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Drug-coated balloon: A better revascularization strategy in patients with multivessel coronary artery disease undergoing one-stop hybrid coronary revascularization surgery

Short title: DCB treatment improves the prognosis of HCR patients

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WHAT'S NEW?

One-stop hybrid coronary revascularization (HCR) combines the long-term survival advantage of the left internal mammary artery (LIMA) to left anterior descending (LAD) graft with the less invasive percutaneous coronary intervention procedure for non-LAD lesions, and achieves complete revascularization simultaneously. in patients with multivessel coronary artery disease undergoing one-stop HCR, drug-coated balloon might be the better revascularization strategy

for non-small non-LAD lesions compared to drug-eluting stent, with a significant reduced mid-term major adverse cardiovascular and cerebrovascular events rate.

ABSTRACT

Background: The optimal revascularization strategy for non- left anterior descending coronary artery (LAD) lesions during one-stop hybrid coronary revascularization (HCR) surgery remains “evidence-free”.

Aims: This study aimed to compare the outcomes of drug-coated balloon (DCB) and drug-eluting stent (DES) strategy in patients with non-small non-LAD lesions undergoing one-stop HCR.

Methods: A total of 141 consecutive patients with multivessel coronary artery disease (MVCAD) undergoing one-stop HCR between June 1, 2018 and March 1, 2022 were retrospectively included in this study. In-hospital outcomes and mid-term major adverse cardiovascular and cerebrovascular events (MACCE) were observed. Kaplan-Meier curve analysis was used to evaluate MACCE-free survival rate. Cox proportional hazard model was used to identify risk factors of mid-term MACCE.

Results: 38 and 103 patients received only DCB or DES therapy in this study. There were no significant differences in demographic characteristics and laboratory parameters between two groups. The in-hospital MACCE rate of DES group was numerically higher than that of DCB group (9.7% vs. 5.3%, respectively), but the difference was not statistically significant (P = 0.4). The incidence of MACCE after patients’ discharge was significantly higher in DES group (22% vs. 5.3%, respectively, P = 0.02) during a median follow-up time of 20 months. After multivariable Cox proportional hazard analysis, DCB therapy was independently associated with the reduced risk of mid-term MACCE (hazard ratio, 0.21; 95% confidence interval, 0.06–0.91; P = 0.04).

Conclusion: For patients with multivessel coronary artery disease (MVCAD) undergoing one-stop HCR, DCB therapy may be the optimal revascularization strategy for non-small non-LAD coronary artery lesions with significantly lower rate of mid-term MACCE.

Key words: drug-coated balloon, hybrid coronary revascularization, major adverse cardiovascular and cerebrovascular events, percutaneous coronary intervention, prognosis

Introduction

For patients with multivessel coronary artery disease (MVCAD), coronary artery bypass grafting (CABG) remains the gold standard of treatment, and the longevity of the left internal mammary artery (LIMA) to left anterior descending (LAD) graft provides most of the survival benefit of the surgery [1, 2]. One-stop hybrid coronary revascularization (HCR) combines the long-term survival advantage of the LIMA-LAD grafting with the less invasive percutaneous coronary intervention (PCI) procedure for non-LAD lesions, and achieves complete revascularization (CR) simultaneously [3]. Previous studies have demonstrated the safety and feasibility of one-stop HCR, this revascularization strategy may provide favorable outcomes in selected patients with MVCAD compared with CABG and PCI [3–5].

Drug-coated balloon (DCB) is a novel revascularization strategy for atherosclerotic lesions, it can fast deliver antiproliferative drugs into the vessel wall during the balloon inflation with no permanent implants [6]. With the rapid advancement of DCB technique, it has changed the strategy of PCI treatment to some extent, the safety and efficacy of DCB have been proved for *de novo* coronary lesions (e.g., small-vessel disease, non-small-vessel disease and bifurcation lesions) and in-stent restenosis (ISR). However, data on the application of DCB during one-stop HCR is scarce, the optimal revascularization strategy for non-small coronary artery lesions in non-LAD vessels among MVCAD patients undergoing one-stop HCR remains "evidence-free".

Hence, the aim of the present study was to investigate the short- and mid-term outcomes of different revascularization strategy (DCB vs. drug-eluting stent, DES) for non-small non-LAD lesions during one-stop HCR in patients with MVCAD.

