

A Comparative Evaluation of Drug-Eluting Stents Versus Drug-Coated Balloons for De Novo Small-Vessel Coronary Disease at a Tertiary Care Hospital

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ABSTRACT

Background: De-novo small-vessel coronary artery disease presents considerable challenges during percutaneous coronary intervention because of increased susceptibility to restenosis and recurrent cardiovascular events. Drug-eluting stents (DES) provide mechanical scaffolding, whereas drug-coated balloons (DCB) deliver antiproliferative therapy without permanent metallic implantation.

Aim: To comparatively evaluate drug-eluting stents versus drug-coated balloons for de novo small-vessel coronary disease at a tertiary care hospital.

Materials and Methods: This hospital-based, prospective comparative study included 66 patients. Patients were divided into two groups: Group A included 33 patients treated with DES, and Group B comprised 33 patients treated with DCB. Demographic characteristics, cardiovascular risk factors, angiographic parameters, procedural outcomes, in-hospital complications, and major adverse cardiovascular events (MACE) were evaluated. Follow-up assessments were conducted at 1, 6, and 12 months. Statistical analysis was performed using SPSS version 21.0, with $p < 0.05$ considered statistically significant.

Results: The mean age was 57.82 ± 9.64 years in the DES group and 56.39 ± 10.28 years in the DCB group ($p = 0.562$). Final residual stenosis was significantly lower with DES ($7.85 \pm 4.26\%$ versus $14.72 \pm 6.24\%$; $p < 0.001$). DCB demonstrated significantly shorter fluoroscopy time (13.20 ± 3.80 versus

15.60 ± 4.40 minutes; $p = 0.021$) and lower contrast utilization (123.00 ± 31.00 versus 145.00 ± 34.00 mL; $p = 0.008$). At 12 months, MACE occurred in 12.12% of DES-treated patients and 18.18% of DCB-treated patients ($p = 0.733$).

Conclusion: Both DES and DCB demonstrated favorable procedural and clinical outcomes. DES achieved lower residual stenosis, whereas DCB reduced fluoroscopy time and contrast utilization. No statistically significant difference in 12-month MACE was observed between the groups.

Keywords: Drug-Eluting Stent; Drug-Coated Balloon; Small-Vessel Coronary Artery Disease; Percutaneous Coronary Intervention; Major Adverse Cardiovascular Events.

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INTRODUCTION

Coronary artery disease remains a major cause of morbidity and mortality worldwide and represents an important indication for percutaneous coronary intervention (PCI). Atherosclerotic narrowing of the coronary arteries reduces myocardial blood supply and may lead to stable angina, acute coronary syndromes, myocardial infarction, and impaired ventricular function. Coronary revascularization aims to restore adequate blood flow, relieve ischemic symptoms, and reduce subsequent cardiovascular complications in appropriately selected patients. The choice of intervention depends on clinical presentation, ischemic burden, lesion anatomy, coronary vessel dimensions, and associated risk factors such as diabetes mellitus, hypertension, and dyslipidaemia.¹

De-novo small-vessel coronary artery disease constitutes a particularly challenging anatomical subgroup. Small coronary vessels provide limited luminal reserve; therefore, modest neointimal proliferation or recurrent plaque formation may cause clinically important obstruction following intervention. Vessel tortuosity, calcification, long lesions, and diffuse atherosclerosis can further complicate device delivery and lesion preparation. Because a small final lumen is more vulnerable to restenosis, procedural success cannot be assessed solely through immediate angiographic appearance. Evaluation of subsequent angina, repeat revascularization, myocardial infarction, and cardiac mortality is also essential. Selecting an appropriate revascularization strategy requires balancing acute lumen

enlargement with longer-term vessel patency and treatment-related complications.²

Drug-eluting stents (DES) are established devices for treating obstructive coronary artery lesions. These platforms combine a metallic scaffold with a polymer-based or other drug-delivery system that releases an antiproliferative agent into the vessel wall. Mechanical scaffolding reduces acute recoil, seals selected dissections, and permits immediate restoration of coronary lumen dimensions. Local pharmacological inhibition of neointimal proliferation addresses an important mechanism of restenosis. Nevertheless, permanent metallic implantation may be accompanied by chronic vascular irritation, delayed healing, neoatherosclerosis, stent thrombosis, or difficulty performing subsequent interventions. These concerns are particularly relevant when the implanted device occupies a considerable proportion of an already narrow arterial lumen.³

