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Tryton dedicated bifurcation stent in treatment of unprotected distal left main bifurcation disease☆

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ABSTRACT

Percutaneous coronary interventions involving coronary bifurcation lesions are more complex and associated with adverse outcomes (both angiographic and clinical) compared to non-bifurcation lesions. Tryton, a dedicated bifurcation stent, has been introduced with the aim to simplify treatment of bifurcation lesions. Tryton stent in combination with conventional drug eluting stent is safe and associated with reduced stenosis and bail-out stenting of side branch compared to provisional stenting involving a large side. However, little is known regarding safety and efficacy of Tryton stent in left main (LM) bifurcation lesion. We describe two cases of unprotected LM bifurcation stenting using Tryton stent in combination with drug eluting stent.

1. Introduction

Coronary bifurcation lesions are encountered in approximately 15–20% of all percutaneous coronary interventions (PCI) performed [1,2]. PCIs involving coronary bifurcation lesions are more complex and associated with adverse outcomes (both angiographic and clinical) compared with non-bifurcation lesions [3]. Dedicated bifurcation stents have recently been introduced with the aim to simplify treatment and improve early and late outcomes following stenting of bifurcation lesions. Tryton bifurcation stent (Tryton Medical, Inc., Durham, NC, USA) in combination with conventional drug eluting stent has been shown to be safe and is associated with reduced stenosis and bail-out stenting of side branch (SB) compared to provisional stenting involving a large SB (>2.25 mm by quantiave coronary angiography) [4]. However, little is known regarding safety and efficacy of Tryton stent in left main (LM) bifurcation lesions. We describe two cases of unprotected LM bifurcation stenting using Tryton stent in combination with drug eluting stent.

2. Case description

2.1. Case 1

A 66 year old male with prior history of type A aortic dissection status post aortic root replacement with aortic valve repair presented with acute heart failure. Echocardiography revealed severe left ventricular systolic dysfunction with an ejection fraction of 15% and moderate mitral regurgitation. After optimization of his volume status, he underwent cardiac catheterization, which showed distal LM bifurcation disease with 80% ostial left anterior descending (LAD) artery and 70% ostial left circumflex (LCX) artery stenoses (medina 0,1,1), a mid LAD 70% stenosis and a small nondominant right coronary artery (RCA) (Fig. 1a–b, Video 1). He was evaluated by a heart team and deemed to be a poor candidate for coronary artery bypass graft surgery given his severely impaired LV systolic function and redo-surgery. The mid LAD lesion was treated first with two 3.0 × 15 Xience Alpine stents (Abbott Vascular, Santa Clara, CA). The LM bifurcation lesion was then treated using a Tryton 3.5 × 4.0 × 15 mm-6Fr stent and a 4.0 × 18 mm Xience Alpine stent (Fig. 2, Video 2). IMPELLA CP (Abiomed, Danvers, MA) through right femoral artery was used for hemodynamic support during PCI. Intravascular ultrasound (IVUS) was used for optimization of PCI. He was discharged home the next day and has been doing well at 10-month follow up.

2.2. Case 2

A 67 year old male presented to the hospital with Non ST-elevation myocardial infarction and acute exacerbation of heart failure with

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reduced ejection fraction. He had initially presented one month ago with acute congestive heart failure and was found to have new onset severe left ventricular systolic dysfunction with ejection fraction of 30%. Diagnostic coronary angiogram showed distal LM 75% stenosis involving ostial LAD and LCX (medina 1,1,1) along with a mid LCX 70% and mid RCA 80% stenoses (Fig. 3, Video 3). The revascularization of coronary artery was put on hold due to ongoing induction chemotherapy for chronic lymphocytic leukemia. Meanwhile, he was being treated with guideline-directed medical therapy, but continued to have recurrent hospitalizations for acute on chronic congestive heart failure. He was deemed to be a poor candidate for surgical revascularization by heart team evaluation. He underwent PCI of mid RCA with 3.0 × 23 and distal RCA with 2.5 × 18 Xience Alpine stents. One week later, he was brought back for PCI of mid LCX and distal LM. Impella 2.5 through left femoral artery was used for hemodynamic support during PCI. The mid LCX was treated first with 3.0 × 33 Xience Alpine stent. LM bifurcation lesion was treated with 3.0 × 3.5 × 15 mm-6FR Tryton stent and 3.5 × 38 mm Xience Alpine stent with IVUS guidance (Fig. 4, Video 4). He was discharged home the next day and was noted to be doing well at 6-month follow up.

