Zagazig University Medical Journal
www.zumj.journals.ekb.eg
https://doi.org/10.21608/zumj.2025.431008.4243 Volume 31, Issue 12, December. 2025
Manuscript ID:ZUMJ-2510-4243
DOI:10.21608/zumj.2025.431008.4243
ORIGINAL ARTICLE

Using Drug-Coated Balloon Versus Stenting the Side Branch After Its Compromisation During Provisional Stenting of the Main Branch in Coronary Artery Disease Patients Undergoing Percutaneous Coronary Intervention

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SubmitDate 08-10-2025
ReviseDate 01 -11-2025
Accept Date 10-11-2025

ABSTRACT

Background: Bifurcation lesions are common during percutaneous coronary intervention (PCI), and provisional stenting of main vessel is the preferred approach. However, side branch (SB) compromisation is a frequent challenge. Conventional two-stent techniques increase metal burden and restenosis risk. An alternative to stents is drug-coated balloon (DCB) therapy, which administers antiproliferative medications straight to the arterial wall, potentially restoring SB patency without additional stenting. So, we aimed to compare the drug coated balloon versus stenting of the side branch after its compromisation during provisional stenting of the main branch in coronary artery disease (CAD) patients undergoing PCI.

Methods: This prospective comparative study enrolled patients with CAD undergoing PCI with provisional main branch stenting who developed SB compromisation. Patients were randomized into: Group I treated with DCB and Group II treated with SB stenting. The primary endpoint was angiographic success and SB patency. Procedure duration, contrast use, in-hospital complications, restenosis, and major adverse cardiac events (MACE) at follow-up were secondary endpoint.

Results: Both strategies achieved high procedural success. DCB use was associated with shorter procedural time and reduced contrast volume compared to SB stenting. At 6-month follow-up, MACE occurred in 5.9% of patients in the DCB group versus 16.7% in the DES group (p = 0.603; 95% CI: 0.02–0.39).

Conclusions: DCB represents an effective and safe alternative to SB stenting following compromisation during provisional main branch PCI. By avoiding an additional stent, DCB reduces metal burden, procedure duration, and contrast use while maintaining comparable clinical outcomes.

Keywords: Percutaneous coronary intervention; Drug-coated balloon; Drug-eluting stent; Side branch; Bifurcation lesion

INTRODUCTION

More than 160 fatalities per 100,000 individuals in the US are attributable to coronary artery disease (CAD), a cardiovascular condition that is the leading cause of death globally [1].

The most reliable and precise method for assessing ischemic coronary heart disease is cardiac catheterization. However, there are dangers Related to this invasive operation [2].

The purpose of percutaneous coronary intervention (PCI), a non-surgical, invasive technique, is to Restore blood flow to the ischemic region and relieve coronary artery constriction or blockage. Several techniques are typically used to do this, but the most popular ones are stent deployment to maintain the artery open or inflating the narrow portion [3].

According to recent research, protecting the side branch (SB) during provisional stenting with a drug-coated balloon (DCB) is an appealing strategy. In DCB, a relatively new device category for PCI, drug coatings are employed to provide an anti-intimal hyperplasia activity on the balloon's surface [4]. DCB dilates the stenosis of the diseased artery during PCI, releasing the antiproliferative medications into the vessel wall [5].

Vascular wall tissue quickly absorbs the drug coating, which makes it easier to prevent intimal hyperplasia. Paclitaxel, the most widely used pharmacological coating for DCB, inhibits the production of microtubules, preventing restenosis and lowering cell differentiation. Furthermore, the damage to the artery wall following balloon dilatation triggers the release of growth factors, migration of smooth muscle cells, and an inflammatory response [6].

Paclitaxel can prevent vascular smooth muscle cells from migrating to the intima and decrease the release of platelet-derived growth factors [7]. Previous studies have demonstrated the benefits of DCB in treating in-stent restenosis [8] and small coronary artery lesions [9]. Furthermore, early case series have consistently demonstrated that SB protection with DCB is safe and linked to positive short-term clinical and angiographic results [10].

The drug-coated balloon (DCB), which delivers antiproliferative medications to local vascular tissue without leaving an implant behind, expands the interventionists' treatment options. This new technology has already shown itself to be a successful substitute for drug-eluting stents (DES) in cases of in-stent restenosis (ISR) and small channel coronary artery disease [11].

