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Original article

Combined Main Branch Stenting and Side Branch Drug-Coated Balloon versus Two-Stent Strategy in Patients with Left Main Bifurcation Lesions

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Abstract:

Background: Left Main Coronary Artery (LMCA) disease is a high-risk subset of coronary artery disease, with bifurcation lesions comprising nearly 50% of cases. Advances in percutaneous coronary intervention (PCI) using drug-eluting stents (DES) and drug-coated balloons (DCB) offer novel treatment options. This study compares the efficacy and safety of DES with DCB versus the conventional two-stent technique in treating left main bifurcation lesions. **Methods:** This observational study included 60 patients with true left main bifurcation lesions undergoing revascularization at Benha University. Patients were divided into two groups: Group I (DES + DCB) and Group II (2-DES). Pre- and post-procedure intravascular ultrasound (IVUS) assessments were performed. All participants received dual antiplatelet therapy and statins. Follow-up was conducted over six months through medical records, outpatient visits, and telephone consultations. **Results:** In the LAD artery, the 2-DES group demonstrated lower postoperative luminal stenosis (8.4 ± 1.8%) compared to DES + DCB (10.19 ± 1.58%, P = 0.003). In the left circumflex artery, the 2-DES group had a higher minimum luminal diameter (3.3 ± 0.27 mm vs. 3 ± 0.37 mm, P = 0.01) and lower luminal stenosis (12.02 ± 2.42% vs. 20.31 ± 3.85%, P < 0.001). Major adverse cardiac events (MACE) occurred in 10% of the 2-DES group and 3.3% of the DES + DCB group (P = 0.612). **Conclusion:** The two-stent technique achieved superior immediate postoperative luminal outcomes, while DES + DCB demonstrated comparable safety and efficacy with a lower incidence of MACE at six months.

Keywords: Left Main Coronary Artery; Bifurcation Lesions; Drug-Eluting Stents; Drug-Coated Balloons; Percutaneous Coronary Intervention.

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Introduction

Left Main Coronary Artery (LMCA) is crucial as it supplies at least 75% of the blood to the left ventricle. Thus, LMCA disease is regarded as the most perilous category of CAD. Within this classification, lesions at the LM bifurcation are the most common, constituting nearly 50% of the instances. Current guidelines from the ACC/AHA and the ESC recommend revascularizations for all patients with ≥50% stenosis of the LM, regardless of symptomatic status or ischemic burden [(1)].

Historically, CABG has served as the benchmark revascularization approach for substantial LMCA disease, owing to its established long-term durability and mortality benefits. However, with recent advancements in PCI—encompassing enhanced device technology, refined techniques, pharmacotherapy, and procedural proficiency—the clinical outcomes of CABG and PCI employing new-generation DESs have become comparable for patients with low to intermediate-risk LM bifurcation lesions, as indicated by a SYNTAX score of ≤32 points [(2)].

Despite these advancements, treating distal LM bifurcation remains challenging. Single-stent and double-stent implantation techniques are the prevailing PCI approaches for addressing LM bifurcation lesions. Recent meta-analyses have highlighted that the single-stent strategy is more streamlined and results in a reduced incidence of TLR during follow-up compared to the double-stent technique. Despite this, certain clinical scenarios still warrant the placement of a second stent in the SB, a practice supported by expert consensus and current guidelines [(3)].

The field of LMCA disease is evolving, with expanding evidence for optimal patient evaluation and treatment selection. DCBs have recently gained prominence in the treatment of coronary bifurcation lesions. A novel therapeutic approach is gaining traction, which combines SB DCB dilation with MB DES implantation. Clinical studies have substantiated the safety and efficacy of the DES plus DCB combination in the management of coronary artery bifurcation lesions. This combination has been shown to reduce the necessity for additional stenting in the SB and minimize late lumen loss (LLL) during angiographic follow-up. However, these studies have been limited by the insufficient inclusion of LM bifurcation lesions and the lack of direct comparisons with conventional double-stent strategies [(4)].

This study aimed to evaluate the comparative efficacy and safety of combining main branch stenting with side branch DCB against the conventional two-stent strategy in patients presenting with left main bifurcation lesions.