METHODS

Study population

This is a retrospective study including 141 consecutive patients with MVCAD undergoing one-stop HCR from June 1, 2018 to March 1, 2022 in Beijing Chaoyang Hospital (Figure 1). The choice of revascularization strategies was discussed by the heart team, including interventional cardiologists, cardiac surgeons and anesthesiologists, to make the most appropriate decision regarding CABG, PCI or HCR.

The inclusion criteria for one-stop HCR were as follows: (1) MVCAD (lumen diameter stenosis greater than 50% in at least two major coronary arteries) confirmed by coronary angiogram (CAG), involving unprotected left main (LM) or LAD lesions not favorable for PCI, with non-LAD lesions amenable for PCI; (2) patients were not suitable for traditional CABG due to poor condition of right coronary artery (RCA) or left circumflex artery (LCx) for bypass, lack of available conduits, contraindications for sternotomy or patient desire for less invasive procedures. The exclusion criteria were: (1) contraindicated to minimally invasive LIMA-LAD grafting, such as history of sternotomy, stenosis of left subclavian artery or LIMA, distal LAD anastomosis impracticable, etc; (2) need for a concomitant cardiac surgery, such as valve repair or replacement; (3) small non-LAD coronary artery lesions (diameter ≤2.5mm); (4) significant hemodynamic instability.

This study was approved by the Ethics Committee of Beijing Chaoyang Hospital (2021-D-5). Written informed consents were obtained from all participants.

One-stop HCR surgery and antithrombotic therapy

Aspirin was continued perioperatively (100 mg/day) and clopidogrel was discontinued at least 7 days before the surgery. Minimally invasive direct coronary artery bypass and PCI were performed in hybrid operation room simultaneously. Briefly, LIMA conduit was harvested through a small (5 to 7 cm) anterior thoracotomy in the fourth or fifth intercostal space and the distal anastomosis of in situ LIMA-LAD grafting was performed through the same incision. After closure of the thorax, angiography was performed immediately to assess the patency of LIMA-LAD graft through the femoral artery (FA). After the confirmation of LIMA-LAD graft patency, a loading dose of clopidogrel (300 mg) was administered through the nasogastric tube and PCI was then performed on non-LAD lesions through the FA. Unfractionated heparin was administered before PCI and the activated clotting time (ACT) remained between 250 and 350 seconds during the PCI procedure. Patients in DCB therapy group received the paclitaxel-coated balloon SeQuent Please (B Braun Melsungen AG, Melsungen, Germany) and patients in DES therapy group received one of the two second-generation DESs: the paclitaxel-eluting Taxus Element stent (Boston Scientific, Natick, MA, USA) or the everolimus-eluting Xience stent (Abbott Vascular, Santa Clara, CA, USA). The residual stenosis of the target lesions were <20% after DCB or DES treatment. The dosage of aspirin was 100 mg/day since the first day after the surgery for lifetime, while the dosage of clopidogrel was 75 mg/day for one year.

Data collection

The demographic features and clinical variables such as age, gender, body mass index (BMI), family and medical history, status of smoking and medications were retrospectively collected from electronic medical records. Venous blood samples were collected and analyzed on the first 6 hours after patients' admission. The SYNTAX score was based on the assessment of CAG by two professional interventional cardiologists (www. syntaxscore.com). The EuroSCORE II was calculated based on the anatomy of coronary lesions and baseline risk factors of all patients (www. euroscore. pil-media.com).

Follow-up and outcome measurements

MACCE, including all-cause mortality, stroke, myocardial infarction (MI) and repeated revascularization, was the primary endpoint of the present study. The composite endpoint was assessed by time to the first event. After discharge, all patients were required to return for an outpatient follow-up at one and six months, and then once every year. For patients that did not return for the outpatient visits, phone reviews were conducted by the research staff using standard forms. All phone reviews were completed within 1 week before the drafting of the manuscript. The second endpoint was in-hospital outcomes, including all-cause mortality, postoperative MI, stroke, repeated revascularization, new onset atrial fibrillation (NOAF), incision infection, chest tube drainage, mechanical ventilation time (MVT), length of intensive care unit (ICU) and hospital stay. The follow-up time was from HCR surgery to event time, or to the phone reviews time.

