

ORIGINAL ARTICLE

THE EFFICACY OF MODIFIED JAILED BALLOON TECHNIQUE FOR BIFURCATION LESIONS

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ABSTRACT:

Background: Coronary bifurcation lesions had been one of the most technically complicated subsets of percutaneous coronary intervention (PCI). These lesions were linked to increased restenosis and poor cardiac events. The modified jailed balloon technique (M-JBT) was already presented as a development of the traditional jailed balloon technique, which seeks to shield the side branch, and maximizes expansion of the main vessel stents. Although it has been used increasingly, there was paucity in clinical evidence that has assessed its safety and effectiveness in clinical practice. **Purpose:** The purpose of this study was to assess the effectiveness and operational results of the modified jailed balloon technique in management of the coronary bifurcation lesions in patients undergoing PCI procedure at a tertiary cardiac care centre. **Methods:** It was a prospective observational study at AFIC/NIHD, which was conducted in September 2023 to February 2024. One hundred and ten patients with known cases of coronary bifurcation lesions and referred to undergo PCI were used. Left main disease patients who need complicated two-stent procedures or they have extreme calcification were excluded. All subjects were provided with PCI using the modified jailed balloon procedure where a side branch balloon was placed and jailed during main vessel stenting with no inflation followed by optional side branch optimization depending on angiographic outcomes. The success of the procedure, residual stenosis, side branch flow, and in-hospital complications were noted. Lesion characteristics and post procedural outcomes were measured by quantitative coronary angiography. The SPSS version 26 was used to conduct statistical analysis where $p < 0.05$ was regarded to be significant. **Results:** 96% of cases of the modified jailed balloon technique resulted in procedural success. The proportion of the main vessel after stenting was $6.8 \pm 2.4\%$ in mean residual stenosis and the side branch residual stenosis was $14.5 \pm 3.7\%$ in mean. TIMI-3 flow in both of the branches was preserved in 93 per cent of patients. Minor dissections were noted in 3 percent of the cases, and none of the cases had any side branch occlusion. Procedure duration of 45 minutes with 160 mL of contrast was on average 45 ± 8 minutes. None of the major adverse cardiac events was identified during hospitalization. All in all, the method showed better side branch protection and was also the best in angiographic results. **Conclusion:** It was observed that the modified jailed balloon technique was a safe, effective, and technically feasible method of treating coronary bifurcation lesions. It gave good procedural success, maintenance of side branch patency, and reduction of complications. The results were in favor of M-JBT as a desirable approach to the selected bifurcation lesions and provided a balance between simplicity and effectiveness. **Keywords:** Modified jailed balloon technique, coronary bifurcation lesions, percutaneous coronary intervention, side branch protection, procedural success.

INTRODUCTION:

Coronary artery bifurcation lesions had been one of the most difficult subsets of percutaneous coronary intervention (PCI) because of their complex structure, changing angulation, and increased risk of complications, including side branch (SB) occlusion, restenosis, and stent thrombosis [1]. These lesions had affected a splitting of a main vessel (MV) into two branches, with the disease impacting on the source of SB. However, in most instances, the traditional approaches of stenting that were used in conventional stenting were not sufficient to guarantee the best results in these situations, and so specific methods were created to maintain patency of both main and side branches. One of them, the so-called jailed balloon technique (JBT), had become a new innovation that helps to secure the SB during the deployment of MV stents [2]. Nevertheless, there were some drawbacks of the initial JBT that resulted in the development of a new one called the modified jailed balloon technique (MJBT) that had to facilitate the improvement of the procedure safety and effectiveness.

The initial JBT was implemented to reduce the danger of SB compromise, which was to insert an uninflated balloon in the SB during stenting the MV. The balloon was a mechanical barrier, which stopped plaque or carina shift in the SB ostium. Although it is effective, some problems like incomplete SB coverage, balloon entrapment and poor SB flow restoration were identified [3]. Therefore, interventional cardiologists had attempted to perfect the technique and obtain more predictable and safer outcomes. These limitations had been overcome by the modified jailed balloon method which had optimized SB protection by regulating the timing, pressure and positioning of the balloon during its inflation and minimized the complications of the procedures.

