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Impact of Side Branch Predilatation on Provisional Bifurcation Percutaneous Coronary Intervention Outcomes: Insights From PROGRESS-BIFURCATION Registry

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ABSTRACT

Background: Whether side branch (SB) predilatation should be performed in patients undergoing bifurcation percutaneous coronary interventions (PCI) remains controversial.

Methods: We performed an observational cohort study across six international centers from 2013 to 2024, as part of the Prospective Global Registry of PCI in Bifurcation Lesions (PROGRESS-BIFURCATION). We analyzed procedural characteristics and in-hospital outcomes of patients undergoing provisional bifurcation PCI with and without SB lesion predilatation. Significant SB lesions were defined as those with ≥50% diameter stenosis. Multivariable adjusted hazard ratios (aHR) with 95% confidence intervals [CI] were calculated using mixed effects Cox regression.

Results: Of 1042 lesions treated with provisional bifurcation PCI, 428 (41.1%) had significant SB lesions (true bifurcation lesions). Among these, 143 (33.4%) underwent predilatation. Lesions that underwent SB predilatation had longer SB lesion length (median 10.0 mm [IQR 5.0–10.0] vs. 5.0 mm [IQR 5.0–10.0], $p = 0.001$) and more SB diameter stenosis (median 90% [IQR 70%–95%] vs. 70% [IQR 60–90]). Technical success (95.1% vs. 87.7%; $p = 0.015$) and procedural success (93.7% vs. 82.8%; $p = 0.003$) were more common in the SB predilatation group, although the rates of crossover to a 2-stent technique were also higher in the SB predilatation group (23.1% vs. 10.9%; $p < 0.001$). The incidence of procedural complications (22.3% vs. 21.3%, $p = 0.897$) and in-hospital major adverse cardiovascular events (2.4% vs. 6.4%, $p = 0.097$) was similar between the groups.

Conclusion: In provisional bifurcation PCI of true bifurcation lesions, SB predilatation was performed in approximately one-third and was associated with higher technical and procedural success, higher rates to crossover to a 2-stent technique, and similar incidence of in-hospital and long-term follow-up outcomes.

1 | Introduction

Provisional stenting using only one stent in the main vessel (MV) is the preferred strategy in most bifurcation percutaneous coronary interventions (PCIs) [1–3]. However, side-branch (SB) compromise can occur in up to 15–20% of the cases [4, 5]. Predilatation of the SB may decrease the risk of SB compromise and facilitate SB recrossing; however, the benefit of SB

predilatation in provisional bifurcation PCI is still under debate [6]. We compared the procedural, in-hospital, and long-term outcomes of SB predilatation versus no SB predilatation in provisional bifurcation PCI in a multicenter bifurcation registry.

2 | Methods

The study patients were part of a global, observational, retrospective and prospective cohort study across 6 centers in the United States, Russia, and Turkey between 2013 and 2024 (different centers joined at different times), as part of the Prospective Global Registry of PCI in Bifurcation Lesions (PROGRESS-BIFURCATION, NCT05100992). In patients undergoing provisional bifurcation PCI for true bifurcation lesions, outcomes were compared between those with versus those without SB predilatation. Study data were collected and managed using REDCap (Research Electronic Data Capture) electronic data capture tools hosted at the Minneapolis Heart Institute Foundation. The study was approved by the institutional review board of each center.

2.1 | Definitions

Bifurcation lesions were defined as coronary artery stenoses occurring adjacent to and/or involving the origin of a significant (>1.5 mm) SB [7]. True bifurcation lesions were defined as those with SB stenosis (>50%) as well as significant MV (>50%, Medina classification 1.1.1, 1.0.1, or 0.1.1) lesions. Assessment of coronary artery stenosis was based on invasive coronary angiography visual estimation by the operator.

Provisional stenting was performed according to the European Bifurcation Club (EBC) consensus document [8]. Technical success was defined as the achievement of <30% residual diameter stenosis and thrombolysis in myocardial infarction (TIMI) 3 flow in both MV and SB (when SB PCI was attempted). Procedural success was defined as the achievement of technical success without in-hospital major adverse cardiac events (MACE). In-hospital MACE was defined as the composite of all-cause mortality, myocardial infarction (MI), urgent repeat revascularization with either PCI or coronary artery bypass graft (CABG) surgery, and cardiac tamponade requiring either pericardiocentesis or surgery before hospital discharge. Periprocedural MI was defined using the Third Universal Definition of MI (type 4a MI), that is, elevation of cardiac troponin values associated with either (1) symptoms suggestive of myocardial ischemia, or (2) new ischemic electrocardiographic changes or new left bundle branch block, or (3) angiographic loss of patency of a major coronary artery, or (4) imaging demonstration of new loss of viable myocardium or new regional wall motion abnormality [9]. Long-term MACE was defined as composite of all-cause mortality, MI, stroke, target-vessel revascularization with either PCI or CABG.

