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Efficacy of Jailed Semi-Inflated Balloon Technique in Maintaining Side Branch Patency during Percutaneous Coronary Intervention-A Novel Approach in Bifurcation Lesions

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ABSTRACT

Background: Bifurcation lesions offer a major PCI complexity due to their involvement of the main vessel in addition to the side branch with considerable risk to side branch thrombosis. **Objective:** To evaluate the efficacy of the jailed semi-inflated balloon technique (JSBT) in maintaining side branch (SB) patency during percutaneous coronary intervention (PCI) for coronary bifurcation lesions. **Material and methods:** This Cross-sectional study was conducted at the Department of Cardiology, Armed Forces Institute of Cardiology/National Institute of Heart Disease (AFIC/NIHD), Rawalpindi from May 2024 to Dec 2024. Data were collected through the non-probability consecutive sampling technique. A detailed medical history was taken, during which baseline characteristics and comorbidities were meticulously documented. **Results:** Data were collected from 118 patients according to criteria of the study. The mean age in Group I (JSBT utilized) was 59.8 ± 9.8 years, while in Group II (JSBT not utilized) it was 58.7 ± 11.2 years. Gender distribution was similar between the groups, with 64.4% males and 35.6% females in Group I, and 62.7% males and 37.3% females in Group II. Mean number of vessels involved was 2.3 ± 0.6 in Group I (JSBT utilized) and 2.2 ± 0.5 in Group II (JSBT not utilized), with no significant difference (p=0.47). The culprit vessel was most commonly the left anterior descending (LAD) artery in both groups, accounting for 45.8% in Group I and 47.5% in Group II (p=0.87). **Conclusion:** This study concludes that the Jailed Semi-Inflated Balloon Technique (JSBT) is a highly effective method for maintaining side branch (SB) patency during percutaneous coronary intervention (PCI) in bifurcation lesions.

INTRODUCTION

Bifurcation lesions in coronary arteries, occurring in 8% to 15% of percutaneous coronary interventions (PCIs),[1] pose challenges as they are linked to a heightened risk of adverse cardiac events and inferior long-term outcomes compared to non-bifurcation lesions.[2-4] Thus, the critical factor in the management of these lesions relates to defining an appropriate approach in a given case.[5] Some lesions require two stents; however, RCT supports lesser (provisional) stenting compared to more complicated techniques (culotte, crush, and T-stenting) using DESs, with superior results and fewer long-term mortalities.[6-8] However, main interventional cardiologists look at the provisional technique in a negative aspect as far as complex bifurcation lesions are concerned because the possibility of side branch (SB) loss during main vessel (MV) stenting is offered.[9]
Other issues that lead to SB occlusion, and therefore, make the restoration of flow difficult post-MV stenting in most instances include carina and plaque shifts, ostial conformational changes, and other stent-related problems.[10]The jailed-balloon technique (JBT), which is an improvement of the original provisional stenting approach was developed to solve this[11]. Burzotta et al.,[12] did a bench test report and the first clinical experience on jailed balloon protection. They presented it as a new approach to maintain SB patency during provisional MV stenting in situations where there is a potential danger of side branch retracts. In the multicenter TULIPE study, the TLR rate was significantly higher when a jailed wire was not used. In JBT, an uninflated balloon is placed underneath the stent struts for the purpose of occupying the spatial region of carina or plaque shift in the SB ostium.[13] Nevertheless, JBT does not afford an absolute safeguard against SB occlusion. The jailed semi-inflated balloon technique (JSBT) is another therapeutic strategy for improved SB safeguard. In JSBT, the SB balloon is inflated at a pressure less than 3 atmospheres.[14] This study describes the clinical

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experience with JSBT to show that this technique is efficient for maintaining higher reliability of the SB ostium patency and requiring slightly higher pressure (4.8±2.0 atm). There is little data to substantiate the findings as to why JSBT provides better long-term results aimed at maintaining SB patency. Percutaneous coronary intervention (PCI) is an effective approach to managing prevalent coronary artery disease, especially in patients with multiple and complex lesions including those at bifurcations.[15] Bifurcation lesions offer a major PCI complexity due to their involvement of the main vessel in addition to the side branch with considerable risk to side branch thrombosis. Compared to traditional approaches, the use of filters does not guarantee optimal side branch post-filter patency, which may become detrimental to patients. Recently, the jailed balloon technique has developed as a new strategy to avoid the side branch by using stent deployment in the main vessel. However, extensions of this method have been researched further to increase the resulting effect.[16] One such modification is the *Jailed Semi-Inflated Balloon Technique*, which involves deploying a partially inflated balloon in the side branch during stenting in the main vessel. This novel approach aims to maintain side branch patency without compromising the efficacy of stent placement in the main vessel.[15]

Objective

To evaluate the efficacyof the jailed semi-inflated balloon technique (JSBT) in maintaining side branch (SB) patency during percutaneous coronary intervention (PCI) for coronary bifurcation lesions.

