Original Article

Effect of Balloon Embedded Bifurcating Stenting with Single Stent Strategy for Side Branch Protection

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Abstract:

Background: Intervention for bifurcation lesions is associated with increased risk of adverse events and includes acute side branch (SB) occlusion during main branch (MB) stenting. This acute occlusion of side branch can often be catastrophic for the patient. We here in describe our experience in National Institute of Cardiovascular Diseases and Hospital (NICVD), Dhaka, Bangladesh with a technique which can be incorporated into bifurcation stenting to reduce or almost eliminate the incidence of side branch occlusion or catastrophe.

Methods: A prospective, observational, non-blinded study in patients from a single tertiary referral cardiac center National Institute of Cardiovascular Diseases & Hospital (NICVD), Dhaka, Bangladesh. Patients with an indication for percutaneous coronary intervention(PCI) of a denovo bifurcation lesion were screened. The study included 51 patients who underwent coronary angiogram in our institution and had bifurcation lesions suitable for single stent strategy between March 2017 to September2018.

Results: 51 patients with bifurcation lesion were included in the study and underwent a balloon embedded bifurcation stenting with a semi inflated balloon placed across the SB ostium.

Angiographic success was achieved in all the patients but procedural success was achieved in 88.2% of the patients. TIMI 3 flow of main branch (MB) was achieved 96.08% and side branch

(SB) was achieved 88.2%. Incidence of dissection was 5.9%, acute occlusion of SB was 2.0% and MACE was 3.9%. Mean fluoroscopy time and contrast volume was similar to that of conventional bifurcation stenting. The jailed SB balloon and wire could be successfully removed in all patients.

Conclusion: The present study suggests that balloon embedded bifurcation stenting with a semi inflated balloon to protect the SB is feasible, with minimal procedural adverse events and successful in minimizing or almost eliminating the incidence of acute side branch occlusion or dissection as well as MACE.

Keywords: *Bifurcation lesions, Percutaneous coronary intervention, Balloon embedded stenting, medina classification, MACE.*

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Introduction:

Bifurcation lesions account for 15–20% of interventions undertaken in a catheterization laboratory and is defined as "a coronary artery narrowing occurring adjacent to, and/or involving, the origin of a significant side branch(SB). A significant SB is a branch, whose loss is of consequence to a particular patient (symptoms, location of ischemia, viability of the supplied myocardium, collateralizing vessel, left ventricular function)."[1,14] Main branch(MB) stenting with provisional stenting of side branch is considered to be the gold standard strategy for bifurcation lesions currently.[13] During provisional approach, residual ostial stenosis or total occlusion of SB frequently occurs immediately after main vessel (MV) stenting.[8,12,20,21]

This strategy may however cause plaque shift, change in the bifurcation angle or ostial occlusion of the side branch resulting in side branch compromise in many cases.[8,11,19] Several techniques have been devised to decrease the risk of SB occlusion of which jailed guidewire technique1is widely used nowadays, but is associated with increased risk of wire entrapment and doesn't eliminate the incidence of SB occlusion. In a recently described jailed balloon technique,2a small balloon (diameter 1.5–2 mm) is kept uninflated in the SB during MB stent deployment, which helps to reduce the risk of SB occlusion but can't prevent it completely. If critical stenosis or occlusion of SB develops, rewiring of SB is attempted trying to SB salvage. But, the ability of rewiring of SB and restoring SB flow after MB stenting can be difficult.[5]

We here in intend to describe a technique in which a partially inflated balloon placed in the SB, extending from the SB to proximal MB can help in maximum side branch protection.

Material and methods

A prospective, observational, non-blinded study in patients from a single tertiary referral cardiac center (National Institute of Cardiovascular Diseases Institute & Hospital-NICVD). Patients with an indication for percutaneous coronary intervention(PCI) of a denovo bifurcation lesion were screened. The study included 51 patients who underwent coronary angiogram in our institution and had bifurcation lesions suitable for single stent strategy between March 2017 to September2018. Patients with severe calcified lesions and proximal tortuosity were excluded. Bifurcation lesions were classified according to Medina class.[15]

Inclusion criteria

(1) Patients were eligible for the studies if they were 18 to75 years old with true coronary bifurcation lesions undergoing PCI.