2.2 | Statistical Analysis

Categorical variables were expressed as *n* (percentages) and were compared using the Pearson's chi-square test. Continuous variables are presented as mean ± standard deviation or as median (interquartile range) and were compared using the independent-samples *t*-test for normally distributed variables and the Mann−Whitney *U* test for non-parametric variables, as appropriate. The effect of SB predilatation on technical success and periprocedural or in-hospital MACE was examined using univariable logistic regression; thereafter, multivariable adjustment was performed by entering variables exhibiting significant univariable association ($p < 0.10$) in the models. Variables were selected based on clinical/angiographic significance.

Long-term outcomes were based on Kaplan−Meier estimates in time-to-first-event analysis with log-rank test and mixed effects Cox proportional hazard ratios (HR). HRs were adjusted for confounding using a multivariable analysis including baseline and angiographic characteristics. All statistical analyses were performed using R Statistical Software, version 4.4.0 (R Foundation for Statistical Computing, Vienna, Austria). A *p* value of <0.05 was considered statistically significant (Figure 1).

3 | Results

Out of 1549 bifurcation PCIs (1333 patients), 1042 (67.3%) were performed using the provisional technique, of which 428 (41.1%) were performed in true bifurcations and were included in the present analysis. SB predilatation was performed in 143 of 428 lesions (33.4%). Patients in the SB predilatation group had a lower prevalence of hypertension, lower left ventricular ejection fraction, and a higher prevalence of peripheral arterial disease (Table 1). Table 2 shows angiographic characteristics of the study lesions and procedural techniques. The SB predilatation group had higher SB diameter stenosis and longer SB lesion length, with 126 lesions (88.1%) exhibiting severe stenosis in the SB (defined as ≥ 70% SB stenosis).

As shown in Figure 1, SB predilatation was associated with higher rates of technical (95.1% vs. 87.7%; $p = 0.015$) and procedural (93.7% vs. 82.8%; $p = 0.003$) success. Logistic regression analysis revealed that SB predilatation was independently associated with technical (OR 3.38; 95% CI 1.15−12.7; $p = 0.04$) and procedural (OR 5.53; 95% CI 1.78−17.20; $p = 0.003$) success. Crossover to a 2-stent technique was higher in the SB predilatation group (23.1 vs. 10.9%; $p < 0.001$). As shown in Table 3, in-hospital complications and SB occlusion rates were similar between groups, as was procedural time (76.4 [54.9−107.3] vs. 75.0 [49.0−113.6] min; $p = 0.318$) and fluoroscopic time (20.6 [13.9−29.2] vs. 19.6 [12.0−33.1] min; $p = 0.803$) times, air kerma radiation dose (1.45 [1.03−2.05] vs. 1.21 [0.78−2.03] gray; $p = 0.074$), and contrast volume (180 [140−210] vs. 160 [51−103] mL; $p = 0.557$).

In a subgroup analysis excluding patients with crossover to a 2-stent technique, SB predilatation remained associated with higher technical (93.6% vs. 86.2%; $p = 0.04$) and procedural (90.6% vs. 81.6%; $p = 0.04$) success, and similar incidence of in-hospital complications and long-term follow-up MACE. These results are displayed in Supporting Information S1: Tables 1−3.

All steps of the provisional technique according to EBC consensus were more frequently performed in patients who