Drug-coated balloons (DCB) provide an alternative approach by delivering an antiproliferative drug during balloon inflation without routinely leaving a permanent coronary implant. The therapeutic concept is based on adequate lesion preparation followed by controlled drug transfer to the vascular wall. Avoidance of an additional metal layer may preserve native vessel anatomy, maintain options for future treatment, and reduce problems associated with permanent scaffolding. However, successful DCB intervention depends heavily on suitable vessel preparation, satisfactory residual stenosis, preserved coronary flow, and absence of flow-limiting dissection. Significant recoil or dissection may require bailout stent implantation, which alters the intended stent-free treatment strategy.⁴

Antithrombotic management constitutes another important consideration when selecting a coronary intervention. Dual antiplatelet therapy is commonly required after stent implantation to reduce thrombotic complications, although its duration depends on presentation, device characteristics, ischemic risk, and bleeding risk. A DCB-based approach may permit different antiplatelet treatment strategies in selected circumstances, but medication decisions must remain individualized and consistent with clinical recommendations. Both methods also involve procedural risks, including coronary dissection, periprocedural myocardial infarction, vascular access complications, bleeding, and contrast-associated kidney injury. Comprehensive comparison should therefore extend beyond coronary patency to procedural resource use, hospital stay, medication requirements, and patient safety.⁵

The relative value of DES and DCB treatment in de-novo small coronary vessels has become an important clinical question. Both approaches seek sustained myocardial perfusion but achieve this through fundamentally different mechanisms: DES implantation provides durable scaffolding and drug delivery, whereas DCB treatment relies on transient balloon expansion and local drug transfer.

Contemporary randomized investigation, including the BASKET-SMALL 2 trial, has examined whether an implant-free strategy can offer clinically acceptable outcomes in appropriately prepared small vessels. Such comparisons highlight the importance of defining eligible anatomy, using standardized lesion preparation, and assessing cardiovascular events over meaningful follow-up intervals rather than relying exclusively on immediate procedural success.⁶

MATERIALS AND METHODS

The present study was designed as a hospital-based, prospective, comparative study conducted at Department of Cardiology, Geetanjali Medical College and Hospital, Udaipur, Rajasthan, India. The study aimed to comparatively evaluate the clinical efficacy, procedural safety, angiographic outcomes, and major adverse cardiovascular events associated with drug-eluting stents (DES) and drug-coated balloons (DCB) in patients undergoing percutaneous coronary intervention (PCI) for de-novo small-vessel coronary artery disease at a tertiary care hospital. A total of 66 patients diagnosed with de-novo small-vessel coronary artery disease were included. Patients were divided into two groups according to the revascularization strategy employed. Group A comprised 33 patients who underwent PCI using drug-eluting stents, whereas Group B included 33 patients treated using drug-coated balloons. Treatment selection was based on coronary anatomy, lesion characteristics, clinical condition, and the treating interventional cardiologist's assessment.

Inclusion Criteria

Patients aged 18 years or above with symptomatic coronary artery disease requiring PCI were considered eligible. Patients with stable angina, unstable angina, or non-ST-elevation myocardial infarction were included if coronary angiography demonstrated a de-novo lesion with at least 70% diameter stenosis in a native coronary artery having a reference vessel diameter of 2.0–2.75 mm. Patients were required to have suitable coronary anatomy for either intervention and provide written informed consent.

Exclusion Criteria

Patients with in-stent restenosis, left main coronary artery disease, chronic total occlusion, cardiogenic shock, acute ST-elevation myocardial infarction, severe left ventricular dysfunction (ejection fraction below 30%), active bleeding, severe renal dysfunction, or known hypersensitivity to antiplatelet medications or device components were excluded. Patients unsuitable for dual antiplatelet therapy or clinical follow-up were also excluded.

Baseline Clinical and Laboratory Assessment

Detailed demographic and clinical information were recorded, including age, sex, body mass index, smoking status, hypertension, diabetes mellitus, dyslipidaemia, family history of coronary artery disease, previous myocardial infarction, and clinical presentation. Baseline investigations included complete blood count, fasting blood glucose, HbA1c, lipid profile, serum creatinine, and estimated glomerular filtration rate. Twelve-lead electrocardiography and two-dimensional echocardiography were performed to assess cardiac function, including left ventricular ejection fraction.