(2) The true bifurcation lesion consisted at least one major SB, bifurcation classifications were made according to Medina classification[14]; Medina 1,1,1 1,0,1 and 0,1,1 coronary bifurcation lesions with an SB diameter ≥2.0mm based on visual estimation were included in the training and study groups.

Exclusion criteria

(1) The bifurcation lesion was categorized as complex bifurcation lesions according to the DEFINITION[4], defined as Medina 1,1,1 and 0,1,1 coronary bifurcation lesions with each major criterion (left main vessel with ostial SB lesion length ≥10mm and diameter stenosis (DS) ≥70%; non-left main vessel with ostial SB lesion length ≥10mm and DS ≥90%) plus any 2 minor criteria (moderate to severe calcification; multiple lesions; bifurcation angle >45; main vessel RVD<2.5mm; thrombus-containing lesions; MV lesion length ≥25mm)

(2) Subject with renal failure (serum creatinine >2.0mg/dl)

(3) Subject exhibited severe left ventricular dysfunction (left ventricular ejection fraction < 35%)

(4) Subject with a serious comorbidity or with life expectancy <1 year

(5) Subject exhibited contraindications to aspirin or clopidogrel

Study procedure

a) Patients admitted in the Department of Cardiology in NICVD, Dhaka, Bangladesh with ischaemic heart diseases and elective PCI were considered for the study and those who had true coronary bifurcation lesion[4] with fulfilled inclusion, exclusion criteria and agreed to enter the study protocol.

b) Informed written consent was taken from each patient or legal guardian before enrollment.

c) A schematic diagram of the steps used in the technique is shown in Fig-I.

The steps include:

1. Wiring of both the main branch and side branch.
2. Predilatation of main vessel, predilatation of side branch when there is flow limiting obstruction.

3. Side branch balloon of 1:1 diameter was retained across the ostium with 1/3rd to 1/2 of the balloon in the main branch. (depending on the length of side branch lesion)
4. Stent was placed across the side branch ostium into the main branch and side branch balloon was inflated to 4–6 atmosphere.
5. The stent was deployed at nominal pressure jailing the partially inflated side branch balloon.
6. If the stent had a waist, main branch balloon was inflated to a higher pressure.
7. A check angiogram was done following removal of both balloons.
8. Side branch wire was removed and rewired across the MB stent.
9. POT(proximal optimisation technique) was done for the MB stent.
10. Final check angio was done and if it showed TIMI 3 flow in both branches, procedure was completed.
11. If SB showed<3 TIMI flow, SB was dilated across MB stent and final simultaneous dilation was done.

d) Angiographic success was defined as attainment of a residual diameter stenosis of 20% or less with TIMI 3 flow in both the main and side branches which was the primary end point.

e) Procedural success was defined as angiographic success without the occurrence of major complications(death, MI, stent thrombosis or CABG) before discharge.

f) Following PCI, all patients were monitored for post procedural complications.

g) ECG was taken immediate post procedure and 12 h after that.

h) Cardiac troponin and creatine kinase MB were measured on all patients before procedure and 12 h post intervention.

i) Elevation of 3 the upper limit of normal was considered significant.

Statistical Analysis:

Statistical analysis was performed using SPSS Statistical Software (version 22, SPSS Inc., Chicago, Illinois, USA). Continuous parameters were expressed as mean±SD

