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The Tryton® dedicated bifurcation stent: Five year clinical outcomes☆

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ABSTRACT

Aims: We report the first 5 year clinical follow-up data for the Tryton® bifurcation stent.
Methods and results: Clinical outcomes at five years were collected from 8 centres. Non-hierarchical Major Adverse Cardiovascular Events (MACE) and Major Adverse Cerebrovascular and Cardiovascular Events (MACCE) were collected. Diabetic and non-diabetic populations were compared, along with small (≤2.5 mm) vs large (>2.5 mm) side branch size.
173 patients with a follow up rate of 98% at 5 years were analysed. Non-hierarchical MACE was low at 9.8%, consisting of cardiac death of 1.2% (n = 2) and MI of 1.7% (n = 3). Target lesion revascularization (TLR) rate was 6.9% (n = 12). Non-hierarchical MACCE was also low, with major bleeding in 2.3% (n = 4) and strokes in 1.7% (n = 3) of patients. There was only 1 case (0.6%) of stent thrombosis that was definite and occurred very late (782 days). All-cause mortality was low, with 8.7% combined cardiac and non-cardiac death (n = 15). Diabetic patients had significantly higher event rates, but there was no difference in events with lesion stratification by side branch size.
Conclusions: The Tryton® Side-Branch Stent has a non-hierarchical MACE of 9.8% and MACCE of 13.9% at 5 years. The TLR was 6.9% with only 1 case of stent thrombosis recorded.

1. Introduction

Treatment of de novo coronary bifurcation lesions remains a challenge within interventional cardiology, with lower treatment success rates, despite representing up to 20% of percutaneous coronary intervention (PCI) procedures [1,2]. The provisional approach, without routine stenting of the side branch, is the current standard therapy after studies failed to show benefit with routine side branch stenting [3–5]. However, definitive conclusions have been difficult and the optimal technique to treat side branches is wanting. The Tryton® Side-Branch Stent (Tryton® Medical, Inc., 1000 Park Forty Plaza, Suite 325, Durham, NC 27713, USA) is a balloon expandable cobalt chromium bare metal stent (BMS), designed specifically for treatment of de novo coronary bifurcation lesions with three unique zones (Fig. 1).

There have been compelling clinical results published so far, with initial non-randomized studies demonstrating good clinical outcomes [6–10]. More recently, the Tryton® Pivotal study compared use of the Tryton® stent to a provisional approach and demonstrated reduced side branch restenosis in the Tryton® group [11]. Non-inferiority for Major Adverse Cardiac Events (MACE) was not met, but this was due to unintentional enrollment of patients which small side branches. Post-hoc analysis, in conjunction with the Tryton® Confirmatory Study [12], met non-inferiority for MACE in patients with large side branches at 9-months compared to provisional stenting. However, longer-term outcomes have not previously been published.

☆ Declarations of interest: None.

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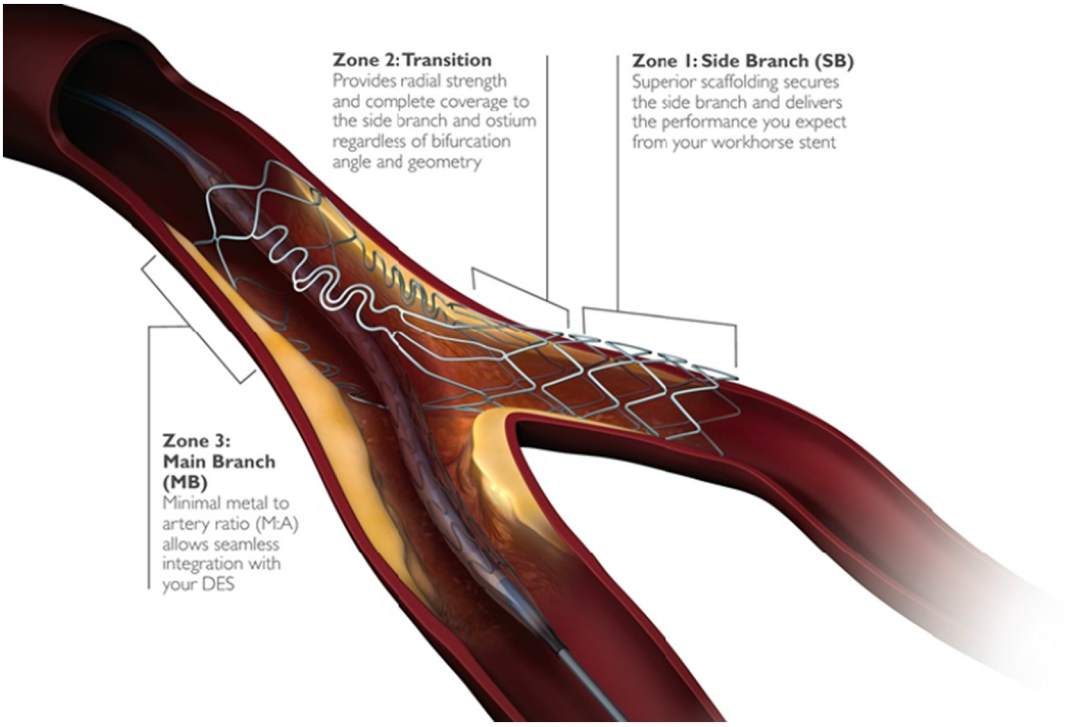