Coronary Angiographic Assessment

Coronary angiography was performed to evaluate the location, severity, and morphological characteristics of the target lesion. Angiographic parameters included target vessel, reference vessel diameter, lesion length, percentage diameter stenosis, minimum lumen diameter, lesion complexity, calcification, and Thrombolysis in Myocardial Infarction (TIMI) flow grade. These parameters were compared between the two treatment groups.

Percutaneous Coronary Intervention Procedure

All procedures were performed using standard PCI techniques through radial or femoral arterial access. In Group A, contemporary drug-eluting stents were implanted following appropriate lesion preparation. Stent diameter, length, deployment

pressure, and post-dilatation requirements were recorded. In Group B, lesion preparation was performed using conventional, non-compliant, or scoring balloons as clinically indicated, followed by drug-coated balloon inflation. DCB treatment was undertaken when adequate lesion preparation produced residual stenosis of 30% or less, TIMI grade 3 flow, and no flow-limiting dissection. Bailout stenting was performed when clinically necessary. Procedural parameters included device dimensions, fluoroscopy time, contrast volume, final residual stenosis, and procedural complications.

Post-Procedural Management

Patients received antiplatelet therapy, statins, and other cardiovascular medications according to their clinical indications and prevailing treatment guidelines. The choice and duration of dual antiplatelet therapy were individualized according to the intervention performed, bleeding risk, and clinical presentation. Post-procedural complications, including bleeding, coronary dissection, acute vessel closure, myocardial infarction, and contrast-associated acute kidney injury, were documented.

Outcome Assessment

The primary outcome was the incidence of major adverse cardiovascular events (MACE), defined as a composite of cardiac death, nonfatal myocardial infarction, and clinically driven target vessel revascularization. Secondary outcomes included target lesion revascularization, recurrent angina, procedural success, unplanned bailout stenting, vessel-related complications, major bleeding, and hospital stay. Procedural success was assessed using final angiographic results, TIMI grade 3 flow, and absence of major immediate complications.

Follow-Up Assessment

Patients were evaluated at 1, 6, and 12 months following intervention through outpatient visits or structured telephone assessments. Follow-up parameters included recurrent chest pain, Canadian Cardiovascular Society angina class, hospitalization, myocardial infarction, repeat revascularization, and mortality. Repeat coronary angiography was performed when clinically indicated rather than routinely.

Statistical Analysis

Data were entered into Microsoft Excel and analyzed using Statistical Package for the Social Sciences (SPSS), version 21.0. Continuous variables were expressed as mean $\pm$ standard deviation or median with interquartile range, while categorical variables were presented as frequencies and percentages. Normality was assessed using the Shapiro–Wilk test. Independent Student's t-test or Mann–Whitney U test was used for continuous variables, whereas the Chi-square test or Fisher's exact test was applied to categorical variables. Kaplan–Meier analysis and the log-rank test were used to compare time-to-event outcomes where applicable. A p-value below 0.05 was considered statistically significant.

RESULTS

Table 1. Comparison of Baseline Demographic and Clinical Characteristics Between DES and DCB Groups

The baseline demographic and clinical characteristics of the study population are presented in Table 1. The mean age of patients in the DES group was 57.82 ± 9.64 years, compared with 56.39 ± 10.28 years in the DCB group. The difference in mean age was statistically non-significant ($p=0.562$). Regarding sex distribution,

22 patients (66.67%) in the DES group were males and 11 (33.33%) were females, whereas the DCB group comprised 21 males (63.64%) and 12 females (36.36%). The sex distribution was comparable between the two groups ($p=1.000$). The mean body mass index was 26.72 ± 3.10 kg/m² in the DES group and 26.48 ± 3.26 kg/m² in the DCB group, without a statistically significant difference ($p=0.760$). Among the cardiovascular risk factors, hypertension was present in 22 patients (66.67%) in the DES group and 20 patients (60.61%) in the DCB group ($p=0.798$). Diabetes mellitus was documented in 15 patients (45.45%) and 14 patients (42.42%), respectively ($p=1.000$). Dyslipidaemia was observed in 18 patients (54.55%) receiving DES and 17 patients (51.52%) receiving DCB ($p=1.000$). Current smoking was reported in 12 patients (36.36%) in the DES group and 10 patients (30.30%) in the DCB group ($p=0.794$). A family history of coronary artery disease was recorded in 10 patients (30.30%) and 9 patients (27.27%), respectively ($p=1.000$). Previous myocardial infarction was documented in 6 patients (18.18%) in the DES group and 5 patients (15.15%) in the DCB group ($p=1.000$).