3. Interventional details (Fig. 5)

We describe interventional details of case 1 as a representative case. Sailent features of both cases are described in Table 1. Through right radial access, the left coronary artery was engaged with a 7-Fr Extra BackUp (EBU) 3.5 Guide catheter. The lesion was then wired with an Asahi Sion Blue (Abbott Vascular, Santa Clara, CA) into the LCX and Asahi Prowater (Abbott Vascular, Santa Clara, CA) into the LAD.

1. Predilation of SB (LCX) with 3.0 × 12 mm compliant balloon (panel a)
2. Deployment of a 3.5 × 4.0 × 15 mm-6Fr Tryton stent from the proximal main branch (MB) into the SB (LM into LCX) (panel b)
3. Proximal optimization technique with post dilation of proximal MB (LM) stent with 4.5 × 12 NC balloon (panel c)
4. Rewiring the distal MB (LAD) and removal of jailed LAD wire
5. Predilation of distal MB (LAD) with 4.0 × 12 NC balloon (panel d)
6. Placement of Xience Alpine 4 × 18 mm stent from proximal MB into the distal MB (LM into LAD) through the Tryton stent (panel e)
7. Rewiring the SB (LCX) and removal of jailed sidebranch (LCX) wire
8. Post dilatation with double kissing Technique with two 4.0 × 12 NC balloons in LAD and LCX (panel f)

4. Discussion

These two cases illustrate that the use of the Tryton stent in combination with conventional drug eluting stent in treatment of LM bifurcation disease is feasible and safe in high risk patients. In addition, it also provides excellent angiographic results with adequate luminal gain as assessed by intravascular ultrasound. Compared to LM ostial or midshaft disease, PCI of LM bifurcation disease is associated with more adverse outcomes, especially target vessel revascularization [5–7]. In true LM bifurcation lesions, general consensus is to use a two-stent technique to achieve better angiographic results with SB patency. However, two-stent technique is more complex and technically demanding. It is also unclear if two-stent technique leads to better long-term clinical outcomes. Registry data have shown significantly higher rates of target vessel revascularization with two-stent technique when compared to provisional one stent technique [5–7]. This could be secondary to variations in these complex two-stent techniques and their inherent limitations such as failure to cover SB ostium completely in T-stent technique and crowding of struts at the bifurcation with crush techniques. On the other hand, a recent randomized controlled trial showed PCI of true distal LM bifurcation lesions using a planned double kissing (DK) crush 2-stent strategy resulted in a lower rate of target lesion failure at 1 year (5.0 vs 10.7%; HR = 0.42, 95% CI = 0.21–0.85; p = 0.02) than a provisional stenting strategy for the treatment of unprotected distal LM true bifurcation lesions [8].

The aim of Tryton stent is to simplify bifurcation stenting. In the post-hoc analysis of Tryton trial, tryton stent in patients with bifurcation lesions involving a large SB (>2.25 mm by quantiave coronary angiography) was associated with numerically lower rate of target vessel failure at 9 months compared to provisional stenting (11.3% vs 15.6%; P = 0.38) with significantly reduced stenosis and bail-out stenting of SB [4]. However, this study excluded patients with LM bifurcation disease and it is yet to be approved for use in LM disease. Magno et al. reported the findings of Tryton LM registry, a European Registry involving 9 centers, in 52 patients with LM bifurcation lesions (44 had true bifurcation lesions) treated with Tryton stent [9]. It was associated with very high procedural success rate (98%) with excellent angiographic results and optimal luminal gain in all three branches. However, 22% of these patients had major adverse vascular events (composite of cardiac death, MI, and ischemia-driven TVR) at 6 months. Target lesion

