

# A comparison of drug-eluting stent and coronary artery bypass grafting in mildly to moderately ischemic heart failure

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## Abstract

**Aims** The best revascularization strategy for patients with ischaemic heart failure (IHF) remains unclear. Current evidence and guidelines mainly focus on patients with severe ischaemic heart failure (ejection fraction [EF] < 35%). There are limited data comparing clinical outcomes of coronary artery bypass grafting (CABG) with implantation of drug-eluting stents (DESs) in patients with mild to moderate ischaemic heart failure (EF 35–50%). It is therefore unknown whether percutaneous coronary intervention (PCI) with DES implantation can provide comparable outcomes to CABG in these patients.

**Methods and results** From January 2016 to December 2017, we enrolled patients with mildly to moderately reduced EF (35–50%) who had undergone PCI with DESs or CABG. Patients with a history of CABG, presented with acute ST-elevation myocardial infarction (MI) or acute heart failure, and patients who had undergone CABG concomitant valvular or aortic surgery were excluded. Propensity score-matching analysis was performed between the two groups. Kaplan–Meier analysis and multivariate Cox proportional hazard regression were applied to assess all-cause mortality and individual end points. A total of 2050 patients (1330 PCIs and 720 CABGs) were included, and median follow-up was 45 months (interquartile range 40 to 54). There were significant differences in all-cause death between the two groups: 77 patients in the PCI group and 27 in the CABG group (DES vs. CABG: 5.8% vs. 3.8%,  $P = 0.045$ ). After propensity score matching for the entire population, 601 matched pairs were obtained. The long-term cumulative rate of all-cause death was significantly different between the two groups (DES vs. CABG: 5.8% vs. 2.7%,  $P = 0.006$ ). No differences were found in the rates of cardiac death (DES vs. CABG: 4.8% vs. 3.0%,  $P = 0.096$ ), recurrent MI (DES vs. CABG: 4.0% vs. 2.8%,  $P = 0.234$ ), and stroke (DES vs. CABG: 6.8% vs. 5.2%,  $P = 0.163$ ). The rate of repeat coronary revascularization was significantly higher in the PCI group than in the CABG group (12.1% vs. 6.0%,  $P = 0.000$ ).

**Conclusions** Considering the higher long-term survival rate and lower repeat-revascularization rate, CABG may be superior to DES implantation in patients with mildly to moderately reduced EF (35–50%) and significant CAD.

**Keywords** Ischaemic heart failure; Revascularization; Coronary artery bypass grafting; Drug-eluting stent implantation

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## Introduction

Coronary artery disease CAD remains the most common cause of chronic heart failure.<sup>1</sup> Compared with medical therapy, coronary revascularization is superior in improving survival in patients with CAD and severe reduction of ejection fraction (<35%) and is recommended in clinical practice.<sup>2,3</sup>

However, it is unclear whether myocardial revascularization presents superior results when compared with drug therapy in patients with ischaemic heart disease and mildly to moderately reduced ejection fraction (35–50%). There is growing evidence that coronary artery bypass grafting (CABG) is effective and provides a better prognosis than medical therapy in patients with ventricular dysfunction and CAD.<sup>4,5</sup>

Percutaneous coronary intervention (PCI) with drug-eluting stent (DES) implantation is commonly used for revascularization of these patients; however, there have been few comparisons between PCI and CABG.

According to US guidelines,<sup>6,7</sup> CABG is a reasonable approach to improve morbidity and mortality for patients with severe left ventricular (LV) dysfunction (ejection fraction [EF] < 35%) and significant CAD (IIa B). CABG would be the class IIa recommendation for patients with mildly to moderately reduced ejection fraction (35–50%) and significant multivessel CAD or proximal left anterior descending (LAD) artery stenosis when viable myocardium is present. PCI did not receive a clear recommendation from the guidelines due to insufficient data. In the recent European Society of Cardiology/European Association for Cardio-Thoracic Surgery guidelines on myocardial revascularization,<sup>8</sup> CABG is recommended as the first revascularization strategy choice in patients with multivessel disease and acceptable surgical risk (I B), including patients with chronic heart failure and systolic LV dysfunction (EF < 35%). In patients with one- or two-vessel disease, PCI should be considered as an alternative to CABG when complete revascularization can be achieved (IIa C).