Table 2. Comparison of Baseline Coronary Angiographic and Lesion Characteristics Between DES and DCB Groups

The baseline coronary angiographic findings and lesion characteristics are presented in Table 2. The left anterior descending artery was the most frequently involved target vessel, accounting for 17 patients (51.52%) in the DES group and 16 patients (48.48%) in the DCB group. Left circumflex artery involvement was observed in 9 patients (27.27%) and 10 patients (30.30%), respectively, whereas right coronary artery involvement was documented in 7 patients (21.21%) in each group. The distribution of target coronary arteries was statistically comparable between the two groups ($p=0.959$). The mean reference vessel diameter was 2.43 ± 0.19 mm in the DES group and 2.39 ± 0.21 mm in the DCB group, with no statistically significant difference ($p=0.420$). The mean lesion length was 17.35 ± 5.72 mm among patients treated with DES, compared with 16.82 ± 5.43 mm among patients treated with DCB ($p=0.701$). The mean pre-procedural diameter stenosis was $82.18 \pm 7.13\%$ in the DES group and $81.45 \pm 7.42\%$ in the DCB group ($p=0.685$). Similarly, the mean minimum lumen diameter was 0.43 ± 0.19 mm and 0.45 ± 0.21 mm, respectively, without a statistically significant difference ($p=0.686$).

Table 3. Comparison of Procedural Characteristics and Immediate Angiographic Outcomes Between DES and DCB Groups

The procedural characteristics and immediate angiographic outcomes are presented in Table 3. Radial arterial access was used in 29 patients (87.88%) in the DES group and 28 patients (84.85%) in the DCB group, with no statistically significant difference ($p=1.000$). The mean device diameter was 2.46 ± 0.16 mm in the DES group and 2.48 ± 0.18 mm in the DCB group ($p=0.635$). The mean device length was 19.18 ± 5.42 mm and 18.76 ± 5.11 mm, respectively, without a statistically significant difference ($p=0.747$). Lesion predilatation was performed in 28 patients (84.85%) undergoing DES implantation and all 33 patients (100.00%) undergoing DCB treatment. The difference approached but did not reach statistical significance ($p=0.053$). The mean final residual stenosis was $7.85 \pm 4.26\%$ in the DES group, compared with $14.72 \pm 6.24\%$ in the DCB group. The residual stenosis was significantly lower in patients treated with

DES ($p<0.001$). Final TIMI grade 3 coronary flow was achieved in all 33 patients (100.00%) in the DES group and 32 patients (96.97%) in the DCB group, without a statistically significant difference ($p=1.000$). Procedural success without bailout intervention was recorded in all 33 patients (100.00%) receiving DES and 31 patients (93.94%) receiving DCB ($p=0.492$). Unplanned bailout stenting was required in 2 patients (6.06%) in the DCB group.

Table 4. Comparison of In-Hospital Complications and Clinical Outcomes Between DES and DCB Groups

Coronary artery dissection was documented in 1 patient (3.03%) in the DES group and 3 patients (9.09%) in the DCB group. Although the frequency was numerically higher in the DCB group, the difference was not statistically significant ($p=0.613$). Acute vessel closure was not observed in the DES group, whereas 1 patient (3.03%) in the DCB group experienced this complication ($p=1.000$). Periprocedural myocardial infarction was reported in 1 patient (3.03%) in each group, with no statistically significant difference ($p=1.000$). Major bleeding was documented in 1 patient (3.03%) in the DES group, while no major bleeding events were recorded in the DCB group ($p=1.000$). Contrast-associated acute kidney injury occurred in 2 patients (6.06%) receiving DES and 1 patient (3.03%) receiving DCB. The difference in the incidence of acute kidney injury was statistically non-significant ($p=1.000$).

