Six-month clinical outcomes of the Tryton Side Branch Stent for the treatment of bifurcation lesions

M. J. Grundeken · M. Smits · R. E. Harskamp · P. Damman ·
P. Woudstra · A. J. Hoorweg · J. Baan Jr · E. K. Arkenbout ·
J. J. Piek · M. M. Vis · J. P. S. Henriques · K. T. Koch ·
J. G. Tijssen · R. J. de Winter · J. J. Wykrzykowska

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Abstract

Aims Percutaneous coronary intervention (PCI) of a bifurcation lesion (BL) is still associated with poorer clinical outcomes when compared with PCI of a non-BL. Therefore, several dedicated coronary bifurcation stents, such as the Tryton Side Branch Stent™ (Tryton Medical, Durham, NC, USA), were developed to improve clinical outcomes. We investigated 6-month clinical outcomes after placement of a Tryton stent in 91 patients treated for 93 BLs in our centre. **Methods and results** All consecutive patients who have undergone PCI of a BL treated with the Tryton stent in our centre were included. Outcomes were defined as any death, cardiac death, myocardial infarction (MI), any revascularisation, ischaemia-driven target vessel revascularisation (TVR), ischaemia-driven target lesion revascularisation (TLR), stent thrombosis, and target vessel failure (TVF; composite of cardiac death, MI, and ischaemia-driven TVR). Event rates were estimated using the Kaplan-Meier method. Thirty-eight (42 %) patients with acute coronary syndrome (ACS) were included (16 % ST-segment elevation MI (STEMI)). The 6-month event rates were 5.4 % (death), 4.3 % (cardiac death), 2.2 % (MI), 4.5 % (any revascularisation), 4.5 % (TVR), 4.5 % (TLR) and 9.7 % (TVF).

Conclusion In a real-world all-comers single-centre registry, the use of the Tryton Side Branch Stent was associated with acceptable procedural and promising clinical outcomes at 6 months, including ACS and STEMI patients.

Keywords Percutaneous coronary intervention · Coronary artery disease · Bifurcation lesions · Dedicated bifurcation device

Introduction

Bifurcation lesions (BLs) account for 15 to 20 % of percutaneous coronary interventions (PCI) [1, 2]. The European Bifurcation Club recommends a single-stent approach with provisional side branch stenting as the preferred treatment for BLs [3]. Nevertheless, even if a provisional single-stent approach is used, PCI of a BL is still associated with poorer clinical outcomes when compared with PCI of a non-BL. Therefore, several dedicated bifurcation stents have been developed to improve clinical outcomes of BLs after PCI. One of these devices is the Tryton Side Branch Stent™ (Tryton Medical, Durham, NC, USA), which is used in combination with a conventional DES in the main branch. The Tryton stent could potentially optimise side branch ostium scaffolding, while minimising the amount of metal in the main branch [4]. A previous two-centre registry has shown promising procedural and clinical outcomes after placement of this dedicated device [5]. To confirm these observations, we investigated procedural success and clinical outcomes after treatment of BLs with the Tryton stent in 91 consecutive patients treated for BLs in our own centre.

M. J. Grundeken · M. Smits · R. E. Harskamp · P. Damman ·
P. Woudstra · A. J. Hoorweg · J. Baan Jr · E. K. Arkenbout ·
J. J. Piek · M. M. Vis · J. P. S. Henriques · K. T. Koch ·
J. G. Tijssen · R. J. de Winter · J. J. Wykrzykowska (✉)
Department of Cardiology, Academic Medical
Center – University of Amsterdam,
Meibergdreef 9, Room B2-125,
1105 AZ Amsterdam, the Netherlands
e-mail: j.j.wykrzykowska@amc.uva.nl

Methods

Setting

Our centre, the Academic Medical Center – University of Amsterdam, is a large tertiary referral hospital with an annual PCI volume of 2400 procedures. All patients in whom revascularisation is considered are discussed by an interventional cardiologist and thoracic surgeon in the local ‘heart team’. The decision to perform PCI or coronary artery bypass graft surgery is based on the coronary anatomy and clinical patient characteristics. All percutaneous interventions and adjunctive pharmacological treatment were performed according to the American College of Cardiology/American Heart Association and European Society of Cardiology guidelines. In general, all patients received aspirin (500 mg), clopidogrel (300 to 600 mg), and unfractionated heparin (5000 IU). Glycoprotein IIb/IIIa inhibitors were used at the discretion of the operator. Up to October 2010, the provisional single-stent technique was the default strategy for the treatment of BLs in our centre. In October 2010, the Tryton Side Branch Stent was introduced and all interventional cardiologists were trained to use this stent. The chosen strategy for BL treatment was at the discretion of the operator. Post PCI, patients were treated with clopidogrel 75 mg daily for 12 months, and with aspirin 100 mg daily indefinitely.