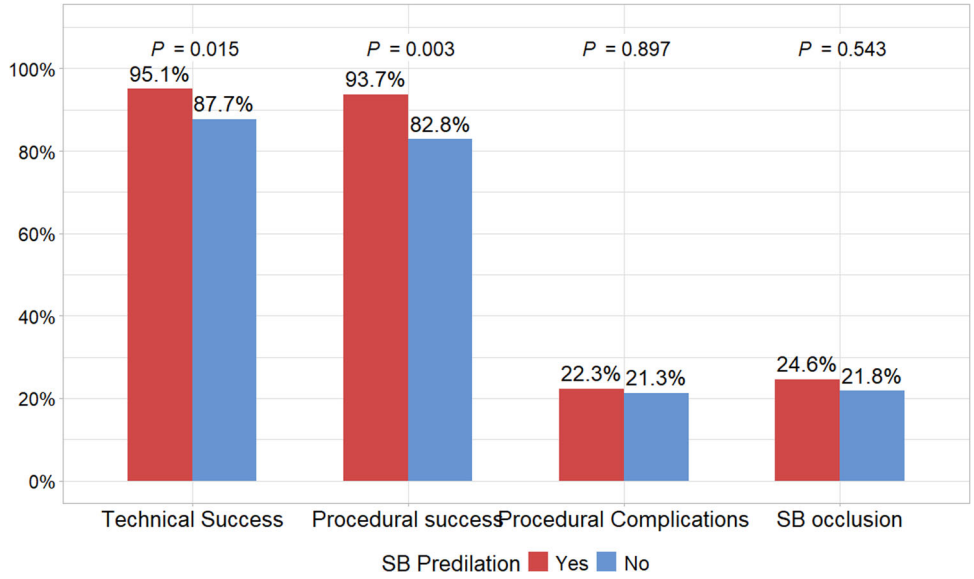

FIGURE 1 | Procedural outcomes with SB predilatation versus non-SB predilatation provisional bifurcation PCI.

TABLE 1 | Comparison of baseline clinical characteristics of patients who underwent SB predilatation versus non-SB predilatation in provisional bifurcation PCI.

Variables	No SB predilatation ($n = 251$)	SB predilatation ($n = 125$)	p value
Age (years)	66.54 ± 11.70	65.98 ± 12.63	0.543
Gender, male	72.1% (176)	83.9% (104)	**0.013**
BMI	30.03 ± 6.23	29.40 ± 5.35	0.495
Hypertension	80.7% (197)	69.4% (86)	0.014
Dyslipidemia	77.9% (190)	78.2% (97)	0.938
Smoking, current	16.7% (42)	20.8% (26)	0.334
Diabetes mellitus	33.3% (81)	33.9% (42)	0.918
Left ventricular ejection fraction (%)	55.46 ± 12.41	51.35 ± 14.32	**0.014**
Family history of CAD	23.4% (55)	21.7% (26)	0.712
Heart failure	20.2% (49)	23.4% (29)	0.475
Prior CABG	14.8% (36)	16.9% (21)	0.585
Prior PCI	43.0% (105)	40.3% (50)	0.619
Prior MI	36.9% (90)	33.3% (41)	0.503
Cerebrovascular disease	11.5% (28)	11.3% (14)	0.947
Peripheral arterial disease	4.9% (12)	12.1% (15)	**0.013**
CAD presentation			0.397
Stable angina	29.5% (71)	28.7% (35)	
Unstable angina	21.6% (52)	16.4% (20)	
NSTEMI	25.7% (62)	30.3% (37)	
STEMI	12.9% (31)	18.0% (22)	
No symptoms	10.0% (24)	5.7% (7)	
Nonischemic sypmtoms	0.4% (1)	0.8% (1)	
Baseline creatinine (mg/dL)	1.00 [0.81, 1.22]	0.97 [0.80, 1.19]	0.141

Note: Bold values indicate statistically significant.
Abbreviations: CABG = coronary artery bypass graft, CAD = coronary artery disease, MI = myocardial infarction, NSTEMI = non-ST segment elevation myocardial infarction, PCI = percutaneous coronary intervention, STEMI = ST segment elevation myocardial infarction.

TABLE 2 | Angiographic comparison of SB predilatation vs non-SB predilatation in provisional bifurcation PCI lesions.

