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Safety Profile of Drug-Coated Balloon Angioplasty for Isolated Side Branch Lesions: A Single-Center Experience

ABSTRACT

Background: The optimal treatment strategy for isolated side branch (SB) lesions remains uncertain. In this study, the aim was to evaluate the safety and efficacy of drug-coated balloon (DCB) angioplasty for the treatment of de novo isolated SB stenosis.

Methods: This single-center, retrospective study included patients with symptomatic isolated SB occlusion who underwent percutaneous coronary intervention using DCB. The primary endpoint was procedural success, and the secondary endpoint was the occurrence of major adverse cardiac events, defined as death from all causes, myocardial infarction, target vessel revascularization, or revascularization of target lesions.

Results: Forty-eight patients were included between April 2022 and June 2025. The mean age was 62.8 ± 13.9 years, and the majority were male (n = 35, 72.9%). The cohort exhibited a high cardiovascular risk profile. Procedural success was achieved in 97.9% (n = 47). Thrombolysis in myocardial infarction grade 3 flow was obtained in all patients, with a mean residual stenosis of 26% ± 14.9. One patient (2.1%) required bailout stenting, and no cases of acute thrombosis were observed. During a mean follow-up of 423 days, 8 patients (16.7%) underwent repeat coronary angiography for angina, 6 patients (12.5%) required additional medical therapy, and 1 patient (2.1%) experienced myocardial infarction.

Conclusion: These findings suggest that, with appropriate lesion preparation and patient selection, DCB angioplasty represents a safe and feasible revascularization strategy for isolated SB occlusions. However, larger, controlled, and long-term studies are needed to confirm these results.

Keywords: Coronary bifurcation, drug-coated balloon, isolated side branch stenosis, percutaneous coronary intervention

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INTRODUCTION

Isolated side branch (SB) stenosis in coronary artery disease represents one of the most challenging lesion subsets in interventional cardiology. Compared with non-bifurcation lesions, these lesions are associated with a higher risk of ischemic events. The small vessel diameter, close anatomical relation with the main vessel, and difficulty in maintaining main vessel flow during the procedure make treatment decisions complex. As these lesions constitute less than 5% of all bifurcation lesions, the rarity and unique characteristics of Medina 0.0.1 bifurcation lesions result in limited evidence regarding optimal treatment strategies and necessitate an individualized approach.[1,2]

In recent years, drug-coated balloon (DCB) technology has emerged as an innovative stentless option that provides homogeneous local drug delivery, accelerates vessel healing, reduces neointimal proliferation, and preserves physiological vasomotion.[3,4] The use of DCBs in coronary bifurcation lesions offers several advantages. First, compared with plain old balloon angioplasty, DCBs can potentially enhance the procedural success of a provisional strategy.[5,6] Second, DCBs maintain the original carina anatomy and reduce both procedural complexity and the complications related to permanent metallic implants. Third, DCBs allow for late lumen enlargement.[7] Lastly, despite their relatively small diameter

(usually ≤2.75 mm), SBs supply a significant myocardial area; thus, several studies have shown that DCBs are at least as effective as drug-eluting stents in the treatment of small vessels.[8–11]

METHODS

Study Design and Participants

Between April 2022 and June 2025, all patients who underwent coronary angiography for stable angina, unstable angina, or acute coronary syndrome were screened. Patients with isolated SB *de novo* occlusion (Medina, 0.0.1) identified as the culprit lesion and treated with DCB were included (n = 48). The follow-up period ranged from 155 to 858 days (mean, 423 days). Follow-up of 32 patients was conducted face-to-face through outpatient clinic visits. Clinical information of 16 patients—who were not followed up at the center—was obtained through the national database and telephone contact. These patients were asked whether they experienced chest pain after the procedure and whether they were using any new medication or had undergone coronary angiography. This study is designed as a hypothesis-generating retrospective observational cohort evaluating procedural safety and feasibility rather than a comparative efficacy trial. Ethical approval was obtained from the Ethics Committee of Lokman Hekim University (University of Health Sciences) (Approval No.: 2025/148, dated May 30, 2025). All procedures were performed in accordance with the Declaration of Helsinki.

Definitions

Vessel Stenosis Parameters

Minimal lumen diameter (MLD): Diameter at the narrowest point of the stenosis (mm).

Reference vessel diameter (RVD): Calculated as the diameter of the normal vessel segment immediately distal to the stenosis.

Percent diameter stenosis (DS%): $DS\% = (1 - MLD/RVD) \times 100$.

Major Adverse Cardiac Events (MACE): According to the Academic Research Consortium definitions, MACE is defined as: 1) Death from all causes (including isolated cardiac death), 2) myocardial infarction (MI), and 3) target vessel revascularization or revascularization of target lesions (TLR).