Statistical analysis

SPSS (Version 23, IBM, US) and STATA software (Version 16.0; Stata Corporation, US) were used for all statistical analyses. Kolmogorov-Smirnov test was used to test the normal distribution of continuous variables. Normally and abnormally distributed data were expressed as mean [standard deviation (SD)] and median (interquartile range [IQR]). Student' s t test and Mann-Whitney U test was used to compare the continuous variables between two groups. Categorical variables were expressed as a proportion, and analyzed with Pearson χ^2 or Fisher's precision probability test. Logistic regression analyses were used to identify the risk factors for

in-hospital outcomes. Kaplan–Meier survival curves with log-rank test were applied to compare cumulative MACCE-free rates between two groups. Cox proportional hazards model analyses (forward conditional method) were conducted to identify the independent predictors of mid-term MACCE. A *P*-value <0.05 (two-tailed) was considered statistically significant.

RESULTS

Baseline characteristics

A total of 141 consecutive MVCAD patients (75.2% male) undergoing one-stop HCR were finally enrolled in this study. They were divided into two groups according to the different revascularization strategy on non-LAD lesions during the surgery. 38 (27%) and 103 (73.1%) patients received DCB and DES therapy respectively during one-stop HCR. The mean age of the study population was 64.8 ± 9 years old. Baseline characteristics of the participants were shown in Table 1, with no significant difference was observed between two groups. All patients received CR strategy during the surgery. 52 and 167 non-LAD target lesions were revascularized in DCB and DES group respectively. Compared with DES, the mean length of DCB was longer (28.5 [4.5] mm vs. 24.2 [6.8] mm, respectively; *P* <0.001), but there was no statistical difference between the mean diameter of DCB and DES (2.9 [0.4] mm vs. 3.2 [0.4] mm; *P* = 0.47). A total of 13 postoperative MACCE (9.2%) occurred during hospitalization: three cases of all-cause mortality (2.1%), six cases of MI (4.3%) and four cases of stroke (2.8%). After logistic regression analysis, DCB therapy was associated with a trend of lower in-hospital MACCE incidence (odds ratio [OR], 0.517; 95% confidence interval [CI], 0.108–2.474; *P* = 0.4).

MACCE free survival rates between two groups

During a median (IQR) follow-up time of 20 (11–30) months after patients' discharge, a total of 24 MACCE (17.4 %) occurred (Table 2). The incidence of MACCE was significantly lower in DCB therapy group (5.3% vs. 22%; *P* = 0.02), but significant differences were not observed in each event between two groups (all *P* with no difference, Table 2). The Kaplan–Meier survival analysis showed a significantly increased MACCE-free survival rate in DCB therapy group (94.7% vs. 78%, log-rank *P* = 0.02, Figure 2).

Cox proportional hazards analysis for risk factors of MACCE

The univariate Cox proportional hazards analysis showed that DCB therapy was correlated with lower risk of mid-term MACCE (hazard ratio [HR], 0.2; 95% CI, 0.05–0.89; *P* = 0.03, Table 3). After multivariable adjustment, number of DES (HR, 1.35; 95% CI, 1.02–2.08; *P* = 0.04) and EuroSCORE II (HR, 2.16; 95% CI, 1.09–3.51; *P* = 0.04) were independently predictors of mid-term MACCE, and DCB therapy was independently associated with mid-term MACCE-free (HR, 0.21; 95% CI, 0.06–0.91; *P* = 0.04, Table 3).

DISCUSSION

In this study, we demonstrated that DCB therapy was associated with a trend to lower in-hospital MACCE rate and was independently related to the decrease of mid-term MACCE incidence in MVCAD patients undergoing one-stop HCR. To the best of our knowledge, this is the first study that evaluate the optimal revascularization strategy for non-small non-LAD lesions during one-stop HCR surgery in MVCAD population.

MVCAD accounts for 40%–60% of patients undergoing CAG and has a significantly worse prognosis compared to single-vessel disease [7]. Traditional CABG is recommended by modern guidelines as the gold standard of treatment for patients with MVCAD [1, 8]. However, CABG is relatively high-risk and despite the long-term patency rate of LIMA-LAD graft, the saphenous venous graft (SVG) to non-LAD vessel is prone to progressive stenosis, with the patency rate from about 80% at one year to an average of 70% at five years, and the patency rate at ten years is less than 60% [2, 9]. With the rapid development of PCI techniques, it has become an alternative option to CABG and the long-term outcomes of PCI with new-generation DES are not inferior to those of CABG in patients with low to intermediate SYNTAX scores [10]. However, the long-term target lesion restenosis is still a big issue of DES, especially in patients with MVCAD or higher SYNTAX scores [11, 12].