The usage of the DCB is gradually growing in a variety of clinical situations, even though the DES is the most widely used and well-established therapeutic approach in contemporary PCI. Like the Bioresorbable Scaffold (BRS), DCB technology is anticipated to be a therapeutic technique that supports the "leave nothing behind" concept. However, additional research is required to assess the DCB's clinical indications outside of small vessel disease or classical ISR. Additionally, the "gold standard" DES for the treatment of de novo CADs should be highlighted alongside other scientific evidence supporting the DCB-only approach [12, 13].

METHODS

Study Design:

This prospective comparative study was carried out at the Cardiology Department, Zagazig University's Faculty of Medicine in Egypt. The study included patients with coronary artery disease (CAD) who had side branch (SB) impairment following main vascular stenting (MV) and percutaneous coronary intervention (PCI). The Research received approval from Zagazig University's Faculty of Medicine's ethics committee (IRB 489-28-July-2024). Every patient provided written, informed consent.

Study Population:

Thirty-six patients undergoing bifurcation PCI were enrolled and divided into two groups: DCB (n = 18) and DES (n = 18). Inclusion and exclusion criteria were clearly defined.

All eligible patients were adults with angiographically significant bifurcation lesions requiring PCI. Exclusion criteria included hemodynamic instability, contraindications to dual antiplatelet therapy, severe renal impairment, or prior stenting at the target lesion.

Patients were randomly assigned in a 1:1 ratio to either the DCB or DES group using a computer-generated randomization sequence. Allocation concealment was maintained using sealed opaque envelopes.

Due to the nature of the interventions, operators were not blinded to treatment assignment; however, clinical outcome assessors and angiographic analysts were blinded to group allocation to minimize bias.

In the case where the initial DCB strategy required bailout stenting, the patient was shifted to the DES group.

The study protocol was approved by the institutional review board (IRB No. 489-28-

July-2024). All participants provided written informed consent before enrollment.

Patient data were anonymized to ensure confidentiality, and the study was conducted in accordance with the Declaration of Helsinki and Good Clinical Practice guidelines.

Procedural Technique:

Using conventional PCI procedures, all operations were carried out either trans-radially or trans-femorally. Following the wiring of the SB and MV, the MV was stented using the drug eluting stent. In cases where SB compromise occurred, treatment was performed according to the randomized group assignment. In the DCB group, lesion preparation with predilatation was performed before drug-coated balloon inflation. In the stent group, an appropriately sized drug-eluting stent was implanted in the SB. Kissing balloon inflation and final Proximal optimization technique (POT) were performed whenever indicated.

Data Collection and Endpoints

Baseline demographic and clinical data, as well as angiographic characteristics, were recorded. The primary endpoint of the study was angiographic success and SB patency immediately post-procedure. Secondary endpoints included total procedure duration, amount of contrast used, periprocedural complications, in-hospital outcomes, restenosis rates, and major adverse cardiac events (MACE) during follow-up.

Follow-up

Patients were followed clinically during hospital admission and subsequently at scheduled outpatient visits. Angiographic follow-up was performed according to protocol or whenever clinically indicated. All events were approved by the study investigators.

Statistical Analysis

All data were collected, tabulated in Microsoft Excel (Office 2019), and statistically analyzed using the Statistical Package for Social Sciences (SPSS) version 27 for Windows 10.

Data distribution was tested for normality using the Shapiro–Wilk test, and homogeneity of variances was assessed using Levene's test.

Parametric tests (independent-samples t-test, ANOVA, and Pearson's correlation) were used when assumptions of normality and equal variances were satisfied; otherwise, non-parametric alternatives (Mann–Whitney U test, Kruskal–Walli's test, and Spearman's correlation) were applied.

Categorical variables were analyzed using the Chi-square test or Fisher's exact test as appropriate.

Results were presented as mean ± standard deviation (SD) or median (interquartile range) for continuous variables and as frequencies (percentages) for categorical data.

A p-value < 0.05 was considered statistically significant, while p-values between 0.05 and 0.10 were interpreted as trends toward significance.

For key comparisons, 95% confidence intervals (CIs) and effect sizes (Cohen's d or odds ratios, as appropriate) were calculated to enhance the precision and interpretability of results.