HIGHLIGHTS

- The success of drug-coated balloon (DCB) treatment of isolated side branch (SB) occlusions depends on appropriate lesion preparation.
- Drug-coated balloon treatment of isolated SB occlusions offers the advantages of shorter procedure times, less radiation exposure, and less contrast material use.
- No risk of acute thrombosis has been identified with DCB application in isolated SB occlusions.
- Drug-coated balloon treatment is a promising treatment strategy for patients with Medina 0.0.1 lesions who experience chest pain despite medical treatment.

Myocardial infarction: Defined as cardiac enzymes ≥ 3× upper normal limit.

Definition of successful procedure: Following DCB application; residual stenosis <30% (<20% in some studies), thrombolysis in myocardial infarction (TIMI) grade 3 flow, absence of acute vessel closure, no severe dissection (≥ type C), and no elastic recoil or flow-limiting dissection in the branch ostium.

Procedure

For isolated SB lesions identified as the culprit, predilation was performed with semi-compliant or non-compliant balloons. After adequate lesion preparation, DCB angioplasty was performed if the following angiographic criteria were met: TIMI flow grade 3, residual stenosis ≤30%, and absence of dissection ≥type C. A DCB matched 1 : 1 to the vessel diameter was inflated at nominal pressure for at least 60 seconds. In patients who experienced chest discomfort during DCB inflation, the balloon was deflated for 15 seconds and then reinflated twice for 30 seconds each. All DCB procedures were performed using SeQuent Please NEO (B. Braun Medical, Melsungen, Germany).

Statistical Analysis

Descriptive statistics for continuous variables are expressed as mean ± SD or median (interquartile range). Categorical variables are presented as counts (n) and percentages (%), and 95% CIs were calculated using the Wilson method. The primary safety endpoints were periprocedural complications which consisted of dissection, bailout stenting, acute thrombosis, and periprocedural myocardial infarction. Owing to the small sample size and multiple comparisons, the analysis was considered hypothesis generating. All analyses were performed using Python 3.11 (pandas, statsmodels).

RESULTS

A total of 48 patients with isolated SB occlusion (Medina 0.0.1) treated only with DCB were included in this study. The baseline demographic and clinical characteristics are detailed in Tables 1 and 2. The mean age of the patients was 62.8 ± 13.9 years, and the population was predominantly male (n = 35, 72.9%). The cohort exhibited a high-risk profile, with a significant prevalence of cardiovascular risk factors. Hypertension was present in 75% (n = 36) of patients, hyperlipidemia in 87.5% (n = 42), and current smoking in 75% (n = 36). Diabetes mellitus was diagnosed in half of the patients (n = 24, 50%), with 20.8% (n = 10) of the total cohort requiring insulin therapy. The clinical history revealed a substantial burden of coronary artery disease. A majority of patients had a history of prior percutaneous coronary intervention (PCI) (n = 30, 62.5%) and myocardial infarction (n = 27, 56.2%). A smaller proportion had undergone prior coronary artery bypass grafting (n = 4, 8.3%) or had a history of stroke (n = 4, 8.3%). The mean left ventricular ejection fraction was 50.3% ± 10.4, indicating predominantly preserved to mildly reduced systolic function (Table 2).

The primary clinical presentation for the index procedure was unstable or stable angina pectoris in 87.5% (n = 42) of cases, while the remaining 12.5% (n = 6) presented with an acute

Table 1. Demographic Characteristics, Clinical, and Laboratory Findings

Variables	Mean ± SD (n = 48)
Age (years)	62.8 ± 13.9
Height (cm)	169.2 ± 8.7
Weight (kg)	82.1 ± 12.9
Ejection fraction (%)	50.2 ± 10.4
Hemoglobin (g/dL)	13.3 ± 2.3
Hematocrit, %	39.7 ± 4.5
Platelets (10^5/μL)	244.4 ± 74.1
White blood cells	8.9 ± 3.2
Creatinine (mg/dL)	1.4 ± 0.2
Urea (mg/dL)	41.4 ± 25.4
Glucose (mg/dL)	152.7 ± 55.5
LDL cholesterol (mg/dL)	94.5 ± 53.9
HDL cholesterol (mg/dL)	41.2 ± 12.8
Triglycerides (mg/dL)	166.1 ± 83.9
Total cholesterol	170.0 ± 59.2
Number of antianginal drugs	1.5 ± 0.6

HDL, high-density lipoprotein; LDL, low-density lipoprotein.