Fig. 1. The Tryton® Side-Branch Stent. Reproduced from Tryton® Medical with permission.

We publish here the first 5 year outcome results of the Tryton® stent in a real-world population.

2. Methods

2.1. Study population

Since May 2009 >1800 patients have been treated with the Tryton® stent within clinical studies and registries across Europe. As of the first quarter of 2015, 379 patients had potential 5 year follow-up data available.

All eligible centres were contacted and requested to collect 5 year follow-up data (±1 month) on their patient cohort. Data collection was on a dedicated Clinical Event Form (CRF) (Supplementary Attachment), which was automatically stored on a secure on-line database, run by an independent data collator and analyst (ClinFlows, Bielefeld, Germany). Completion of the CRF was either done directly online, or a paper copy was completed and subsequently transcribed to the online form, at the investigating centre's discretion.

Ethical approval and consent had previously been obtained locally when patients were initially enrolled at the time of index PCI.

Data was submitted by 8 centres: University Medical Centre, Utrecht, Netherlands; Paula Stradiņa Klīniskā Universitātes Slimnīca, Rīga, Latvia; Ziekenhuis Oost-Limburg, Limburg, Belgium; Universitair Ziekenhuis Brussel, Brussels, Belgium; Universitair Ziekenhuis Leuven, Leuven, Belgium; Hospital Son Dureta de Palma de Mallorca, Palma, Spain; Clinico Universitario Valladolid, Valladolid, Spain; University Hospital, Krakow, Poland. Data on a total of 173 patients was collected. The follow-up rate from each centre was >90% of all eligible patients with potential 5 year data (Fig. 2), with the exception of Krakow which had a follow-up rate of 75% due to the small number of patients enrolled (n = 4). Overall, the follow-up rate for all the responding centres combined was 98% of eligible patients.

After data had been received, all centres were re-contacted and requested to confirm that the data was correct and that there were no further eligible submissions.

2.2. Study endpoints

Non-hierarchical Major Adverse Cardiac Events (MACE) at 5 years post Tryton® stent implantation was assessed, consisting of cardiac death, myocardial infarction (MI) (Q-wave or non-Q-wave) and Target Lesion Revascularization (TLR). Non-hierarchical Major Adverse Cerebrovascular or Cardiovascular Events (MACCE) at 5 years was also assessed, consisting of MACE plus stroke (ischaemic and haemorrhagic) and bleeding. All-cause mortality (cardiac and non-cardiac) was also collected. Sub-analysis of diabetic vs non-diabetic populations was performed (data unavailable for 4 patients). Patients with small side branch vessels (≤2.5 mm) by visual angiographic analysis at time of implant were also compared with those with large side branch vessels (>2.5 mm) (data unavailable for 4 patients).

2.3. Definitions

During the period of assessment the definitions for MI reflected the changes made by the governing societal bodies. As such an MI was

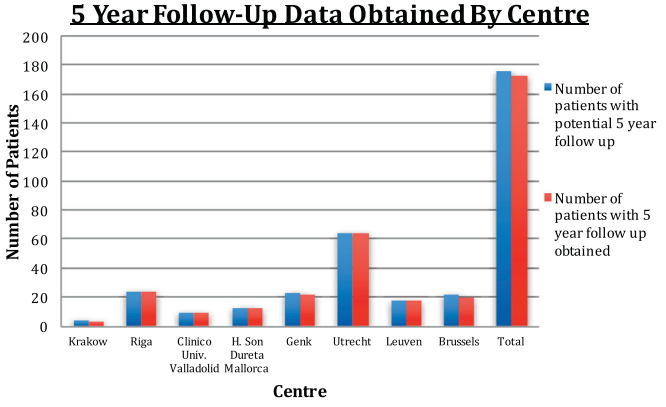

Fig. 2. Response rate by centre.

