



# Long-term outcomes of percutaneous coronary intervention in grafts and native vessels in coronary artery bypass grafting patients with diabetes mellitus

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**Background:** Atherosclerosis in diabetic patients progresses fast. Evidence on how to choose target vessels of percutaneous coronary interventions (PCIs) in diabetic patients post-coronary artery bypass graft (post-CABG) is insufficient.

**Methods:** One hundred and fifty-seven patients with diabetes and previous CABG, who underwent PCI of either a graft vessel (GV) (n=44) or a native vessel (NV) (n=113) in the National Center for Cardiovascular Disease, China, were studied. In-hospital and long-term clinical outcomes were compared between the groups.

**Results:** Diabetic patients with prior CABG had more PCI to native arteries, but the proportion of grafts PCI increased as time went on. Both groups had similar baseline characteristics. Group GV patients compared with group NV had more totally occluded NVs, less totally occluded grafts and more in-stent restenosis. However, there was no difference in in-hospital mortality and long-term incidence of major adverse cardiac event (MACE), cardiac death, nonfatal myocardial infarction (MI), or revascularization. Multivariate logistic regression analysis showed that PCI success [hazard ratio (HR), 11.488; 95% confidence interval (CI), 1.135–116.303;  $P < 0.05$ ] was independent predictor of MACE.

**Conclusions:** It suggested similar long-term clinical outcomes after PCI in GV or NV in prior CABG patients with diabetes. Thus, the vessel with higher estimated PCI success rate should be prioritized by operators.

**Keywords:** Stent; coronary artery bypass graft (CABG); percutaneous coronary intervention (PCI); diabetic mellitus

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## Introduction

Diabetes mellitus is a metabolic disease globally, with nearly 285 million adults affected worldwide (1). It is quite common that diabetic patients are complicated by coronary

artery disease (CAD). Furthermore, atherosclerosis within diabetic patients is frequently diffuse and rapidly progressive (2,3). Several large trials (4-8) and guidelines (9,10) suggested that coronary artery bypass graft (CABG)

surgery was prior to percutaneous coronary intervention (PCI) in diabetic patients with multi-vessel CAD. However, repeat revascularization is often required due to bypass graft failure, and lesion progression in the native vessels (NVs) (11,12). Since redo-CABG has poorer clinical prognosis, PCI is the most common revascularization procedure after CABG (13). Nevertheless, information on choose either NV or graft vessel (GV) as the target of PCI is scarce, especially in diabetic patients. This research is to compare the long-term clinical outcome of diabetic patients with a history CABG following either NV or graft PCI.

## Methods

This was an observational study, conducted in National Center for Cardiovascular Disease, China. We identified 171 consecutive diabetic patients with prior CABG, who subjected to PCI of either a graft or a NV from January 2009 to June 2015. Patients who underwent PCI in NVs and GVs simultaneously or missed follow-up data were excluded. No patients underwent staged PCI of NV and GV during the same admission. A total of 157 patients met the study criteria.

All patients were performed with standard PCI and treated with routine dual antiplatelet therapy (aspirin 300 mg and clopidogrel 300 mg or ticagrelor 180 mg) before PCI. Anticoagulation regimens were decided by operators and included unfractionated heparin. After PCI, aspirin 100 mg per day indefinitely thereafter. Clopidogrel was prescribed for 12 months following drug-eluting stent.

Clinical follow-up information of the patients was obtained by review of clinic visit or by telephone. All patients provided written informed consent prior to undergoing urgent or elective PCI. The study complied with the Declaration of Helsinki and was approved by the Hospital's Institutional Ethical Review Board (Fuwai Hospital, National Center for Cardiovascular Diseases).

## Definitions

Diabetes mellitus was defined as either a previous diagnosis of diabetes mellitus treated with diet, oral agents or insulin, or a new diagnosis during hospitalization upon the published guidelines.

Procedural success was defined as the residual diameter stenosis of <50% in the absence of death, urgent repeat revascularization or new-onset myocardial infarction (MI) during hospitalization.