coronary syndrome. The most frequently treated vessel was the left anterior descending artery/diagonal branches (n = 23, 47.9%), followed by the left circumflex artery (LCx) (n = 13, 27.1%) and obtuse marginal branches (n = 10, 20.8%). Angiographic analysis demonstrated a high degree of lesion severity. The mean baseline stenosis of the treated vessel was greater than 90%, with 47.9% exhibiting stenosis of 95% or greater. All patients underwent lesion preparation with predilation prior to DCB application. Non-compliant balloons were used for predilation in 60.4% (n = 29) of cases, while semi-compliant balloons were used in 39.6% (n = 19). The mean diameter of the primary predilation balloon was 2.28 ± 0.51 mm. The average number of DCBs used per patient was 1.1 ± 0.4. The mean diameter and length of the primary DCB were 2.54 ± 0.47 mm and 23.9 ± 7.5 mm, respectively. The DCB was inflated to a mean pressure of 8 atm for an average duration of 63.5 ± 11.9 seconds. The procedural and angiographic outcomes were highly successful. As documented in the provided literature, achieving optimal lesion preparation is paramount for DCB success. In this cohort, post-procedural TIMI flow was grade 3 in all 48 patients. The mean residual stenosis after the DCB procedure was 26% ± 14.9, meeting the generally accepted criterion of <30% for a successful angiographic result (Tables 3 and 4).

Table 2. Demographic Characteristics

Variables	n (%)
Sex (male)	35 (72.9)
Angina	45 (93.8)
PCI history	30 (62.5)
CABG history	4 (8.3)
MI history	27 (56.2)
HT	36 (75)
Stroke history	4 (8.3)
DM	24 (50)
Insulin	10 (20.8)
HLP	42 (87.5)
Smoking	36 (75)

CABG, coronary artery bypass grafting; MI, myocardial infarction; PCI, percutaneous coronary intervention; DM, Diabetes Mellitus; HLP, hyperlipidemia; HT, hypertension.

Table 3. Pre-Procedure Angiographic Findings

Variables	Mean ± SD (n = 48)
Predilation balloon diameter 1 (mm)	2.28 ± 0.51
Predilation balloon diameter 2 (mm)	2.3 ± 0.7
Predilation balloon diameter 3 (mm)	2.5
Number of DCB balloons used	1.1 ± 0.4
DCB 1 diameter (mm)	2.54 ± 0.47
DCB 1 length (mm)	23.8 ± 7.5
DCB 2 diameter (mm)	2.5 ± 0.3
DCB 2 length (mm)	28 ± 9
DCB 3 diameter (mm)	2.7
DCB 3 length (mm)	15
Predilation inflation count	1.6 ± 0.6
Inflation pressure (atm)	8
DCB inflation time (s)	63.5 ± 11.9
TIMI flow after balloon	3
Residual stenosis after DCB (%)	26 ± 14.9

DCB, drug-coated balloon; TIMI, thrombolysis in myocardial infarction.

Procedural Complications and Clinical Outcomes

The overall procedural success rate was 97.9% (n = 47) (Figure 1). Although type A/B coronary dissections were observed in 35.4% (n = 17) of procedures, the incidence of flow-limiting dissections requiring intervention was minimal. This finding is further supported by the fact that bailout stenting, which is the primary remedy for a failed DCB-only strategy, was required in only 1 patient (2.1%) (Table 4). No instances of post-DCB acute thrombosis were recorded. In-hospital and short-term clinical outcomes were also favorable. There was 1 reported case of post-procedural death (2.1%) and 1 case of post-procedural MI (2.1%). No strokes were observed. At follow-up, 16.7% (n = 8) of patients underwent a subsequent coronary angiography, and 12.5% (n = 6) reported post-procedural angina (Table 5).

DISCUSSION

In this study, DCB angioplasty was found to be a safe and feasible therapeutic option for one of the most technically demanding lesion types in interventional cardiology, specifically isolated SB occlusion (Medina 0.0.1), treated without stent implantation.

As Medina 0.0.1 lesions account for only 3%-5% of all bifurcations, clinical evidence remains scarce, and an individualized approach is needed. Compared with other bifurcation patterns, isolated SB lesions present several technical difficulties: the risk of main vessel injury during SB intervention,