RESULTS

This study included 36 patients after performing 1200 case with main branch coronary artery disease who underwent PCI. The patients included were classified into 2 groups: drug coated balloons (DCB group) and side branch stenting (DES group). The study included a total of 36 patients with coronary artery disease, Were divided into two groups: the drug- coated balloon (DCB) group (17 cases) and the drug-eluting stent (DES) group (19 cases), Even though the study was intended to be conducted on two equal groups, crossover occurred in the DCB case because dissection occurred after the DCB technique was performed. The DCB and DES groups did not Statistically significantly differ from one another, as indicated by the p-value of 0.87 and the population's mean age of 58.28 years (SD: 11.61). The mean Body Mass Index (BMI) was likewise comparable among groups, with a t-value of 0.132 and a p-value of 0.895, suggesting no appreciable differences in these demographic traits. The gender distribution of the sample was 36.1% female and 63.9% male,

with no Statistically significant variations between the categories (p = 0.729). 61.1% of patients reported having no family history (FH) of coronary artery disease, and there was no Statistically significant difference between the groups in this regard (p = 0.494). Furthermore, 41.7% of patients did not smoke, indicating a similar smoking status (p = 0.735). (Table 1).

The prevalence of hypertension (HTN) was identical in both groups, with 61.1% of patients diagnosed (p = 1.000). Similarly, diabetes mellitus (DM) was present in 27.8% of the overall cohort, with no Statistically significant differences between groups (p = 1.000). Hepatic and renal disorders showed no Statistically significant differences either, with p-values of 0.546 and 0.457 respectively (Table 1S).

The left anterior descending artery (LAD) and its diagonal branches were the most damaged, making up 58.3% of the 36 occurrences that were documented. The DCB group experienced 64.7% of incidents in this category, while the DES group experienced 52.6%. The obtuse marginal (OM) and left circumflex artery (LCX) branch accounted for 22.3% of all occurrences; the incidence was higher in the DES group (31.6%) than in the DCB group (11.8%). The right coronary artery (RCA) and posterior descending artery (PDA) had a total of 5 events, with the DCB group reporting 11.8% and the DES group 15.8%. Lastly, the RCA and left posterior artery (PL) exhibited a total of 2 events, with both occurring in the DCB group and none in the DES group. There were no statistically significant differences between both groups regarding Angiographic Findings (Table 2).

The overall mean heart rate (HR) was 91.94 bpm (SD: 14.92), with a Statistically significant difference observed between groups. The DCB group had a higher mean HR of 100.52 bpm (SD: 11.42), while the DES group exhibited a mean HR of 84.50 bpm (SD: 13.59), resulting in a very significant p-value of 0.000 and a t-value of 3.85. Systolic blood pressure (SBP), on the other hand, did not significantly differ across groups (p = 0.645). Additionally, there was no Statistically significant difference in diastolic blood pressure (DBP) (p = 0.051) (Table 3).

The overall mean hemoglobin (Hb) level was 11.66 g/dL (SD: 1.91), with the DCB group showing a significantly lower mean of 10.85 g/dL (SD: 1.69) compared to the DES group (12.38 g/dL, SD: 1.85), yielding a p-value of 0.014 and a t-value of -2.586. With p-values ranging from 0.250 to 0.915, several laboratory indicators, including the liver enzymes (SGOT and SGPT), platelet count (PLT), fasting blood glucose (FBG), postprandial blood glucose (PPBG), and white blood cell count (WBC), did not show any discernible differences between the groups. (Table S2).

The mean left ventricular end-systolic diameter did not significantly differ between the DCB and DES groups. (LVESD), which was 40.14 mm (SD: 7.77) (p = 0.789). The percentage of left ventricular ejection (EF) was also similar across groups (overall: 50.00%, DCB: 49.71%, DES: 50.26%; p = 0.879), indicating stable cardiac function (Table 4).

The mean contrast volume used in the overall cohort was 153.8 mL, with the DCB group utilizing significantly less at 125.88 mL compared to the DES group's 178.95 mL, the difference is statistically significant (p < 0.0001). Additionally, the overall mean procedure time was 40.27 minutes, with the DCB group experiencing a notably shorter duration of 30 minutes versus the 49.47 minutes for the DES group (Table 5).

In relation to the incidence of major adverse cardiac events (MACE) within six months, with no discernible group differences, 88.9% of patients did not have MACE overall (DCB: 94.1%, DES: 83.3%; p = 0.603). 11.1% of individuals experienced MI, and there were no appreciable variations between groups (Table 6, Figure FS1).

There was a positive correlation between diabetes mellitus (DM) and MACE (r = 0.373, p = 0.025), patients with diabetes are at an increased risk of MACE. renal disorders also exhibited a statistically significant correlation (r = 0.369, p = 0.029). Other factors such as

fasting blood glucose (FBG), postprandial blood glucose (PPBG), HbA1c, SGOT, SGPT, and creatinine demonstrated strong positive correlations with MACE, all with p-values indicating statistical significance. Factors like age, gender, family history, and hypertension did not show significant correlations, suggesting that traditional risk factors may require reevaluation in the context of MACE outcomes (Table 7).

