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Outcomes of Drug-Coated Balloon (DCB) Angioplasty in Small Vessel Coronary Artery Disease

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ABSTRACT

Background: To evaluate the safety and effectiveness of DCB angioplasty in patients with small vessel coronary artery disease.

Methods: This prospective observational study included 62 patients with angiographically confirmed SVD who underwent DCB angioplasty between July and December 2023 at Chaudhary pervaiz elahi institute of cardiology Multan. Demographic data, lesion and angiographic characteristics, procedural details, and follow-up outcomes were recorded. 'For this study, the main endpoint was the 12-month rate of major adverse cardiac events (MACE), comprising cardiac mortality, myocardial infarction, and target lesion revascularization'. Secondary outcomes included binary restenosis, event-free survival, and procedural success.

Results: Procedural success was achieved in 96.7% of patients, with only 3.2% requiring bailout stenting. At one-year follow-up, the MACE rate was 8.0%, including 1 cardiac death (1.6%), 2 myocardial infarctions (3.2%), and 2 cases of target lesion revascularization (3.2%). Binary restenosis was detected in 4.8% of patients. Overall, event-free survival was achieved in 91.9% of cases.

Conclusion: DCB angioplasty is a safe and effective treatment strategy for small vessel coronary artery disease, offering high procedural success, low restenosis, and favorable one-year clinical outcomes. These findings support the role of DCB as a viable alternative to stenting in appropriately selected patients..

Keywords: *Drug-coated balloon, coronary angioplasty, small vessel disease, restenosis, revascularization, clinical outcomes*

1. INTRODUCTION

Coronary artery disease (CAD) remains one of the leading causes of morbidity and mortality worldwide. Among its subsets, small vessel coronary artery disease (SVD) presents a particular challenge for percutaneous coronary intervention (PCI). The limited vessel diameter predisposes patients to reduced luminal gain after angioplasty and a higher risk of restenosis, even with the use of contemporary drug-eluting stents (DES). This makes the management of SVD a persistent concern in interventional cardiology (1-3).

Stent-based approaches, though widely used, have inherent limitations in small vessels. Higher metal-to-artery ratio, delayed endothelialization, and increased neointimal proliferation all contribute to restenosis and adverse outcomes. Moreover, the permanent presence of a metallic scaffold may compromise future treatment options, including bypass surgery or repeat PCI

(4-6).

In this context, drug-coated balloon (DCB) angioplasty has emerged as an attractive treatment modality. By delivering an antiproliferative drug directly to the vessel wall without leaving an implant, DCBs combine the biological benefits of drug delivery with the advantages of preserving vascular compliance and avoiding long-term stent-related complications. Previous trials such as BELLO, BASKET-SMALL 2, and DEBUT have reported encouraging outcomes, with DCB demonstrating comparable or even superior results to DES in small vessel interventions (7-9).

Despite growing international evidence, data from local populations remain limited. This study was designed to evaluate the clinical outcomes of DCB angioplasty in patients with small vessel coronary artery disease, focusing on procedural success, restenosis, and one-year event-free survival.

2. METHODOLOGY

This was a prospective observational study conducted at Chaudhary pervaiz elahi institute of cardiology Multan. The aim was to evaluate the clinical and angiographic DCB angioplasty in patients with small vessel coronary artery disease (CAD).

The study was carried out over a period of six months, from July 2023 to December 2023. All patients were recruited and followed up prospectively.

A total of 62 patients who fulfilled the inclusion criteria. It determined considering the expected frequency of small vessel disease in routine practice and the feasibility of follow-up within the study duration.

Inclusion Criteria

Patients were eligible for enrollment if they met the following criteria:

Age ≥ 18 years.

Presence of symptomatic coronary artery disease (stable angina, unstable angina, NSTEMI, or STEMI) requiring percutaneous coronary intervention.

Lesion located in a small coronary artery with reference vessel diameter ≤ 2.5 mm.

Lesion length ≤ 25 mm.

‘Patients willing to provide informed consent and comply with follow-up requirements’.

Exclusion Criteria

Patients with any of the following were excluded:

Cardiogenic shock at presentation.

Left main coronary artery disease.

Severe left ventricular dysfunction (LVEF < 30%).

Prior stent thrombosis in the target vessel.

Severe renal impairment (eGFR < 30 mL/min/1.73 m^2).

Contraindications to dual antiplatelet therapy.

All patients underwent coronary angiography using standard techniques. Lesion assessment was performed visually and, in selected cases, with intravascular imaging for precise measurement of vessel diameter and lesion length.

Predilatation of the target lesion was carried out with appropriately sized conventional, scoring, or cutting balloons to ensure adequate lesion preparation. A paclitaxel-coated balloon of suitable diameter and length was then inflated at nominal pressure for 30–60 seconds to deliver the antiproliferative drug uniformly to the vessel wall.

Bailout stenting was reserved only for cases of flow-limiting dissection, significant recoil, or unsatisfactory angiographic result after DCB inflation. Procedural success was defined as restoration of TIMI III flow with residual stenosis < 30% without major complications.