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Table 1a
Patient demographics (total).

Total	173
Male sex	133 (76.9)
Age	65.8 ± 9.7
Previous/current smoking	79 (45.7)
Hypertension	109 (63.0)
DM	34 (19.7)
Family history	55 (31.8)
Hypercholesterolaemia	111 (64.2)
Previous stroke/TIA	9 (5.2)
Previous MI	46 (26.6)
Previous PCI	68 (39.3)
Previous CABG	5 (2.9)
PVD	13 (7.5)
CCF	8 (4.6)
Renal dysfunction	11 (6.4)
Unknown	2 (1.2)

Key: n (%). Age in years ± standard deviation. DM = Diabetes Mellitus, TIA = Transient Ischaemic Attack, MI = Myocardial Infarction, PCI = Percutaneous Coronary Intervention, CABG = Coronary Artery Bypass Grafting, PVD = Peripheral Vascular Disease, CCF = Congestive Cardiac Failure.

defined by either the criteria used in the original First In Man (FIM) study [6] (new abnormal Q-waves in accordance with the Minnesota Code for pathologic Q-Waves or creatinine kinase [CK] 2× local laboratory upper limit of normal [ULN] with an associated rise in the level of the MB isoenzyme of CK [CK-MB]), or the newer SCAI guidelines [13] (isolated CK-MB ≥10× ULN/troponin ≥70× ULN or new Q waves/left bundle branch block [LBBB] with CK-MB ≥5× ULN/troponin ≥5× ULN or new ST-segment elevation or depression). Stroke was defined by the guidelines of the Stroke Council of the American Heart Association/American Stroke Association [14]. TLR was defined as any repeat treatment of a lesion located within the index coronary segment.

2.4. Statistics

Continuous variables are presented as mean ± standard deviation and categorical variables are presented as counts and frequencies. Continuous variables were tested with the two-tailed *t*-test and categorical variables with either the χ^2 test or Fisher's Exact Test if any cell had an expected count <5. Statistical significance was set at 0.05 (5%). All statistical analysis was done using SPSS software package version 24 (IBM Corp., Armonk, NY, USA).

Table 1b
Patient demographics (diabetic vs non-diabetic).

	Diabetics (n = 34)	Non-diabetics (n = 135)	p value
Male sex	25 (73.5)	107 (79.3)	0.470
Age	68.6 ± 9.3	65.0 ± 9.8	0.052
Previous/current smoking	13 (38.2)	65 (48.1)	0.300
Hypertension	30 (88.2)	78 (57.8)	0.001
Family history	6 (17.6)	48 (35.6)	0.045
Hypercholesterolaemia	27 (79.4)	83 (61.5)	0.050
Previous stroke/TIA	3 (8.8)	6 (4.4)	0.309
Previous MI	11 (32.4)	35 (25.9)	0.452
Previous PCI	16 (47.1)	51 (37.8)	0.323
Previous CABG	0 (0)	4 (3.0)	0.310
PVD	5 (14.7)	8 (5.9)	0.086
CCF	4 (11.8)	5 (3.7)	0.061
Renal dysfunction	5 (14.7)	7 (5.2)	0.053

Key: n (%). Age in years ± standard deviation. DM = Diabetes Mellitus, TIA = Transient Ischaemic Attack, MI = Myocardial Infarction, PCI = Percutaneous Coronary Intervention, CABG = Coronary Artery Bypass Grafting, PVD = Peripheral Vascular Disease, CCF = Congestive Cardiac Failure.

Table 1c
Patient demographics (small vs large side branch).

	Small (≤ 2.5 mm) side branch (n = 119)	Large (> 2.5 mm) side branch (n = 50)	p value
Male sex	93 (78.2)	38 (76.0)	0.760
Age	66.2 ± 9.3	65.0 ± 10.4	0.464
Previous/current smoking	54 (45.4)	24 (48.0)	0.755
Hypertension	71 (59.7)	36 (72.0)	0.129
DM	23 (19.3)	11 (22.0)	0.692
Family history	37 (31.1)	17 (34.0)	0.711
Hypercholesterolaemia	79 (66.4)	31 (62.0)	0.585
Previous stroke/TIA	7 (5.9)	2 (4.0)	1.000
Previous MI	27 (22.7)	18 (36.0)	0.074
Previous PCI	46 (38.7)	20 (40.0)	0.879
Previous CABG	3 (2.5)	2 (4.0)	0.633
PVD	8 (6.7)	5 (10.0)	0.530
CCF	5 (4.2)	4 (8.0)	0.452
Renal dysfunction	6 (5.0)	6 (12.0)	0.185

Key: n (%). Age in years ± standard deviation. DM = Diabetes Mellitus, TIA = Transient Ischaemic Attack, MI = Myocardial Infarction, PCI = Percutaneous Coronary Intervention, CABG = Coronary Artery Bypass Grafting, PVD = Peripheral Vascular Disease, CCF = Congestive Cardiac Failure.