Minimally invasive strategies for surgical myocardial revascularization have drawn a lot of attention in recent years, particularly the one-stop HCR technique [13]. one-stop HCR combines the advantages of long-term LIMA-LAD graft patency and less invasiveness of PCI procedure for non-LAD lesions, and achieves complete coronary revascularization at once [10]. It has been proven that complete coronary revascularization strategy improves the prognosis of MVCAD patients, whether it is accomplished by PCI or CABG [14, 15]. One-stop HCR can not only achieve the goal of CR, but also reduce the incidence of ischemic events during the

waiting period caused by incomplete revascularization of staged PCI or HCR [16, 17]. Additionally, one-stop HCR can evaluate the LIMA-LAD anastomosis immediately after the grafting and revise it if there are any major problems [18]. Moreover, complex PCI is suggested performing with the protection of LAD territory, which can be supplied by LIMA-LAD graft, and surgical bailout can rescue possible complications in the hybrid suite if necessary [13]. Finally, the one-stop procedure reduces hospital stay, costs and readmission of patients, which provides convenience and significantly improves patients' satisfaction [13].

The safety and feasibility of one-stop HCR have been proved by many studies. A study by Shen et al. [3] demonstrated that one-stop HCR could provide favorable mid-term outcomes in selected patients with MVCAD, compared to PCI and traditional CABG, during a three-years follow-up. A study by Li et al. [17] showed that compared to off-pump coronary artery bypass grafting (OPCAB), one-stop HCR is efficacious with less invasiveness and shorter postoperative recovery time in MVCAD patients. Similar results can also be seen in the study of Song et al., which conducted in patients with diabetes mellitus and MVCAD [16]. However, none of the published studies evaluated the optimal revascularization strategy for non-small non-LAD lesions during one-stop HCR, leaving this field an "evidence-free" zone.

DCB stands for a concept of sustained anti-stenotic therapy with no permanent implantation, the appearance and rapid development of DCB techniques has somehow changed the modern PCI strategy [6, 19]. According to the guidelines, DCB is recommended in the treatment of ISR, but it is beginning to have more indications in de novo coronary lesions [8 19 20]. For instance, the SPARTAN DCB study showed that compared with non-paclitaxel second-generation DES, DCB is a safe option for the treatment of de novo coronary artery disease in up to 5 years follow-up [21]. The REVELATION Randomized Trial indicated that DCB strategy was a safe and feasible strategy which was noninferior to DES strategy in patients with ST-segment elevation myocardial infarction (STEMI) [22]. Other studies also demonstrated the safety and effectiveness of DCB in the treatment of de novo coronary lesions, including small-vessel, large-vessel, calcified and chronic total occlusion (CTO) coronary lesions [6, 23–26]. Nevertheless, the efficacy and safety of this novel revascularization strategy are poorly defined in comparison with DES for MVCAD patients undergoing one-stop HCR. Our study showed that the mid-term MACCE rate of all discharged participates was 17.4%, similar to the results of previous studies [3, 17]. After a Kaplan-Meier curve analysis with the subsequently log-rank test, DCB therapy during one-stop HCR was associated with a significantly decreased incidence of mid-term MACCE compared to DES therapy (5.3% vs. 22%, respectively, log-

rank $P = 0.02$). However, significant differences in the rate of each adverse prognostic event (all-cause death, re-hospitalization for MI, repeated revascularization and stroke) were not observed for DCB and DES groups (all P with no difference). This may be due to the relatively small sample size of the current study. Furthermore, after multivariable Cox proportional hazard analyses, EuroSCORE II (HR, 2.16; 95% CI, 1.09–3.51; $P = 0.04$) and number of DES (HR, 1.35; 95% CI, 1.02–2.08; $P = 0.04$) were two independent risk factors of mid-term MACCE, and DCB therapy during one-stop HCR was an independent predictor of mid-term MACCE-free (HR, 0.21; 95% CI, 0.06–0.91; $P = 0.04$). The results of our study suggested that DCB therapy might be the optimal revascularization strategy for non-small non-LAD lesions during one-stop HCR surgery.