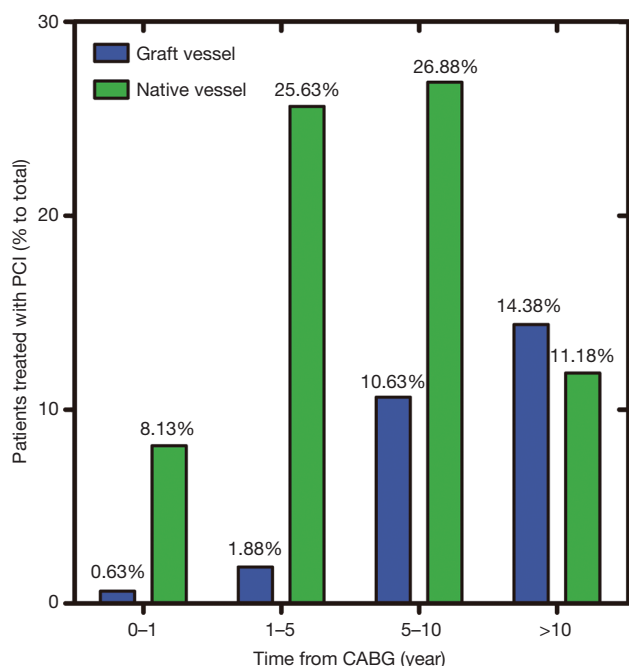
The primary end-point was major adverse cardiac events (MACEs), defined as the combined occurrence of cardiac death, nonfatal MI, or need for a new revascularization strategy [including target lesion revascularization (TLR) and target vessel revascularization (TVR)]. Nonfatal MI was defined as chest discomfort and/or ST-segment and/or T-wave abnormalities in at least 2 contiguous leads of the electrocardiogram and/or new pathologic Q waves or left bundle branch block accompanied by elevated troponin I or creatine kinase isoenzyme-MB (CK-MB). TLR was related to clinically driven repeat PCI or CABG of the previous stent or in the 5-mm distal or proximal segments. TVR was defined as clinically driven repeat PCI or CABG related to the previously stented vessel.

## Statistical analysis

Continuous normally distributed variables were reported as mean  $\pm$  standard deviation (SD) and categorical variables were presented as frequency (%). The continuous variables between groups were compared with student *t*-test and categorical variables between groups were compared with chi-square test. Survival analysis was demonstrated by Kaplan-Meier curves and the curves were compared with the log-rank test. Multivariate adjusted Cox regression model was conducted to determine the risk factors associated with the MACEs among prior CABG patients who underwent PCI. The following variables were entered into the model: age, NV *vs.* GV intervention, durations of hospital stay and if PCI success or not. For all analyses reported, P values are 2-sided, and P values <0.05 were considered significant. SAS version 9.3 (SAS Institute, Cary, NC, USA) was used to perform all the analyses.

## Results

Between January 1<sup>st</sup> 2009 and June 1<sup>st</sup> 2015, 171 consecutive diabetic patients with prior CABG were subjected to PCI in our hospital. Patients were excluded if PCI was performed in both GVs and NVs (11/171; 6.4%) or if follow-up data were missing (3/171; 1.8%). In the remaining 157 patients (mean age of 62.8 $\pm$ 8.5; 76.4% men), most target vessels were native coronary arteries (n=113, 72.0%, group NV) and less frequently GVs (n=44, 28.0%, group GV). In group GV, 41 patients (93.2%) were performed PCI in saphenous vein graft (SVG), 3 (6.8%) in arterial graft, and nobody in both SVG and arterial graft. The percentage of grafts as PCI target vessels increased significantly after 5 years from



**Figure 1** Comparison target vessel in diabetic patients with prior CABG. Comparison of the PCI target vessel in diabetic patients with prior CABG surgery with different time intervals from CABG. CABG, coronary artery bypass graft; PCI, percutaneous coronary intervention.

CABG (Figure 1).

There was no difference in most demographic characteristics and presentation symptom between the groups as depicted in Table 1. More group NV diabetic patients were combined with hypertension (76.99% vs. 61.36%,  $P=0.0486$ ). Table 2 presented the baseline characteristics of the study population. Most stents implanted were drug eluting stents (DESs). The time from CABG to PCI was longer in group GV than group NV (118 vs. 71 months,  $P<0.001$ ). Compared with group NV, group GV patients had more occluded NVs ( $P=0.0049$ ) and less occluded GVs ( $P<0.001$ ). In group GV, 10 patients (22.73%) were treated with distal protection device; none were used in NV ( $P<0.001$ ). Although group GV patients were treated with shorter stent length compared with group NV patients ( $P=0.0109$ ), they presented more in-stent restenosis (6.82% vs. 0.88%,  $P=0.0341$ ). Two groups of patients received similar drug treatment. Group GV patients had a lower pre-PCI thrombolysis in myocardial infarction (TIMI) flow grade compared with group NV ( $P=0.0480$ ). However, there was no significant difference in TIMI flow grade post-

PCI. Procedural success was achieved in 152 (96.82%) patients (97.73% in group GV and 96.46% in group NV,  $P=0.6847$ ).