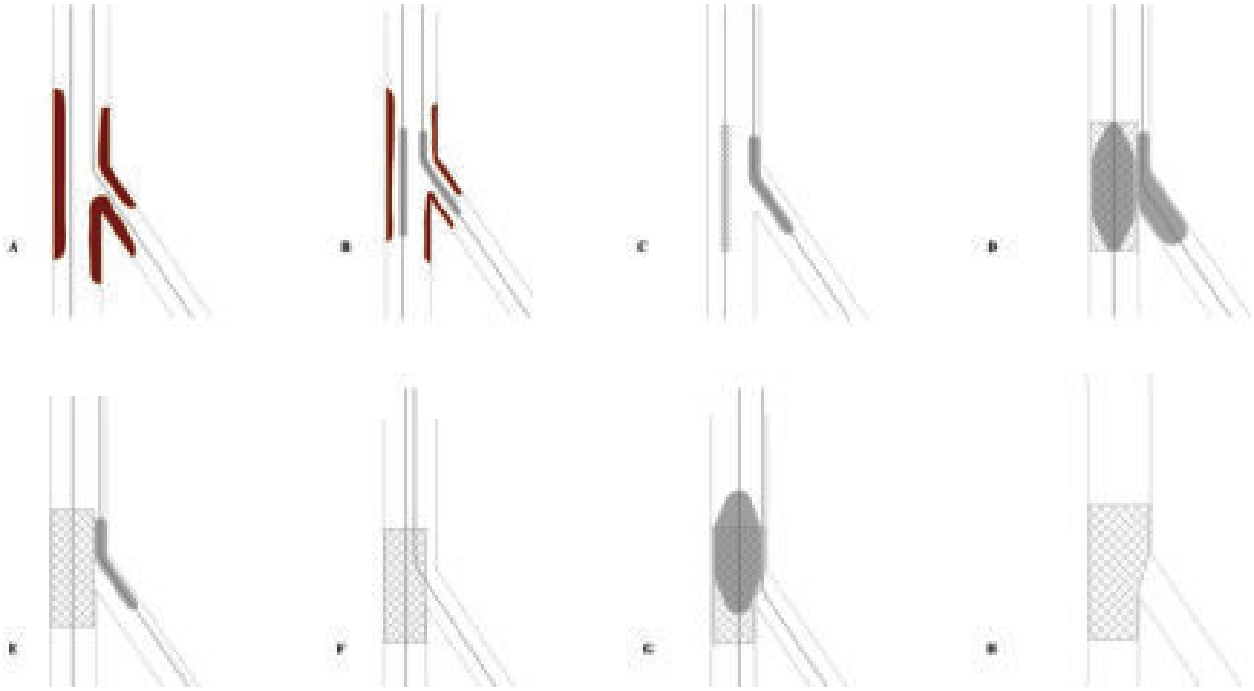

Figure-I. Schematic diagram showing steps used in the technique. A- Wiring of both the branches. B- Predilatation of both the branches. C- Stent in the main branch with an uniflated balloon across the side branch. D- Deploying the main branch stent while retaining the partially inflated balloon across the side branch. E- Deflating both the balloons. F- Rewiring the side branch across the main branch stent. G- POT for the main branch stent. H- Final result.

and categorical parameters as frequency and percentage.

Results:

This study included 51 patients of which 36 were males. Mean age of patients was 56.33 ± 11.24 years. History of an acute coronary syndrome(ACS) was present in 38 patients while the remaining 13 had a history of exertional angina grade II–III. (Table-I)

Out of 51 patients, majority (29) had lesions at bifurcation between left anterior descending(LAD) and diagonal(D) artery. Eight patients had significant obstruction between left main coronary artery (LMCA) and LAD artery, whereas six patients had lesion at left circumflex-obtuse marginal(LCX-OM) bifurcation. (Table-II)

Data regarding medina class, main vessel stent size, length, sidebranch balloon size, length and inflation pressure of each system is as shown in Table-III.

Procedural success rate was 88.2%. There was one SB loss and three side branch dissection and. The jailed SB balloon and wire could be successfully removed in all patients. (Table-IV)

Table-I

Baseline clinical characteristics (n = 51).

Characteristics	Results
Age, years(mean ± SD)	56.33 ± 11.24
Male	36(70.6%)
Diabetes Mellitus	27(52.9%)
Hypertension	39(76.5%)
Smokers	33(64.7%)
Family history of CAD	16(31.4%)
Dyslipidemia	42(82.4%)
History of ACS	38(74.5%)
history of exertional angina grade II–III	13(25.5%)

Table-II

Distribution of lesion in patients (n=51).