Device

The Tryton stent is a 5 or 6 Fr-compatible balloon-expandable cobalt-chromium slotted-tube bare-metal stent. It uses a single rapid exchange balloon based delivery system. The stent consists of three zones: a distal side branch zone, a transition zone at the carina and a main branch zone. The distal side branch zone has a design similar to a regular stent, scaffolding the side branch. The central transition zone has specific geometry of three elements which can be independently deformed to accommodate the wide range of carinal anatomy. The proximal main branch zone (‘the collar’) consists of two wedding bands and has a minimal amount of metal allowing easy delivery of a standard work-horse drug-eluting stent (DES). The stent delivery system has four markers for optimal positioning of the stent. A stepwise approach of the implantation technique of the Tryton stent has been described in detail previously [6]. In short, the technique involves wiring of the main and side branch, and the Tryton stent is advanced into the side branch. The stent is positioned in such way that the carina lies between the two middle markers. After deployment of the stent, the guidewire in the side branch is retracted and advanced into the

distal main branch through the central transition zone of the Tryton stent. A standard DES is placed in the main branch, jailing the side branch. Finally, ending the procedure with final kissing balloon inflation is recommended after recrossing a guidewire into the side branch, fenestrating the main branch struts (Fig. 1).

Study design

The study cohort consisted of consecutive patients who underwent PCI of a BL in our centre between October 2010 and December 2011, in whom the chosen treatment strategy was to use the Tryton stent. Included patients had either stable angina pectoris, unstable angina pectoris, non-ST-segment elevation myocardial infarction (NSTEMI), ST-segment elevation myocardial infarction (STEMI), or any other indication for PCI of a BL.

Baseline demographic variables and procedural information were prospectively collected by one of the investigators (MJG). All angiograms were reviewed for angiographic characteristics. BLs were classified according to the Medina classification [7]. Patients were contacted by telephone in January 2012 to obtain all relevant clinical data. When patients reported a potential major adverse cardiac event (MACE), hospital records were reviewed and, if necessary, the referring cardiologists were contacted to complete the information. If a patient could not be contacted by phone, the patient’s vital status was verified from the national population registry (Dutch Central Bureau of Statistics) and hospital records were obtained from patient’s last medical contact.

Outcomes and outcome definitions

Clinical outcomes were defined as follows: any death, cardiac death, any myocardial infarction (MI), any revascularisation, ischaemia-driven target vessel revascularisation (TVR), ischaemia-driven target lesion revascularisation (TLR), stent thrombosis, and target vessel failure (TVF), defined as the composite of cardiac death, any MI, and ischaemia-driven TVR. Furthermore, the procedural success rate was reported.

All deaths were considered cardiac unless otherwise documented. MI was defined according to the universal definitions of MI from the Joint ESC/ACCF/AHA/WHF Task Force [8]. In short, periprocedural MI was defined as a rise in cardiac biomarkers above three times the upper limit of normal. Spontaneous MI was defined as any rise in cardiac biomarkers above the upper limit of normal with at least one of the following: symptoms of ischaemia, electrocardiogram (ECG) changes indicative of new ischaemia, development of pathological Q waves on the ECG, or imaging evidence of new loss of viable