The median follow-up of the research was  $45\pm 18$  months. There was no difference in the follow-up period after PCI performance in the two groups. None patients in two groups died during hospitalization. As for long-term outcomes (Table 3), 34 patients had MACEs (25.00% vs. 20.35%,  $P=0.5241$ ) and 7 patients had cardiac death, 2 in group GV and 5 in the group NV (4.55% vs. 4.42%,  $P=0.9738$ ). There were 22 TVR (18.18% vs. 12.39%,  $P=0.3477$ ), 17 TLR (15.91% vs. 8.85%,  $P=0.2524$ ) and 8 MI (6.82% vs. 4.42%,  $P=0.6871$ ) without significant difference between the two groups. Kaplan-Meier plots showed that there was no difference in cumulative freedom from MACE (64.4% vs. 74.1%,  $P=0.479$ ), cardiac death (86.2% vs. 91.9%,  $P=0.945$ ), revascularization (76.6% vs. 85.8%,  $P=0.307$ ) and nonfatal MI (92.6% vs. 93.2%,  $P=0.521$ ) (Figure 2). Multivariate Cox regression analysis (Table 4) showed that PCI failure [hazard ratio (HR), 11.488; 95% confidence interval (CI), 1.135–116.303;  $P<0.05$ ] was independently associated with MACE.

## Discussion

Our research suggested that in prior CABG patients with diabetes mellitus, most PCIs (71.97%) were performed in native coronary arteries, especially in the early stage. Previous studies focused mostly on general patients and showed different results: NV PCI was performed in 44% of 95 patients reported by Chen *et al.* (14) vs. 62.5% of 300,902 patients reported by Brilakis and colleagues (15). Chen *et al.* first showed that graft PCI accounted for the majority in the late stage (14), whereas Brilakis and colleagues suggested NV was the most common target vessel of PCI both early and late post-CABG (15). In a recent study, Brilakis *et al.* found that about 75% of PCIs involved native coronary artery lesions (16). However, the data from the group of diabetic patients was scarce. In 2002, Cole *et al.* found among diabetic patients, 43.19% of PCI involved a SVG lesion (17). In our study, the most common target vessel of PCI in diabetic patients during early stage after CABG was native coronary artery. However, after 5 years, graft PCI increased significantly and even after 10 years, graft PCI accounted for more than half of PCI (Figure 1). One explanation for this finding may be lesions of SVG progress more slowly with longer

**Table 1** Baseline characteristics of the study participants

Variables	Overall (n=157)	Group GV (n=44)	Group NV (n=113)	P value
<b>Demographics</b>				
Age, years	62.83±8.54	63.75±7.72	62.47±8.84	0.400
Sex, male	120 (76.43)	38 (86.36)	82 (72.57)	0.0673
History of diabetes, month	111.91±87.89	104.73±83.31	114.71±89.81	0.524
Glycosylated hemoglobin	7.59±1.29	7.64±1.16	7.57±1.34	0.771
Fasting blood-glucose	7.46±2.83	7.73±2.43	7.35±2.98	0.458
<b>Comorbidities</b>				
Hypertension	114 (72.61)	27 (61.36)	87 (76.99)	0.0486
Dyslipidemia	117 (74.52)	34 (77.27)	83 (73.45)	0.6216
Ever smoked	89 (56.69)	24 (54.55)	65 (57.52)	0.7353
Prior MI	62 (39.49)	15 (34.09)	47 (41.59)	0.3878
Prior PCI	49 (31.21)	12 (27.27)	37 (32.74)	0.5064
LVEF <45%	6 (3.82)	2 (4.55)	4 (3.54)	0.7550
BMI	26.47±3.13	26.04±2.92	26.64±3.20	0.2833
CKD	3 (1.91)	0	3 (2.65)	0.2751
Cerebrovascular disease	22 (14.01)	6 (13.64)	16 (14.16)	0.9324
Peripheral arterial disease	21 (13.38)	8 (18.18)	13 (11.50)	0.2696
COPD	3 (1.91)	1 (2.27)	2 (1.77)	0.8363
Family history of CAD	34 (21.66)	8 (18.18)	26 (23.01)	0.5096
<b>Presentation symptoms</b>				0.1733
STEMI	4 (2.55)	3 (6.82)	1 (0.88)	
NSTEMI	11 (7.01)	3 (6.82)	8 (7.08)	
UA	84 (53.50)	26 (59.09)	58 (51.33)	
SA	50 (31.85)	10 (22.73)	40 (35.40)	
Other	8 (5.10)	2 (4.55)	6 (5.31)	