The current evidence and guidelines mainly focus on patients with severe ischaemic heart failure (EF < 35%). There are limited data comparing the clinical outcomes of CABG and DES implantation in patients with mild to moderate ischaemic heart failure (EF 35–50%). Therefore, a comparison of revascularization methods is important given the current scarcity of data on these patients. We used observational real-world data to compare long-term outcomes with the use of propensity score matching in patients with mildly to moderately reduced ejection fraction (35–50%) who underwent CABG or DES in Tianjin chest hospitals.

## Methods

### Study population

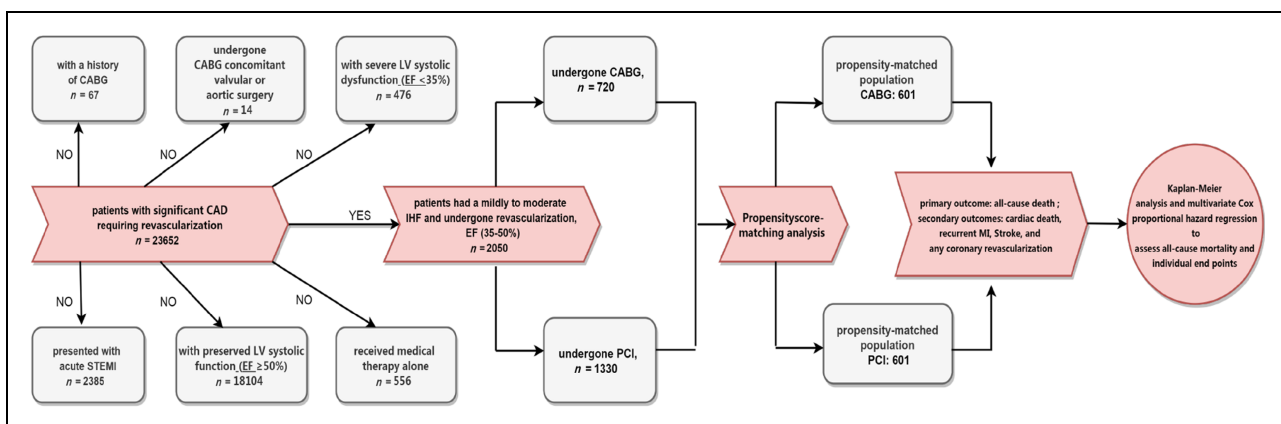
This was a retrospective, single-centre, observational study comparing the long-term prognosis in patients with mild to moderate ischaemic heart failure (EF 35–50%) in China. The relevant Ethics Committees approved the research protocol, and the need for written informed consent was waived because of the retrospective enrolment. Patient information was obtained from the cardiovascular catheterization and surgery databases of Tianjin Chest Hospital (Tianjin, China). Patients with LVEF 35–50% who had undergone PCI with DES or CABG from January 2016 to December 2017 were included.

We identified 3082 patients with chronic HF with reduced LV ejection fraction among 23 652 patients requiring myocardial revascularization. Patients with preserved LV systolic function (EF ≥ 50%, a history of CABG, presented with acute ST-elevation myocardial infarction (MI) or acute heart failure, and patients who had undergone CABG concomitant valvular or aortic surgery were excluded. After excluding 476 patients with severe LV systolic dysfunction (EF < 35%), and 556 patients who received medical therapy alone, the study population consisted of 2050 patients (1330 PCIs and 720 CABGs) with mildly to moderately reduced ejection fraction (35–50%) and significant CAD (*Figure 1*).

### Data collection and follow-up

Information on patient demographics, medical history, laboratory test findings, echocardiography results, coronary angiographic results, procedures, and outcomes at admission and discharge were included in this analysis. LVEF was

**Figure 1** Study flow.



measured by echocardiography performed by experienced operators. DES or CABG was selected according to the preference of patients and their physician. Coronary interventions were performed according to current standard procedural guidelines. The follow-up clinical status was documented by a review of the hospital records and telephone interviews.

## Endpoints and definitions

The primary outcome was all-cause death during follow-up. The secondary outcomes included individual outcomes of cardiac death, recurrent MI, stroke, and any coronary revascularization with PCI or CABG during follow-up. Death was regarded as cardiac in origin unless obvious noncardiac causes could be identified. MI was defined according to the definition in the Arterial Revascularization Therapy Study.<sup>9</sup> Periprocedural MI was not considered as recurrent MI. Stroke during follow-up was defined as an ischaemic or a haemorrhagic stroke requiring hospitalization with symptoms lasting >24 h. Any coronary revascularization was defined as revascularization of either target or nontarget vessels using PCI or CABG. Scheduled staged coronary revascularization procedures performed within 3 months of the initial procedure were not regarded as follow-up events. A significant lesion was defined as stenosis  $\geq 50\%$  of the diameter of a vessel with a reference diameter >2.0 mm by visual estimation. Complete revascularization was considered to have been accomplished when all vessels with significant lesions were successfully revascularized.