Table 4. Angiographic Findings

Variables		n (%)
Presentation	ACS	6 (12.5)
	USAP/SAP	42 (87.5)
Treated vessel	LAD/Diagonal	23 (47.9)
	LCX	13 (27.1)
	OM	10 (20.8)
	RCA PI	2 (4.2)
Stenosis degree	100	6 (12.5)
	99	10 (20.8)
	98	3 (6.2)
	95	4 (8.3)
	90	13 (27.1)
	85	2 (4.2)
	80	8 (16.7)
	70	2 (4.2)
Stenosis 2 vessel	LAD/Diagonal	3 (75)
	LCX	1 (25)
Stenosis 2 degree	90	1 (25)
	95	2 (50)
	99	1 (25)
Stenosis 3 vessel	LCX	1 (100)
Stenosis 3 degree	98	1 (100)
Predilation balloon type	NC	29 (60.4)
	SC	19 (39.6)
Bailout stent	No	47 (97.9)
	Yes	1 (2.1)
Dissection	Type A-B	17 (35.4)
Post-DCB acute thrombosis		0
Outcome, successful		47 (97.9)

ACS, acute coronary syndrome; DCB, drug-coated balloon; NC, non-compliant; SAP, stable angina pectoris; SC, semi-compliant; USAP, unstable angina pectoris; LAD, left anterior descending; LCX, left circumflex artery; OM, obtuse margin; RCA, right coronary artery; PL, posterolateral.

a fibrocalcific plaque structure with high recoil potential and limited acute gain,[12] and a small vessel diameter that increases the risk of restenosis and stent thrombosis.[13] Recent

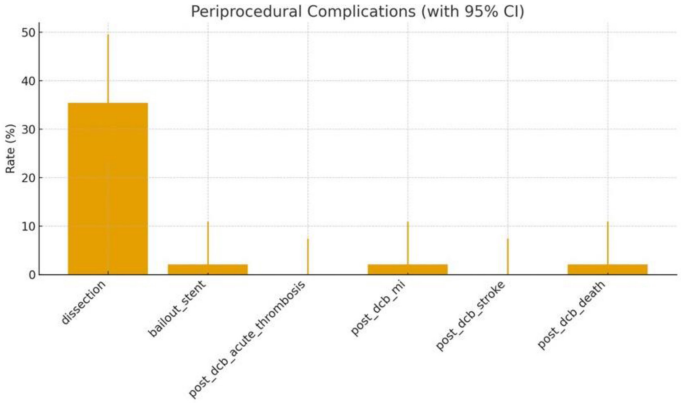

Figure 1. Overall procedural success rate of drug-coated balloon (DCB) angioplasty in isolated side branch lesions.

Table 5. Post–Drug-Coated Balloon Follow-Up

Variables	n (%)
Post-DCB CAG	8 (16.7)
Post-DCB angina	6 (12.5)
Post-DCB death	1 (2.1)
Post-DCB stroke	0
Post-DCB MI	1 (2.1)

CAG, coronary angiography; DCB, drug-coated balloon; MI, myocardial infarction.

registry-based studies have shown that lesions involving only the SB ostium (Medina 0.0.1) were associated with the worst 1-year outcomes compared with other subtypes.[14] This finding highlights the ongoing challenge of determining the optimal PCI strategy for isolated SB lesions.

In previous studies evaluating Medina 0.0.1 lesions treated with either stent implantation or medical therapy, MACE rates were found to be high. A recent meta-analysis comparing 1-stent and 2-stent strategies in Medina 0.0.1 lesions found similar rates of MACE between the 2 techniques.[15] Nonetheless, the overall risk of adverse events remains relatively high. Brueck et al[16] reported that interventional treatment of isolated diagonal branch lesions resulted in higher rates of rehospitalization and reintervention for angina

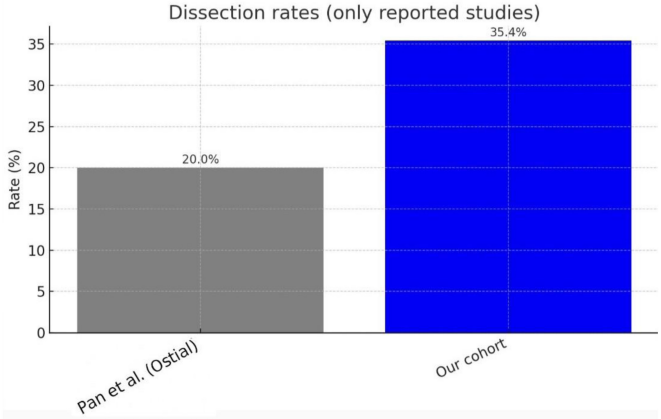

Figure 2. Distribution of dissection rates reported in different studies.

