



Original Article

Balloon embedded bifurcation stenting with single stent for side branch protection – Preliminary results from an Indian population



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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 Indian population with a technique which can be incorporated into bifurcation stenting to reduce or almost eliminate the incidence of side branch occlusion.

Method and results: 70 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 and procedural success were achieved in all the patients. TIMI 3 flow was achieved in both the MB and SB in all cases and there was no incidence of dissection or acute occlusion of SB. Mean fluoroscopy time and contrast volume was similar to that of conventional bifurcation stenting.

Conclusion: The present study suggests that balloon embedded bifurcation stenting with a semi inflated balloon to protect the SB is feasible, not associated with procedural adverse events and successful in minimising or almost eliminating the incidence of acute side branch occlusion.

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1. 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 Main branch(MB) stenting with provisional stenting of side branch is considered to be the gold standard strategy for bifurcation lesions currently.^{2,3} 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.⁴ Several techniques have been devised to decrease the risk of SB occlusion of which jailed guidewire technique⁵ is 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,⁶ a 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. We here in intend to describe a technique in Indian population in which a partially inflated balloon placed in the SB, extending from the SB to proximal MB can help in maximum side branch protection.

2. Material and methods

A prospective, observational, non-blinded study in patients from a single tertiary referral cardiac centre. Patients with an indication for percutaneous coronary intervention(PCI) of a de-novo bifurcation lesion were screened. The study included 70 patients who underwent coronary angiogram in our institution and had bifurcation lesions suitable for single stent strategy between March 2016 to September 2017. Patients with severe calcified lesions and proximal tortuosity were excluded. Bifurcation lesions were classified according to Medina class.⁷ 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. Procedural success was defined as angiographic success without the occurrence of major complications(death, MI or CABG) before discharge. Following PCI, all patients were monitored for post procedural complications.

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ECG was taken immediate post procedure and 12 h after that. Cardiac troponin and creatine kinase MB were measured on all patients before procedure and 12 h post intervention. Elevation of ≥ 3 the upper limit of normal was considered significant. In patients with left main coronary artery(LMCA) bifurcation, ticagrelor plus aspirin was used where as in patients with non LMCA lesions, clopidogrel plus aspirin was used for dual anti platelet therapy All patients provided written informed consent and the study was approved by the institutional Ethics Committee. Appropriate statistical analysis was applied. All the continuous variables were expressed as mean \pm standard deviation and categorical variables as percentages.

3. Technique

A schematic diagram of the steps used in the technique is shown in Fig. 1. 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 $1/3^{\text{rd}}$ 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 kissing dilatation was done.

Table 1

Baseline clinical characteristics (n = 70).

Age, years(mean \pm SD)	60.18 \pm 9.40
Male	42(60.0%)
Diabetes Mellitus	30(42.8%)
Hypertension	47(67.1%)
Smokers	33(47.1%)
Family history of CAD	22(31.4%)
Dyslipidemia	51(72.8%)
History of ACS	48(68.5%)

4. Results

Baseline clinical characteristics of the patients included in the study are shown in Table 1. The study included 70 patients of which 42 were males. Mean age of patients was 60.18 ± 9.40 years. Risk factors included Diabetes Mellitus(n = 30), hypertension(n = 47), smokers(n = 33), dyslipidemia(n = 51) and positive family history of coronary artery disease(CAD)(n = 22). History of an acute coronary syndrome(ACS) was present in 48 patients while the remaining 22 had a history of exertional angina grade II–III.

Out of 70 patients, majority(34) had lesions at bifurcation between left anterior descending(LAD) and diagonal(D) artery. Thirteen patients had significant obstruction between left main coronary artery (LMCA) and LAD artery, whereas eight patients had lesion at left circumflex-obtuse marginal(ICX-OM) bifurcation. Distribution of lesion in all the patients is mentioned in Fig. 2. Few cases of special mention include a case with combined balloon embedded culotte stenting⁸ for LAD-D₁ lesion and balloon embedded stenting with single stent for LMCA-LAD lesion (Fig. 3), a case where the technique was used for LMCA trifurcation and a patient with post percutaneous transluminal coronary angioplasty(PTCA) who presented with in-stent restenosis(ISR). Data regarding Medina class, main vessel stent size, length, side branch balloon size, length and inflation pressure of each system is as shown in Table 2.