The potential reasons that DCB therapy is more beneficial for the prognosis of one-stop HCR patients are as follows: first, DCB therapy can simplify the complexity of PCI procedure and shorten the procedure duration, thus reduce the risk of coronary injury and ischemia [24]. For instance, DCB avoids the post-dilatation step of DES therapy and makes the treatment of bifurcation lesions more convenient. Second, DCB makes the antithrombotic management more flexible. The abnormal activation of platelet function and inflammatory status of whole body related to the surgery will lead to the dysfunction of coagulation, which can increase the risk of both hemorrhage and thrombosis [27]. According to the modern guideline, the recommended shortest dual anti-platelet therapy (DAPT) duration of DCB in the treatment of CAD is one month, much shorter than that of the DES [1]. As a result, it is easier for physicians to adjust the antithrombotic therapy according to individual conditions of patients received DCB treatment during one-stop HCR. Finally, in our experience, due to the drugs used for anesthesia and blood pressure maintaining, coronary arteries are prone to spasm during the procedure of one-stop HCR, even with repeated intracoronary nitroglycerin injection. This may cause a diameter underestimation of the diseased vessel segment followed by an inaccurate DES selection. The implantation of unsuitable DES may finally result in adverse prognosis, such as failure of the target vessel revascularization, MI or even cardiac death [11].

Taken together, although DCB therapy was not related to a significant lower risk of in-hospital MACCE in MVCAD patients undergoing one-stop HCR, it independently associated with an increased mid-term MACE-free survival rate. The findings of our study suggest that DCB therapy might be the optimal revascularization strategy for non-LAD lesions during one-stop HCR in patients with MVCAD. Still, individualization managements are necessary.

Limitations

First, as a single-center retrospective study, the sample size was relatively small and potential cause-effect was unknown. The benefits of DCB therapy should be ideally verified in future large randomized controlled trials. Second, most of the participants were male (75.2%) in the current study, the results may lack generality to full spectrum of population. Finally, DCB is not applicable to all lesions, for severe dissection after balloon dilatation or coronary calcification, stenting is still recommended.

CONCLUSIONS

In patients with MVCAD undergoing one-stop HCR, DCB might be the better revascularization strategy for non-small non-LAD lesions compared to DES. DCB therapy was associated with a trend to lower in-hospital MACCE and was independently associated with a significant reduced mid-term MACCE rate. Based on these findings, DCB therapy should be the preferred choice when interventional cardiologists treating non-LAD lesions during one-stop HCR in MVCAD population.

Article information

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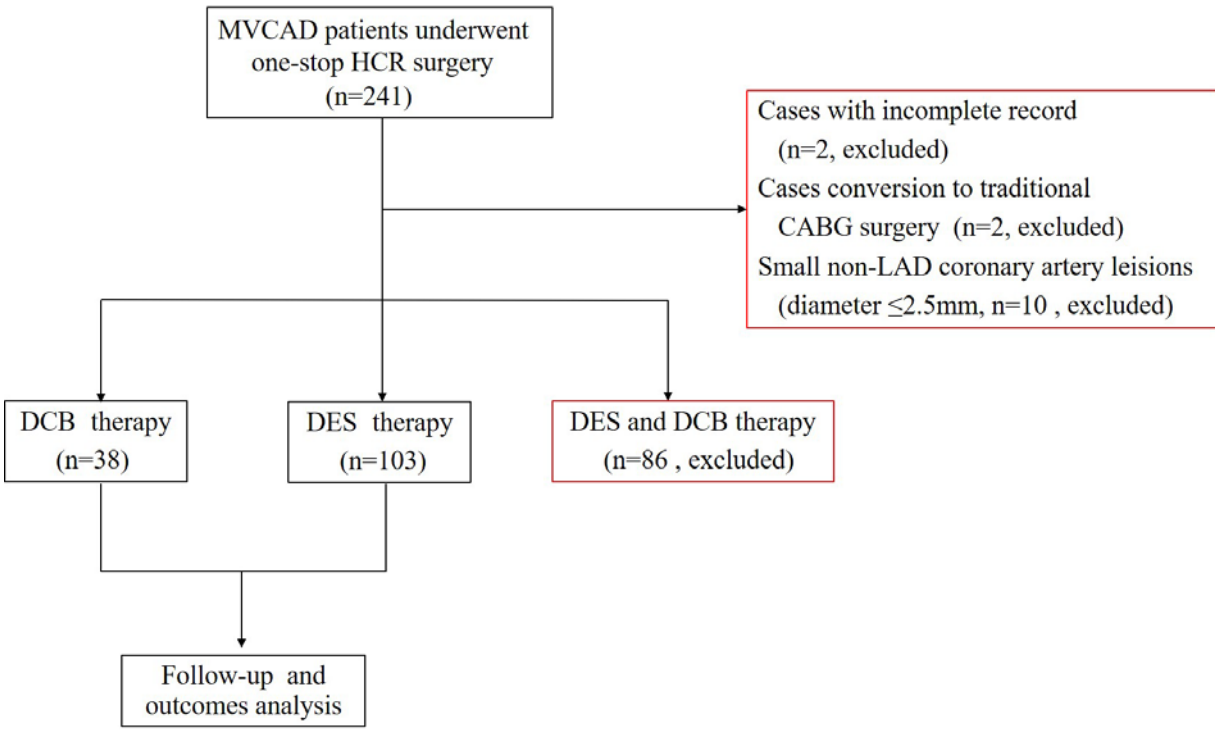