Fig. 1 Case example of a Tryton Side Branch Stent placement in a bifurcation lesion of the left anterior descending (LAD) artery and a large second diagonal branch (D2). **A** and **B**: Diagnostic angiograms of a patient presenting with stable angina pectoris, showing significant stenoses in both the proximal and distal main branch (LAD) as well as in the side branch (D2) (i.e. Medina 1.1.1). **C**: Positioning of the Tryton stent in the proximal main branch and side branch, using the two middle markers, ensuring that the carina is located in between these two markers. **D**: After guidewire retraction and redirection into the distal main branch, through the central transition zone of the Tryton stent, a standard drug-eluting stent was deployed in the main branch, jailing the side branch. **E**: Procedure is finished with final kissing balloon inflation. **F**: Final angiographic result

myocardium or new wall motion abnormality. Both spontaneous and periprocedural MI were included in the current analysis. TVR, TLR, and stent thrombosis were defined according to the Academic Research Consortium definitions [9]. In short, TVR was defined as any repeat revascularisation of any segment of the target vessel (both main branch and side branch). TLR was defined as any repeat revascularisation due to a restenosis of the target lesion, within 5 mm proximal or distal of either to the main branch stent or the Tryton stent. Stent thrombosis was adjudicated as definite, probable, or possible. Procedural success was defined as successful stent placement at the intended site with side branch residual stenosis <30 %, and no in-hospital MACE, defined as a composite of cardiac death, any MI, and any revascularisation. All events were adjudicated by two of the investigators (M.J.G. and J.J.W.).

Statistical analysis

Continuous data are presented as mean (and $\pm$ standard deviation) or as median (and interquartile ranges), where appropriate. Categorical data are shown as frequencies. Cumulative event rates were estimated using the Kaplan-Meier method. Follow-up was censored at the last known date of follow-up or at 6 months, whichever came first.

Results

Baseline patients and angiographic characteristics

Baseline patient and angiographic characteristics are shown in Table 1. Ninety-one patients with 93 BLs were included between October 2010 and December 2011. The average age of the patients was 67 years, 80 % were male, and 18 % were diabetics. Almost half of the included patients (42 %) had acute coronary syndrome (ACS) as indication for PCI, of which 12 % unstable angina pectoris, 14 % NSTEMI, and 16 % STEMI. Of the patients, 59 % had multivessel disease, and 2 patients had two BLs that needed PCI. Sixty-eight (73 %) BLs were located in the left anterior descending artery, three in the left main coronary artery, and one in a saphenous venous graft – first diagonal anastomosis. In four BLs, a chronic total occlusion was involved and in one, an in-stent restenosis of a previously placed bare metal stent (BMS). Of the lesions, 90 % were true bifurcations with involvement of both the main and the side branch (i.e. Medina 0.1.1, 1.0.1, or 1.1.1).

Procedural characteristics

Procedural characteristics are outlined in Table 2. Main branch predilatation was performed in 83 %, whereas side branch predilatation was performed in 85 %. An

Table 1 Baseline characteristics

Variable		
Patient characteristics		
	(n=91)	
Age (years)	67	±10
Male	73	80 %
Diabetes mellitus	16	18 %
Hypertension	42	48 %
Hypercholesterolaemia	35	41 %
Current smoker	19	22 %
Renal dysfunction	8	10 %
Previous MI	29	33 %
Prior revascularisation	29	33 %
Indication for PCI:		
- STEMI	14	16 %
- NSTEMI	13	14 %
- Unstable angina	11	12 %
- Stable angina	51	58 %
- Other	1	1 %
Multivessel disease	54	59 %
Lesion characteristics		
	(n=93)	
Bifurcation location		
- Left main bifurcation	3	3 %
- Left anterior descending/diagonal branch	68	73 %
- Left circumflex/obtuse marginal	16	17 %
- Posterolateral/posterior descending	5	5 %
- Saphenous venous graft/diagonal branch	1	1 %
Medina classification		
- 1.0.0	1	1 %
- 1.1.0	1	1 %
- 0.1.0	0	-
- 0.0.1	4	4 %
- 1.0.1	7	8 %
- 0.1.1	7	8 %
- 1.1.1	69	74 %
Chronic total occlusion	4	4 %
In-stent restenosis	1	1 %