Table (1): Patient Demographics and Baseline Characteristics

	Overall		DCB group (N=17)		DES group (N=19)		t	p value
	Mean	SD	Mean	SD	Mean	SD		
Age	58.28	11.61	57.94	11.33	58.58	12.16	-0.162	0.872
BMI	25.58	2.93	25.65	3.59	25.52	2.27	0.132	0.895
	event	%	Event	%	event	%	Chi-square	p value
Gender								
Male	23	63.9	10	58.8	13	68.4	0.120	0.729
Female	13	36.1	7	41.2	6	35.3		
FH								
No	22	61.1	11	64.7	11	57.9	0.468	0.494
Yes	14	38.9	6	35.3	8	42.1		
Smokers								
No	15	41.7	7	41.2	8	42.1	0.114	0.735
Yes	21	58.3	10	58.8	11	57.9		

Table (2): Angiographic Findings in both groups

Angiography findings	overall		DCB group		DES group		Chi-square	p value
	event	%	event	%	event	%		
LAD&DIAGONAL	21	58.3 %	11	64.7%	10	52.6%	3.740	0.300
LCX&OM	8	22.3 %	2	11.8%	6	31.6%		
RCA&PDA	5	13.9 %	2	11.8%	3	15.8%		
RCA&PL	2	5.6%	2	11.8%	0	0.0%		

Table (3): Hemodynamic Parameters in both groups

	Overall		DCB group		DES group		t	p value
	Mean	SD	Mean	SD	Mean	SD		
HR	91.94	14.92	100.53	11.42	84.26	13.62	3.858	0.000
SBP	149.92	14.63	148.71	12.45	151.00	16.61	-0.464	0.645
DBP	72.69	9.27	69.53	6.40	75.53	10.61	-2.022	0.051

Table (4): Echocardiographic Parameters in both groups

	Overall		DCB group		DES group		T	p value
	Mean	SD	Mean	SD	Mean	SD		
LVESD	40.14	7.77	39.76	7.84	40.47	7.90	- 0.270	0.789
EDD mm	54.86	13.50	57.06	6.68	52.89	17.49	0.922	0.363
EF%	50.00	10.76	49.71	12.10	50.26	9.74	- 0.153	0.879

Table (5): Contrast volume and Procedure time in both groups

	Overall		DCB group		DES group		T	p value
	Mean	SD	Mean	SD	Mean	SD		
Contrast volume	153.8	33.06	125.88	20.33	178.95	18.83	-8.096	0.000
Procedure Time	40.27	11.09	30.00	3.24	49.47	6.41	-11.295	0.000

Table (6): Major Adverse Cardiac Events (MACE) in both groups

	Overall		DCB group		DES group		Chi-square	p value
	event	%	event	%	event	%		
6-month MACE								
No	32	88.9%	16	94.1%	16	83.3%	1.125	0.603
MI	4	11.1%	1	5.9%	3	16.7%		

Table (7): The correlation analysis between various factors and MACE

	R	P value
groups	0.157	0.359
Gender	0.102	0.553
Age	0.115	0.504
FH	0.081	0.640
BMI	0.257	0.130
Smoke	-0.239	0.160
HR	0.115	0.503
HTN	-0.081	0.640
DM	0.373*	0.025
Renal disorders	0.369*	0.029
FBG	0.583**	0.000
PPBG	0.579**	0.000
HBA1c	0.597**	0.000
Creatinine	.366*	0.028
Bun	0.057	0.742
LVESD	-0.122	0.479
EDD mm	-0.327	0.052
EF%	0.008	0.962
Contrast volume	-0.096	0.576
Procedure time	0.096	0.577

DICUSSION

Despite growing interest in drug-coated balloon (DCB) therapy, evidence on its optimal role in bifurcation PCI remains scarce, particularly in real-world, non-left main settings. Previous studies have mainly addressed main-branch stenting, leaving a gap regarding side-branch protection strategies.

This study contributes local, practical insight into the use of a DCB-only approach inside-branch treatment, providing data from a population where such evidence is limited.

Our findings align with recent meta-analyses which demonstrated comparable outcomes between DCB and DES but extend these observations by focusing specifically on side-branch management. Although the methodological design is consistent with prior reports, the study adds regional evidence that supports the clinical feasibility and safety of a DCB-only strategy [14, 15].