Figure 1. Flow chart of the present study

Abbreviations: CABG, coronary artery bypass grafting; DCB, drug-coated balloon; DES, drug-eluting stent; HCR, hybrid coronary revascularization; MVCAD, multivessel coronary artery disease

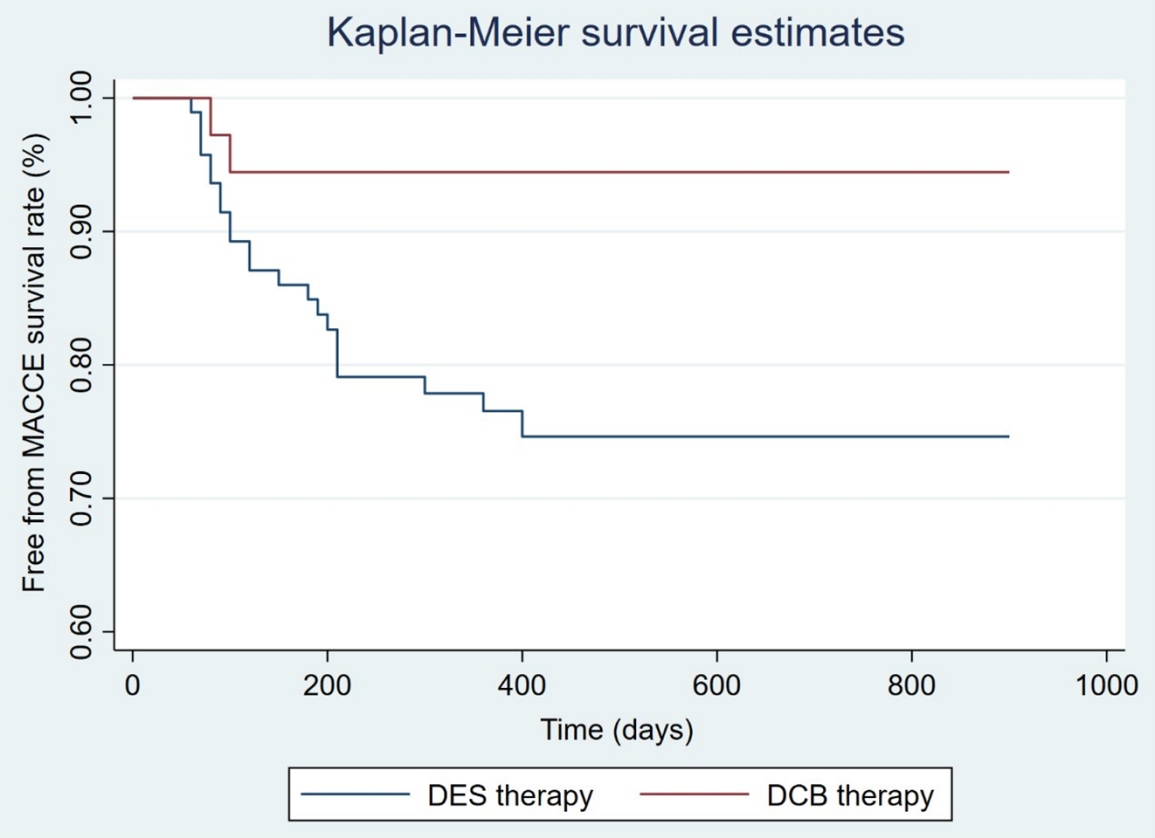

Figure 2. Kaplan-Meier curves for cumulative MACCE-free survival rate (log-rank *P* = 0.02). Abbreviations: MACCE, major adverse cardiovascular and cerebrovascular events; other — see Figure 1