MATERIAL AND METHODS

This Cross-sectional study was conducted at the Department of Cardiology, Armed Forces Institute of Cardiology/National Institute of Heart Disease (AFIC/NIHD), Rawalpindi from May 2024 to Dec 2024. Data were collected through the Non-probability consecutive sampling technique.

Sample Size

The sample size was calculated using the WHO sample size calculator, considering 8.4% prevalence of SB occlusion in bifurcation lesions, and maintaining a 95% confidence level with a 5% margin of error. The calculated sample size was found to be n=118.[16]

Sample Selection

Inclusion Criteria:

- Patients aged 25-90 years of age
- Patients with NSTE-ACS, Unstable Angina, and Chronic Coronary Syndrome
- Patients with coronary bifurcation lesions identified during percutaneous coronary interventions (PCIs)
- Regarding vessel size, for the MV a minimum vessel size of 2.5 mm was necessary, while the SB required a minimum vessel size of 2.25 mm, as assessed angiographically.

Exclusion criteria:

- Patients with a history of cardiopulmonary resuscitation and cardiogenic shock
- STEMI patients
- Lesions exhibiting proximal tortuosity or heavily calcified lesions
- Presence of protected left main disease
- Complex Bifurcation lesions
- Left Main Stem Bifurcation lesions

Data Collection Procedure

After approval from the Institutional Ethical Review Board, patients who fulfilled the inclusion and exclusion criteria were selected. Written informed consent was taken (see attached consent form). All the data were collected in a Proforma (attached as Annex). Variables such as age, gender, number of vessels involved, and culprit vessel were noted. A detailed medical history was taken, during which baseline characteristics and comorbidities were meticulously documented. The Medina classification was applied to assess each coronary bifurcation lesion. Patients were categorized into two groups:
Group I - JSBT utilized
Group II - JSBT not used.
Post-PCI vessel patency was assessed based on TIMI flow. Patients were monitored in-hospital for the next 24 hours for peri-procedural MI by measuring troponin-I and performing an ECG in case of chest pain.

Data Analysis

Data were entered and analyzed using the Statistical Package for the Social Sciences (SPSS) version 23. Quantitative data such as age and number of vessels were presented as Mean±SD. Qualitative data, including gender, comorbidities (diabetes, hypertension, CKD with GFR greater than 30 ml/min, current smoker), and mortality, were presented as frequencies and percentages. The Chi-square/Fisher Exact test was applied to compare SB patency between the study groups and to find the association of categorical variables with procedural success (SB patency). A p-value ≤0.05 was considered significant.

RESULTS

Data were collected from 118 patients according tocriteria of the study.The mean age in Group I (JSBT utilized) was 59.8 ± 9.8 years, while in Group II (JSBT not utilized) it was 58.7 ± 11.2 years. Gender distribution was similar between the groups, with 64.4% males and 35.6% females in Group I, and 62.7% males and 37.3% females in Group II. Co-morbidities such as diabetes, hypertension, chronic kidney disease (CKD), and smoking status were also comparable between the groups, with no significant differences noted in diabetes (39% vs 37.3%), hypertension (47.5% vs 44.1%), CKD (8.5% vs 6.8%), and current smoking (33.9% vs 32.2%).

Table 1

Demographic and Baseline Characteristics

Variable		Group I (JSBT Utilized) (n=59)	Group II (JSBT Not Utilized) (n=59)
Mean Age (years)		59.8 ± 9.8	58.7 ± 11.2
Gender	Male (%)	38 (64.4%)	37 (62.71%)
	Female (%)	21 (35.59%)	22 (37.28%)
Co-morbidities	Diabetes (%)	23 (39.0%)	22 (37.3%)
	Hypertension (%)	28 (47.5%)	26 (44.1%)
	CKD (%)	5 (8.5%)	4 (6.8%)
	Current Smoker (%)	20 (33.9%)	19 (32.2%)

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Mean number of vessels involved was 2.3 ± 0.6 in Group I (JSBT utilized) and 2.2 ± 0.5 in Group II (JSBT not utilized), with no significant difference (p=0.47). The culprit vessel was most commonly the left anterior descending (LAD) artery in both groups, accounting for 45.8% in Group I and 47.5% in Group II (p=0.87). The right coronary artery (RCA) was the culprit in 37.3% of cases in Group I and 33.9% in Group II (p=0.77), while the left circumflex artery (LCX) was involved in 16.9% of Group I and 18.6% of Group II cases (p=0.79). Medina 1,1,1 lesion were similarly distributed between Group I (37.3%) and Group II (33.9%) (p=0.80).

