, 1.51; 95% CI, 1.17 to 1.93) in patients, whereas single previous PCI did not increase these adverse outcomes [3]. Considering this adverse effect of multiple previous PCIs, the clinical outcome after subsequent CABG in a previous (single or multiple) PCI cohort appears to be strongly affected by the proportion of multiple previous PCIs in the whole cohort. This possibility was confirmed in a meta-analysis that reported that as the proportion of patients with a history of multiple PCIs in a CABG cohort increases, early mortality after CABG also increases [14]. Because of the difference in coronary revascularization strategies among institutions, the proportion of multiple previous PCIs is widely different in each institution. This variation in the proportion of patients with a history of multiple PCIs could be reduced by using a large dataset from a multicenter trial or a national database. Large studies including more than 10,000 patients from multiple institutions have reported that previous PCI does not increase early mortality rates [8, 9, 13].

In the present study, a previous PCI procedure was not a significant risk factor for operative mortality and morbidity in any high-risk subgroups. Several studies have evaluated the adverse effects of a history of previous PCI in patients with diabetes mellitus. A risk-adjusted analysis of 1,758 patients with diabetes mellitus who underwent CABG showed that patients with previous PCI had significantly higher operative mortality and MACE than did those without previous PCI [18]. Thielmann and colleagues [19] also reported an increased risk of mortality and morbidity in patients with a history of PCI by analyzing CABG-treated patients with diabetes mellitus and triple-vessel disease. In contrast, another study showed that coronary stenting before CABG in patients with diabetes was not associated with an increased risk of mortality and morbidity after CABG [20]. Because of a lack of data on the number of previous PCI events (single or multiple) in these previous studies, whether the operative risk of patients with diabetes is significantly increased by even a single previous PCI is unclear. This issue needs to be investigated in the future to determine whether any subgroup of CABG-treated patients is more sensitive to a history of previous PCI than others.

The present study has several limitations. First, although the large sample size in the present study provided statistical power, multivariate logistic regression and propensity score analysis could not completely adjust for potential selection bias. In particular, patients with previous PCI took medication, such as statins and angiotensin receptor blockers, more frequently than did patients without previous PCI. Even though medications were adjusted for, there is concern that the clinical outcomes in the previous-PCI group could be affected by lifestyle or dietary changes accompanying medication. Second, because of our database limitations, our data on previous PCI procedures were lacking certain items, including single or multiple previous PCI events, type of PCI (with or without stent placement), the target vessel of PCI, and the time interval between CABG and previous PCI. In a multicenter registry from Japan, 6.7% of patients were treated by PCI without stents among those undergoing PCI as the first coronary revascularization [21]. Therefore, most patients with previous PCI in our cohort are thought to have been treated by PCI with coronary stenting. Finally, because of the lack of long-term data in the present study, our assessment of the clinical effect of previous PCI is limited to short-term outcomes.

In conclusion, a previous PCI procedure does not increase postoperative adverse events after subsequent CABG. In the setting of repeat coronary revascularization, the most appropriate method of revascularization, including CABG, should be selected by the heart team, without being affected by the history of a previous PCI procedure.

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