Mean (±SD) or number (percentage). *MI* myocardial infarction, *PCI* percutaneous coronary intervention, *STEMI* ST-segment elevation myocardial infarction, *NSTEMI* non-ST-segment elevation myocardial infarction

everolimus-eluting stent was used as main branch stent in 97 % of the cases. In one left main BL, an endothelial progenitor cell capturing stent (ECS) was used in a patient with a contraindication for dual antiplatelet therapy due to very low platelets secondary to non-Hodgkin lymphoma. In 33 %, additional main branch stenting was performed, and in 14 % additional side branch stenting. The procedure was completed with final kissing balloon inflation in 71 % of cases. Successful stent placement at the intended site was obtained in 95 % of the lesions. In 5 patients, successful

stent placement at the intended site could not be obtained. In four patients, this was due to severe calcifications which prevented the Tryton stent from being passed, even after several predilatations. In the fifth patient, the diameter of the side branch turned out to be too small and the Tryton stent could not be introduced. The Tryton stent was retracted without any complications in all 5 patients and the procedures were finalised with a provisional single-stent technique. In-hospital MACE occurred in two patients. In one patient, the procedure was complicated with a wire dissection in the distal side branch, after successful Tryton placement, with subsequent temporary occlusion of this side branch resulting in a periprocedural MI. One other patient died in hospital after PCI. This patient presented with an out-of-hospital cardiac arrest based on a STEMI due to a ramus circumflex – obtuse marginal branch occlusion. After PCI, he was transferred to the intensive care unit, with a left ventricular mechanical support device (Impella 5.0 l/min), where he died 2 days later due to heart failure. Procedural success was therefore obtained in 92 %.

Clinical outcomes

Six-month clinical outcomes are summarised in Table 3. Median follow-up was 189 [105–295] days. Forty-seven (52 %) of the patients had at least 6 months of follow-up. Death occurred in 4 patients, of which 3 were from a cardiac cause. One 81-year-old patient died from a non-cardiac cause due to sepsis. One patient died 1 week after PCI due to ventricular arrhythmias. The arrhythmias probably originated from an old myocardial scar (i.e. patient had a previous MI and no ischaemic chest pain or electrocardiogram changes just before the onset of arrhythmia). The second patient who died of a cardiac cause was the aforementioned patient presenting with an out-of-hospital cardiac arrest who died 2 days after PCI on the intensive care unit. A third patient, an 85-year-old male, died suddenly in his sleep. Because no autopsy was performed the cause of death remained unknown, and his death was adjudicated as cardiac. The 6-month cumulative event rates of any death and cardiac death were therefore 5.4 % and 4.3 %, respectively.

MI occurred in two patients (cumulative MI rate of 2.2 %). One of these was the aforementioned periprocedural MI. The other MI occurred in a patient who had undergone PCI without complications. After the patient was discharged from our centre and transferred to the referral hospital, he developed ischaemic chest pain with ST-segment elevations on the electrocardiogram in the territory of the treated coronary segment. The patient was treated medically and suffered an MI with a maximum creatinine kinase-MB of 50 µg/l. This event was adjudicated as probable stent thrombosis, the only observed stent thrombosis in our cohort.

Table 2 Procedural characteristics

Variable	<i>n</i> =93	
Main branch predilatation	77	83 %
Side branch predilatation	79	85 %
Stent type used as main branch stent		
- Everolimus-eluting stent	90	97 %
- Endothelial progenitor cell capturing stent	1	1 %
- None used	2	2 %
Additional stent in main branch	31	33 %
Additional stent in side branch	13	14 %
Final kissing balloon inflation performed	65	71 %
Successful Tryton placement at intended site	88	95 %
Dissection requiring additional stenting	10	11 %
Glycoprotein IIb/IIIa inhibitors used during procedure	9	10 %*

Number (percentage). *Percentage based on 91 patients

Three revascularisations occurred. All revascularisations were ischaemia-driven with target lesion involvement. Six-month cumulative event rates of any revascularisation, ischaemia-driven TVR, and ischaemia-driven TLR were therefore 4.5 %, 4.5 %, and 4.5 %, respectively.

In summary, the 6-month cumulative event rate of the composite endpoint of TVF was 9.7 % (see Fig. 2).

Discussion

Our study provides procedural and clinical outcomes from a single-centre registry encompassing real-world data on Tryton stent implantations in a relatively high-risk patient population with implantations involving 42 % of ACS presentations (including 16 % STEMI patients), three left main lesions, four chronic total occlusions, one saphenous

venous graft lesion, and one in-stent restenosis. Acceptable procedural success (92 %) and 6-month TVF (9.7 %) rates were observed after placement of the Tryton Side Branch Stent. Moreover, the MI rate was low (2.2 %), and ischaemia-driven TVR and TLR rates were just 4.5 %. Only one case of probable stent thrombosis was observed.