The procedural and clinical outcomes are as shown in Table 3. Procedural success rate was 100%. There was no SB loss and all patients had TIMI 3 flow in both MB and SB. The jailed SB balloon

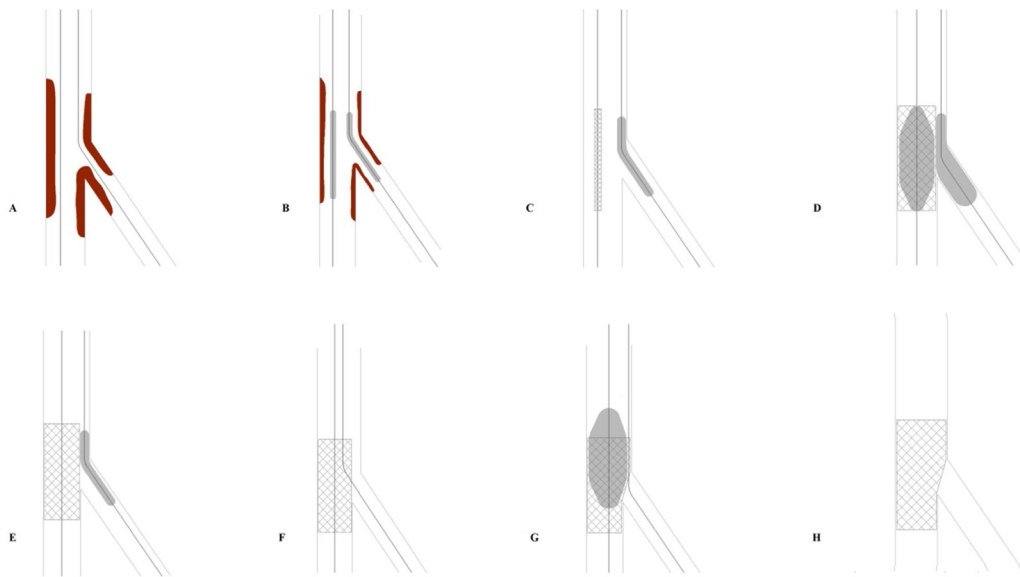


Fig. 1. Schematic diagram showing steps used in the technique. A- Wiring of both the branches. B- Predilatation of both the branches. C- Stent in the main branch with an uninflated balloon across the side branch. D- Deploying the main branch stent while retaining the partially inflated balloon across 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.

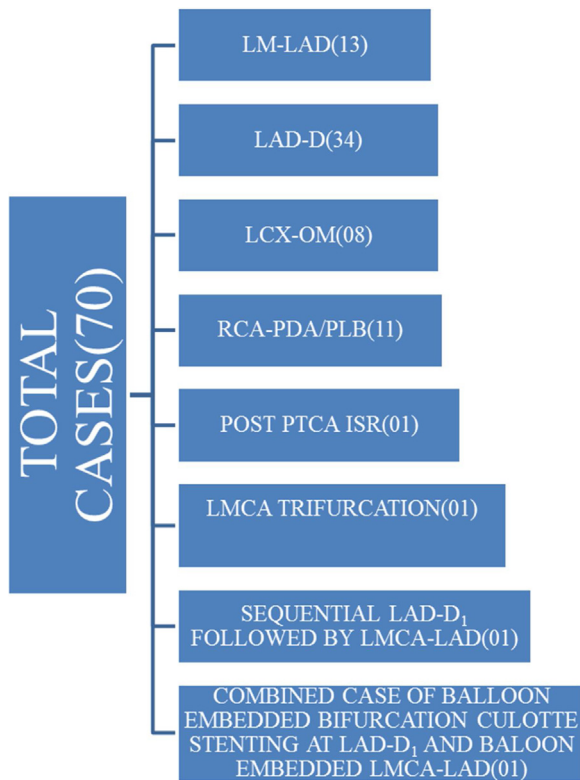


Fig. 2. Distribution of lesion in patients.

and wire could be successfully removed in all patients. The periprocedural MI rate was 0%. and there was no major adverse cardiovascular events (MI, stent thrombosis, stroke) during in-hospital stay.

The mean procedural time was 59 ± 06 min and mean fluoro time was 21 ± 03 min which was comparable with the time taken

for conventional bifurcation stenting done by the same operator. All the patients were discharged on the second day and are under regular follow up.

5. Discussion

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.⁹ Side 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.

In the jailed guidewire technique,⁵ 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,⁶ a small uninflated balloon is kept in the SB during MB stent deployment which helps in preventing carinal or plaque shift. Burzotta et al⁶ showed that the rate of SB loss was 15% with this technique. Cayli et al¹⁰ described an extension 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, 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 49(70.0%) of the patients included in the study had true