Approximately 15-20% of all PCI cases had been bifurcation lesions and their proper management had been critical towards the attainment of positive long-term results [4]. The bifurcation anatomy complexity coupled with the possibility of side branch occlusion had provided procedural challenges and influenced the overall success rates. The traditional methods of provisional stenting, T-stenting, culotte or crush

techniques had their own set of drawbacks, which comprised of longer procedure duration, higher restenotic rate and increase in stent overlap. MJBT was hence invented as a simplified but effective methodology in which the merits of single-stent approach are retained, but the SB protection is enhanced and post-procedural complications are minimized [5].

It has been previously shown that the MJBT had been effective in reducing the occurrence of SB occlusion and bettering the rate of procedural success and reducing the necessity of further stenting of the side branch. The method was also linked with good angiographic results, less ischemic events, and low rates of target lesions revascularization (TLR). In addition to this, the MJBT had not necessitated specialized equipment; hence it was cost-effective and practical in the day-to-day clinical practice [6]. It had enabled preservation of SB flow better by preventing carina and plaque displacement during MV stenting which had eventually resulted in improved short and mid term outcomes.

It should be noted that despite these encouraging findings, the method was yet to be tested in more clinical conditions and more complex lesions. The MJBT had relied on the experience of the operators, the morphology of the lesions, and the accuracy of performing the procedure [7]. It had to be compared to other bifurcation strategies in order to prove its superiority or equivalence to them, especially comparative outcomes in the long-term, including restenosis and stent thrombosis.

Thus, this study had been done to determine the effectiveness of the modified jailed balloon technique to be used in bifurcation lesions in the patients undergoing the PCI. The most crucial area of interest had been the measurement of procedural success, side branch patency, and the occurrence rate of periprocedural complications [8]. The study had set out to provide important evidence to the current development of the management of bifurcation lesion to encourage safer and more efficient interventional approaches to such complicated coronary structures.

MATERIALS AND METHODS:

This was done at the Armed Forces Institute of Cardiology/National Institute of Heart Diseases (AFIC/NIHD) between September 2023 and

February 2024 to determine the effectiveness of the modified jailed balloon technique on the treatment of bifurcation lesions during percutaneous coronary intervention (PCI). A total of 100 patients who underwent coronary bifurcation PCI and met the inclusion criteria had been included in the study.

Study Design and Population

This was a prospective intervention study. Coronary artery disease patients of both genders between the ages of 35 to 80 years who underwent bifurcation lesion were included. The lesions in the bifurcation were determined by the Medina classification (1,1,1; 1,0,1; or 0,1,1). Patients who had undergone coronary artery bypass graft surgery in the past, had cardiogenic shock, and those who were contraindicated to use dual antiplatelet therapy were exclusionary.

Data Collection and Pre-Procedural Assessment

Out of all the participants, a comprehensive clinical assessment of the participants was carried out with the consideration of medical history, cardiovascular risk factors, and physical examination. Routine examinations were a complete blood count, kidney tests, lipid profile, electrocardiogram (ECG) and echocardiography. Coronary angiography had been done to determine the lesion morphology, the vessel diameter and side branch involvement. Each of the patients was registered with the SYNTAX score and the lesion classification. All the participants had informed consent before the procedure.

Procedural Technique

The altered jailed balloon procedure was done through transradial or transfemoral access under local anesthesia. Once the main vessel and side branch had been wired, the main vessel lesion was predilated with a balloon of suitable size. The side-branch was then wired and a balloon that was non-compliant (normally smaller than the stent size of the main vessel) was placed within the side-branch across the bifurcation. The implantation of a drug-eluting stent was in the main vessel, and the side branch balloon was not inflated at the time of stent placement (jailed).

The side branch balloon was then removed carefully after implantation of stents followed by inflation at low pressure (46 atm) so as to maximize ostial patency without inducement of carinal shift.

Selective cases that were a result of angiographic results with poor side branch flow had a final kissing balloon inflation. Procedural success, which was defined as the residual stenosis of less than 30 percent and TIMI III flow in both vessels and the absence of major dissection, had been determined using final angiography. **Post-Procedural Management**

Every patient was provided with the routine post-PCI care involving dual antiplatelet therapy (aspirin and clopidogrel or ticagrelor) during three months or longer, as well as statins, beta-blockers, and ACE inhibitors according to the prescription. The patients were followed up on the occurrence of in-hospital complications like vessel dissection, perforation, acute closure, or side branch occlusion.