3. Results

3.1. Demographics and lesion characteristics

Demographics obtained at the time of screening prior to Tryton® stent implantation are shown (Tables 1a–1c) along with stented main vessel lesion characteristics (Tables 2a–2c). The majority of patients were male, with 26.6% having had a previous MI. The majority of treated lesions were in the LAD (73.4%) and were American College of Cardiology/American Heart Association (ACC/AHA) class B2 (63.6%). Thirty four (19.7%) patients were diabetic, who had statistically significant higher rates of hypertension, hypercholesterolaemia and family history of coronary artery disease. There were no statistical differences in lesion type or location. In 119 (68.8%) lesions the treated side branches were small. There was no statistically significant difference in either demographics or lesion characteristics between side branch cohorts.

3.2. Overall MACE and MACCE

There was a low rate of non-hierarchical MACE at 5 years, with only 2 cardiac deaths (1.2%), 3 MIs (1.7%) and 12 cases of TLR (6.9%) (Table 3a, Fig. 3a). Rates of non-hierarchical MACCE were also low, with only 4 cases of major bleeding (2.3%) and 3 strokes (1.7%) in addition (Table 3a, Fig. 3b). All-cause mortality was also low, with only 15 combined cardiac and non-cardiac deaths (8.7%) (Table 3a, Fig. 4).

Table 2a
Main vessel lesion characteristics (total).

Total		173
Lesion location	RCA	11 (6.4)
	LMS	6 (3.5)
	LAD	127 (73.4)
	LCx	25 (14.5)
	Unknown	3 (1.7)
Lesion ACC/AHA classification	Class A	1 (0.6)
	Class B1	19 (11.0)
	Class B2	110 (63.6)
	Class C	40 (23.1)
	Unknown	2 (1.2)
Side branch size	Large (>2.5 mm)	50 (28.9)
	Small (≤2.5 mm)	119 (68.8)
	Unknown	4 (2.3)

Key: n (%). RCA = Right Coronary Artery, LMS = Left Main Stem, LAD = Left Anterior Descending, LCx = Left Circumflex, ACC/AHA = American College of Cardiology/American Heart Association.

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Table 2b
Main vessel lesion characteristics (diabetic vs non-diabetic).

		Diabetics (n = 34)	Non-diabetics (n = 135)	p value
Location	RCA	1 (2.9)	10 (7.4)	0.696
	LMS	3 (8.9)	3 (2.2)	0.056
	LAD	27 (79.4)	99 (73.3)	0.467
	LCx	3 (8.9)	21 (15.6)	0.416
	Unknown	0 (0)	2 (1.5)	1.000
Lesion ACC/AHA classification	Class A	0 (0)	1 (0.7)	1.000
	Class B1	1 (2.9)	18 (13.3)	0.127
	Class B2	22 (64.7)	86 (63.8)	0.913
	Class C	11 (32.4)	29 (21.5)	0.183
	Unknown	0 (0)	1 (0.7)	1.000

Key: n (%). RCA = Right Coronary Artery, LMS = Left Main Stem, LAD = Left Anterior Descending, LCx = Left Circumflex, ACC/AHA = American College of Cardiology/American Heart Association.

Table 2c
Main vessel lesion characteristics (small vs large side branch).

		Small (≤ 2.5 mm) side branch (n = 119)	Large (> 2.5 mm) side branch (n = 50)	p value
Location	RCA	9 (7.6)	1 (2.0)	0.510
	LMS	2 (1.7)	4 (8.0)	0.064
	LAD	92 (77.3)	35 (70.0)	0.315
	LCx	16 (13.4)	9 (18.0)	0.447
	Unknown	0 (0)	1 (2.0)	0.296
Lesion ACC/AHA classification	Class A	0 (0)	0 (0)	N/A
	Class B1	13 (10.9)	6 (12.0)	0.840
	Class B2	77 (64.7)	33 (66.0)	0.872
	Class C	29 (24.4)	11 (22.0)	0.741

Key: n (%). RCA = Right Coronary Artery, LMS = Left Main Stem, LAD = Left Anterior Descending, LCx = Left Circumflex, ACC/AHA = American College of Cardiology/American Heart Association.