Methods

Study Design and Patients:

This observational study encompassed sixty patients diagnosed with true left main bifurcation lesions via CAG, who underwent revascularization through either a combined approach of main branch stenting with side branch drug-coated balloon or a two-stent strategy. The procedures were conducted at the Cardiology Department of the Faculty of Medicine, Benha University, between October 2022 and April 2024.

Written informed consent was secured from all participants, who were each assigned a confidential code number. Additionally, the purpose of the study was clearly explained to every patient. The study was done after being approved by the Research Ethics Committee, Faculty of Medicine, Benha University {Approval number: M.D.9.10.2022}

Inclusion criteria were patients of both genders who are over the age of 18 were confirmed to have true left main bifurcation lesions by CAG in accordance with the Medina classification **[(5)]**. The left main stem exhibited no unobstructed bridging vessels, and there was a notable

deficiency in collateral circulation necessary for effective right-to-left shunting.

Exclusion criteria were patients who had previous CABG, acute myocardial infarction, chronic total occlusion, left main bifurcation stent implantation, severely calcified lesions requiring rotational atherectomy, primary cardiomyopathy, or those who refused.

Grouping: Patients were selected and divided into two equal groups: Group I: Thirty patients were included in the DES + DCB cohort, employing a strategy that combined MB stenting with SB DCB intervention. Group B: Thirty patients were managed using a two-stent approach (2-DES group).

All studied cases were subjected to the following: Comprehensive history collection, including [Personal history; name, age, gender and body mass index (BMI), Present history: onset, course and duration of ischemic symptoms, Past history of any medical condition or previous hospital admission and Family history of similar condition]. **Full clinical examination:** General examination including [General comment on Vital signs: respiratory rate, pulse, blood pressure, and JVP]. **Routine laboratory investigations [**Pre-procedural mandatory investigations were done including CBC, liver function tests (ALT and AST), renal function tests (Urea and Creatinine), and lipid profile. **Radiological investigations** included [Echocardiography to assess LVEF].

All patients were administered dual antiplatelet and statin therapies prior to surgery. Multi-positional imaging was conducted via radial or femoral artery access to assess the left main bifurcation and other lesions, with blood perfusion evaluated using the TIMI flow grade. The left main stem and LAD artery were designated as the MB during interventional therapy, while the LCx artery was deemed the SB. In the DES + DCB group, the lesion underwent pre-dilation, followed by DES implantation in the MB, bifurcation dilation, and DCB placement in the SB, concluding with final kissing balloon inflation and proximal optimization technique (POT). The SB DCB was positioned prior to the implantation of the MB stent if the MB-SB angle was greater than 90°. For the 2-DES group, after pre-dilation, operators used one of four techniques: Crush, Culotte, T-stenting, or V-stenting.

IVUS was performed pre- and post-PCI using a 3.2F, 30-MHz or 2.9F, 40-MHz transducer (Boston Scientific), with automated pullback at 0.5 mm/s from distal to the LAD-LCx bifurcation to the LMCA aorto-ostial junction, recorded on Super VHS for analysis. Images were analyzed blindly using computerized planimetry to measure reference vessel diameter, pre- and post-operative MLD, and luminal stenosis. Patients were administered long-term statins and DAPT for a minimum of 12 months following their PCI. DCB catheters were 2 mm longer than the target lesion, with diameters matching reference vessels (ratio 0.8–1.0), and were inflated for at least 30 seconds at >10 atm.

The primary endpoint was the immediate post-procedural outcomes assessed by IVUS, while secondary endpoints included the incidence of six-month MACE (non-fatal MI, CV death, and TLR). All patients were followed for 6 months through medical record reviews, outpatient visits, and telephone follow-ups.

Sample size calculation

The sample size was determined utilizing G*power software version 3.1.9.2, with calculations based on the anticipation of a significant effect size concerning the immediate postoperative MLD differences between the study groups (6). The minimum sample size needed to detect a similar effect was 52 patients (26 in each group). The alpha level and statistical power were set at 0.05 and 0.8, respectively.