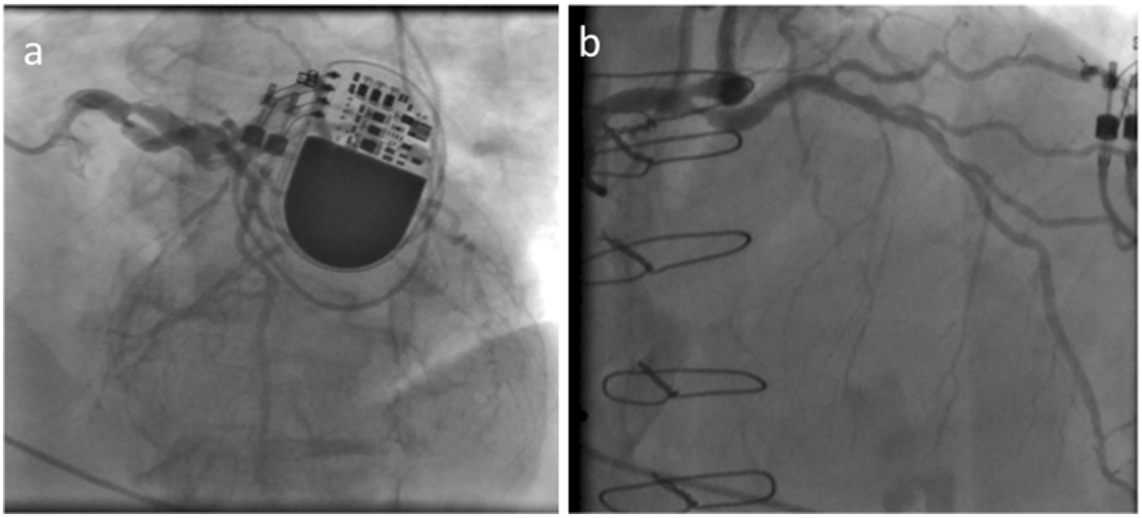

Fig. 1. Coronary angiogram showing left main bifurcation lesion panel a – LAO cranial, panel b – RAO cranial.

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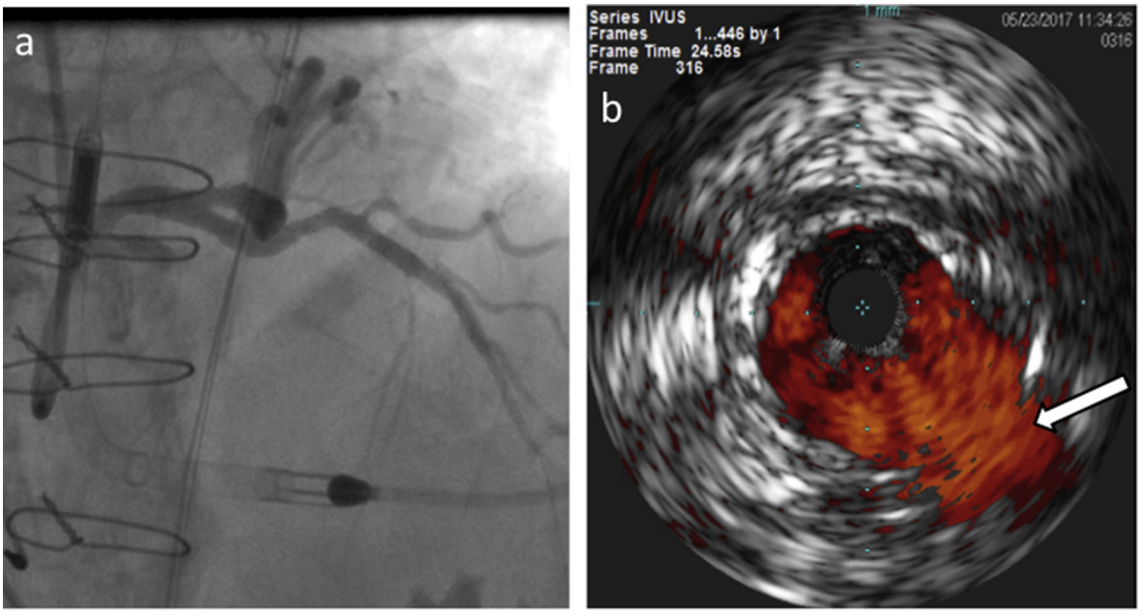