## Statistical analysis

Continuous variables are presented as means  $\pm$  SD, and categorical variables are presented as numbers or percentages. Continuous variables were compared using *t*-test or Wilcoxon rank sum test, where applicable. Categorical data were tested using  $\chi^2$  test or Fisher's exact test as appropriate. Survival and incidence curves for clinical outcomes were generated using the Kaplan–Meier method and compared with log-rank tests. Propensity scores were estimated with multivariate logistic regression analyses including gender, age, hypertension, diabetes mellitus, serum creatinine, chronic obstructive lung disease, history of MI, history of PCI; previous stroke; LVEF; number of diseased vessels, left main disease, target chronic total occlusion, target proximal LAD coronary artery as the covariates (Table 1). The discrimination and calibration ability of the propensity score model were assessed using the C-statistic and Hosmer–Lemeshow statistic, respectively. The hazard ratios (HRs) of PCI compared with those of CABG were estimated by the stratified Cox proportional hazard models; the models included PCI or CABG as the covariate and were stratified by the quartiles of propensity score and institute to adjust for confounding factors. The effects of PCI compared with those of CABG for individual end points are expressed as HRs with 95% confidence intervals (CIs). Statistical analyses were performed using the SPSS software, version 25.0 (IBM Corporation, Armonk, NY, USA). All *P* values are two sided, and *P* < 0.05 was considered statistically significant.

**Table 1** Baseline and angiographic characteristics of the study population

Variable	Total population			Propensity-matched population		
	DES (n = 1330)	CABG (n = 720)	<i>P</i>	DES (n = 601)	CABG (n = 601)	<i>P</i>
Age (years)	64.1 ( $\pm 10.0$ )	63.3 ( $\pm 8.3$ )	0.043	63.7 ( $\pm 10.5$ )	63.5 ( $\pm 8.2$ )	0.703
Men	984 (74.0)	550 (76.4)	0.231	451 (75.0)	455 (75.7)	0.789
Diabetes mellitus	499 (37.5)	296 (41.1)	0.111	237 (39.4)	242 (40.3)	0.768
Hypertension	928 (69.8)	489 (67.9)	0.385	418 (69.6)	409 (68.1)	0.575
COPD	17 (1.3)	4 (0.5)	0.121	6 (1.0)	4 (0.7)	0.525
Previous MI	537 (40.4)	310 (43.1)	0.240	246 (40.9)	264 (43.9)	0.293
Previous PCI	468 (35.2)	156 (21.7)	0.000	149 (24.8)	150 (25.0)	0.947
Previous stroke	248 (18.6)	139 (19.3)	0.716	119 (19.8)	111 (18.5)	0.557
SCr	80.3 ( $\pm 25.4$ )	78.4 ( $\pm 19.5$ )	0.053	80.0 ( $\pm 23.8$ )	78.5 ( $\pm 19.0$ )	0.253
LV ejection fraction (%)	44.4 ( $\pm 3.6$ )	43.9 ( $\pm 3.7$ )	0.003	44.3 ( $\pm 3.7$ )	44.1 ( $\pm 3.6$ )	0.356
Narrowed coronary arteries (n)						
1	128 (9.6)	10 (1.4)	0.000	7 (1.2)	10 (1.7)	0.464
2	348 (26.2)	71 (9.9)	0.000	65 (10.8)	70 (11.6)	0.648
3	853 (64.1)	636 (88.3)	0.000	528 (87.9)	520 (86.5)	0.490
Left main	142 (10.7)	224 (31.1)	0.000	120 (20.0)	127 (21.1)	0.617
Left anterior descending	1248 (93.8)	708 (98.3)	0.000	588 (97.8)	589 (98.0)	0.840
CTO	400 (30.1)	364 (50.6)	0.000	299 (49.8)	299 (49.8)	1.000
Complete revascularization	390 (29.32)	252 (35.0)	0.008	44 (7.3)	207 (34.4)	0.000

CABG, coronary artery bypass grafting; COPD, chronic pulmonary obstructive disease; CTO, chronic total occlusion; DES, drug-eluting stent; LV, left ventricular; MI, myocardial infarction; PCI, percutaneous coronary intervention; SCr, serum creatinine. Data are presented as *n* (%) or mean (range).