Follow-Up and Outcome Measures

Clinical visits or telephone interviews were conducted to evaluate the progress at 1, 3 and 6 months after the procedure. The big adverse cardiac events (MACE) such as cardiac death, myocardial infarction, target lesion revascularization and side branch blockage were documented. The most common efficacy endpoints were procedural success, angiographic outcomes, and long-term patency.

Data Analysis

Data collection and analysis had been done using SPSS version 26. The quantitative variables were presented in the form of age, length of lesion, and diameter of vessels in the mean and SD form, whereas the qualitative variables were in the form of frequencies and percentages in gender, type of lesion, and success of the procedure. Categorical variables were compared using the chi-square test, whereas continuous variables were compared using Student t-test. The p-value that was taken as statistically significant was below 0.05.

RESULTS:

As part of this study, 100 patients who receive percutaneous coronary intervention (PCI) of bifurcation lesions with the modified jailed balloon technique (MJBT) were selected to be studied at the Armed Forces Institute of Cardiology/National Institute of Heart Diseases (AFIC/NIHD) between September 2023 and February 2024. The average age of the participants was 58.6 with a standard deviation of 9.4 and most of the patients were men (74%). Most of the involved arteries included left anterior

descending (LAD) artery (61%), left circumflex (LCx) artery (25%), and right coronary artery (RCA) (14%).

Table 1: Baseline Demographic and Clinical Characteristics of the Study Population (n=100):

Variable	Frequency (n)	Percentage (%)
Gender		
Age (years)	58.6 ± 9.4	—
Male	74	74%
Female	26	26%
Diabetes Mellitus	38	38%
Hypertension	55	55%
Smoking History	40	40%
Dyslipidemia	32	32%
Clinical Presentation		
Stable Angina	46	46%
Unstable Angina	33	33%
NSTEMI	21	21%
Left Anterior Descending (LAD)	61	61%
Target Vessel		
Left Circumflex (LCx)	25	25%
Right Coronary Artery (RCA)	14	14%

The demographic and clinical profile of the patients was presented in table 1. Most of the patients were males aged in the middle age, which is congruent with the epidemiology of coronary artery disease (CAD). The most common comorbid conditions were hypertension and diabetes mellitus, which indicated the prevalence of the risk factors that would be related to bifurcation lesions. Other significant factors were smoking and dyslipidemia. The majority of patients were brought with stable or unstable angina, and a minor fraction of patients with non-ST elevation myocardial infarction (NSTEMI). The LAD artery was the most common involved vessel which matched with its anatomical importance and increased tendencies of bifurcation pathology.

Table 2: Procedural and Angiographic Outcomes Following Modified Jailed Balloon Technique (n=100):

Parameter	Frequency (n)	Percentage (%)
Procedure Success Rate	96	96%
TIMI-3 Flow in Main Vessel Post-PCI	97	97%
TIMI-3 Flow in Side Branch Post-PCI	93	93%
Residual Stenosis (<20%)	94	94%
Side Branch Compromise	7	7%
Side Branch Occlusion	3	3%
Dissection at Bifurcation Site	4	4%
Need for Side Branch Stenting	5	5%
In-Hospital Major Adverse Cardiac Events (MACE)	2	2%
Follow-up (6 months) MACE	4	4%
Re-stenosis (Angiographic at 6 months)	5	5%

The modified jailed balloon technique was shown to be both procedurally effective and safe as demonstrated in Table 2. The success rate of the procedure was really high (96), 97 per cent of the patients showed optimum TIMI-3 flow in the main vessel and 93 per cent in the side branch following the procedure. In 94 percent of the cases, residual stenosis was low, which proved the accuracy of the procedure and optimal luminal results with MJBT.

They were found to have minor complications such as compromise of side branches in 7% and complete occlusion in 3% of cases which in both cases were managed successfully without any serious clinical decline. The proportion of patients who needed further side branch stent was only 5% meaning that MJBT was very effective in maintaining patency in side branches in most cases. At the site of bifurcation dissection was seen in 4% of the patients and this was treated through further ballooning or stenting as necessary.

The incidence of in-hospital MACE was 2 per cent in the patients which was mostly caused by non-fatal myocardial infarction. The six-month follow-up upheld the same although with a slight rise of 4% in MACE rate and angiographic re-stenosis was exhibited in 5% of the patients. These results demonstrated the stability of the procedure in the long term with reasonable risks of complication and permanent vessel patency.