Data are presented as mean ± SD or n (%). GV, graft vessel; NV, native vessel; MI, myocardial infarction; PCI, percutaneous coronary intervention; LVEF, left ventricular ejection fraction; BMI, body mass index; CKD, chronic kidney disease; COPD, chronic obstructive pulmonary disease; CAD, coronary artery disease; STEMI, ST-segment elevation myocardial infarction; NSTEMI, non-ST-segment elevation myocardial infarction; UA, unstable angina; SA, stable angina; SD, standard deviation.

interval from CABG than NV.

Moreover, we found that the choice of target vessel was associated with the severity of the lesions in NVs or GVs. NV PCI may be selected with diffusely degenerated grafts, whereas graft PCI may be preferred in the presence of severely occluded native coronary artery lesion. This conclusion is consistent with previous studies (15,18).

Patients undergoing bypass graft interventions had higher in-stent restenosis (Table 2). Consistently, Keeley

*et al.* (19) also reported SVG stenting restenosis rate was notably high. It is known that SVG interventions have higher risk for no-reflow (20,21), whereas arterial grafts PCI can be complicated by long distance to the target lesion and increased tortuosity (15,22), which probably renders this worse outcome.

The rate of distal embolic protection device use in our study was similar to the mean percentage in foreign hospitals (22% among 19,546 SVG interventions

**Table 2** Procedure characteristics of study population

Variables	Overall (n=157)	Group GV (n=44)	Group NV (n=113)	P value
Time from CABG to PCI, months	84	118	71	<0.001
Treatment				
Enoxaparin	107 (68.15)	29 (65.91)	78 (69.03)	0.7065
IIb/IIIa inhibitors	20 (12.74)	9 (20.45)	11 (9.73)	0.0704
ACEI	66 (42.04)	22 (50.00)	44 (38.94)	0.2073
ARB	53 (33.76)	13 (29.55)	40 (35.40)	0.4861
Number of occluded NVs				0.0042
None	25 (15.92)	6 (13.64)	19 (16.81)	
1	58 (36.94)	10 (22.73)	48 (42.48)	
2	58 (36.94)	18 (40.91)	40 (35.40)	
3	16 (10.19)	10 (22.73)	6 (5.31)	
Mean number of occluded NVs per patient	1.41±0.88	1.73±0.97	1.29±0.81	0.0049
Number of occluded grafts				<0.0001
None	56 (35.67)	27 (61.36)	29 (25.66)	
1	78 (49.68)	16 (36.36)	62 (54.87)	
2	23 (14.65)	1 (2.27)	22 (19.47)	
3	0	0	0	
Mean number of occluded grafts per patient	0.79±0.68	0.41±0.54	0.94±0.67	<0.0001
Procedural success	152 (96.82)	43 (97.73)	109 (96.46)	0.6847
Mean number of lesions treated per patient	1.25±0.53	1.14±0.41	1.30±0.57	0.0457
DES	152 (96.82)	42 (95.45)	110 (97.35)	0.5345
Mean number of stents per patient	1.93±1.05	1.70±0.85	2.02±1.11	0.0936
Total stent length per patient	42.75±28.63	34.50±22.49	45.96±30.18	0.0109
Lesion characteristics				
Chronic total occlusion	32 (20.38)	6 (13.64)	26 (23.01)	0.1904
In-stent restenosis	4 (2.55)	3 (6.82)	1 (0.88)	0.0341
Use of distal protection device	10 (6.37)	10 (22.73)	0	<0.0001
Pre-procedural TIMI flow grade <3	34.52	46.00	30.61	0.0480
Post-procedural TIMI flow grade <3	4.06	2.00	4.76	0.3927