Statistical analysis

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SPSS version 28 (IBM, Armonk, New York, United States) was employed for data administration and statistical analysis. To ascertain the normality of quantitative variables, we employed both the Shapiro-Wilk test and graphical data visualization techniques. Quantitative data were summarized using means and standard deviations, adhering to the assumption of normal distribution. Categorical variables were described using counts and percentages. The independent t-test was utilized to contrast quantitative data across the groups under study. For categorical data comparisons, either the Chi-square test or Fisher's exact test was applied. All statistical tests were conducted as two-sided, with significance levels set at P values below 0.05.

Results

General characteristics:

The studied groups were comparable regarding age (P = 0.689), gender (P = 0.542), DM (P = 0.592), HTN (P = 0.606), smoking (P = 0.795), dyslipidemia (P = 0.438), BMI (P = 0.766), FH of CAD (P = 0.347), MI history (P = 0.706), PCI history (P = 0.766), presentation (P = 0.39), and LVEF (P = 0.37). (**Table, 1)**

Procedural characteristics:

The Medina-type classification showed no significant difference between groups (P = 0.532). Similarly, the pre-operative SYNTAX score (P = 0.969), use of intravascular ultrasound (IVUS) (P = 0.791), MB predilated balloon type (P = 0.205), SB predilated balloon type (P = 0.318), maximum inner diameter of MB (P = 0.183), max inner diameter of SB stent/balloon (P = 0.346), and inflation pressure (P = 0.783). (**Table, 2)**

Immediate postoperative effects:

For the left main artery, the reference vessel diameter (P = 0.596), preoperative minimum luminal diameter (MLD) (P = 0.609), preoperative luminal stenosis (P = 0.420), immediate postoperative MLD (P = 0.401), and immediate postoperative luminal stenosis (P = 0.179) were not significantly different between the groups. (**Table, 3 and Figure, 1-A)**

Table 1: Demographic and general characteristics of the studied groups

		Total (n = 60)	**2-DES (n = 30)**	**DES + DCB (n = 30)**	**P-value**
Age (years)	Mean ±SD	62 ±8	61 ±8	62 ±8	0.689
Gender					
Males	n (%)	46 (76.7)	24 (80)	22 (73.3)	0.542
Females	n (%)	14 (23.3)	6 (20)	8 (26.7)	
DM	n (%)	22 (36.7)	12 (40)	10 (33.3)	0.592
HTN	n (%)	30 (50)	14 (46.7)	16 (53.3)	0.606
Smoking	n (%)	33 (55)	16 (53.3)	17 (56.7)	0.795
Dyslipidemia	n (%)	31 (51.7)	17 (56.7)	14 (46.7)	0.438
BMI	n (%)	15 (25)	8 (26.7)	7 (23.3)	0.766
FH of CAD	n (%)	13 (21.7)	5 (16.7)	8 (26.7)	0.347
MI history	n (%)	8 (13.3)	3 (10)	5 (16.7)	0.706
PCI history	n (%)	15 (25)	7 (23.3)	8 (26.7)	0.766
Presentation					
CCS	n (%)	17 (28.3)	10 (33.3)	7 (23.3)	0.390
ACS	n (%)	43 (71.7)	20 (66.7)	23 (76.7)	
LVEF (%)	Mean ±SD	55 ±8	56 ±9	54 ±6	0.370

SD: Standard deviation; DM: Diabetes mellitus; HTN: Hypertension; BMI: Body mass index; FH of CAD: Family history of coronary artery disease; MI: Myocardial infarction; PCI: Percutaneous coronary intervention; CCS: Chronic coronary syndrome; ACS: Acute coronary syndrome; LVEF: Left ventricular ejection fraction

Table 2: Procedural characteristics in the studied groups.