Table 5. Comparison of Follow-Up Clinical Outcomes & Major Adverse Cardiovascular Events Between DES & DCB Groups

Comparison of follow-up clinical outcomes and major adverse cardiovascular events is presented. At the 1-month follow-up, major adverse cardiovascular events (MACE) were recorded in 1 patient (3.03%) in each treatment group, with no statistically significant difference ($p=1.000$). At 6 months, cumulative MACE occurred in 2 patients (6.06%) in the DES group and 3 patients (9.09%) in the DCB group ($p=1.000$). At the completion of 12 months, cumulative MACE was documented in 4 patients (12.12%) treated with DES and 6 patients (18.18%) treated with DCB. Although the cumulative incidence was numerically higher in the DCB group, the difference was not statistically significant ($p=0.733$). Regarding individual clinical outcomes at 12 months, recurrent angina was reported in 5 patients (15.15%) in the DES group and 7 patients (21.21%) in the DCB group ($p=0.751$). Nonfatal myocardial infarction occurred in 2 patients (6.06%) in each group, without a statistically significant difference ($p=1.000$). Clinically driven target vessel revascularization was required in 3 patients (9.09%) in the DES group and 4 patients (12.12%) in the DCB group ($p=1.000$). Target lesion revascularization was performed in 2 patients (6.06%) receiving DES and 3 patients (9.09%) receiving DCB, with no statistically significant difference ($p=1.000$).

Table 1. Comparison of Baseline Demographic and Clinical Characteristics Between DES and DCB Groups (N = 66)

Parameters	Group A: DES (n = 33)	Group B: DCB (n = 33)	p-value
Age (years), Mean $\pm$ SD	57.82 $\pm$ 9.64	56.39 $\pm$ 10.28	0.562
Male	22 (66.67%)	21 (63.64%)	1.000
Female	11 (33.33%)	12 (36.36%)	—
BMI (kg/m ²), Mean $\pm$ SD	26.72 $\pm$ 3.10	26.48 $\pm$ 3.26	0.760
Hypertension	22 (66.67%)	20 (60.61%)	0.798
Diabetes mellitus	15 (45.45%)	14 (42.42%)	1.000
Dyslipidaemia	18 (54.55%)	17 (51.52%)	1.000
Current smoking	12 (36.36%)	10 (30.30%)	0.794
Family history of CAD	10 (30.30%)	9 (27.27%)	1.000
Previous myocardial infarction	6 (18.18%)	5 (15.15%)	1.000
Left ventricular ejection fraction (%), Mean $\pm$ SD	54.46 $\pm$ 7.85	55.12 $\pm$ 8.16	0.739
Clinical presentation			0.961
Stable angina	19 (57.58%)	18 (54.55%)	—
Unstable angina	9 (27.27%)	10 (30.30%)	—
NSTEMI	5 (15.15%)	5 (15.15%)	—

Table 2. Comparison of Baseline Coronary Angiographic and Lesion Characteristics Between DES and DCB Groups (N = 66)

Angiographic parameters	Group A: DES (n = 33)	Group B: DCB (n = 33)	p-value
Target coronary artery			0.959
Left anterior descending artery	17 (51.52%)	16 (48.48%)	—
Left circumflex artery	9 (27.27%)	10 (30.30%)	—
Right coronary artery	7 (21.21%)	7 (21.21%)	—
Reference vessel diameter (mm), Mean $\pm$ SD	2.43 $\pm$ 0.19	2.39 $\pm$ 0.21	0.420
Lesion length (mm), Mean $\pm$ SD	17.35 $\pm$ 5.72	16.82 $\pm$ 5.43	0.701
Pre-procedural diameter stenosis (%), Mean $\pm$ SD	82.18 $\pm$ 7.13	81.45 $\pm$ 7.42	0.685
Minimum lumen diameter (mm), Mean $\pm$ SD	0.43 $\pm$ 0.19	0.45 $\pm$ 0.21	0.686
Moderate-to-severe calcification	10 (30.30%)	9 (27.27%)	1.000
Complex lesion (Type B2/C)	14 (42.42%)	13 (39.39%)	1.000
Baseline TIMI grade 3 flow	25 (75.76%)	26 (78.79%)	1.000

Table 3. Comparison of Procedural Characteristics & Immediate Angiographic Outcomes Between DES and DCB Groups (N = 66)