Data are presented as mean ± SD or n (%). GV, graft vessel; NV, native vessel; CABG, coronary artery bypass graft; PCI, percutaneous coronary intervention; ACEI, angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker; DES, drug eluting stent; TIMI, thrombolysis in myocardial infarction; SD, standard deviation.

included in the American College of Cardiology National Cardiovascular Data Registry) (23). With the start of proximal embolic protection devices, more and more SVG lesions can currently be protected (24). Thus, distal embolic

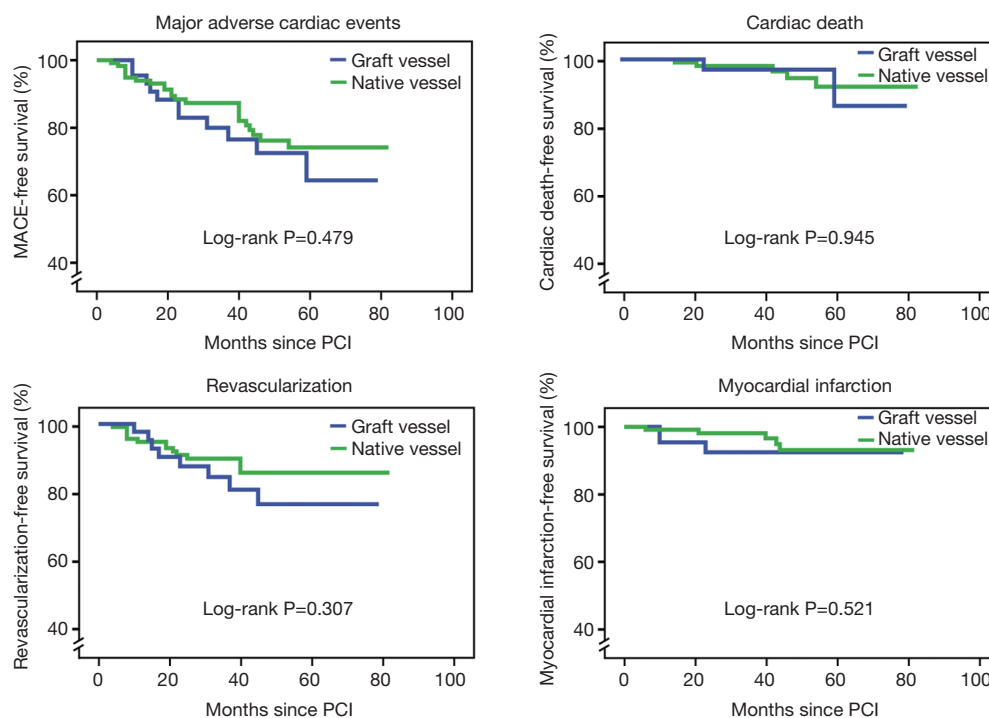
protection in SVG interventions could potentially prevent procedural complications such as no-reflow and improve the procedural outcomes.

As for long-term clinical outcomes, we found that there

**Table 3** Outcomes of study population

Outcomes	Total	Graft	Native	P value
In hospital mortality, n (%)	0	0	0	–
Dissection, n (%)	1 (0.64)	1 (2.27)	0 (0)	0.2803
Bleeding, n (%)	8 (5.10)	0 (0)	8 (7.08)	0.1067
Composite MACE, n (%)	34 (21.66)	11 (25.00)	23 (20.35)	0.5241
Cardiac death, n (%)	7 (4.46)	2 (4.55)	5 (4.42)	0.9738
TVR, n (%)	22 (14.01)	8 (18.18)	14 (12.39)	0.3477
TLR, n (%)	17 (10.83)	7 (15.91)	10 (8.85)	0.2524
MI, n (%)	8 (5.10)	3 (6.82)	5 (4.42)	0.6871

MACE, major adverse cardiac event; TVR, target vessel revascularization; TLR, target lesion revascularization, MI, myocardial infarction.