## Results

A total of 2050 patients who had undergone revascularization with mildly to moderately reduced ejection fraction (35–50%) were included in the final analysis. The DES and CABG groups included 1330 and 720 patients, respectively. The baseline clinical and angiographic characteristics are listed in *Table 1*. Compared with patients in the CABG group, those in the DES group were older and had a higher prevalence of history of PCI and one- and two-vessel disease. In contrast, patients in the CABG group had a higher prevalence of history of low LVEF, three-vessel disease, left main CAD, target chronic total occlusion, target proximal LAD coronary artery, and complete revascularization than patients in the DES group.

After performing propensity score matching for the entire population, 601 matched pairs were obtained. The C-statistic for the propensity score model was 0.781, indicating good discrimination (Hosmer-Lemeshow goodness of fit,  $P = 0.878$ ). The propensity-matched subjects no longer had any significant differences in baseline clinical or angiographic characteristics with the exception of the complete revascularization.

Median follow-up was 45 months (interquartile range 40 to 54 months). The cumulative clinical outcomes for all patients are listed in *Table 2*. There were significant differences in all-cause death between the two groups: 77 patients in the PCI group and 27 in the CABG group (DES vs. CABG: 5.8% vs. 3.8%, adjusted HR 1.525, 95% CI 0.984 to 2.364,  $P = 0.045$ ). Both groups were characterized by comparable rates of cardiac death (DES vs. CABG: 3.9% vs. 4.7%, adjusted HR 0.773, 95% CI 0.499 to 1.197,  $P = 0.248$ ), recurrent MI (DES vs. CABG: 4.2% vs. 2.8%, adjusted HR 1.505, 95% CI 0.903 to 2.507,  $P = 0.117$ ), and stroke (DES vs. CABG: 6.3% vs. 4.9%,

adjusted HR 1.285, 95% CI 0.867 to 1.907,  $P = 0.212$ ). The repeat revascularization rate was significantly lower in the CABG group (5.0%) compared with the DES group (11.1%) (adjusted HR 2.265, 95% CI 1.573 to 3.260,  $P = 0.000$ ).

The cumulative clinical outcomes for the propensity-matched population are listed in *Table 3* and shown in *Figure 2*. Among matched-pair patients, all-cause death occurred in 35 in the DES group and 16 in the CABG group, which was significantly different (DES vs. CABG: 5.8% vs. 2.7%; adjusted HR 2.278, 95% CI 1.261 to 4.116,  $P = 0.006$ ). No differences were found in the rates of cardiac death (DES vs. CABG: 4.8% vs. 3.0%, adjusted HR 1.648, 95% CI 0.915 to 2.968,  $P = 0.096$ ), recurrent MI (DES vs. CABG: 4.0% vs. 2.8%, adjusted HR 1.458, 95% CI 0.783 to 2.715,  $P = 0.234$ ), and stroke (DES vs. CABG: 6.8% vs. 5.2%, adjusted HR 1.394, 95% CI 0.874 to 2.222,  $P = 0.163$ ). The repeat revascularization rate was significantly higher in the PCI group (DES vs. CABG: 12.1% vs. 6.0%; adjusted HR 2.162, 95% CI 1.450 to 3.224,  $P = 0.000$ ).

## Discussion

Despite being a retrospective study, this is the first study to compare long-term clinical outcomes of DES and CABG in patients with mildly to moderately reduced ejection fraction (35–50%) and CAD. Compared with DES, CABG was associated with significantly higher baseline incidence of complete revascularization, lower all-cause mortality and need for repeat coronary revascularization. Collectively, our results suggest that PCI with DES implantation may be inferior to CABG in mild to moderate ischaemic heart failure. However,

**Table 2** Clinical outcomes for all patients during follow-up

Total population	DES (n = 1330)	CABG (n = 720)	Unadjusted HR (95% CI)	P
All-cause death	77 (5.8)	27 (3.8)	1.525 (0.984–2.364)	0.045
Cardiac-cause death	49 (3.9)	34 (4.7)	0.773 (0.499–1.197)	0.248
Recurrent MI	56 (4.2)	20 (2.8)	1.505 (0.903–2.507)	0.117
Stroke	84 (6.3)	35 (4.9)	1.285 (0.867–1.907)	0.212
Any coronary revascularization	148 (11.1)	36 (5.0)	2.265 (1.573–3.260)	0.000

CABG, coronary artery bypass grafting; DES, drug-eluting stent; HR, hazard ratio; MI, myocardial infarction.