Because percutaneous coronary intervention (PCI) has been so successful, drug-eluting stents (DES) have revolutionized the treatment of acute and chronic coronary syndromes. However, despite their proven efficacy, DES implantation is not without complications. Clinical difficulties persist due to adverse events like stent thrombosis and in-stent restenosis, which are frequently brought on by neo atherosclerosis, delayed re-reendothelialization, stent malposition, and hypersensitivity reactions. Stent thrombosis, though relatively infrequent with an incidence of 1–2%, remains a serious and potentially life-threatening complication. Moreover, up to 2% of patients still require re-intervention each year due to in-stent restenosis [13].

Drug-coated balloons (DCBs) have become a viable substitute in this regard. DCBs provide consistent drug distribution and do away with the need for polymers by delivering antiproliferative medications straight to the vascular wall without leaving a permanent implant. This may lessen inflammation, the duration of dual antiplatelet therapy and the risk of thrombosis. Their use is growing to include larger arteries, complex lesions, multivessel treatments, and even bifurcation and left main stem lesions. Initially, they were advised for small vessel disease and in-stent restenosis. However, there is still little erratic evidence from randomized controlled studies, especially when it comes to long-term results [14].

Comparing the effects of side branch stenting and drug-coated balloon (DCB) angioplasty during provisional main branch stenting in patients with coronary artery disease (CAD) undergoing PCI was the major objective of this study. Second, it sought to compare side branch stenting and DCB angioplasty after side branch compromise during temporary main branch stenting.

This randomized interventional clinical trial was conducted on 36 patients with coronary artery disease undergoing percutaneous coronary intervention (PCI) at the Cardiology Department, Faculty of Medicine, Zagazig University, from April 2024 to April 2025. The study included patients with bifurcation coronary lesions classified as Medina (1,1,0), (1,0,0), or (0,1,0) with less than 50% affection of the side branch in order to compare the outcomes of drug-coated balloon (DCB) angioplasty versus drug-eluting stent (DES) implantation following side branch compromise during provisional stenting of the main branch. Two groups of participants were formed: the DCB group, which included 17 patients, and the DES group, which included 19 patients.

There were no statistically significant variations between the DCB and DES groups in the study population's baseline characteristics and comorbidity profiles, suggesting that the cohorts were well-matched and comparable. Important demographic factors such as smoking status, age, BMI, gender distribution, and family history of coronary artery disease were comparable between groups ($p > 0.05$). Similarly, there was no statistically significant difference in the prevalence of comorbid illnesses such diabetes mellitus (27.8%), hypertension (61.1%), hepatic disorders, and renal disorders between the groups.

Accordingly, in a matched analysis of 199 DCB vs. 398 DES patients by **Pan et al.** [15] no baseline differences were found in age, gender, diabetes, hypertension, family history, or LVEF (all $p > 0.05$), demonstrating similar profiles across groups**.**

Similarly, a one-year outcome study by **Goto et al.** [16] contrasted drug-coated balloons (DCB) with drug-eluting stents (DES) in 337 PCI patients (75 DCB vs. 262 DES). Baseline factors that were identical between the two groups included age, sex, BMI, hypertension, diabetes, smoking status, renal function, and

left ventricular ejection fraction (LVEF) (all p-values > 0.05).

Additionally, a propensity-matched real-world cohort study by **Baumer et al.** [14] compared DCB and DES in coronary lesions. After 1:1 matching (303 patients per group), demographics and comorbidities—including age, sex, hypertension, and diabetes—were evenly distributed, confirming well-balanced cohorts**.**

There were no statistically significant differences between the DCB and DES groups, according to the angiogram results (p = 0.3). With 58.3% of all cases, the LAD and diagonal branches were the most frequently impacted vessels, with 52.6% in the DES group and 64.7% in the DCB group. 22.3% of instances were from the LCX and OM branches, and the incidence was higher in the DES group (31.6%) than in the DCB group (11.8%). RCA and PDA accounted for 13.9% of cases, while RCA and PL were the least affected (5.6%), both occurring only in the DCB group. These findings suggest a balanced distribution of lesion locations across both groups.