Only one case of stent thrombosis occurred, resulting in an MI and subsequent TLR. This was a definite stent thrombosis and occurred very late at 782 days. The characteristics of this case are given in Table 4.

3.3. Diabetic population

Patients with diabetes had significantly higher rates of both cardiac (5.9% vs 0%) and non-cardiac (20.6% vs 3.7%) death (Table 3b, Fig. 5a–b). Rates of TLR (14.7% vs 4.4%) and bleeding (11.8% vs 0%) were also significantly higher. This also reflects the higher cardiovascular risk factors (Hypertension, Family History and Hypercholesterolaemia) noted in this population.

Table 3a
Total non-hierarchical MACE/MACCE rates.

Death	Cardiac	2 (1.2)
	Stent thrombosis	0 (0)
	Non-cardiac	13 (7.5)
MI	Total	3 (1.7)
	Target Lesion Involved	2 (1.2)
	Stent Thrombosis	1 (0.6)
TLR	Total	12 (6.9)
	CABG	1 (0.6)
	Emergency PCI	0 (0)
	Semi-elective PCI	2 (1.2)
	Elective PCI	8 (4.6)
	Unknown	1 (0.6)
Bleeding		4 (2.3)
Stroke	Ischaemic	3 (1.7)
	Haemorrhagic	0 (0)

Key: n (%). MI = Myocardial Infarction, TLR = Target Lesion Revascularization, CABG = Coronary Artery Bypass Grafting, PCI = Percutaneous Coronary Intervention.

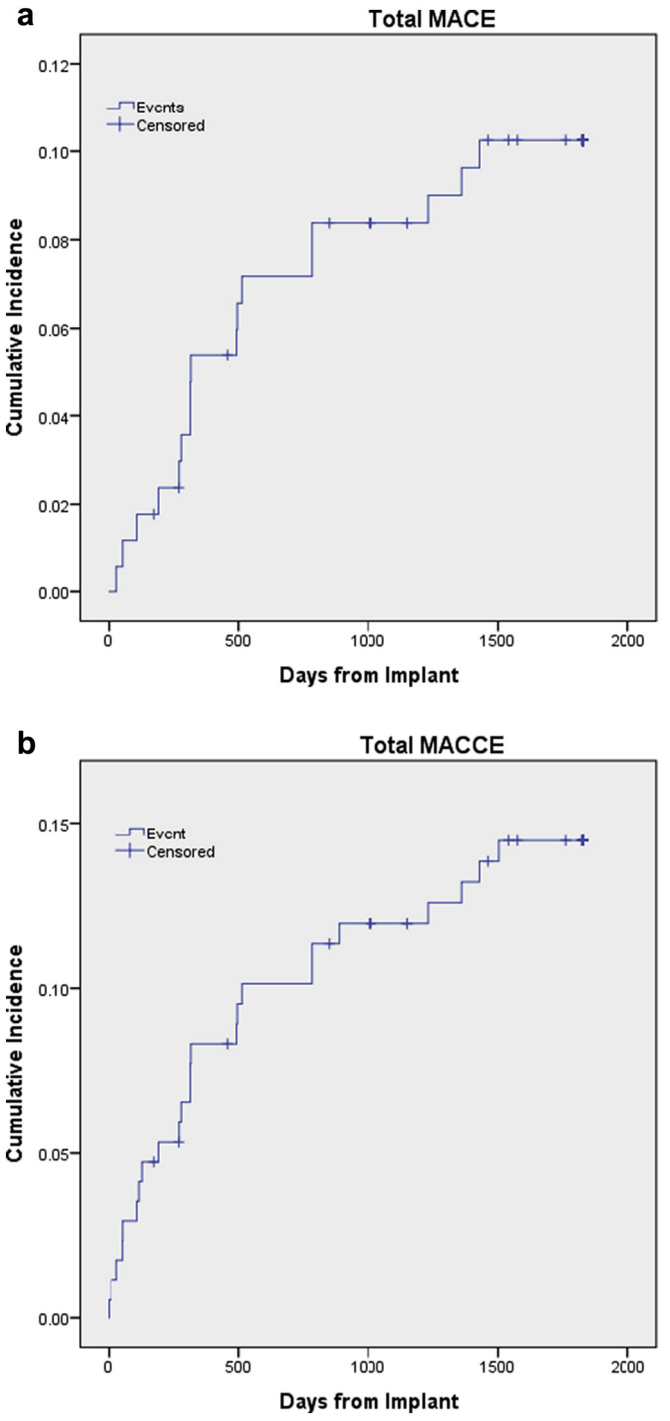

Fig. 3. a: Kaplan-Meier event curve of total non-hierarchical MACE. b: Kaplan-Meier event curve of total non-hierarchical MACCE.