Variables	No SB predilatation ($n = 285$)	SB predilatation ($n = 143$)	p value
LM stenosis (%)	0.00 [0.00, 30.00]	5.00 [0.00, 47.50]	0.237
Proximal LAD stenosis (%)	70.00 [30.00, 90.00]	70.00 [30.00, 90.00]	0.505
Mid-distal LAD, diagonal stenosis (%)	80.00 [50.00, 95.00]	90.00 [71.25, 99.00]	0.009
CIRC, OM, LPDA, LPL branches stenosis (%)	70.00 [30.00, 90.00]	70.00 [30.00, 95.00]	0.323
RCA, RPDA, RPL branches stenosis (%)	70.00 [30.00, 100.00]	60.00 [30.00, 100.00]	0.559
Ostial lesion (within 5 mm of aortocoronary ostium)	6.5% (18)	7.8% (11)	0.627
Proximal main vessel			0.632
LMCA	17.6% (50)	18.2% (26)	
LAD	51.1% (145)	52.4% (75)	
RCA	13.0% (37)	9.1% (13)	
Circumflex	16.5% (47)	19.6% (28)	
Bypass graft	1.8% (5)	0.7% (1)	
Proximal main vessel diameter (mm)	3.30 [3.00, 3.75]	3.30 [3.00, 3.75]	0.552
Proximal main vessel lesion length (mm)	8.00 [5.00, 10.00]	8.00 [5.00, 10.00]	0.944
Proximal main vessel diameter stenosis (%)	80.00 [60.00, 90.00]	80.00 [60.00, 95.00]	0.586
Distal main vessel diameter (mm)	3.00 [2.50, 3.18]	3.00 [2.75, 3.00]	0.529
Distal main vessel lesion length (mm)	10.00 [5.00, 15.00]	10.00 [5.00, 13.00]	0.365
Proximal main vessel tortuosity			0.741
Straight (< 70 degrees, 1 Bend)	56.1% (160)	61.5% (88)	
Slight (> 70 degrees, 1 Bend)	23.5% (67)	21.0% (30)	
Moderate (2 Bends > 70 degrees or 1 Bend > 90 degrees)	16.5% (47)	14.7% (21)	
Severe (2 Bends > 90 degrees or 1 Bend > 120 degrees)	3.9% (11)	2.8% (4)	
Side branch diameter (mm)	2.25 [2.00, 2.50]	2.50 [2.10, 2.73]	0.085
Side branch lesion length (mm)	5.00 [5.00, 10.00]	10.00 [5.00, 10.00]	**0.001**
Distal main vessel diameter stenosis (%)	80.00 [70.00, 90.00]	90.00 [70.00, 95.00]	0.091
Calcification			0.480
None	28.8% (82)	28.7% (41)	
Mild (Spots)	33.0% (94)	29.4% (42)	
Moderate (≤ 50% Reference Lesion Diameter)	18.9% (54)	25.2% (36)	
Severe (> 50% Reference Lesion Diameter)	19.3% (55)	16.8% (24)	
Medina classification			0.291
1,1,1	66.3% (189)	71.3% (102)	
1,1,0	4.2% (12)	2.1% (3)	
1,0,1	8.4% (24)	5.6% (8)	
0,1,1	17.5% (50)	16.8% (24)	
1,0,0	0.4% (1)	0.0% (0)	
0,1,0	1.4% (4)	0.0% (0)	
0,0,1	1.8% (5)	4.2% (6)	
Side branch diameter stenosis (%)	70.00 [60.00, 90.00]	90.00 [75.00, 95.00]	**< 0.001**
Pretreatment IVUS/OCT	16.5% (47)	17.7% (25)	0.748

Note: Bold values indicate statistically significant.
Abbreviations: CIRC = circumflex, IQR = interquartile range; IVUS = intravascular ultrasound, LAD = left anterior descending, LM = left main, LPDA = left posterior descending artery, LPL = left posterolateral, OCT = optical coherence tomography, OM = obtuse marginal, RCA = right coronary artery, RPDA = right posterior descending artery, RPL = right posterolateral.

TABLE 3 | Comparison of procedural outcomes and complications of patients who underwent SB predilatation versus non-SB predilatation provisional bifurcation PCI.

Variables	No SB predilatation ($n = 251$)	SB predilatation ($n = 125$)	p value
Provisional to 2-stent conversion	10.9% (31)	23.1% (33)	**< 0.001**
MACE	6.4% (16)	2.4% (3)	0.097
Death	3.2% (8)	0.0% (0)	0.056
Acute MI	1.6% (4)	0.8% (1)	> 0.999
Repeat PCI	1.6% (4)	0.8% (1)	> 0.999
Stroke	1.2% (3)	0.8% (1)	> 0.999
Emergency CABG	0.4% (1)	0.0% (0)	> 0.999
Bleeding	0.4% (1)	0.0% (0)	> 0.999
Side branch occlusion	21.8% (54)	24.6% (30)	0.543
Equipment loss	0.0% (0)	0.8% (1)	0.332
Pericardiocentesis	0.4% (1)	0.0% (0)	> 0.999
Perforation	2.4% (6)	1.6% (2)	> 0.999
Dissection	3.6% (9)	2.4% (3)	0.758
Thrombus	0.8% (2)	0.8% (1)	> 0.999
Tamponade	0.4% (1)	0.0% (0)	> 0.999
Contrast volume, mL	160.00 (120.00, 220.00)	180.00 (140.00, 210.00)	0.318
Fluoroscopy time	19.60 (12.00, 33.10)	20.60 (13.90, 29.20)	0.803
Air Kerma radiation dose (Gray)	1.21 (0.78, 2.03)	1.45 (1.03, 2.05)	0.074
Procedure time	75.00 (49.00, 113.55)	76.44 (54.95, 107.33)	0.557