Table 1. Baseline characteristics of the study population

Variables	**DCB therapy（n = 38）**	**DES therapy（n = 103）**	***P*-value**
Age, years	64.6 ± 8.5	65.6 ± 9.2	0.56
Male sex, n (%)	33（86.8）	73（70.9）	0.08
HT, n (%)	28（73.7）	75（72.8）	0.44
DM, n (%)	16（42.1）	39（37.9）	0.57
History of MI, n (%)	10（26.3）	18（17.5）	0.23
CHF, n (%)	3（7.9）	4（3.9）	0.42
CKD, n (%)	0（0）	1（1）	0.62
COPD, n (%)	2（5.3）	1（1）	0.27

History of PCI, n (%)	12（31.6）	20（19.4）	0.17
History of stroke, n (%)	9（23.7）	23（22.3）	0.86
Current smoker, n (%)	25（65.8）	52（50.5）	0.12
BMI, kg/m^2	26.2 ± 4.9	25.4 ± 3	0.44
Clinical diagnose			
UAP, n (%)	33（86.8）	83（80.6）	0.39
STEMI, n (%)	2（5.3）	10（9.7）	0.4
NSTEMI, n (%)	3（7.9）	10（9.7）	0.74
Medications			
Stain, n (%)	23（92）	99（96.1）	0.93
β-RB, n (%)	18（72）	67（65.1）	0.6
ACEI/ARB, n (%)	14（56）	40（38.8）	0.33
Laboratory investigations			
HbA1c, %	6.1（5.7–6.8）	6.2（5.8–7.4）	0.52
BNP, pg/ml	86.2（48.0–217.6）	94.5（37.2–313.2）	0.5
WBC, $\times 10^9/l$	7.2 ± 1.8	7.5 ± 1.6	0.72
CK–MB, ng/ml	1.2（0.7–2）	1.3（0.7–2.2）	0.2
CTnI, ng/ml	0.02（0–1）	0.01（0–1）	0.17
TC, mmol/l	3.6 ± 1	3.3 ± 0.8	0.5
LDL, mmol/l	2.2 ± 1	1.9 ± 0.9	0.49
SCR, μmol/l	70.5 ± 10.1	74.4 ± 11.6	0.24
LVEF, %	65(53.5–70.5)	64(60–69)	0.75
Coronary lesions			
LM, n (%)	16（42.11）	47（45.6）	0.53
LAD, n (%)	38（100）	103（100）	N/A
LCx, n (%)	23（60.5）	58（56.3）	0.65
RCA, n (%)	17（44.7）	51（49.5）	0.61
Number of DCB/DES, n (%)	1（1–2）	2（1–2）	N/A
1	20（52.6）	49（47.6）	N/A

2	13 （34.2）	39（37.9）	N/A
3	5（13.2）	9（8.7）	N/A
4	0	4（3.9）	N/A
5	0	2（1.9）	N/A
Diameter of DCB/DES, mm	2.9 ± 0.4	3.2 ± 0.4	0.47
Length of DCB/DES, mm	28.5 ± 4.5	24.2 ± 6.8	<0.001
Rotational atherectomy, n (%)	1（2.6）	2（1.9）	0.8
IVUS, n (%)	1（2.6）	3（2.9）	0.93
Perioperative IABP, n (%)	1（2.6）	3（2.9）	0.93
SYNTAX score	28.6 ± 8.3	30.5 ± 9	0.33
EuroSCORE II	1.9(1–4)	1.5(1.1–2.4)	0.29
Postoperative outcomes			
In–hospital MACCE, n (%)	2（5.3）	10（9.7）	0.4
In–hospital mortality, n (%)	0（0）	3（2.9）	0.39
MI, n (%)	2（5.3）	4（3.9）	0.66
Stroke, n (%)	0（0）	4（3.9）	0.26
Repeated revascularization, n (%)	0（0）	0（0）	N/A
Reoperation for bleeding, n (%)	0（0）	6（5.8）	0.22
Incision infection, n (%)	3（7.9）	2（2）	0.12
NOAF, n (%)	3（7.9）	5（4.9）	0.54
MGF, ml/min	21.9 ± 11.4	24.7 ± 14.6	0.36
PI	2.1(1.9–2.6)	2.2(1.75–2.6)	0.95
Drainage of first 24 hours, ml	420（330–640）	490（320–700）	0.74
MV time, hours	16（14–17）	16（15–17）	0.19
ICU stay, hours	78（66–146）	85（62–134）	0.28
LOS in hospital, days	20（16–26）	23（16–30）	0.39