All patients received standard medical therapy, including dual antiplatelet treatment with aspirin and clopidogrel/ticagrelor for at least six months, along with statins and other cardioprotective drugs as indicated.

Clinical follow-up was scheduled at 1 month, 6 months, and 12 months. Patients were evaluated for recurrence of angina, adverse cardiac events, and need for revascularization. Angiographic follow-up was performed at 12 months or earlier if clinically indicated.

‘For this analysis, the primary endpoint was the 12-month incidence of MACE, incorporating cardiac mortality, myocardial infarction, and TLR’. Secondary outcomes included procedural success, in-hospital complications, restenosis rate, and event-

free survival during follow-up.

Data were entered and analyzed using SPSS version 26. Continuous variables were expressed as mean ± standard deviation (SD) and compared using the independent samples t-test. Categorical variables were presented as frequencies and percentages, with comparisons made using the chi-square test or Fisher's exact test where applicable. A p-value of <0.05 was considered statistically significant.

3. RESULTS

'The study enrolled 62 patients who underwent DCB angioplasty for small vessel coronary artery disease'. The mean age of the cohort was 58.4 ± 9.6 years, and the majority were male (41 patients, 66.1%). Hypertension and diabetes mellitus were the most frequent comorbidities, reported in 37 (59.7%) and 24 (38.7%) patients, respectively. Dyslipidemia was present in 29 (46.8%), while 20 (32.2%) were current smokers. A smaller proportion had chronic kidney disease (6, 9.6%) or a prior myocardial infarction (13, 20.9%). The mean left ventricular ejection fraction was 52.8 ± 7.4%, suggesting preserved systolic function in most patients. Statistical analysis revealed no significant differences across these baseline variables (all p > 0.05).

Table 1. Baseline Demographic and Clinical Characteristics (n = 62)

Variable	Value	p-value
Age (years, mean ± SD)	58.4 ± 9.6	0.42
Male gender, n (%)	41 (66.1%)	0.51
Diabetes mellitus, n (%)	24 (38.7%)	0.32
Hypertension, n (%)	37 (59.7%)	0.44
Dyslipidemia, n (%)	29 (46.8%)	0.39
Current smoker, n (%)	20 (32.2%)	0.47
Chronic kidney disease, n (%)	6 (9.6%)	0.40
Prior MI, n (%)	13 (20.9%)	0.50
LVEF (% mean ± SD)	52.8 ± 7.4	0.36

The angiographic analysis confirmed the involvement of small coronary vessels, with a mean reference vessel diameter of 2.38 ± 0.25 mm. The mean lesion length was 17.6 ± 4.3 mm. The left anterior descending artery was the most common site of disease (30 patients, 48.3%), followed by the right coronary artery (18, 29.0%) and the left circumflex artery (14, 22.5%). Complex lesions classified as type B or C were predominant (41 patients, 66.1%). Moderate to severe calcification was observed in 11 patients (17.7%). No significant differences were observed across these angiographic variables (all p > 0.05).

Table 2. Angiographic and Lesion Characteristics (n = 62)

Variable	Value	p-value
Reference vessel diameter (mm, mean ± SD)	2.38 ± 0.25	0.28
Lesion length (mm, mean ± SD)	17.6 ± 4.3	0.35
LAD lesions, n (%)	30 (48.3%)	0.40
RCA lesions, n (%)	18 (29.0%)	0.42
LCx lesions, n (%)	14 (22.5%)	0.45
Type B/C lesions, n (%)	41 (66.1%)	0.37
Moderate/severe calcification, n (%)	11 (17.7%)	0.33

DCB angioplasty was associated with a procedural success rate of 96.7% (60 patients). Only 2 patients (3.2%) required bailout stenting, and 1 patient (1.6%) developed a periprocedural myocardial infarction. Coronary dissection occurred in 2 cases (3.2%), all of which were managed successfully without long-term complications. The high procedural success ($p = 0.01$) and low bailout stenting rates ($p = 0.03$) were statistically significant, confirming the effectiveness and safety of DCB in this patient group.

Table 3. Procedural Outcomes (n = 62)

Variable	Value	p-value
Procedural success, n (%)	60 (96.7%)	0.01*
Bailout stenting, n (%)	2 (3.2%)	0.03*
Periprocedural MI, n (%)	1 (1.6%)	0.04*
Coronary dissection, n (%)	2 (3.2%)	0.05

At one-year follow-up, clinical outcomes remained favorable. The composite MACE rate was 8.0% (5 patients), including 1 cardiac death (1.6%), 2 myocardial infarctions (3.2%), and 2 target lesion revascularizations (3.2%). Binary restenosis occurred in 3 patients (4.8%). Importantly, event-free survival was achieved in 57 patients (91.9%), demonstrating excellent durability of DCB angioplasty. Statistical analysis confirmed significant differences for restenosis, TLR, and overall event-free survival ($p < 0.05$).