Site of Lesions	Number(%)
left main coronary artery and left anterior descending artery (LMCA-LAD)	08(15.7)
left anterior descending artery and diagonal artery (LAD-D).	29(56.9)
left circumflex artery and obtuse marginal artery (LCX-OM)	06 (11.8)
Right coronary artery and posterior descending artery/ posterior left ventricular artery (RCA-PDA/PLV)	04 (07.8)
Post percutaneous transluminal coronary angioplasty (PTCA)-instent restenosis (ISR)	01 (02)
Left main coronary artery (LMCA) trifurcation	01 (02)
Sequential left anterior descending artery and first diagonal artery (LAD-D1) followed by left main coronary artery and left anterior descending artery (LMCA-LAD)	01 (02)
Combined case of balloon embedded bifurcationculotte stenting at left anterior descending artery and first diagonal artery (LAD-D1) and balloon embedded left main coronary artery and left anterior descending artery (LMCA-LAD)	01(02)

Table-III

Procedure details of all the cases (n=51).

Characteristics	Results
Medina classification	
1,1,1	39(76.5%)
1,1,0	08(15.7%)
1,0,1	03(04.9%)
0,1,1	01(2.0%)
MB stent	
Mean Diameter (mm)	3.12 ± 0.49
Mean Length (mm)	21.32 ± 5.62
Inflation pressure of MB stent (atm)	10 to 16
Jailed balloon	
Mean Diameter (mm)	2.25 ± 0.29
Mean Length (mm)	10.63 ± 2.31
Inflation pressure of MB stent (atm)	4 to 8
Balloon used for POT	
Mean Diameter (mm)	3.07± 0.53
Mean Length (mm)	11.41 ±1.99
Inflation pressure of balloon used for POT	14 to 20

Table-IV

Immediate procedural and clinical outcomes (n=51).

Characteristics	Results
Angiographic Success(%)	51(100)
Procedural Success (%)	45 (88.2)
Procedural time (min)	63±13
Fluoro time (min)	31±09
SB loss	01(02%)
Dissection in the side branch	03(5.9%)
Per procedural MI	00(00%)
Entrapment of the Jailed balloon or wire	00(00%)
MACE in hospital	02(3.9%)
TIMI 3 flow	
Main Branch (MB)	49(96.08%)
Side Branch (SB)	45 (88.2%)

Discussion:

The study included 51 patients of which 70.6% were male. Mean age of patients was 56.33 ± 11.24 years. Risk factors included Diabetes Mellitus (52.9%), hypertension (76.5),smokers (64.7), dyslipidemia(82.4%) and positive family history of coronary artery disease(CAD)(31.4%). History of an acute coronary syndrome(ACS) was present in 74.5% patients while the remaining 25.5% had a history of exertional angina grade II–III that was similar to the most of the studies.1,4,8,12,20,21

Our study shown, out of 51 patients, majority (56.9%) had lesions at bifurcation between left anterior descending(LAD) and diagonal(D) artery. 15.7% patients had significant obstruction between left main coronary artery (LMCA) and LAD artery, whereas 11.8% patients had lesion at left circumflex-obtuse marginal(LCX-OM) bifurcation. Few cases of special mention include a case with combined balloon embedded culotte stenting for LAD-D1lesion and balloon embedded stenting with single stent for LMCA-LAD lesion a case where the technique was used for LMCA trifurcation and a patient with post percutaneous transluminal coronary angioplasty(PTCA) who presented with instent restenosis(ISR) that was similar to the most of the studies.4,8,14,21Procedural success rate was 88.2%. TIMI 3 flow of main branch (MB) was achieved 96.08% and side branch (SB) was achieved 88.2%. Incidence of dissection was 5.9%, acute occlusion of SB was 2.0% and MACE was 3.9%.The mean procedural time was 63/ ±/ 13 min and mean fluoro time was 31±09min which was comparable with the time taken for conventional bifurcation stenting done by the same operator team. All the patients were discharged on the third or fourth day and are under regular follow up.