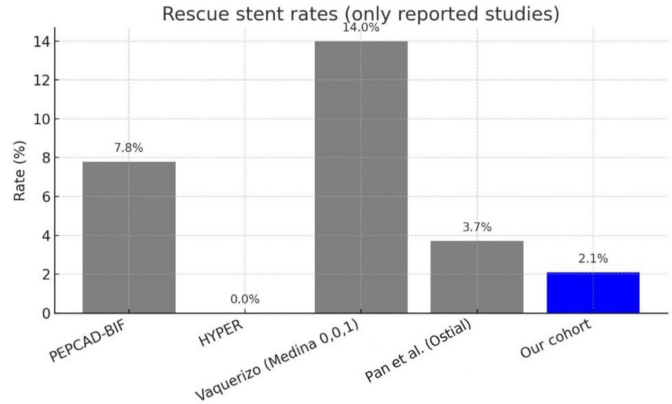

Figure 3. Comparison of bailout stent rates across published trials.

compared with conservative therapy.These findings suggest that patient selection may be more crucial than the specific PCI technique used.

Certain complications may occur in patients undergoing DCB treatment. Regarding type A-B coronary dissections, the incidence in this study (35.4%) was comparable to that reported by Gitto et al[17] (39.1%).In ostial-focused studies by Pan et al,[18] only flow-limiting dissections (type C or higher) were reported, with an incidence of approximately 20%. Most dissections are clinically insignificant and heal spontaneously. The inherent fragility of ostial and bifurcation regions predisposes them to dissection. Two-stent strategies may further increase the risk of SB injury, reinforcing the importance of meticulous lesion preparation and DCB sizing (Figure 2). When non-flow-limiting dissections remain after DCB treatment, the majority of dissections heal biologically over time without any significant adverse impact on late lumen loss or target vessel failure/MACE. Advanced optical coherence tomography (OCT) studies support the notion that DCB promotes healing at the dissection site and reduces neointimal hyperplasia. In this study, 35.4% of dissections that occurred were not flow-limiting, therefore not treated with a stent.[17,19]

In cases of flow-limiting dissection, treatment with bailout stenting may be necessary. In this cohort, the bailout stent rate was 2%, which is lower than that reported in the DCB-BIF (~4%) and PEPCAD-BIF (7.8%) trials.[20,21] No bailout stenting was reported in the HYPER study, whereas the Vaquerizo series reported a rate of 14%.[22,23] Thus, the current findings fall within the lower-to-mid range of reported rates in the literature (Figure 3). Another potential complication, periprocedural myocardial infarction, occurred at a lower rate in this study (2%) than in DCB-BIF (4.6%) and DEBUT (6.8%), and it was similar to that observed in HYPER (2%).[21,23] Evidence suggests that optimal lesion preparation before DCB angioplasty reduces MACE and spontaneous MI compared with uncoated balloon angioplasty.[20]

When these results—in the absence of acute thrombosis, 97.9% procedural success, and low adverse event rates—are considered alongside these data, DCB angioplasty appears to be a safe and feasible approach for Medina 0.0.1 lesions. The present findings align with those of Erdoğan et al[24], who treated major branches of the left main trunk with ostial DCB. Furthermore, this study obtained similar results to the PICCOLETO II – Side Branch Sub-Study, BASKET-SMALL 2 Sub-Analysis, DEBSIDE Study, and PEPCAD-BIF Trial, all of which evaluated DCB treatment outcomes in isolated SB occlusions.[9,21,25,26]

Study Limitations

This study has several limitations. This study is designed as a hypothesis-generating retrospective observational cohort evaluating procedural safety and feasibility rather than a comparative efficacy trial. It is a retrospective, single-center study with a limited number of patients and no control group. The absence of intravascular imaging (Intravascular Ultrasound-OCT) and pre/post-procedure physiological evaluation (fractional flow reserve) is another limitation. Furthermore, direct comparison of angiographic outcomes was not possible because routine follow-up angiography was not performed. Despite these constraints, the available follow-up data provide meaningful insight into the safety and feasibility of DCB angioplasty in this specific lesion subset.

CONCLUSION

This single-center, retrospective study with a small sample size demonstrates that DCB angioplasty can be performed safely and feasibly in isolated SB lesions, with low complication rates. Bailout stenting and periprocedural MI were uncommon, and most dissections were minor. Proper lesion preparation and patient selection are key to procedural success. Larger, prospective studies with longer follow-up are needed to validate these results.

Ethics Committee Approval: Ethical approval was obtained from the Ethics Committee of Lokman Hekim University (University of Health Sciences) (Approval No.: 2025/148; Date: May 30, 2025).

Informed Consent: Written informed consent was obtained from the patients who agreed to take part in the study.

Peer-review: Externally peer-reviewed.

Artificial Intelligence: The authors declare that they did not use artificial intelligence (AI)-supported technologies (such as Large Language Models [LLM], chatbots, or visual generators) in the production of the work.

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