Note: Bold values indicate statistically significant.
Abbreviations: ACABG = coronary artery bypass graft, MACE = major adverse cardiac events, MI = myocardial infarction, PCI = percutaneous coronary intervention.

received SB predilatation. SB jailed wiring (e.g., wire jailing at the SB before MV stenting) was performed in 83.5% of these patients, compared with 49.2% in patients without SB predilatation. Logistic regression analysis revealed that the use of a jailed SB wire was also independently associated with higher technical (OR 4.03; 95% CI 1.86−9.29; $p < 0.001$) and procedural success (OR 2.27; 95% CI 1.14−4.59; $p = 0.02$). After MV stenting, SB balloon inflation (59.9% vs. 46.3%; $p = 0.02$) and the use of kissing balloon inflation (40.8% vs. 28.1%; $p = 0.02$) were more frequently performed in the SB predilatation group (Figure 2).

During a median follow-up of 1095 days, the SB predilatation group had similar rates of MACE (33.0% vs. 31.0%; $p = 0.727$), all-cause mortality (17.5% vs. 15.0%; $p = 0.577$), CABG (1.0% vs. 1.1%; $p = 0.999$), stroke (4.9% vs. 2.7%; $p = 0.334$), MI (9.7% vs. 4.8%; $p = 0.107$), and target-vessel revascularization (8.7% vs. 13.9%; $p = 0.196$). These results are displayed in Table 4. After adjusting for confounding variables, SB predilatation was not associated with higher long-term MACE (aHR 1.44; 95% CI 0.83−2.41; $p = 0.19$; Figure 2).

4 | Discussion

In patients undergoing provisional bifurcation PCI of true bifurcation lesions, SB predilatation was performed in about one-third of the cases. Compared with those without SB predilatation, SB predilatation patients had (a) higher technical and procedural success; (b) higher rates of crossover to a 2-stent technique; and (c) similar rates of in-hospital and long-term follow-up outcomes.

The benefit of SB predilatation in patients with true bifurcation lesions remains debatable. Pan et al. randomized 372 patients with true bifurcation lesions to provisional techniques with or without SB predilatation [10]. This study found similar clinical outcomes and SB stenting rates, but higher TIMI flow in the SB post-PCI with SB predilatation. In contrast, in a small randomized controlled trial of 60 patients by Peighambari et al. there was numerically higher occurrence of coronary dissection in the SB predilatation group compared with the non-predilatation group, although this was not statistically significant [11]. A meta-analysis of eight studies including 2860 patients showed that SB predilatation was associated with similar long-term MACE, SB dissection, and intraprocedural SB occlusion [12].

In our cohort, patients undergoing SB predilatation had more severe disease in the SB, with higher degrees of stenosis and longer lesions. Of note, 88.1% of these lesions had SBs stenosis equal or higher than 70%, leading to SB predilatation to prevent SB compromise as per operator discretion. Several techniques have been proposed to prevent SB compromise and reduce periprocedural risk in bifurcation PCI, such as jailed wire, SB predilatation, and upfront 2-stent techniques. Our study showed that SB predilatation was independently associated with higher technical and procedural success, likely because it increases the likelihood of maintaining blood flow in the SB after MV stenting.