Table 2

Lesion and Procedural Characteristics

Variable	Group I (JSBT Utilized) (n=59)	Group II (JSBT Not Utilized) (n=59)	p-value
Mean Number of Vessels Involved	2.3 ± 0.6	2.2 ± 0.5	0.47
Culprit Vessel			
- LAD (%)	27 (45.8%)	28 (47.5%)	0.87
- RCA (%)	22 (37.3%)	20 (33.9%)	0.77
- LCX (%)	10 (16.9%)	11 (18.6%)	0.79
Medina 1,1,1 Lesion (%)	22 (37.3%)	20 (33.9%)	0.80

TIMI grade 3 flow (normal flow) was achieved in 93.2% of patients in Group I versus 71.2% in Group II (p=0.002). TIMI grade 2 flow (partial flow) was observed in 6.8% of Group I and 18.6% of Group II (p=0.03). No patients in Group I experienced TIMI grade 0/1 flow (minimal/no flow), while 10.2% of patients in Group II had TIMI grade 0/1 flow (p=0.01). These results demonstrate the effectiveness of JSBT in preserving side branch patency during PCI.

Table 3

Side Branch Patency Post-PCI (TIMI Flow)

TIMI Flow Grade	Group I (JSBT Utilized) (n=59)	Group II (JSBT Not Utilized) (n=59)	p-value
TIMI 3 (Normal Flow)	55 (93.2%)	42 (71.2%)	0.002
TIMI 2 (Partial Flow)	4 (6.8%)	11 (18.6%)	0.03
TIMI 0/1 (Minimal/No Flow)	0 (0%)	6 (10.2%)	0.01

The peri-procedural outcomes revealed that Group I (JSBT utilized) had significantly fewer peri-procedural myocardial infarctions (MI) compared to Group II (JSBT not utilized), with 3.4% versus 11.9% incidence (p=0.04). ECG changes indicative of ischemia was observed in 8.5% of Group I and 16.9% of Group II (p=0.05). In-hospital mortality was low in both groups, with no deaths reported in Group I and a 3.4% mortality rate in Group II (p=0.15).

Table 4

Peri-procedural Myocardial Infarction and In-hospital Outcomes

Outcome	Group I (JSBT Utilized) (n=59)	Group II (JSBT Not Utilized) (n=59)	p-value
Peri-procedural MI (%)	2 (3.4%)	7 (11.9%)	0.04
ECG Changes (Ischemia) (%)	5 (8.5%)	10 (16.9%)	0.05
In-hospital Mortality (%)	0 (0%)	2 (3.4%)	0.15

The data shows that both groups had 100% coronary bifurcation lesions, with a similar distribution of Medina 1,1,1 lesion (37.3% in Group I and 33.9% in Group II). The size of the main vessel and side branch (SB) was >2.5 mm and >2.25 mm, respectively, in all patients. More patients in Group II had side branch stenosis >50% (40.7%) compared to Group I (30.5%).In Group I, all patients (100%) received JSBT, while Group II did not. Most patients in Group I (96.6%) used a 1:1 SB balloon size, and all had balloon inflation at 3 atm. Post-procedure SB stenosis >50% was more frequent in Group II (25.4%) compared to Group I (5.1%).TIMI flow in the main vessel was similar between groups, with the majority achieving TIMI III flow (98.3% in Group I and 88.1% in Group II). However, post-procedure TIMI flow in the side branch was significantly better in Group I, with 93.2% achieving TIMI III flow compared to 71.2% in Group II.Peri-procedural MI was more frequent in Group II (11.9%) than in Group I (3.4%), and fewer patients in Group I had side branch patency compromised (5.1%) compared to Group II (20.3%). Procedural success was higher in Group I (96.6%) compared to Group II (83.1%).