Data are number (%), mean (SD), or median (IQR)

Abbreviations:

ACEI, angiotensin–converting enzyme inhibitor; ARB, agiotensin receptor blocker; BMI, body mass Index; BNP, B-type natriuretic peptide; CAD, Coronary artery disease; CHF, chronic heart failure; CKD, chronic kidney disease; CK–MB, creatine kinase MB; COPD, chronic obstructive pulmonary disease; CTnI, cardiac troponin I; DCB, drug–coated balloon; DES, drug-eluting stent; DM, diabetes mellitus; HbA1c, Glycosylated Hemoglobin, Type A1C; HT, hypertension; IABP, intra-aortic balloon pump; ICU, intensive care unit; IVUS, intravascular ultrasound; LAD, left anterior descending artery; LCx, left circumflex artery; LDL-C, low-density lipoprotein cholesterol; LM, left main artery; LOS, length of stay; LVEF, Left ventricular ejection fraction; MACCE, major adverse cardiovascular and cerebrovascular events; MGF, mean graft flow; MI, myocardial infarction; MV, mechanic ventilation; ND, no difference; NOAF, new onset atrial fibrillation; NSTEMI, non-ST-segment elevation myocardial infarction; PCI, percutaneous coronary intervention; PI, pulsatility index; RCA, right coronary artery; SCR, serum creatinine; STEMI, ST-segment elevation myocardial infarction; TC, total cholesterol; UAP, unstable angina, pectoris; WBC, white blood cell; β–RB, β-receptor blocker

Table 2. MACCE characteristics between two groups

Variables	**Total (n = 138)**	**DCB therapy (n = 38)**	**DES therapy (n = 100)**	***P*-value**
MACCE, n (%)	24 (17.4)	2 (5.3)	22 (22)	0.02
All-cause mortality, n (%)	7 (5.1)	0 (0)	7 (7)	0.09
Stroke, n (%)	5 (3.6)	0 (0)	5 (5)	0.16
Re-hospitalization for MI, n (%)	6 (4.4)	1 (2.6)	5 (5)	0.54
Repeated revascularization, n (%)	6 (4.4)	1 (2.6)	5 (5)	0.54

Abbreviations: DCB, drug-coated balloon; DES, drug-eluting stent; MACCE, major adverse cardiovascular and cerebrovascular events

Table 3. Univariate and multivariable Cox proportional hazards analysis

Variables	**Univariate analysis**	**Multivariable analysis**

	HR（95% CI）	***P*-value**	**HR（95% CI）**	***P*-value**
DCB therapy	0.2（0.05–0.89）	0.03	0.21 (0.06–0.91）	0.04
Male	0.79（0.33–1.9）	0.6		
Age	1.05（0.97–1.12）	0.51		
DM	1.22（0.54–2.74）	0.64		
History of MI	1.72（0.74–4.01）	0.21		
Current smoker	1.12（0.5–2.52）	0.79		
HT	1.02（0.97–1.06）	0.5		
BMI	0.99（0.89–1.1）	0.86		
LVEF	0.98（0.94–1.05）	0.67		
PI	1.08（0.77–1.54）	0.65		
MGF	0.98（0.95–1.02）	0.38		
Drainage of first 24 hours	1（0.99–1.01）	0.06		
Number of DES	1.47（1.03–2.11）	0.04	1.35（1.02–2.08）	0.04
Number of DCB	0.57（0.4–1.12）	0.09		

SYNTAX score	1.02（0.98–1.06）	0.44		
EuroSCORE II	2.24（1.11–3.73）	0.03	2.16（1.09–3.51）	0.04

Abbreviations: BMI, body massindex; DCB, drug-coated balloon; DM, diabetes mellitus; DES, drug-eluting stent; HR, hazard ratio; HT, hypertension; LVEF, left ventricular ejection fraction; MACCE, major adverse cardiovascular and cerebrovascular events; MI, myocardial infarction; MGF, mean graft flow; PI, pulsatility index