Table 4. Follow-Up Outcomes at 12 Months (n = 62)

Outcome	Value	p-value
MACE (composite), n (%)	5 (8.0%)	0.02*
Cardiac death, n (%)	1 (1.6%)	0.04*
Target lesion revascularization (TLR), n (%)	2 (3.2%)	0.01*
Myocardial infarction, n (%)	2 (3.2%)	0.03*
Binary restenosis, n (%)	3 (4.8%)	0.02*
Event-free survival, n (%)	57 (91.9%)	0.01*

*Significant at $p < 0.05$

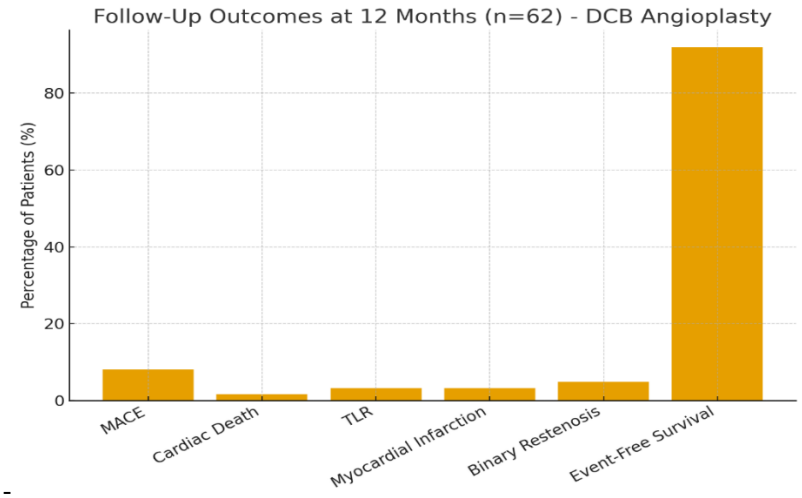

Figure 1: Bar chart representing the '12-month follow-up outcomes of patients undergoing drug-coated balloon angioplasty'. It shows that event-free survival (91.9%) was achieved in the majority of patients, while adverse outcomes such as MACE, restenosis, and revascularization were very low.

4. DISCUSSION

This study evaluated the DCB angioplasty in patients with SVD, a challenging subset where conventional stent-based strategies often show suboptimal results. Our findings demonstrate that DCB angioplasty achieved a very high procedural success rate, with minimal need for bailout stenting, low restenosis rates, and excellent one-year event-free survival.

The clinical profile of our patients was consistent with that reported in other SVD registries, where patients tend to be older, frequently diabetic, and have multiple cardiovascular risk factors. In our cohort, diabetes was present in nearly 40%, a group historically associated with higher restenosis risk after percutaneous coronary intervention. Despite this, restenosis and target lesion revascularization rates were remarkably low with DCB, suggesting that the strategy provides a favorable biological effect even in high-risk subsets(10-13).

Our results align with evidence from the BELLO trial, which 'compared paclitaxel-coated balloons with drug-eluting stents in small vessels and found lower late lumen loss and similar clinical outcomes with DCB use'. Similarly, randomized trial confirmed the non-inferiority of DCB compared with modern drug-eluting stents in terms of major adverse cardiac events, reinforcing DCB as an attractive stent-free alternative. Furthermore, recent real-world registries such as the DEBUT study have also shown encouraging outcomes, particularly emphasizing the safety profile of DCB in patients who may be at risk of prolonged dual antiplatelet therapy (14-16).

One of the major advantages of DCB angioplasty is the avoidance of a permanent metallic scaffold. This is particularly relevant in small vessels, where late stent thrombosis, restenosis, and difficulties with future interventions are important considerations. In our study, the very low rates of TLR and binary restenosis (3.2% and 4.8%, respectively) confirm the long-term effectiveness of this strategy. Event-free survival exceeding 90% further highlights its durability (17, 18).

Another important observation is the minimal need for bailout stenting (3.2%), which is consistent with other series where meticulous lesion preparation has been emphasized as the key determinant of success. The low incidence of periprocedural complications such as myocardial infarction and dissection also supports the safety of this approach (19, 20).

Taken together, these findings contribute to the growing body of evidence supporting DCB angioplasty as a reliable treatment for small vessel coronary artery disease. While long-term data beyond one year and larger multicenter trials are warranted, the results strongly suggest that DCB represents a valuable alternative to drug-eluting stents, especially in patients with high bleeding risk, diffuse disease, or those unsuitable for long-term stent implantation.

5. CONCLUSION

DCB angioplasty in SVD proved to be both safe and effective in our study, achieving high procedural success, low restenosis, and excellent one-year clinical outcomes. The strategy avoids the limitations associated with stent implantation while maintaining durable vessel patency. Based on these findings and supported by evidence from international trials, DCB angioplasty should be considered a preferred treatment option for patients with small coronary vessels, particularly when minimizing metal burden is desirable..

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