		Total (n = 60)	2-DES (n = 30)	DES + DCB (n = 30)	P-value
Medina type					
1, 1, 1	n (%)	47 (78.3)	22 (73.3)	25 (83.3)	
1, 0, 1	n (%)	1 (1.7)	1 (3.3)	0 (0)	
0, 1, 1	n (%)	12 (20)	7 (23.3)	5 (16.7)	0.532
Preop SYNTAX score	Mean ±SD	27 ±3	27 ±3	27 ±3	0.969
IABP use	n (%)	0 (0)	0 (0)	0 (0)	-
Temporary pacemaker use	n (%)	0 (0)	0 (0)	0 (0)	-
IVUS use	n (%)	37 (61.7)	19 (63.3)	18 (60)	0.791
OCT use	n (%)	0 (0)	0 (0)	0 (0)	-
MB predilated balloon type					
Semi-compliant balloon	n (%)	29 (48.3)	17 (56.7)	12 (40)	
Non-compliant balloon	n (%)	29 (48.3)	13 (43.3)	16 (53.3)	
Cutting balloon	n (%)	2 (3.3)	0 (0)	2 (6.7)	0.205
SB predilated balloon type					
Semi-compliant balloon	n (%)	37 (61.7)	20 (66.7)	17 (56.7)	
Non-compliant balloon	n (%)	21 (35)	10 (33.3)	11 (36.7)	
Cutting balloon	n (%)	2 (3.3)	0 (0)	2 (6.7)	0.318
Maximum inner diameter of MB (mm)	Mean ±SD	4.74 ±0.31	4.67 ±0.26	4.81 ±0.35	0.183
Max inn. diam. of SB stent/balloon (mm)	Mean ±SD	3.33 ±0.35	3.39 ±0.26	3.28 ±0.42	0.346
Two-stent PCI technique					
Crush	n (%)	-	16 (53.3)	-	
Culotte	n (%)	-	1 (3.3)	-	
T-stenting	n (%)	-	11 (36.7)	-	
V-stenting	n (%)	-	2 (6.7)	-	-
Inflation pressure (atm)	Mean ±SD	11 ±2	11 ±2	11 ±2	0.783

*Significant P-value; IABP: Intra-aortic balloon pump; IVUS: Intravascular ultrasound; OCT: Optical coherence tomography; MB: Main branch; SB: Side branch; PCI: Percutaneous coronary intervention; atm: Atmosphere

Table 3: Immediate postoperative effects in the studied groups.

		Total (n = 60)	2-DES (n = 30)	DES + DCB (n = 30)	P-value
Left main:					
Reference vessel diameter (mm)	Mean ±SD	4.89 ±0.3	4.87 ±0.26	4.92 ±0.34	0.596
Preoperative MLD (mm)	Mean ±SD	2.14 ±0.48	2.18 ±0.6	2.1 ±0.31	0.609
Preoperative luminal stenosis (%)	Mean ±SD	68.26 ±13.25	66.45 ±14.7	70.07 ±11.77	0.420
Imm. postop. MLD (mm)	Mean ±SD	4.63 ±0.29	4.59 ±0.27	4.67 ±0.31	0.401
Imm. postop. luminal stenosis (%)	Mean ±SD	9.71 ±2.36	10.25 ±1.7	9.18 ±2.82	0.179
Left anterior descending:					
Reference vessel diameter (mm)	Mean ±SD	3.87 ±0.36	3.83 ±0.29	3.91 ±0.42	0.491
Preoperative MLD (mm)	Mean ±SD	1.65 ±0.44	1.56 ±0.5	1.73 ±0.35	0.236
Preop. luminal stenosis (%)	Mean ±SD	71.16 ±7.79	70.31 ±9.41	72.02 ±5.91	0.520
Imm postop MLD for LAD (mm)	Mean ±SD	3.71 ±0.33	3.67 ±0.28	3.75 ±0.38	0.491
Imm postop luminal stenosis (%)	Mean ±SD	9.29 ±1.9	8.4 ±1.8	10.19 ±1.58	**0.003***
Left circumflex:					
Reference vessel diameter (mm)	Mean ±SD	3.49 ±0.36	3.55 ±0.3	3.44 ±0.41	0.372
Preop MLD (mm)	Mean ±SD	1.43 ±0.26	1.38 ±0.27	1.49 ±0.23	0.195
Preop luminal stenosis (%)	Mean ±SD	70.43 ±7.35	70.3 ±7.85	70.56 ±7.05	0.916
Imm. postop MLD (mm)	Mean ±SD	3.15 ±0.35	3.3 ±0.27	3 ±0.37	**0.01***
Imm. postop luminal stenosis (%)	Mean ±SD	16.16 ±5.26	12.02 ±2.42	20.31 ±3.85	**<0.001***