Data are presented as n (%).

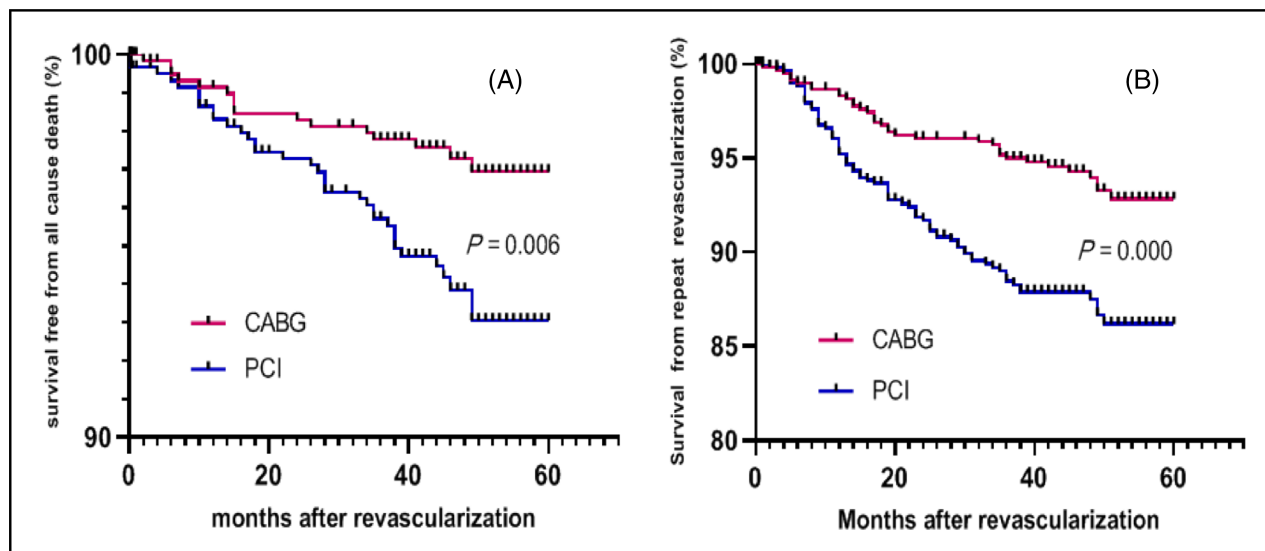
**Table 3** Clinical outcomes for propensity-matched population during follow-up

Total Population	DES (n = 601)	CABG (n = 601)	Unadjusted HR (95% CI)	P
All-cause death	35 (5.8)	16 (2.7)	2.278 (1.261–4.116)	0.006
Cardiac-cause death	29 (4.8)	18 (3.0)	1.648 (0.915–2.968)	0.096
Recurrent MI	24 (4.0)	17 (2.8)	1.458 (0.783–2.715)	0.234
Stroke	41 (6.8)	31 (5.2)	1.394 (0.874–2.222)	0.163
Any coronary revascularization	73 (12.1)	36 (6.0)	2.162 (1.450–3.224)	0.000

CABG, coronary artery bypass grafting; CI, confidence interval; DES, drug-eluting stent; HR, hazard ratio; MI, myocardial infarction.

Data are presented as n (%).

**Figure 2** Kaplan–Meier curves in the drug-eluting stent (DES) and coronary artery bypass grafting (CABG) groups in propensity-matched populations. (A) All-cause death. (B) Repeat revascularization.



it should be emphasized that this finding is for patients with significant CAD (three-main vessel disease). We still do not know whether PCI could be an alternative to CABG in patients with one- or two-vessel disease.