Fig. 2. Final result after PCI [panel a- coronary angiogram, panel b – IVUS showing sparing of carina (white arrow)].

revascularization at 6 months was 12% and almost exclusively due to SB ostium restenosis. However, this study had several limitations in addition to the inherent limitations of registry data; 1. All patients were treated with the single size tryton stent (3.5–2.5-mm) 2. Only 38% had appropriately implanted stent in terms of depth 3. Limited use of intracoronary imaging 4. Five of the seven cases with restenosis at six months occurred in vessels <2 mm. Onuma et al. reported the findings of a prospective registry of 30 patients with 6 month clinical as well as angiographic and intravascular ultrasound follow up [10]. The procedural success rate was 100% with excellent acute gain (1.41 ± 0.62 mm in the proximal MB, 1.07 ± 0.50 mm in the distal MB and 1.06 ± 0.38 mm in the SB). IVUS showed MLA of 6.70 ± 2.12 mm2 in the MB and 4.38 ± 1.88 mm2 in the SB. Late lumen loss was 0.28 ± 0.41 mm in the proximal MB, 0.17 ± 0.37 mm in the distal MB and 0.65 ± 0.46 mm in SB. Late lumen loss in MB appeared to comparable to DK Crush technique however, late lumen loss in SB was higher than DK crush [8]. There was no cardiac death or stent thrombosis but MI occurred in 13% of patients. Target lesion revascularization was seen in 13% of patients, which was exclusively due to SB restenosis.

This case series along with findings of these studies confirmed the feasibility of using Tryton stent in unprotected LM bifurcation lesion with acute device success and predictable angiographic results, especially in maintaining SB patency. It simulates reverse Culotte technique and has advantages over classical Cullotee technique in the setting of LM bifurcation lesions [11]. It minimizes the amount of metal in the LM and its tapered design from proximal MB zone to distal SB has potential advantages especially in the coronary anatomy with LM-LCX mismatch [11]. However, it is unclear if these theoretical advantages translate into improving clinical outcomes. In addition, there are several other procedural challenges