*Significant P-value; MLD: Minimal luminal diameter; Imm. postop.: Immediate postoperative; Preop.: Preoperative; LAD: Left anterior descending

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For the LAD artery, while most variables were not significant, a significant difference was found in immediate postoperative luminal stenosis, with the 2-DES group showing lower stenosis (8.4 ± 1.8%) compared to the DES + DCB group (10.19 ± 1.58%) (P = 0.003). (**Table, 3 and Figure, 1-B)**

For the LCx artery, significant differences were observed in the immediate postoperative MLD and luminal stenosis. The immediate postoperative MLD was higher in the 2-DES group (3.3 ± 0.27 mm) compared to the DES + DCB group (3 ± 0.37 mm) (P = 0.01). Furthermore, immediate postoperative luminal stenosis was significantly lower in the 2-DES group (12.02 ± 2.42%) compared to the DES + DCB group (20.31 ± 3.85%) (P < 0.001) (**Table, 3 and Figure, 1-C)**

Six-month clinical outcome:

The incidence of MACE was 10% in the 2-DES group and 3.3% in the DES + DCB group (P = 0.612). There were no cases of cardiovascular death in either group. The incidence of non-fatal MI was 3.3% in both the 2-DES and DES + DCB groups (P = 1.0). TLR occurred in 10% of the 2-DES group and 3.3% in the DES + DCB group (P = 0.612). (**Table, 4)**

Table 4: Six-month clinical outcome in the studied groups.

		Total (n = 60)	2-DES (n = 30)	DES + DCB (n = 30)	P-value
MACE	n (%)	4 (6.7)	3 (10)	1 (3.3)	0.612
Cardiovascular death	n (%)	0 (0.0)	0 (0.0)	0 (0.0)	-
Non-fatal MI	n (%)	2 (3.3)	1 (3.3)	1 (3.3)	1.0
TLR	n (%)	4 (6.7)	3 (10.0)	1 (3.3)	0.612

MACE: Major adverse cardiovascular events; MI: Myocardial infarction; TLR: Target lesion revascularization

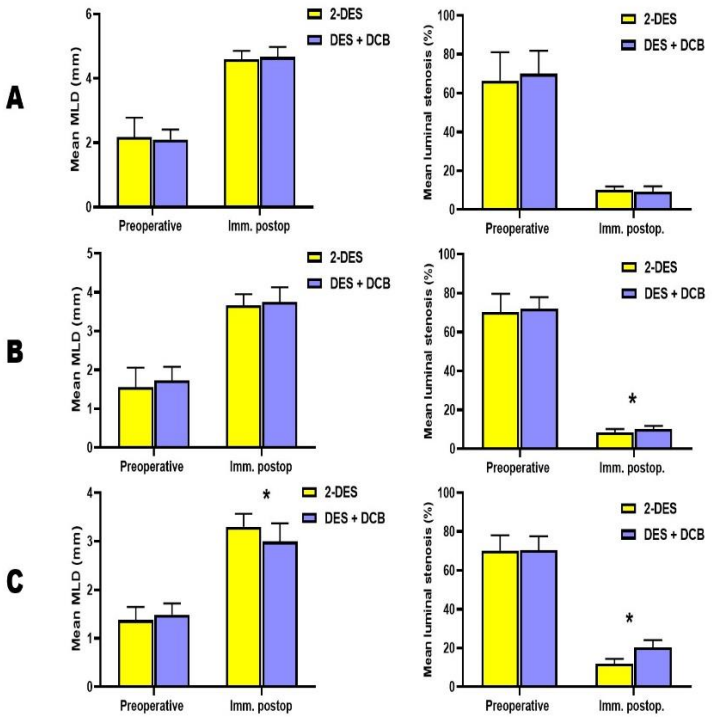

Figure 1: Preoperative and postoperative MLD and luminal stenosis for A) Left main artery; B) Left anterior descending; C) Left circumflex.