**Figure 2** Kaplan-Meier curves for long-term clinical outcomes. Kaplan-Meier curves estimate event-free survival: freedom from MACEs; freedom from cardiac death, revascularization and nonfatal MI respectively. MACEs, major adverse cardiac events; MI, myocardial infarction; PCI, percutaneous coronary intervention.

was no difference in the incidence of MACE, cardiac death, MI, and revascularization in the two groups of diabetic patients. There were previous studies that compared clinical outcomes between general patients subjected to GV-PCI vs. NV-PCI, of which the results were inconclusive. Varghese *et al.* (18) made similar conclusions with us that both groups of patients had similar but relatively high incidence of MI

(5%), repeat revascularization (9%), and mortality (6%) in a retrospective study of 142 patients with a mean follow-up of 2.5 years. Tejada *et al.* (25) also reported no difference in the incidence of MACEs, TLR, and death between two groups, but their study involved a smaller sample of 84 consecutive patients. Meliga and colleagues (26) presented a small series of 24 patients with chronic totally occluded SVG and found



**Table 4** Predictors of MACEs in patients with prior coronary bypass graft who underwent PCI

Factors	P value	HR	95% CI
Age	0.5382	0.985	0.940–1.033
Native vs. graft PCI	0.3997	0.691	0.292–1.633
Time of hospital stay	0.1182	1.079	0.981–1.187
PCI failure	0.0387	11.488	1.135–116.303

MACE, major adverse cardiac event; HR, hazard ratio; CI, confidence interval; PCI, percutaneous intervention.

no difference in the cumulative incidence of MACEs at 3 years between the two groups.

Interestingly, Bundhoo *et al.* (27) in a multi-center retrospective study of 161 post-CABG patients with a mean follow-up of 13.5 months, reported higher incidence rates of TVR (15.0% *vs.* 4.9%,  $P=0.03$ ) and MACEs (21.6% *vs.* 8.9%,  $P=0.048$ ) in the GV group. In the assessment of pexelizumab in acute myocardial infarction (APEX-MI) trial, researchers found that bypass graft PCI patients had higher 90-day mortality (19.0% *vs.* 5.7%) compared with native artery PCI patient in a cohort of ST-segment elevation myocardial infarction (STEMI) patients with prior CABG undergoing PCI of the infarct-related artery (28). Similar conclusions were drawn in a research of 220 prior CABG patients from Mavroudis *et al.* (29) and in a pooled-analysis of 169 prior CABG patients with STEMI (30).

PCI to a native coronary artery has traditionally been recommended in prior CABG patients, because SVG PCI carries higher procedural risk and higher restenosis rates compared to native coronary PCI (31,32). Current data was based on the general patients; however, the data focused on diabetic patients was scarce. Our study merely enrolled the group of diabetic patients and our outcome did not conflict with these recommendations, showing higher incidence of in-stent restenosis after SVG PCI than native coronary PCI. Unexpectedly, no significant difference in long-term clinical outcomes was seen between the native coronary and bypass graft PCI in diabetic patients. One potential explanation is the significantly diffuse and severe lesions in native coronary arteries of diabetic patient (33), which may increase difficulty in operation and subsequently offset the original benefit. Our multivariate analysis also revealed that PCI failure was independent predictor of MACE. From this point of view, it is reasonable that interventionalists should select the vessels easy to reach procedural success as targets. If both feasible, native coronary arteries could be the preferred target to prevent in-stent restenosis in diabetic

patients (18,34,35). Besides, special focus should be placed on modifying aggressive risk factor to step down the disease progression (36,37).

## Conclusions

In our study, we found diabetic patients with prior CABG were liable to be performed with native arteries PCI. However, graft PCI become more preferred after longer time intervals from CABG. Higher rate of in-stent restenosis was seen in graft PCI. During hospitalization and after a 45-month follow-up, we found a similar mortality and incidence of composite MACE in both groups. PCI success or not was the predictor of MACE, which suggested that the vessel with higher estimated operating success rate should be selected as target.

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## Footnote

**Conflicts of Interest:** The authors have no conflicts of interest to declare.

**Ethical Statement:** The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. All patients provided written informed consent prior to undergoing urgent or elective PCI. The study complied with the Declaration of Helsinki and was approved by the Hospital's Institutional Ethical Review Board (Fuwai Hospital, National Center for Cardiovascular Diseases) (No. 2018-1034).

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