Similarly, in a group of 458 lesions that were treated for de novo coronary artery disease using a hybrid approach (DCB/DES) by **Teo et al.** [17] the most frequently treated vessel was the LAD (~47.8%), followed by the RCA (~31.9%) and LCx (~12.4%). Among bifurcation lesions (19.0%), LAD-diagonal bifurcations predominated (9.4%), followed by LCx-OM (2.8%) and RCA-RPDA-PLV (0.2%), with no significant differences in vessel distribution between treatment types**.**

Notably, in a study by **Schulz et al.** [18] involving 39 consecutive de novo bifurcation lesions treated exclusively with DCBs (without stents), lesion distribution reflected real-world patterns: left anterior descending (LAD) bifurcations accounted for approximately 28.2%, left circumflex (LCx) for 20.5%, and right coronary artery (RCA) branches for 17.9%, confirming the predominance of LAD involvement in bifurcation PCI**.**

Hemodynamic and laboratory assessments revealed selective intergroup differences. The DCB group exhibited a significantly higher heart rate (100.53 ± 11.42 bpm) than the DES group (84.26 ± 13.62 bpm), while systolic and diastolic blood pressures remained comparable (p = 0.645 and 0.051, respectively). Hemoglobin levels were also significantly lower in the DCB group (10.85 ± 1.69 g/dL vs. 12.38 ± 1.85 g/dL, p = 0.014). Although the DCB group showed a slightly higher mean heart rate and slightly lower Hemoglobin level, these differences did not appear to have clinical significance and may reflect baseline variability rather than a treatment-related effect.

Such findings should therefore be interpreted with caution, considering the limited sample size and absence of hemodynamic differences between groups. Other laboratory parameters—including glucose levels, HbA1c, liver enzymes, creatinine, and cardiac biomarkers—showed no significant differences, indicating overall biochemical similarity between groups.

Echocardiographic features did not significantly differ between the DCB and DES groups. The groups did not differ significantly; the mean LVESD was 40.14 ± 7.77 mm (p = 0.789) (p = 0.879), and the mean ejection fraction (EF) was 50.00% ± 10.76%. Additionally, the end-diastolic diameter (EDD) was comparable between the two therapy groups (p = 0.363), suggesting that baseline cardiac function was maintained.

Consistently, **Kang et al.** [19] reported on a multicenter registry of patients treated with DCB-based PCI for multivessel disease. Baseline left ventricular function parameters (EF, chamber dimensions) were statistically indistinguishable when compared with DES-only cohorts, aligning with your results**.**

Contrast volume and procedure time were both significantly lower in the DCB group compared to the DES group. The mean contrast volume was 125.88 ± 20.33 mL in the DCB group versus 178.95 ± 18.83 mL in the DES group (p < 0.0001). Similarly, the DCB group had a shorter mean procedure time of 30.00 ± 3.24 minutes compared to 49.47 ± 6.41 minutes in the DES group (p < 0.0001). These findings

suggest procedural efficiency and reduced contrast exposure with the DCB approach.

Supporting our findings, the SPARTAN-LMS study by **Gunawardena et al.** [20] (41 DCB vs. 107 DES patients) demonstrated significantly lower contrast volume in the DCB group (144.5 ± 41.3 mL) compared to the DES group (176.5 ± 67.1 mL, p = 0.006), reinforcing the observation of reduced contrast exposure with DCB use**.**

In contrast, **Zhang et al.** [21] in a randomized study comparing paclitaxel-coated balloons with DES, found no significant differences in contrast volume or procedure time, suggesting that DCB procedures may not necessarily be prolonged and can be equally efficient in many clinical settings**.**

At the 6-month follow-up, there was no appreciable difference in the incidence of major adverse cardiac events (MACE) between the DCB and DES groups (p = 0.603). Overall, 88.9% of patients were able to avoid MACE, with 94.1% in the DCB group and 83.3% in the DES group. The incidence of myocardial infarction (MI), which happened in 11.1% of patients—5.9% in the DCB group and 16.7% in the DES group—did not differ statistically significantly. These findings imply that the two therapies' short-term safety outcomes are similar.

Agreeing with our findings, a systematic review of randomized trials comparing DCB versus DES in acute myocardial infarction patients conducted by **Su et al.** [22] discovered comparable risks of MI (RR 0.48, 95% CI 0.11–2.11; p = 0.33) and no discernible change in MACE rates across the groups over the course of 6–12 months of follow-up (relative risk 1.38; 95% CI 0.65–2.93; p = 0.41).

Similarly, an aggregated analysis of 10 randomized controlled trials conducted by **Abdelaziz et al.** [23] ISR found no statistically significant difference in MI across groups at mid-term follow-up and no statistically significant difference in MACE incidence (15.57% DCB vs. 14.13% DES; OR 1.04, 95% CI 0.87–1.44; p = 0.68), among patients with in-stent restenosis.