Many studies have demonstrated that CABG is effective and confers a better prognosis than medical treatment in patients with severe ischaemic LV dysfunction.<sup>10–13</sup> Myocardial revascularization using CABG has been the preferred treatment of these patients for two decades.<sup>14–18</sup> PCI with DES implantation is commonly used for revascularization in real-world practice, especially for patients with high surgical risk and ischaemic cardiomyopathy; however, no randomized trials have compared the efficacies of CABG versus PCI in the treatment of ischaemic heart failure. The SYNTAX trial recently showed that PCI was a potential treatment option for patients with less complex lesions, whereas CABG showed significant advantages over PCI in patients with diabetes mellitus or high SYNTAX score.<sup>9,19</sup> However, this trial was not designed for patients with heart failure and included few patients with LV systolic dysfunction. The Korean Acute Heart Failure registry<sup>20</sup> compared both revascularization strategies and found that CABG was associated with significantly lower all-cause mortality. However, this trial only included patients with acute heart failure, so it would not be appropriate to apply the results to a population with ischaemic heart disease presenting with chronic heart failure.

A recent meta-analysis by Wolff *et al.*<sup>2</sup> combined 21 studies of 16 191 patients with ischaemic heart failure (EF  $\leq$  40%) to compare outcomes following CABG versus PCI and found that CABG offered a significant survival advantage. A multi-centre, retrospective analysis performed by Iribarne *et al.*<sup>21</sup>

compared the effectiveness of CABG versus PCI in patients with an EF  $<$  35% and multivessel disease and showed that CABG was associated with improved long-term survival, whereas PCI was associated with a higher incidence of repeat revascularization procedures. Bangalore *et al.*<sup>22</sup> also compared the outcomes of CABG and PCI with everolimus-eluting stents in patients with multivessel disease and severe LV systolic dysfunction (EF  $\leq$  35%). Unlike previous studies, they found that those treated with PCI with DES had similar survival outcomes to patients who underwent CABG. The authors concluded that PCI may be an acceptable alternative to CABG in selected patients for whom complete revascularization is possible.

In summary, most previous findings were from studies conducted among patients with CAD and severe left ventricular dysfunction. Few have compared the clinical outcomes of both interventions in patients with mildly to moderately reduced LV systolic function. This study focused on this specific population, for which there is a scarcity of data, and provides a basis for formulating revascularization strategies for these patients.

This real-world study involving patients with mild to moderate ischaemic heart failure (EF 35–50%) revealed that PCI with DESs was associated with a higher risk of all-cause death and repeat revascularization. An important reason for this may be that there were fewer patients with one- or two-vessel disease in the CABG group (*Table 1*) among matched pairs of patients, and the final percentage of patients with three-vessel disease was 86–88% in both the DES and CABG groups. As a result, the characteristics of the matched population were similar to those of the CABG group with three-vessel

disease. A survival advantage of CABG over PCI has been consistently reported for patients with severe three-vessel CAD,<sup>23–25</sup> which explains the higher incidence of complete revascularization and hence better outcomes in the CABG group compared with the PCI group. Therefore, it is reasonable to suggest that CABG be preferred in patients with EF 35–50% and three-vessel disease.

Our work has several limitations. First and most importantly, it was a retrospective observational study. Treatment selection was not based on randomized assignment and so is subject to potential selection bias. Although we performed propensity score-matched analysis to adjust for potential confounding factors, this may not adequately adjust for biases related to unmeasured characteristics. Second, the revascularization strategy selection was determined by anatomic factors without functional guidance. Intravascular imaging might provide the interventional cardiologist guidance with additional diagnostic information when confronted with complex lesions. Third, complete revascularization seems to be associated with a favourable outcome after revascularization. It remains uncertain whether PCI can be an alternative to CABG when complete revascularization can be achieved in patients with one- or two-vessel disease. This question could be addressed by grouping patients with respect to the number of diseased vessels. The small sample size limits the generalizability of our results, which need to be confirmed by further studies. We intend to expand sample size, especially the numbers of patients with single- or two-vessel disease in the CABG group, and carry out subgroup analyses in order to extend our results.

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## Conclusions

Considering the higher long-term survival rate and lower repeat-revascularization rate, CABG may be superior to DES implantation in patients with mildly to moderately reduced EF (35–50%) and significant CAD (three-main vessel disease).

## Acknowledgements

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## Conflict of interest

The authors declare that they have no conflict of interest.

## Author contributions

K.W., L.W., and Y.Z. participated in the study design. K.W., L.W., J.Z., Y.H., R.Z., W.Q., and W.L. participated in data collection. K.W. and L.W. performed the statistical analysis. K.W. drafted the article. All authors contributed to the article and approved the submitted version.

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