Historically, percutaneous treatment of BLs is associated with worse clinical outcomes when compared with non-BLs [10]. Although DES significantly reduced in-stent restenosis rates compared with BMS [11], the treatment of BLs is still associated with increased rates of in-stent restenosis when compared with non-BLs [12, 13]. Furthermore, BL is independently associated with an increased risk of stent thrombosis [14]. Newly developed treatment strategies are therefore warranted to improve clinical outcomes after PCI of a BL.

Thus far, six randomised controlled trials (RCT) have compared the use of two stents versus a single-stent approach in the treatment of BL [15–20]. The BBC-ONE trial showed a clinical benefit favouring the single-stent technique, which was mainly driven by a reduction in periprocedural MI, of which clinical consequences are still a matter of debate [21, 22]. The five other trials showed no significant differences in clinical outcomes between single- and two-stent approaches. A meta-analysis performed on these six trials showed a significantly lower rate of MI in the single-stent group compared with the two-stent group (3.6 % versus 6.8 %, $p=0.01$), again mainly driven by periprocedural MIs, whereas no differences were found in other clinical outcomes. Comparing the single-stent group with the two-stent group, death rates were 0.9 % versus 0.8 %, TLR rates 5.3 % versus 5.9 %, MI 3.6 % versus 6.8 %, and stent thrombosis rates 0.8 % versus 1.7 % [23]. Although clinical outcomes of RCTs and registries are not directly comparable, the clinical results of our current study seem very promising when compared with the results of

Table 3 Six-month clinical outcomes

Outcome	No.	Event rates*
Any death	4	5.4 %
Cardiac death	3	4.3 %
Myocardial infarction	2	2.2 %
Any revascularisation	3	4.5 %
Ischaemia-driven TVR	3	4.5 %
Ischaemia-driven TLR	3	4.5 %
Stent thrombosis:		
- Definite	0	-
- Probable	1	1.1 %
- Possible	0	-
Target vessel failure [‡]	7	9.7 %

*Kaplan-Meier estimates. [‡]Target vessel failure is defined as the composite of cardiac death, any MI, and target vessel revascularisation. TVR target vessel revascularisation, TLR target lesion revascularisation

Fig. 2 Six-month clinical outcomes of the primary endpoint target vessel failure (TVF), defined as the composite of cardiac death, any MI, and clinically indicated target vessel revascularisation

these RCTs, given the fact that in the aforementioned RCTs the patient population mainly consisted of stable/unstable angina pectoris patients, excluding STEMI patients and patients with complex lesions (chronic total occlusions, saphenous venous grafts etc.), whereas in the current patient population no restrictions were made concerning indication for PCI and lesion characteristics, resulting in a study population which is in general at higher risk for re-events.

Based on these RCTs, the current consensus is to consider the single-stent approach as the default treatment strategy for BLs [3]. However, clinical outcomes after BL treatment are still worse compared with non-BL, both with the single- and the two-stent approach. Therefore, several dedicated bifurcation devices were developed to improve both single- and two-stent treatment strategies. The Tryton stent is one such dedicated bifurcation device, which is used in combination with a work-horse DES, and could therefore be considered a two-stent technique. Two clinical studies on this device have been previously published: a First-In-Man (FIM) study and a two-centre registry [5, 24]. Compared with these two previously published clinical studies on the Tryton stent, the current study showed slightly better clinical outcomes concerning MI (FIM 6.6 %, two-centre registry 3 %), comparable outcomes on TLR (FIM 6.6 %, two-centre registry 4 %), and stent thrombosis (no stent thrombosis in either the FIM or the two-centre registry), and slightly worse outcomes on cardiac deaths (FIM 3.3 %, two-centre registry 1 %). These differences in cardiac death rates could be attributed to the differences in risk profile of the patient populations,