Furthermore, A recent propensity-matched outcome study conducted by **Baumer et al.** [14] During a median follow-up of several years, the incidence of MACE and MI was equal for 303 patients treated with DCB and 303 patients treated with DES; hazard ratios did not show any statistically significant differences (e.g., MACE HR 1.10, MI HR 1.08, both p > 0.05).

Finally, a broad meta-analysis of randomized trials in de novo coronary artery disease conducted by **Wang et al.** [24] concluded that DCB and DES had similar rates of MACE and MI, reinforcing equivalence in short- to mid-term clinical safety profiles between the two approaches**.**

With correlation coefficients of r = 0.373 (p = 0.025) and r = 0.369 (p = 0.029), respectively, correlation analysis showed that diabetes mellitus (DM) and renal diseases were substantially linked with higher risk of major adverse cardiac events (MACE). Strong positive correlations were also found between MACE and metabolic parameters, such as liver enzymes SGOT (r = 0.456, p = 0.005) and SGPT (r = 0.422, p = 0.010), creatinine (r = 0.366, p = 0.028), fasting blood glucose (r = 0.583, p < 0.001), postprandial blood glucose (r = 0.579, p < 0.001), and HbA1c (r = 0.597, p < 0.001). However, there were no statistically significant associations between MACE and traditional risk variables including age, gender, family history, or hypertension. This suggests that metabolic and renal parameters may be more important in predicting negative outcomes in our group.

In line with our findings, a registry study by **Benjamin et al.** [25] demonstrated that in 1,198 individuals with small vessel disease receiving treatment with a DCB-only approach, diabetes mellitus was a statistically significant predictor of major adverse cardiovascular events (MACE). Regardless of whether DES or DCB was administered, this shows how crucial metabolic management is to clinical results.

Moreover, in a prespecified subgroup analysis of diabetic patients (n = 252) undergoing PCI with DCB versus DES, **Wöhrle et al.** [26]

discovered no discernible variations in the two treatment groups' three-year MACE rates, including among insulin-treated and non-insulin-treated diabetics. However, diabetes—particularly insulin-treated—and renal dysfunction emerged as independent predictors of adverse outcomes, including MACE and target vessel revascularization (TVR).

Clinical implications

From a clinical standpoint, the use of a DCB-only strategy may offer practical advantages, including reduced procedural time, avoidance of permanent metallic scaffolds, and lower contrast volume—factors that could be particularly beneficial for patients with renal impairment or high bleeding risk.

These aspects highlight the potential role of DCB in optimizing outcomes for selected bifurcation lesions in everyday practice.

Limitations

This study is limited by its small sample size and single-center design, which may restrict the generalizability of the findings. The follow-up duration was relatively short (6 months), and long-term angiographic or clinical outcomes were not assessed. Future multicenter studies with larger populations and extended follow-up are warranted to confirm these findings.

CONCLUSION

When treating bifurcation lesions during provisional stenting, drug-coated balloon (DCB) angioplasty provides similar safety and clinical results to drug-eluting stents (DES), with the added advantages of lower contrast volume and quicker procedure time, while diabetes mellitus and renal dysfunction remain statistically significant predictors of adverse events regardless of the intervention type.

Financial Disclosures: This research received no specific grant from any funding agency in the public, commercial, or non-profit sectors.

Conflict of Interest: The authors declare that they have no competing interest.

Availability of the data: The datasets generated and/or analyzed during the current study are available from the corresponding author on reasonable request.

Authors contribution: A. A. and D. E. were responsible for data collection and analysis, and M. E. and T. M. were responsible for writing and publication

Supplementary files: Tables (S1, S2) – Figure FS1

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Supplementary files:

Table (S1): Comorbidities in both groups

	Overall		DCB group		DES group		Chi-square	p value
	Event	%	event	%	event	%		
HTN								
No	14	38.9	7	41.2	7	36.8	0.000	1.000
Yes	22	61.1	10	58.8	12	63.2		
DM								
No	26	72.2	12	70.6	14	73.7	0.000	1.000
Yes	10	27.8	5	29.4	5	26.3		
Hepatic								
No	33	91.7	16	94.1	17	89.5	0.364	0.546
Yes	3	8.3	1	5.9	2	10.5		
Renal disorders								
No	26	72.2	11	64.7	15	78.9	.554	0.457
Yes	10	27.8	6	35.3	4	21.1		