3.4. Small side-branch population

There was no statistically significant difference in any MACE/MACCE parameter for lesions with small side branches (Table 3c, Fig. 6a–b). Of note the majority (68.8%) of patients had small (≤2.5 mm) side-branches, compared to 28.9% with vessels >2.5 mm diameter.

4. Discussion and limitations

Bifurcation lesions remain challenging targets for revascularization. The treatment of vessel side branches can be technically difficult,

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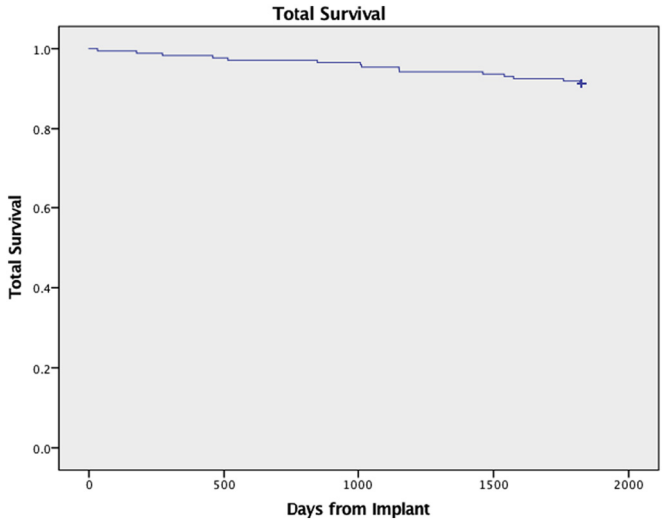

Fig. 4. Kaplan-Meier curve of total survival.

depending on their size and angulation, as well as the degree of plaque burden.

The optimal strategy for treatment of bifurcation lesions therefore remains controversial. Recently EuroIntervention has published a supplement highlighting the views of the European Bifurcation Club [15]. Their recommendation was for a provisional technique to be the first-line choice. However, use of dedicated bifurcation stent systems in "bifurcations needing a two-stent technique may prove of value". The Tryton® stent has evolved to help tackle the issue of side branch occlusion during the provisional technique. There has been some improvement in this by using the Proximal Optimisation Technique (POT), but procedural failure can still occur.

There are a number of salient features that make the Tryton® stent effective for managing bifurcations. First and foremost it allows protection of the side branch by adequate coverage of the ostia with the open cell fronds. This has the advantage of conforming to the proximal vessel diameter, allowing the necessary tapering to the vessel's natural architecture. It is well known that the crush two-stent technique used in the protection of the side branch is inferior to that of the cullotte. The Tryton embodies a modified or 'skeletalized cullotte' such that the proximal part of the stent has just enough metal scaffolding to keep the vessel open to facilitate the standard work-house drug-eluting stent (DES) into the main vessel. This means that within the proximal stent there is essentially limited overlap of two layers (Tryton® and DES). This poses

Table 3b
Non-hierarchical MACE/MACCE (diabetic vs non-diabetic).

		Diabetics (n = 34)	Non-diabetics (n = 135)	p value
Death	Cardiac	2 (5.9)	0 (0)	0.040
	Stent thrombosis	0 (0)	0 (0)	N/A
	Non-cardiac	7 (20.6)	5 (3.7)	0.003
MI		2 (5.9)	1 (0.7)	0.103
	Target lesion involved	1 (2.9)	1 (0.7)	0.363
	Stent thrombosis	0 (0)	1 (0.7)	1.000
TLR	Total	5 (14.7)	6 (4.4)	0.046
	CABG	1 (2.9)	0 (0)	0.201
	Emergency PCI	0 (0)	1 (0.7)	1.000
	Semi-elective PCI	1 (2.9)	1 (0.7)	0.363
	Elective PCI	3 (8.8)	4 (3.0)	0.146
	Stent thrombosis	0 (0)	1 (0.7)	1.000
Stroke	Ischaemic	2 (5.9)	1 (0.7)	0.103
	Haemorrhagic	0 (0)	0 (0)	N/A
Bleeding		4 (11.8)	0 (0)	0.001

Key: n (%). MI = Myocardial Infarction, TLR = Target Lesion Revascularization, CABG = Coronary Artery Bypass Grafting, PCI = Percutaneous Coronary Intervention.