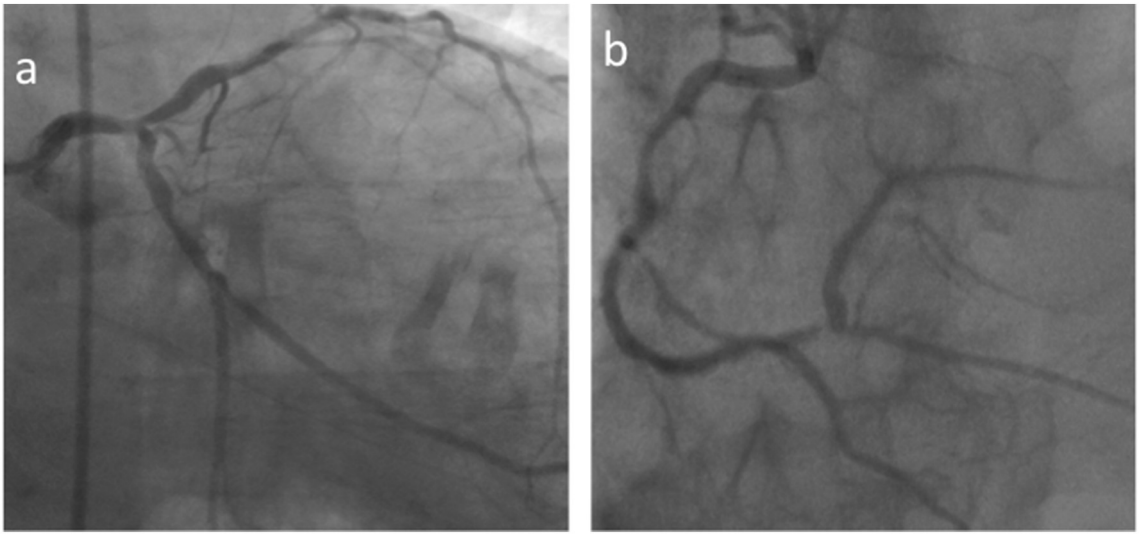

Fig. 3. Coronary angiogram panel a – AP caudal cranial showing distal left main stenosis with involvement of LAD and LCX ostia, panel b – LAO cranial mid RCA and distal RCA stenoses.

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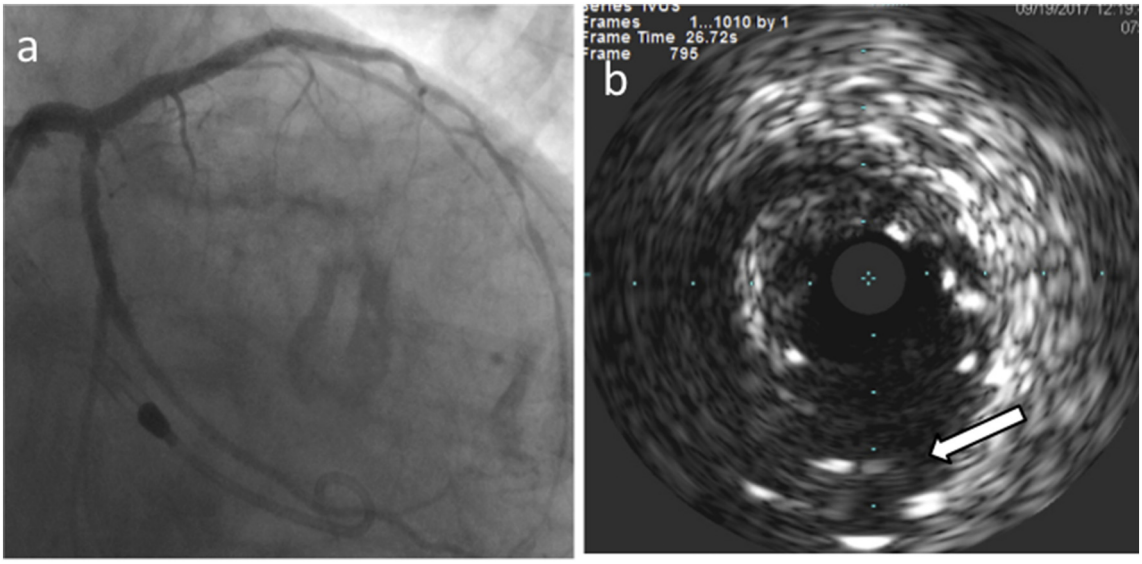

Fig. 4. Final result after PCI [panel a- coronary angiogram, panel b – IVUS showing sparing of carina (white arrow)].

1. Sizing - Though the stents with larger diameter are available more recently, the largest size available is still 4.0–3.5 mm, which is not suitable for patients with larger LM. In addition, tapering design of the stent may not be appropriate for certain anatomy.
2. Depth of implantation into the SB - The two middle markers which indicate transition zone, are meant to guide appropriate depth of implantation and the carina should be in between these two markers. This zone has less radial strength to allow easy recrossing of MB. Therefore, deployment of the stent too deep will result in poor SB ostial scaffolding, which may be one of the reasons for high restenosis. However, inappropriate depth of implantation was not found to be predictive of restenosis at six months in a study.[12] On the other hand too shallow an implantation will result in difficult MB rewiring.
3. Bare Metal SB zone - Though a current generation drug eluting stent is deployed in MB, SB will have a bare metal stent which may be the reason for reported high restenosis. It will be interesting to see if a