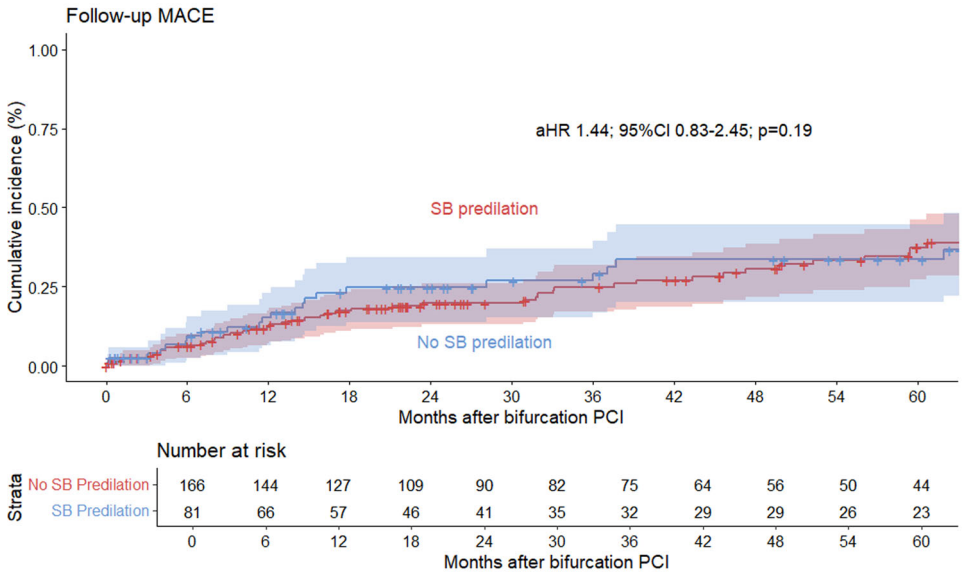

FIGURE 2 | Long-term MACE of SB predilatation versus non-SB predilatation in provisional bifurcation PCI.

TABLE 4 | Comparison of clinical outcomes during long-term follow-up of patients who underwent SB-predilatation versus non-SB predilatation provisional bifurcation PCI.

Variables	No SB predilatation ($n = 187$)	SB predilatation ($n = 103$)	p value
Follow-up MACE	31.0% (58)	33.0% (34)	0.727
CABG	1.1% (2)	1.0% (1)	> 0.999
Death	15.0% (28)	17.5% (18)	0.577
Stroke	2.7% (5)	4.9% (5)	0.334
Spontaneous MI	4.8% (9)	9.7% (10)	0.107
Follow-up target vessel revascularization	13.9% (26)	8.7% (9)	0.196

Abbreviations: CABG = coronary artery bypass graft, MACE = major adverse cardiac events; MI = myocardial infarction.

SB predilatation was associated with similar rates of procedural complications, including coronary dissection, compared with patients without SB predilatation, but higher rates of crossover to a 2-stent technique. The COronary BIfurcation Stent (COBIS) registry also reported higher rates of final kissing-balloon inflation and 2-stent technique conversion in the SB predilatation group [13–15]. This could explain the higher technical and procedural success in the SB group, although these results remained consistent even when excluding patients who crossed over to a 2-stent technique. Our follow-up analysis did not show any difference in the incidence of MACE between groups, even after adjusting for confounding factors.

The benefits of SB predilatation were particularly evident in patients with lesions at higher risk for SB compromise, such as SB ostial lesions, severe SB calcification and stenosis, and long SB disease length [16]. Given the risk of SB compromise during provisional stenting and the high incidence of cross-over to a 2-stent technique in patients undergoing SB predilatation, systematic SB wiring offers significant advantages. It facilitates SB rescue, particularly in cases where SB TIMI flow is <3 following provisional stenting, and simplifies the transition to 2-stent strategy in scenarios such as persistent severe SB stenosis or SB dissection after predilatation.

Our study has limitations. The PROGRESS-Bifurcation is an observational registry with all inherent limitations. SB predilatation was performed more frequently in patients with more severe SB lesions per operator discretion. In patients with SB intermediate lesions (50−69%), the benefits of SB predilatation remain uncertain. Despite multivariable analysis adjustments, confounding and reporting bias are possible. There was no independent adjudication of clinical events or core laboratory assessment of the study angiograms. The included procedures were performed at centers with experienced PCI operators, which may limit the generalizability of the results to centers with less experience.

5 | Conclusion

In provisional bifurcation PCI of true bifurcation lesions, SB predilatation was performed in approximately one-third of SB lesions and associated with higher technical and procedural success, higher rates to crossover to a 2-stent technique, and similar incidence of in-hospital and long-term follow-up adverse outcomes.

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Disclosure

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Conflicts of Interest

The authors declare no conflicts of interest.

Data Availability Statement

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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Supporting Information

Additional supporting information can be found online in the Supporting Information section.