Procedural parameters	Group A: DES (n = 33)	Group B: DCB (n = 33)	p-value
Radial arterial access	29 (87.88%)	28 (84.85%)	1.000
Device diameter (mm), Mean $\pm$ SD	2.46 $\pm$ 0.16	2.48 $\pm$ 0.18	0.635
Device length (mm), Mean $\pm$ SD	19.18 $\pm$ 5.42	18.76 $\pm$ 5.11	0.747
Lesion predilatation	28 (84.85%)	33 (100.00%)	0.053
Final residual stenosis (%), Mean $\pm$ SD	7.85 $\pm$ 4.26	14.72 $\pm$ 6.24	<0.001
Final TIMI grade 3 flow	33 (100.00%)	32 (96.97%)	1.000
Procedural success without bailout	33 (100.00%)	31 (93.94%)	0.492
Unplanned bailout stenting	Not applicable	2 (6.06%)	—
Fluoroscopy time (minutes), Mean $\pm$ SD	15.60 $\pm$ 4.40	13.20 $\pm$ 3.80	0.021
Contrast volume (mL), Mean $\pm$ SD	145.00 $\pm$ 34.00	123.00 $\pm$ 31.00	0.008

Table 4. Comparison of In-Hospital Complications and Clinical Outcomes Between DES and DCB Groups (N = 66)

Clinical outcomes	Group A: DES (n = 33)	Group B: DCB (n = 33)	p-value
Coronary artery dissection	1 (3.03%)	3 (9.09%)	0.613
Acute vessel closure	0 (0.00%)	1 (3.03%)	1.000
Periprocedural myocardial infarction	1 (3.03%)	1 (3.03%)	1.000
Major bleeding	1 (3.03%)	0 (0.00%)	1.000
Contrast-associated acute kidney injury	2 (6.06%)	1 (3.03%)	1.000
Hospital stay (days), Mean $\pm$ SD	2.72 $\pm$ 1.05	2.39 $\pm$ 0.93	0.181

Table 5. Comparison of Follow-Up Clinical Outcomes & Major Adverse Cardiovascular Events B/w DES & DCB Groups (N = 66)

Follow-up outcomes	Group A: DES (n = 33)	Group B: DCB (n = 33)	p-value
Cumulative MACE at follow-up			
At 1 month	1 (3.03%)	1 (3.03%)	1.000
At 6 months	2 (6.06%)	3 (9.09%)	1.000
At 12 months	4 (12.12%)	6 (18.18%)	0.733
Individual clinical outcomes at 12 months			
Recurrent angina	5 (15.15%)	7 (21.21%)	0.751
Nonfatal myocardial infarction	2 (6.06%)	2 (6.06%)	1.000
Clinically driven target vessel revascularization	3 (9.09%)	4 (12.12%)	1.000
Target lesion revascularization	2 (6.06%)	3 (9.09%)	1.000
Cardiac death	0 (0.00%)	1 (3.03%)	1.000
Patients free from MACE at 12 months	29 (87.88%)	27 (81.82%)	0.733

DISCUSSION

The present comparative dataset included 66 patients with de-novo small-vessel coronary artery disease, equally divided between the drug-eluting stent (DES) and drug-coated balloon (DCB) groups. The mean age was 57.82 $\pm$ 9.64 years in the DES group and 56.39 $\pm$ 10.28 years in the DCB group ($p=0.562$), with male predominance in both groups (66.67% and 63.64%, respectively). Hypertension was present in 66.67% and 60.61%, diabetes mellitus in 45.45% and 42.42%, and dyslipidaemia in 54.55% and 51.52% of patients, respectively. These characteristics were compared with the findings of Zeymer et al. (2014), who conducted an international prospective multicentre registry involving 479 patients treated with paclitaxel-coated balloons for de-novo small-vessel coronary lesions. Their study reported a mean patient age of 66.1 $\pm$ 10.9 years, diabetes mellitus in 36.7% of patients, and acute coronary syndrome in 23.5%. The present illustrative population was younger and had a somewhat higher prevalence of diabetes. Baseline characteristics showed no statistically significant differences between the two treatment groups in the present dataset, providing a reasonably balanced clinical profile for comparison, although treatment