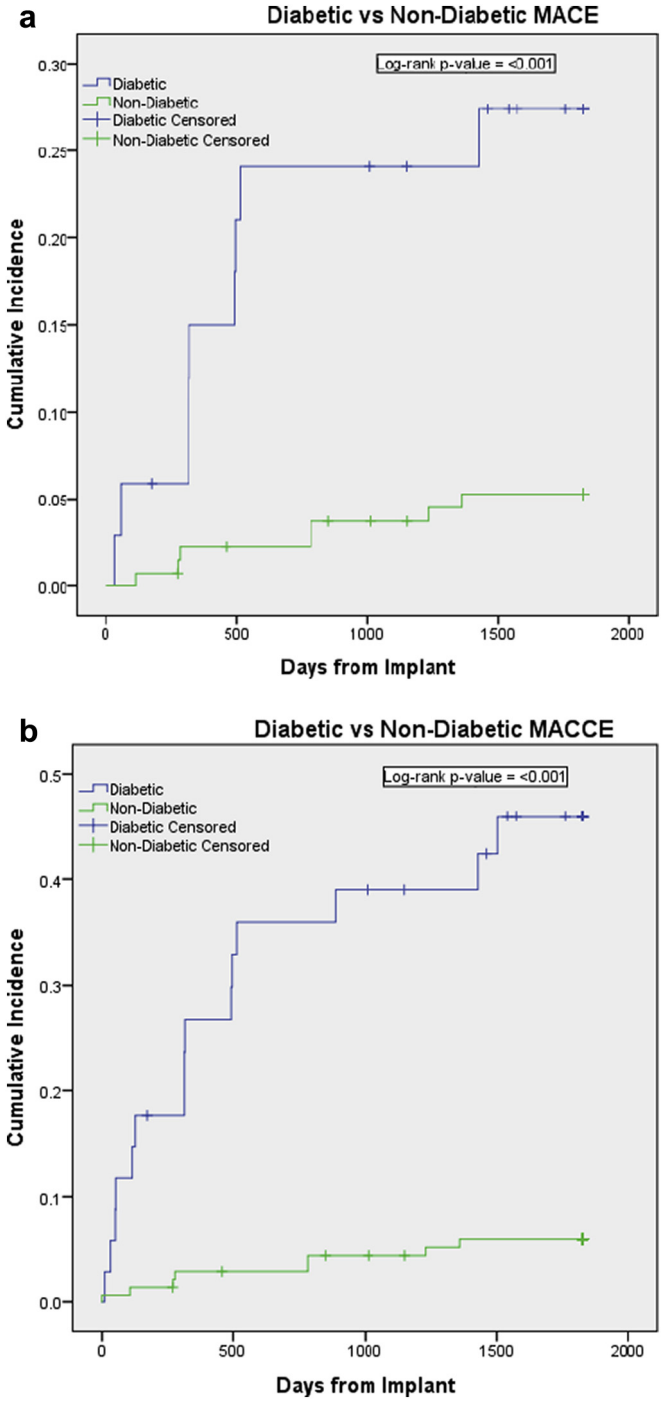

Fig. 5. a: Diabetic vs non-diabetic MACE. b: Diabetic vs non-diabetic MACCE.

two clear advantages; firstly it limits restenosis, but more importantly it allows for facile re-crossing as there are less overlapping cells at the side-branch ostia. A key criticism of the Tryton® is that it is a BMS, however in reality the amount of mesh work the stent contributes at the ostia is relatively small but just enough to maintain recoil. It therefore means than the DES in the main vessel can effectively elute into the ostia to arrest ostial hyperplasia that leads to restenosis. The Tryton® stent inadvertedly adopted the POT technique in its design by recommending that during its deployment an appropriately sized balloon to the proximal vessel be used prior to re-crossing. In addition to ensuring that the 'wedding ring band' (the metallic supporting ring at the proximal end of the stent) is fully apposed, it also 'funnels' into the side-branch ostia as noted in the latterly defined POT technique.

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Table 3c
Non-hierarchical MACE/MACCE (small vs large side branch).