Discussion

Significant advancements in PCI technology have greatly improved the interventional management of LMCA disease in recent years. Clinical studies have demonstrated PCI's reliability for certain patients with left main disease. However, treating left main bifurcation lesions remains a major challenge. Current interventional strategies encompass both single-stent and double-stent approaches, each with its own set of advantages and disadvantages. DCB, a more recent approach, has demonstrated efficacy in the treatment of in-stent restenosis and microvascular lesions and is currently being implemented in the treatment of macrovascular lesions and coronary bifurcation. This investigation offers a practical and theoretical foundation for the implementation of a hybrid DES (main branch) + DCB (side branch) strategy for the treatment of left main bifurcation lesions [(6)].

This study was conducted on patients with true left main bifurcation lesions, as confirmed through CAG. The patients were stratified into two distinct groups according to the interventional approach: Group I, comprising thirty individuals, received treatment via a main branch stenting combined with a side branch DCB approach (DES + DCB group). The second cohort comprised thirty patients who were treated utilizing a dual-stent approach, referred to as the 2-DES group.

We found that for the LAD artery, the 2-DES group had significantly lower immediate postoperative luminal stenosis compared to the DES + DCB group. For the left circumflex artery, the 2-DES group had a significantly higher immediate postoperative MLD and significantly lower immediate postoperative luminal stenosis. These findings suggest that the two-stent strategy may provide better immediate luminal results in both LAD and left circumflex arteries, which could indicate improved short-term vessel patency and potentially better clinical outcomes. However, further long-term follow – up and correlation with outcome measurement are needed to confirm these benefits.

In order to prevent artery dissection and unnecessary SB stent implantation, the use of DCB in the SB was in a conservative manner in our study. The DCB, serving as a carrier for antiproliferative drugs, lacks the ability to extend and maintain the lumen, making it highly dependent on thorough predilatation. As a result, the SB ostium's expansion was limited. In contrast, the dual stent strategy involves selecting stents that match the vessel's inner diameter for better adherence and coverage. Following DCB implantation in the DES + DCB group, elastic vessel recoil was observed, leading to a reduced MLD immediately post-PCI when compared to the 2-DES group, attributable to the lack of structural support from a metal stent.

The DES + DCB cohort exhibited a lower immediate postoperative MLD at the LCX ostium and a greater extent of residual lumen stenosis in comparison to the 2-DES group, as assessed by immediate postoperative angiography ($P < 0.05$), as observed in another investigation [(6)]. Additionally, a study conducted through the HYPER trial assessed the clinical outcomes of a hybrid strategy for the treatment of true coronary bifurcation lesions. This prospective single-arm study revealed comparable results, demonstrating that the diameter stenosis and MLD of segments treated with DES and DCB showed significant deviation from baseline measurements. Even in complex lesions that may typically necessitate two-stent strategies in clinical practice, the intervention obtained a high procedural success rate [(7)].

Our findings are in line with the novel hybrid strategy in which DCB with DES were combined for coronary bifurcation lesions and also reported favorable outcomes with residual stenosis of 19.6 ±

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4.7% in SB and 7.3 ± 2.9% in MB, achieving procedural success in all patients and no MACE during follow-up [8].

Despite the significant differences between both groups in our findings regarding immediate MLD and luminal stenoses, this difference didn't show any reflected significance on developing any outcome during the six-months follow up of patients indicating no clinically apparent outperformance for 2-DES strategy over DES + DCB technique.

In our investigation, the incidence rates of TLR, MI, and cardiac mortality did not exhibit significant disparities between the DES combined with DCB approach and the dual DES cohort following a six-month follow-up period. This observation implies that the innovative DES + DCB strategy demonstrates equivalent efficacy to the conventional double-stent PCI concerning short-term clinical outcomes.

Consistent with our results, an investigation indicated that the DES + DCB group showed a reduced LLL in the left main stem, an increased MLD at the LCX ostium, and lower luminal stenosis and LLL at the six-month follow-up when compared to the 2-DES group. No significant disparity was observed in the rate of restenosis at the target lesion between the two groups. Additionally, the lack of a notable difference in MACE between the two cohorts at the one-year follow-up was attributed to the extended follow-up period employed in the study. Furthermore, patients needing TLR in 2-DES group were double those in DES+DCB group further validating the potential of the DES + DCB strategy as a viable alternative to the traditional two-stent approach for treating left main bifurcation lesions [6].