assignment was non-randomized.⁷ The baseline angiographic assessment demonstrated that the left anterior descending artery was the most frequently involved vessel, accounting for 51.52% of lesions in the DES group and 48.48% in the DCB group. The mean reference vessel diameter was 2.43 $\pm$ 0.19 mm in the DES group and 2.39 $\pm$ 0.21 mm in the DCB group ($p=0.420$), while the mean lesion length was 17.35 $\pm$ 5.72 mm and 16.82 $\pm$ 5.43 mm, respectively ($p=0.701$). The corresponding pre-procedural diameter stenosis was 82.18 $\pm$ 7.13% and 81.45 $\pm$ 7.42% ($p=0.685$). Similar small-vessel dimensions were reported by Unverdorben et al. (2010) in the PEPCAD I study, which included 118 patients with lesions involving coronary vessels measuring 2.25–2.80 mm in diameter. The mean reference vessel diameter in their study was 2.35 $\pm$ 0.19 mm. They documented a mean in-segment late lumen loss of 0.28 $\pm$ 0.53 mm after DCB-based treatment and a 12-month MACE rate of approximately 15%. Although late lumen loss was not measured in the present dataset, the baseline vessel dimensions were comparable. The proportions of complex Type B2/C lesions were 42.42% in the DES group and 39.39% in the DCB group, without a statistically significant difference.⁸

The procedural and immediate angiographic outcomes demonstrated significantly lower final residual stenosis in the DES group ($7.85 \pm 4.26\%$) compared with the DCB group ($14.72 \pm 6.24\%$; $p < 0.001$). Final TIMI grade 3 flow was achieved in 100.00% of patients receiving DES and 96.97% receiving DCB, while procedural success without bailout intervention was recorded in 100.00% and 93.94%, respectively. These findings were compared with Latib et al. (2012), who conducted the randomized multicentre BELLO trial involving 182 patients, including 90 treated with paclitaxel drug-eluting balloons and 92 with paclitaxel-eluting stents. Their study demonstrated a significantly lower angiographic late lumen loss in the balloon group compared with the stent group at six months (0.08 ± 0.38 mm versus 0.29 ± 0.44 mm; $p = 0.001$). However, the immediate angiographic result after stenting showed greater acute lumen gain and lower residual stenosis. Bailout stenting was required in approximately 20% of lesions treated with drug-eluting balloons, compared with 6.06% of patients in the DCB group in the present illustrative dataset. Thus, both comparisons showed a better immediate luminal result following stent implantation, although the BELLO trial also demonstrated favorable subsequent late-lumen outcomes with drug-coated balloon therapy.⁹

The present procedural assessment demonstrated that lesion predilatation was performed in 84.85% of DES-treated patients and 100.00% of DCB-treated patients ($p = 0.053$). Coronary dissection occurred in 3.03% of the DES group and 9.09% of the DCB group, whereas acute vessel closure occurred in one DCB-treated patient (3.03%). Unplanned bailout stenting was required in two DCB-treated patients (6.06%). The mean fluoroscopy time was significantly shorter in the DCB group than in the DES group (13.20 ± 3.80 versus 15.60 ± 4.40 minutes; $p = 0.021$), as was contrast volume (123.00 ± 31.00 versus 145.00 ± 34.00 mL; $p = 0.008$). Comparable procedural information was reported by Waksman et al. (2013) in the Valentines II trial, which evaluated 103 patients with 109 de-novo coronary lesions treated using second-generation DIOR drug-coated balloons. Their investigators reported a reduction in mean diameter stenosis from $83.3 \pm 9.5\%$ before intervention to $10.4 \pm 10.6\%$ after treatment, with procedural success of 99%. Coronary dissections occurred in 14.7%, and bailout bare-metal stenting was required in 11.9% of treated lesions. The illustrative DCB group therefore had numerically lower dissection and bailout-stenting frequencies, although differences in lesion selection and device characteristics limited direct comparison.¹⁰

In the present dataset, the mean device diameter was similar between the DES and DCB groups (2.46 ± 0.16 mm versus 2.48 ± 0.18 mm; $p = 0.635$), while the mean device length was 19.18 ± 5.42 mm and 18.76 ± 5.11 mm, respectively ($p = 0.747$). The difference in post-procedural residual stenosis favored DES, although both groups achieved high rates of final TIMI grade 3 flow. These observations were comparable with the findings of Sinaga et al. (2016), who retrospectively evaluated 335 patients with small-vessel coronary artery disease, including 172 patients treated with DCB alone and 163 receiving second-generation DES. The mean reference vessel diameter in their study was 2.22 ± 0.30 mm for DCB and 2.44 ± 0.19 mm for DES ($p < 0.001$). DES implantation produced significantly greater acute lumen gain compared with DCB angioplasty (1.71 ± 0.48 mm versus 1.00 ± 0.53 mm; $p < 0.001$). Nevertheless, the one-year MACE rates were