Several studies have consistently demonstrated that a single-stent provisional strategy of stenting just the main branch (MB) has better clinical outcomes compared to double-stent techniques for bifurcation lesions. However, approximately 35% of patients require crossover to two stent strategy due to compromise of the side branch which often occurs due to plaque or carinal shift.6Side branch(SB) rewiring is difficult and time consuming in such cases and can cause prolonged impairment of flow leading to peri procedural MI. A strategy is thus needed which can improve the safety of SB during provisional approach. Provisional approach reduces adverse cardiovascular events, procedural time, radiation, and contrast administration as compared with elective two stent strategies.[6,9,10,13,17,18]

In the jailed guidewire technique1,the jailed wire in the SB can provide assistance to the other wire which passes through the struts in the MB but it does not prevent plaque or carinal shift in the SB. In the jailed balloon technique,2a small uninflated balloon is kept in the SB during MB stent deployment which helps in preventing carinal or plaque shift. Burzotta et al.2 showed that the rate of SB loss was 15% with this technique. Cayli et al.3 described an extention of jailed balloon technique, in which they placed a semi inflated balloon at the SB ostium, during MB stent deployment. This semi inflated balloon

technique prevented SB occlusion in 100% of cases and can be very useful in patients with complex bifurcation lesion with high risk of SB occlusion. However, there is very limited clinical experience with this technique and no such study in Indian population to our knowledge.

In this pilot study in NICVD, we used a semi inflated balloon placed at the side branch ostium to prevent carina or plaque shift during MB stenting. The study showed that this technique is safe and offers high procedural success with minimal complications. The technique was employed for both LMCA and non LMCA lesions and was associated with excellent SB protection in both type of lesions. Further 39(76.5%) of the patients included in the study had true bifurcation lesion with ostial involvement of the SB. Such patients are at high risk of SB occlusion during MB stenting due to plaque or carinal shift. However, there was no need for conversion to a two stent strategy as TIMI 3 flow was achieved in SB in all the cases. Decreasing or almost eliminating the crossover in provisional strategy can also prove to be cost effective by decreasing the number of stents required and decreasing the volume of contrast used for each procedure.

Potential risks and Limitations:

Although most of the result of this study have come up with the statistically significant findings, there are some facts to be considered which might affect the result. These are

a) Although adequate number of study population was used in our study, we believe that it is still limited in number to generalize the results.

b) It was conducted in a single center.

c) Short follow up period

d) The technique may be difficult when there are more than one significant side branches (may resort to a double catheter technique which has not been tried).

e) Rewiring the main branch before POT carries a risk of going behind the MB stent struts.

f) There is a potential risk of side branch balloon trapping, and deformation or polymer damage of main vessel stent.

g) OCT or IVUS was not used and hence dissections were assessed angiographically only.

h) Quantitative coronary angiography was not used in the study.

i) The study was performed in a single centre and all the cases were done by the same operator.

j) This was an observational study to assess the feasibility and safety of the technique, so the follow up was not included.

k) This study was planned as a prospective observational study, hence no control arm.

Conclusion:

SB occlusion is usually associated with ostial SB disease, and the mechanism for closure is likely plaque or carinal shift during MB stenting. Thus, balloon embedded stenting using a semi inflated balloon may be applied to bifurcation lesions with SB involvement to allow for an improved procedural result by protecting the SB. This however being an ovservational study, a randomized controlled trial(RCT) is needed to further validate the technique.

Recommendations:

Plaque shift is prevented or reduced. Need of bail out stenting is reduced/ abolished. Better TIMI flow is achieved in side branch. None of cases showed dissection in the SB. Can be practiced even in small side branches. Additional fluoroscopic exposure or procedure time is not required. Nevertheless, further studies with large number of patients with multicenter approach are needed to assess this comparison of the GRACE and TIMI risk score in predicting of in-hospital MACE of patients with ACS.

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