Table (S2): Laboratory Findings in both groups

	Overall		DCB group		DES group		t	p value
	Mean	SD	Mean	SD	Mean	SD		
Hb	11.66	1.91	10.85	1.69	12.38	1.85	-2.586	0.014
WBC	7.06	1.12	7.00	1.15	7.11	1.12	-0.291	0.772
PLT	262.92	54.79	254.00	50.86	270.89	58.27	-0.922	0.363
FBG	97.61	26.08	92.41	22.82	102.26	28.49	-1.150	0.258
PPBG	159.72	48.35	148.59	24.35	169.68	61.61	-1.321	0.195
HBA1c	5.93	2.04	5.76	1.92	6.07	2.19	-0.460	0.649
SGOT	32.53	15.11	31.59	11.25	33.37	18.16	-0.348	0.730
SGPT	44.86	21.16	42.88	17.57	46.63	24.27	-0.535	0.596
Creatinine	1.38	0.93	1.61	1.21	1.17	0.53	1.430	0.162
Bun	34.78	21.93	41.41	24.57	28.84	17.89	1.737	0.093
CK	202.14	71.83	200.76	73.13	203.37	72.62	-0.107	0.915
CK-MB	4.53	0.79	4.43	0.87	4.62	0.73	-0.694	0.493

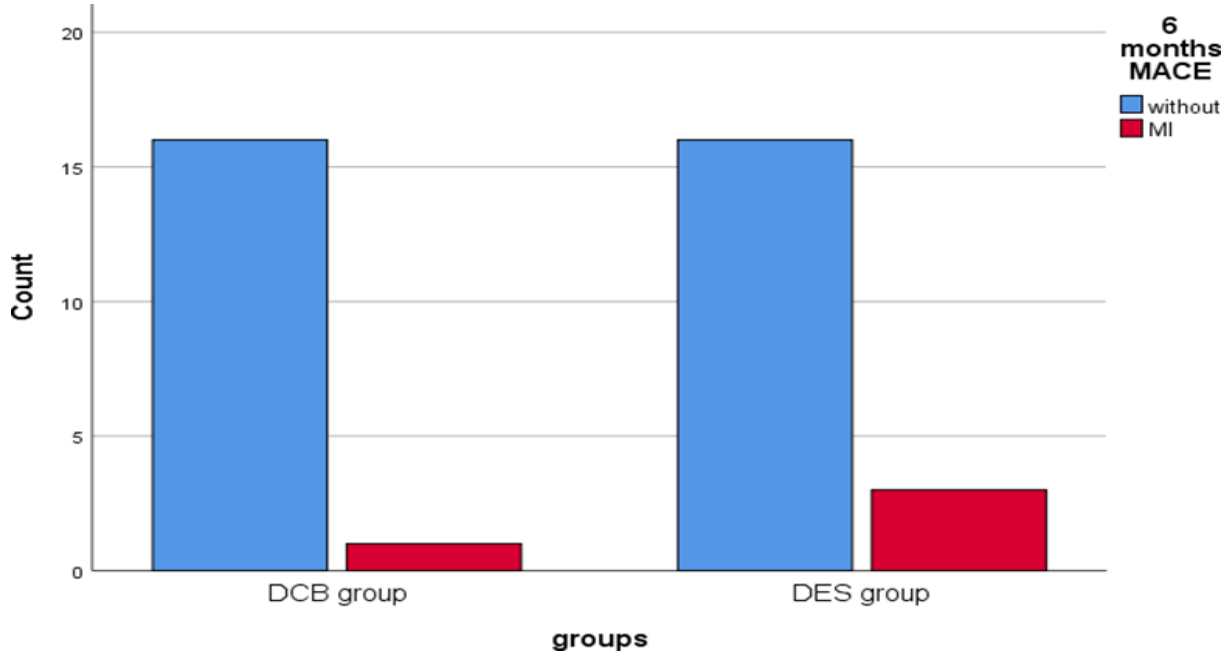

Figure (FS1): Kaplan–Meier curve showing MACE-free survival in DCB vs. DES groups. The DCB group is shown on the left and DES on the right. Time is expressed in month.

Citation

Adel, A., El Menshawy, D., Abdelwahab, M., Moustafa, T. Using Drug Coated Balloon Versus Stenting The side Branch After Its Compromisation During Provisional Stenting Of The Main Branch In Coronary Artery Disease Patients Undergoing Percutaneous Coronary Intervention. ***Zagazig University Medical Journal*****, 2025; (5671-5682): -. doi: 10.21608/zumj.2025.431008.4243**