Table 5

Coronary Bifurcation Lesion and Procedural Outcomes

Variable		Group I (JSBT Utilized) (n=59)	Group II (JSBT Not Utilized) (n=59)
Coronary Bifurcation Lesion	Yes (%)	59 (100%)	59 (100%)
	No (%)	0 (0%)	0 (0%)
Medina Classification	1,1,1 (%)	22 (37.3%)	20 (33.9%)
	Other (%)	37 (62.7%)	39 (66.1%)
Size of Main Vessel > 2.5 mm	Yes (%)	59 (100%)	59 (100%)
	No (%)	0 (0%)	0 (0%)
Size of SB Vessel > 2.25 mm	Yes (%)	59 (100%)	59 (100%)
	No (%)	0 (0%)	0 (0%)
Side Branch Stenosis	>50% (%)	18 (30.5%)	24 (40.7%)
	≤50% (%)	41 (69.5%)	35 (59.3%)
JSBT Utilization	Yes (%)	59 (100%)	0 (0%)
	No (%)	0 (0%)	59 (100%)
Size of SB Balloon 1:1	Yes (%)	57 (96.6%)	0 (0%)
	No (%)	2 (3.4%)	59 (100%)
SB Balloon Inflation at 3 atm	Yes (%)	59 (100%)	0 (0%)
	No (%)	0 (0%)	59 (100%)
Post-procedure SB Stenosis	>50% (%)	3 (5.1%)	15 (25.4%)
	≤50% (%)	56 (94.9%)	44 (74.6%)
Post Procedure TIMI Flow in MV	TIMI 0 (%)	0 (0%)	1 (1.7%)
	TIMI I (%)	0 (0%)	2 (3.4%)
	TIMI II (%)	1 (1.7%)	4 (6.8%)
	TIMI III (%)	58 (98.3%)	52 (88.1%)
Post Procedure TIMI Flow in SB	TIMI 0 (%)	0 (0%)	6 (10.2%)
	TIMI I (%)	0 (0%)	5 (8.5%)
	TIMI II (%)	4 (6.8%)	6 (10.2%)
	TIMI III (%)	55 (93.2%)	42 (71.2%)
Peri-procedural MI / Trop I >5x	Yes (%)	2 (3.4%)	7 (11.9%)
	No (%)	57 (96.6%)	52 (88.1%)
Side Branch Intervention	Balloon Only (%)	5 (8.5%)	7 (11.9%)
	PCI (%)	0 (0%)	3 (5.1%)
	KBI (%)	1 (1.7%)	2 (3.4%)
Side Branch Patency Compromised	Yes (%)	3 (5.1%)	12 (20.3%)
	No (%)	56 (94.9%)	47 (79.7%)
Procedural Success	Yes (%)	57 (96.6%)	49 (83.1%)
	No (%)	2 (3.4%)	10 (16.9%)

DISCUSSION

Bifurcation lesions in coronary artery disease pose a significant challenge during percutaneous coronary intervention (PCI) due to the complexity of maintaining both main vessel (MV) and side branch (SB) patency. Standard approaches often fail the maintenance of SB flow, a problem that results in myocardial ischemia and elevated procedural risk levels. In the present

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investigation, the applicability of a newly proposed technique, the Jailed Semi-Inflated Balloon Technique (JSBT) was assessed for enhancing the SB patency during PCI. These findings provide evidence that JSBT enhances the SB patency, reduces the rate of peri-procedural MI, and increases procedural success.[16] The present investigation also showed reperfusion, in terms of TIMI flow, was significantly higher in the JSBT group as compared to the non-JSBT group. More particularly, we observed that 93.2% of the patients treated with JSBT had TIMI grade 3 flow corresponding to normal flow as opposed to 71.2% in a control group ($p = 0.002$). Furthermore, the frequency of SB occlusion or minimal flow (TIMI 0/1) was significantly lower in the JSBT group (0%) than in the control group (10.2%, $p = 0.01$). The current result correlates with previous studies on the application of modified techniques for bifurcation PCI to shield the SB without negatively affecting MV benefits.[17] Several approaches have been examined in prior investigations to enhance SB patency in bifurcation PCI including the DK-crush, provisional stenting, and KBI.[18] Each technique does have its merits; nevertheless, they tend to imply associated procedural advancements/shortcomings or variations in SB protection. The JSBT can be considered a modification of the jailed balloon technique because during SB stenting, the SB remains partially inflated which eliminates THD without the use of a second stent. In light of the findings of this study, the clinical implications are clear, specifically for high-risk patients with coronary bifurcation lesions.[19] Therefore, by increasing SB patency and decreasing the probability of peri-procedural MI, JSBT may well further the safety and effectiveness of bifurcation PCI. Importantly, the technique does not add complexity to the stenting or the PCI process and does not necessitate major changes from the standard PCI protocol. This simplicity may extend the usage of JSBT to routine perennial use in clinical practices. However, this study has several limitations which deserve consideration.[20] First, they were conducted in only one center, and the sample size in each of these trials was somewhat small to allow the generalization of the results. Second, the follow-up duration was restricted to the immediate hospital stay, thus the data on restenosis or other poor outcomes of the cardiac nature are missing. Future studies with larger cohorts and longer follow-up periods are necessary to validate the durability of the technique.

CONCLUSION

This study concludes that the Jailed Semi-Inflated Balloon Technique (JSBT) is a highly effective method for maintaining side branch (SB) patency during percutaneous coronary intervention (PCI) in bifurcation lesions. The use of JSBT significantly improves post-procedural SB flow, as evidenced by a higher rate of TIMI grade 3 flow, and reduces the incidence of peri-procedural myocardial infarction (MI) compared to standard PCI techniques. Additionally, the technique enhances procedural success without increasing the complexity of the intervention.

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