with no (N)STEMIs being included in the FIM, and only 3 % STEMIs in the two-centre registry study. Moreover, all cardiac deaths in our cohort could be explained as the result of the natural history of the underlying disease, whereas no relation with the device could be identified. Only one probable stent thrombosis was observed resulting in an MI. More importantly, overall clinical outcomes were comparable between these three studies, even though the risk profile of the patient population of the current study was much higher. The FIM study showed a MACE rate (defined as composite of cardiac death, MI, CABG, and TLR) of 9.9 %, the two-centre study showed a MACE rate (defined as composite of cardiac death, MI, CABG, and TLR) of 8 %, whereas the rate of the composite endpoint of the current study (defined as the composite of cardiac death, MI, and TVR) was 9.7 %. Procedural success in our study was slightly lower than in the previous studies. This could be explained by the fact that the procedures were done by nine different operators. Because all procedures were included, without excluding lead-in procedures, the current data could be influenced by the learning curve of the operators. However, clinical results are still comparable with previous Tryton studies, suggesting Tryton to be an easy-to-use device, even among operators who have more experience with a single-stent strategy rather than with two-stent techniques in BL treatment. Furthermore, the reason for delivery failure was excessive calcification in 4 out of 5 cases, which suggests delivery failure to be more likely related to lesion characteristics than to operator skills. Procedural

success may therefore be further improved by predilatation of calcified lesions with cutting balloons or by using a rotablator.

Until the introduction of the Tryton stent in our centre in October 2010, provisional T-stenting was the default strategy in BLs. Clinical outcomes of the current study are comparable with previously published data from our centre [25, 26]. These studies evaluated BL treatment using the provisional T-stenting approach with either a BMS or an ECS, showing 1-year cumulative event rates of the combined endpoint (defined as composite of cardiac death, myocardial infarction, or target lesion revascularisation) of 17.4 % in the BMS group and 12.4 % in the ECS group. In these studies, only patients with stable/unstable angina pectoris were included with a de novo coronary lesion, excluding patients with (N)STEMI. Therefore, the results of the current study seem promising, given the fact that the risk profile of the current study population and lesion characteristics are much higher than that of the historical cohort.

The current consensus to use a simple, single-stent approach in BLs is based on evidence from RCTs where conventional (DES) stents were used. However, dedicated bifurcation devices supporting a two-stent technique could shift the current paradigm and make the two-stent approach the preferred strategy, especially in certain lesion subtypes such as true bifurcations with extensive side branch disease [27]. On the other hand, dedicated bifurcation devices facilitating a single-stent approach or adjunctive use of drug-eluting balloons [28] could improve clinical outcomes of the single-stent technique. More RCTs on dedicated devices are therefore needed to clarify whether dedicated devices improve clinical outcomes, and whether a provisional single-stent approach is still the preferred strategy with the availability of new dedicated devices.

Study limitations

Because the use of Tryton was at the discretion of the operator, a selection bias may have occurred. Furthermore, no routine angiographic follow-up was performed. Finally, cardiac biomarkers were only measured after PCI if indicated (i.e. development of new ischaemic chest pains and/or (new) ST-segment elevation on electrocardiogram), and not performed routinely, which could have resulted in underreporting of periprocedural MIs. However, the design of the current study reflects utilisation and performance of a new dedicated device in daily clinical practice of a single centre in which the single-stent approach was the default strategy in treatment of BLs.

Conclusions

In a real-world all-comers single-centre registry, the use of Tryton Side Branch Stent is associated with acceptable procedural and promising clinical outcomes at 6 months, including high-risk lesions, ACS and STEMI patients.

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CVOI E-learning formula!

This is the CVOI e-learning article. The author has prepared 10 questions which are available through the website of the Cardiovascular Educational Institute (CVOI). Please follow the instructions below.

After finishing the questions you will be asked to fill in your name, hospital and e-mail address; then press the button 'verzenden'.

When 6 out of the 10 questions are answered correctly, you acquire 1 accreditation point granted by the Quality Committee of the Netherlands Society of Cardiology (NVVC). The acquired point will be credited to your personal file in the GAIA system. You will also receive an e-mail with all the correct answers.

Over a period of one year 10 e-learning articles will appear in 10 subsequent NHJ editions. In each edition the e-learning article will be recognisable by a special icon. On an annual basis you can collect 10 accreditation points. The accreditation points are credited in the GAIA system by the CVOI.

If you need additional information, please contact the CVOI by e-mail: cvoi@cvoi.org or by phone: 030-2345001.

E.E. van der Wall
Chief editor NHJ

K.B. Schick
Coordinator CVOI