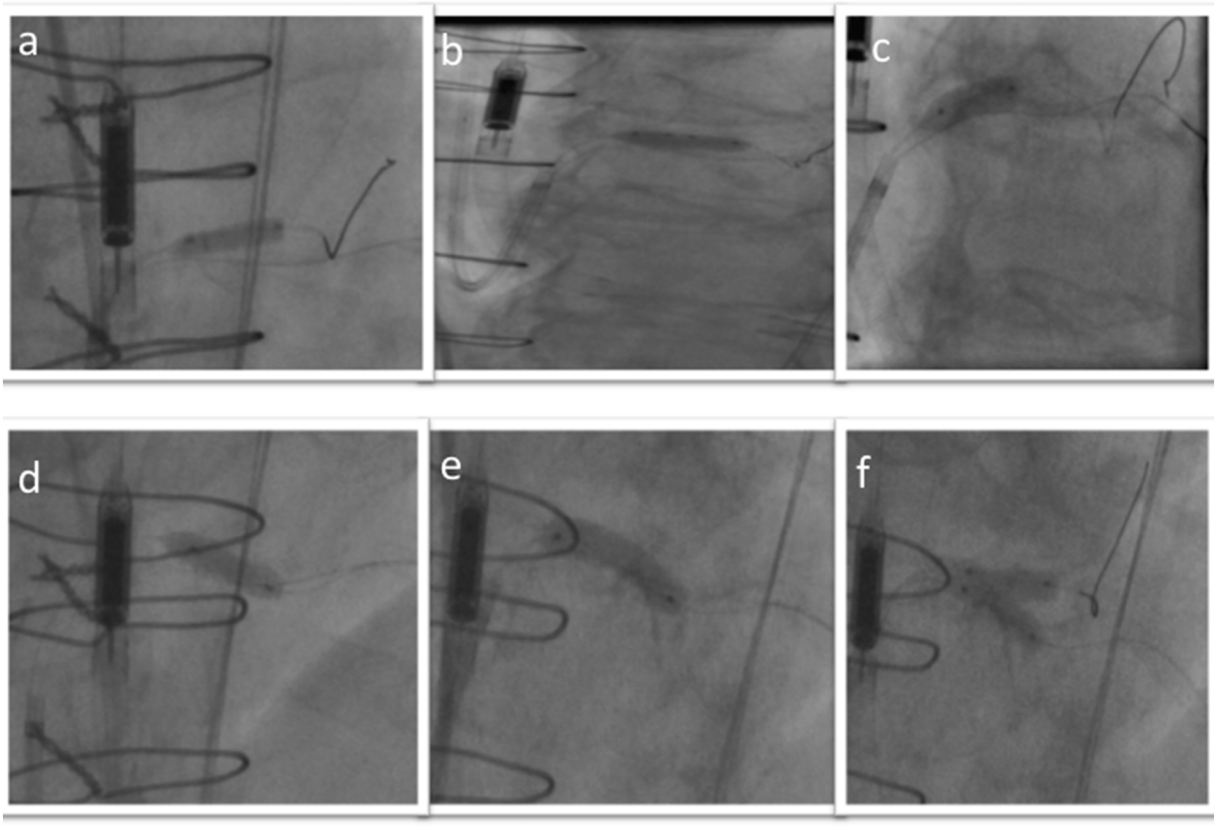

Fig. 5. Steps of PCI using Tryton stent in combination with drug eluting stent (Panel a -Predilation of LCX with 3.0 × 12 mm compliant balloon, panel b - deployment of a 3.5 × 4.0 × 15 mm-6Fr Tryton stent from LM into LCX, panel c - proximal optimization technique with post dilation of LM stent with 4.5 × 12 noncompliant balloon, panel d - predilation of LAD with 4.0 × 12 NC balloon, panel e - placement of Xience Alpine 4.0 × 18 mm stent from LM into LAD through the Tryton stent, Post dilatation with double kissing Technique with two 4.0 × 12 NC balloons in LAD and LCX, panel f).