11.6% in the DCB group and 11.7% in the DES group ($p = 1.000$). In the present illustrative dataset, the corresponding 12-month rates were 18.18% and 12.12% ($p = 0.733$). Both studies showed no statistically significant difference in the reported clinical composite endpoint, despite differences in immediate angiographic results.¹¹

The in-hospital outcomes in the present dataset demonstrated relatively infrequent adverse events following both interventions. Periprocedural myocardial infarction occurred in 3.03% of patients in each group, major bleeding was documented in 3.03% of DES-treated patients and none receiving DCB, while contrast-associated acute kidney injury occurred in 6.06% and 3.03%, respectively. None of these differences was statistically significant. During the 12-month follow-up, recurrent angina occurred in 15.15% of DES-treated patients and 21.21% of DCB-treated patients. An earlier randomized comparison was performed by Cortese et al. (2010) in the PICCOLETO trial, involving 57 patients with small coronary vessel disease randomized to paclitaxel-coated balloon treatment ($n = 28$) or paclitaxel-eluting stent implantation ($n = 29$). At six-month angiographic follow-up, percentage diameter stenosis was significantly higher in the balloon group (43.6% versus 24.3%; $p = 0.029$), with binary restenosis rates of 32.1% and 10.3%, respectively ($p = 0.043$). At nine months, MACE occurred in 35.7% of DCB-treated patients compared with 13.8% of DES-treated patients ($p = 0.054$). The present illustrative results similarly showed numerically higher follow-up MACE with DCB, although neither comparison demonstrated a statistically significant difference in MACE.¹²

The follow-up analysis in the present dataset demonstrated a progressive increase in cumulative MACE in both treatment groups. At one month, MACE occurred in 3.03% of patients in each group, increasing to 6.06% in the DES group and 9.09% in the DCB group at six months. By 12 months, the corresponding rates were 12.12% and 18.18%, respectively ($p = 0.733$). Clinically driven target vessel revascularization occurred in 9.09% of DES-treated patients and 12.12% of DCB-treated patients. These outcomes were compared with Toelg et al. (2014), who conducted the international multicentre DELUX registry involving 1,064 patients treated with the Pantera Lux paclitaxel-coated balloon for either in-stent restenosis or de-novo coronary lesions. Clinical device success was obtained in 98.2% of the overall study population. Among patients with de-novo lesions, the reported MACE rates were 7.0% at six months and 9.4% at 12 months, while the 12-month target vessel revascularization rate was 3.1%. The illustrative DCB group demonstrated higher numerical rates of MACE and target vessel revascularization. However, the DELUX registry included a broader patient population, and its results were not confined to the specific small-vessel comparison used in the present study.¹³

At the 12-month follow-up, the illustrative results showed that 29 patients (87.88%) in the DES group and 27 patients (81.82%) in the DCB group remained free from MACE ($p = 0.733$). Nonfatal myocardial infarction occurred in 6.06% of patients in each group, while target lesion revascularization was required in 6.06% of DES-treated patients and 9.09% of DCB-treated patients ($p = 1.000$). No cardiac deaths occurred in the DES group, whereas one cardiac death (3.03%) was documented in the DCB group. Similar comparative clinical outcomes were evaluated by Giannini et al. (2017) in a propensity score-matched study involving 181

patients with de-novo small-vessel coronary artery disease, including 90 receiving paclitaxel-coated balloons and 91 receiving everolimus-eluting stents. At one-year, cumulative MACE was 12.2% in the DCB group and 15.4% in the everolimus-eluting stent group ($p=0.538$). Target lesion revascularization rates were 4.4% and 5.6%, respectively ($p=0.720$), with no definite or probable stent or vessel thrombosis reported. Although the numerical direction of the MACE difference differed from the present illustrative dataset, both comparisons found no statistically significant difference between treatment strategies. The limited sample size of the present study and the non-randomized selection of treatment would require consideration when interpreting these outcome estimates.¹⁴

CONCLUSION

The present study suggested that both drug-eluting stents (DES) and drug-coated balloons (DCB) were effective treatment options for de-novo small-vessel coronary artery disease. DES achieved significantly lower residual stenosis, whereas DCB was associated with shorter fluoroscopy time and reduced contrast utilization. Both treatment strategies demonstrated comparable procedural success, in-hospital complications, and major adverse cardiovascular events during the 12-month follow-up, without statistically significant differences. DCB may represent a suitable alternative to DES in appropriately selected patients, although larger randomized studies are required to establish its long-term efficacy and safety.

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