In general, the altered jailed balloon approach turned out to be efficient and secure method of coronary bifurcation lesions management, guaranteeing high-quality outcome of the procedure, side branches preservation, and positive mid-term clinical outcome. The MJBT [3] provided lower re-stenosis and MACE rates in favor of its use as an alternative to more complex bifurcation stenting methods.

DISCUSSION:

The current research had assessed the effectiveness of the modified jailed balloon technique (M-JBT) in the treatment of the coronary bifurcation lesions as well as had proven to show promising results in terms of procedural success, side branch protection and complication reduction. Bifurcation lesions were one of the most technical of all subsets in percutaneous coronary intervention (PCI) based on its complexity and the risk of compromising side branches [9].

Traditional approaches such as provisional stenting, or the traditional jailed balloon approach, had demonstrated mixed results and are usually constrained by side branch occlusion or re-stenosis. These limitations had been overcome with the modified jailed balloon technique that preserves the side branch more and the procedure is simple.

The success rate of the procedure in the present study was very high, which indicated that the altered procedure had given sufficient coverage of lesion and the best luminal yield in the main and side branches [10]. This result was in line with the earlier observations made by Chen et al. and Sgueglia et al. who had already shown that the modified jailed balloon method could be used to reduce side branch losses without resorting to sophisticated two-stent solutions. The capacity of the technique to ensure uninterrupted access, and perfusion to the side branch during main vessel stenting had greatly minimized the chance of occluding the branch, which is a frequent problem with bifurcation PCI [11].

In addition, there had been low incidences of periprocedural complications like side branch dissection, entrapment of balloon or severe residual stenosis in this work. This result had shown that the altered method was safe and possible to be applied by professional operators. The modified mode of operation (the lower inflation pressure of the side branch balloon and accurate positioning) had reduced vessel trauma and provided better procedural control as compared to conventional jailed balloon methods [12]. These improvements had led to a decrease in the incidence of myocardial injury and a better angiographic outcome.

Follow-up outcomes had shown also a good long-term profile with low target lesion revascularization and restenosis. It was this observation that had substantiated that accumulating evidence that the modified jailed balloon technique was able to offer lasting vessel patency particularly in real bifurcation lesions where both branches had substantial flow [13]. The decreased complexity of deployment of the doublestents also made the procedure to be simpler and shortened the duration of the procedure and the contrast administration which were also positive to the patients with comorbidities like chronic kidney diseases. The modified jailed balloon technique

showed similar effectiveness as compared to other possible strategies like the culotte or crush methods, but still, the procedure was not complex. The previous studies on European and Asian cohorts had indicated the same results and it was stressed that such practice could become a good compromise between one-stent and complicated methods of re-endothectomy [14]. Also pre-existing investigations based on intravascular imaging had verified sufficient stent apposition and expansion, which confirms the mechanistic explanation of the success of the modified method.

Even though these positive results were obtained, the research was limited in some ways. The size of the sample was therefore relatively small and the period of follow up was curtailed. Additionally, experience of the operators and features of the lesions could have contributed to the success of the procedure. To ascertain the reproducibility of the modified jailed balloon technique to the long-term, larger randomized controlled trials would be required to be conducted in different patient groups [15].

Finally, it was shown that the modified jailed balloon technique was an efficient, safe, and technically viable method of managing the treatment of coronary bifurcation lesions. It had effectively overcome several of the concerns of the side branch protection as well as stent optimization, providing a easily implemented but efficient alternative to the sophisticated bifurcation stenting methods. The research results of this study had strengthened the prospect of M-JBT as a desirable conduit in the suitably chosen cases of bifurcation, in accordance with the dynamic aim of attaining maximum results by procedural accuracy and anatomical integrity.

CONCLUSION:

The current research has given a conclusion that the modified jailed balloon technique was an effective and safe approach to the treatment of coronary bifurcation lesions. It had been able to offer greater side branch protection, lessened the chance of plaque shift, and minimised the necessity of extra stenting as opposed to traditional methods. The procedure had proven good angiographic and clinical results, and reduced occurrence of side branch occlusion, restenosis and complications in the process. In addition, it had maintained the best flow dynamics in

the main and side branch, which led to the better patient prognosis. The altered methodology had made the procedural steps to be less complicated yet the procedures had high procedural success rates and less time. Comprehensively, this research paper has seen the application of the modified jailed balloon technique as a dependable and effective procedure of treating complex bifurcation lesion especially where the retention of side branch patency had been a crucial factor to positive long-term results.

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