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Table 1
Percutaneous coronary intervention details of two cases.

Characteristics	Case 1	Case 2
Presentation	New onset congestive heart failure	Non-STEMI with acute heart failure
Prior coronary revascularization	No	No
Ejection fraction	15%	30%
Medina classification	0,1,1	1,1,1
Lesions involving other arteries	Mid LAD 70%	Mid RCA 80% Mid LCX 70%
Syntax score	20	27
STS score	8	3
Access	Right radial	Right femoral
Hemodynamic support	Impella CP (right femoral)	Impella 2.5 (left femoral)
Guide	7 FR EBU 3.5	7 FR EBU 3.5
Wires	Sion blue in L Cx Asahi prowater in LAD	Sion blue in L Cx Asahi prowater in LAD
IVUS utilization	Yes	Yes
Tryton stent	3.5 × 4.0 × 15 mm-6FR	3.0 × 3.5 × 15 mm-6FR
Drug eluting stent	4.0 × 18 mm Xience alpine	3.5 × 38 mm Xience alpine
Proximal optimization Technique	Yes (4.5 × 12 NC balloon)	Yes (4.0 × 8 NC balloon)
Double kissing	Yes (4.0 × 12 NC balloons in LAD and LCX)	Yes (4.0 × 12 NC balloon in LAD and 3.0 × 8 NC balloon in LCX)
Residual angiographic side branch stenosis	0%	0%
Post PCI IVUS MSA (mm2)	LM-12, LAD-10, LCX-6	LM-12 LAD–9, LCX-7
Angle change	3	2
Other intervention at the same setting	Yes (mid LAD)	Yes (mid LCX)
Anticoagulation	Heparin	Heparin
Procedure time	214 min	208
Contrast	315 cc	325 cc
Fluoroscopic time	60.7	54.6
Radiation	3720 mGy	5389 mGy

Non-STEMI - non ST-elevation myocardial infraction, STS - Society of Thoracic Surgeons, IVUS - intravascular ultrasound, MSA - minimal stent area, i.

drug-eluting version of the Tryton stent will be able to maintain superior SB patency at follow-up.

4. Carina Angle - It can cause significant bifurcation angle change, therefore, may not be suitable for bifurcation lesion with large carina angle. There are reports suggesting the narrowing of the carina angle in bifurcation stenting may result in adverse outcomes [12]. However, Magno et al. reported <5° narrowing while using Tryton in LM bifurcation, which was not related to adverse outcome.
5. Length of the SB stent - There are only 3 stent length available (19, 18 and 15 mm) with SB zone length 6.5 mm in 19 mm stent and 5.5 mm in 18 and 15 mm stent. In addition, patients with >5 mm long SB lesions were excluded from the Tryton trial. Hence, this stent is not suitable for patients with longer and more diffuse SB lesion. The role of second drug eluting stent to treat longer SB lesion is not clear.
6. Length of the proximal MB – Proximal MB has to be long enough to accommodate MB zone of the device to prevent the stent from protruding into the aorta. There are only 2 MB zone stent length available (8 mm in 18 and 19 mm stent and 5 mm in 15 mm stent). This stent is therefore not appropriate for LM shorter than 5 mm.

5. Conclusion

Tryton stent along with contemporary drug eluting stent is feasible for the treatment of distal unprotected LM bifurcation with high procedural success rate and predictable SB patency. However, little is known about its long term safety and efficacy. Therefore, future randomized controlled studies or well-designed prospective registries are required to assess long term safety and efficacy of Tryton Sb stent for distal unprotected LM disease.

Supplementary data to this article can be found online at https://doi.org/10.1016/j.carrev.2018.05.003.

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