The MLD of SB ostium in the majority of patients with balloon angioplasty (DCB) exhibits an increasing trend during the follow-up period, which contributes to the comparability of clinical outcomes between DES+DCB and 2-DES strategies, as reported in studies [9]. This phenomenon's exact mechanism is uncertain; however, it may involve plaque redistribution and positive vascular remodeling, as detailed in the aforementioned study [10].

Moreover, a separate investigation has demonstrated that an integrated approach utilizing both a DES and a DCB represents a secure and effective treatment modality for coronary bifurcation lesions involving a small-caliber SB. This study reported sustained favorable clinical outcomes at the one-year follow-up, with no adverse events attributable to the DCB-treated segments, thereby reinforcing our findings through an extended observation period. The hybrid approach outlined in their research exhibited positive long-term results, with only a single instance of TLR occurring in a DES-treated segment and no complications linked to the DCB deployment in the SB, thus corroborating its safety profile [7].

Similarly, our results are consistent with a study that reported no MACE in patients treated with a hybrid strategy of DCB and DES for coronary bifurcation lesions during a 12- to 18-month follow-up period. Their study also demonstrated high procedural success and significant reductions in residual stenosis and angina scores. The concordance of these results supports the viability and safety of the DES + DCB approach, indicating that it can provide comparable clinical outcomes to the established two-stent technique while potentially simplifying the procedure and reducing stent-related complications [8].

Similarly, a study was carried out and found that there were no significant differences in the incidence of MACE, cardiac death, TVR, TLR per patient, and TLR per bifurcation at two-year follow-up between the DEB and DES groups. These findings are in accordance with our results, which demonstrated that there were no significant differences in the incidence of TLR, MI, and cardiac death between the DES + DCB and the 2-DES groups after

six months of follow-up. This further supports the non-inferiority of the DES + DCB strategy in comparison to the traditional double-stent PCI [11].

In the DEBSIDE clinical trial, which was conducted at eight French institutions, the primary endpoint of side branch LLL was -0.04±0.34 mm, and the secondary endpoint of MB LLL was 0.54±0.60 mm at six months. A single myocardial infarction (2%) and no cardiac fatalities were reported, resulting in a 100% procedural success. Additionally, a single patient (2%) underwent a TLR that was not clinically driven [12].

Eventually, the use of a drug-eluting balloon may be useful to provide an antiproliferative substance to a lesion without the use of a polymer-covered stent. Over the past few years, drug-eluting balloons have demonstrated their clinical safety and efficacy for the treatment of small coronary vessels [13] and in-stent restenosis [14,15]. In the management of in-stent restenosis following implantation of bare metal stents (BMS) or DES, drug-eluting balloons are now endorsed with a Class I recommendation and Level A evidence according to current guidelines [16].

The DEBIUT registry used DEB during the predilatation step in both side and main branches before provisional main branch stenting with a BMS. The intervention achieved successful outcomes across all participants. The application of sequential predilatation using a DEB was deemed both safe and well-tolerated. No stents were placed in the SB. No MACE or reintervention occurred throughout the four-month clinical follow-up period, and there was no subacute vessel closure. This registry provided encouraging results for the use of a DEB in bifurcation treatment to improve long-term side branch patency [17].

However, a limitation of our study was the short follow-up duration of six months, which may not capture long-term outcomes or fully reveal the potential superiority of the DES + DCB strategy over the 2-DES strategy.

Conclusion

From our findings we can conclude that while the two-stent strategy showed lower immediate postoperative luminal stenosis and higher MLD in the LAD and left circumflex arteries, the combined main branch stenting and side branch DCB approach demonstrated comparable efficacy and safety with even lower incidence of MACE and target lesion revascularization at six months. These findings support the potential of the DES + DCB strategy as a viable alternative to the traditional two-stent approach for treating left main bifurcation lesions.

Conflict of interest

None of the contributors declared any conflict of interest

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None to declare.

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