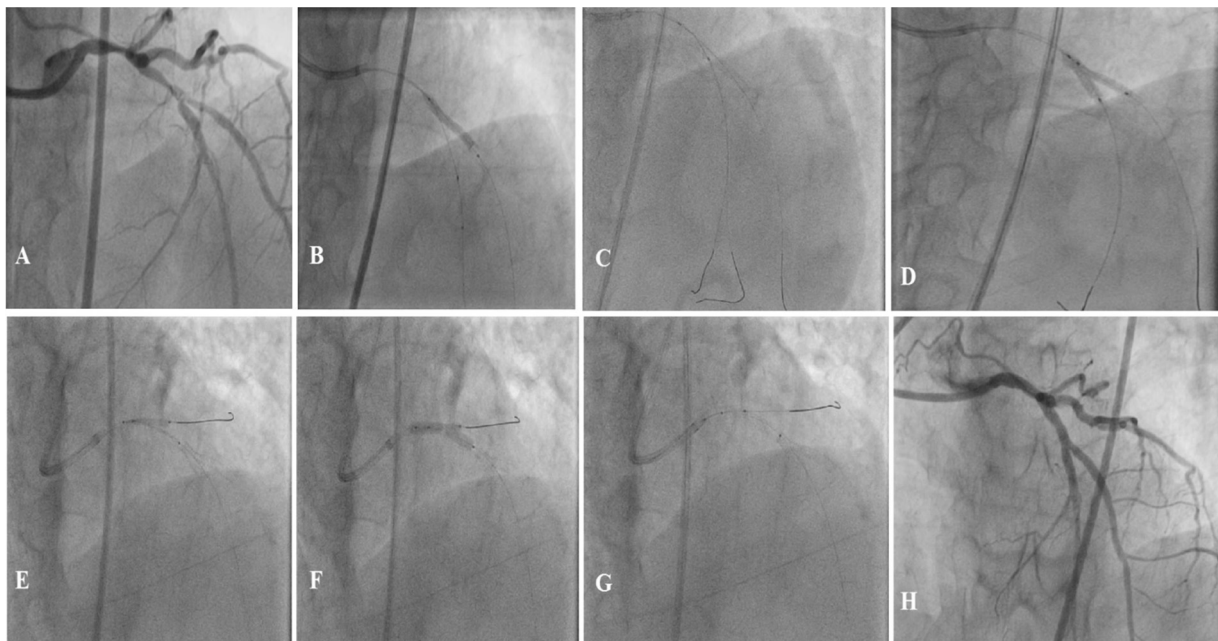


Fig. 3. Balloon embedded culotte stenting at LAD-D₁ bifurcation and balloon embedded stenting using single balloon at LMCA-LAD bifurcation in the same patient. A- CAG showing significant lesion at LMCA-LAD and LAD-D₁ bifurcation. B- Stent being deployed in diagonal while an uninflated balloon is parked in LAD. C- Jailed balloon in LAD being removed. D- Final kissing balloon dilatation after completing culotte stenting at LAD-D₁ bifurcation. E- Stent being placed from LMCA to LAD with a semi-inflated balloon across the side branch. F- Stent being deployed with the semi-inflated balloon jailed across the side branch. G- the jailed balloon being removed. H- Final result.

Table 2
Procedure details of all the cases.

Total no of cases	70
Medina classification	
1,1,1	26(36.6%)
1,1,0	22(30.9%)
1,0,1	17(23.9%)
0,1,1	06(08.4%)
MB stent	
Mean Diameter	3.06 ± 0.52 mm
Mean Length	23.16 ± 6.62 mm
Inflation pressure of MB stent	10 to 16 atm
Jailed balloon	
Mean Diameter	2.25 ± 0.29 mm
Mean Length	11.77 ± 2.38 mm
Inflation pressure of jailed balloon	4 to 6 atm
Balloon used for POT	
Mean Diameter	3.06 ± 0.53 mm
Mean length	11.47 ± 1.93 mm
Inflation pressure of balloon used for POT	14 to 20 atm

Table 3
Immediate procedural and clinical outcomes.

Angiographic Success(%)	70(100)
Procedural Success(%)	70(100)
SB loss	0(0)
Dissections in the side branch	0(0)
Periprocedural MI	0(0)
Entrapment of the Jailed balloon or wire	0(0)
MACE in hospital	0(0)

MACE- major adverse cardiovascular events.

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.

Advantages of the technique include:

- 1 Plaque shift is prevented or reduced.
- 2 Need of bail out stenting is reduced/abolished.
- 3 Better TIMI flow is achieved in side branch.
- 4 None of cases showed dissection in the SB.
- 5 Can be practised even in small side branches.
- 6 Additional fluoroscopic exposure or procedure time is not required.

Potential risks and Limitations:

- 1 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).

- 2 Rewiring the main branch before POT carries a risk of going behind the MB stent struts.
- 3 There is a potential risk of side branch balloon trapping, and deformation or polymer damage of main vessel stent.
- 4 OCT or IVUS was not used and hence dissections were assessed angiographically only.
- 5 Quantitative coronary angiography was not used in the study.
- 6 The study was performed in a single centre and all the cases were done by the same operator.
- 7 This was an observational study to assess the feasibility and safety of the technique, so the follow up was not included.
- 8 This study was planned as a prospective observational study, hence no control arm.

6. 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 observational study, a randomized controlled trial(RCT) is needed to further validate the technique.

Conflict of interest

The authors declare that there is no conflict of interest.

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