		Small (≤ 2.5 mm) side branch (n = 119)	Large (> 2.5 mm) side branch (n = 50)	p value
Death	Cardiac	1 (0.8)	1 (2.0)	0.505
	Stent thrombosis	0 (0)	0 (0)	N/A
	Non-cardiac	7 (5.9)	5 (10.0)	0.341
MI		3 (2.5)	0 (0)	0.556
	Target lesion involved	2 (1.7)	/	N/A
	Stent thrombosis	1 (0.8)	/	N/A
TLR	Total	8 (6.7)	4 (8.0)	0.750
	CABG	0 (0)	1 (2.0)	0.296
	Emergency PCI	1 (0.8)	0 (0)	1.000
	Semi-elective PCI	2 (1.7)	0 (0)	1.000
	Elective PCI	5 (4.2)	3 (6.0)	0.695
	Stent thrombosis	1 (0.8)	0 (0)	1.000
Bleeding		2 (1.7)	2 (4.0)	0.583
Stroke	Ischaemic	1 (0.8)	1 (2.0)	0.505
	Haemorrhagic	0 (0)	0 (0)	N/A

Key: n (%). MI = Myocardial Infarction, TLR = Target Lesion Revascularization, CABG = Coronary Artery Bypass Grafting, PCI = Percutaneous Coronary Intervention.

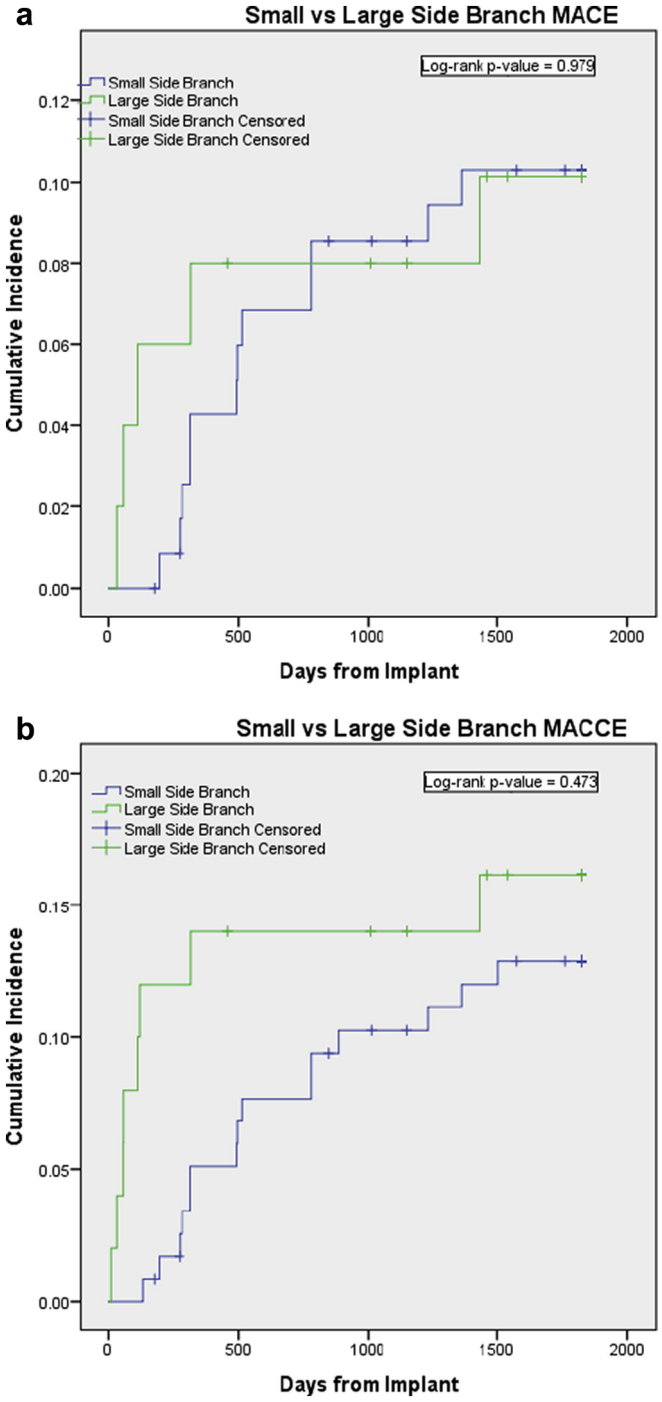

Fig. 6. a: Small vs large side branch MACE. b: Small vs large side branch MACCE.

A few renowned studies on bifurcation strategies have recently published 5 year follow-up data. Five year follow up from the Nordic Bifurcation Study showed total rates of MACE of 15.8% to 21.8%, depending on whether the side branch was routinely stented [3]. Of note is that in this study of 413 patients randomized to either a simple strategy (stenting of the main vessel and optional stenting of the side branch) or a complex strategy (stenting of both the main vessel and side branch) the first generation Sirolimus-eluting Cypher Select® Plus stent (Cordis® Corporation, 14201 NW 60th Ave, Miami Lakes, FL 33014, USA) was used in all cases. Even though the rates of all adverse outcomes were numerically higher with the complex strategy it was not statistically significant. Oddly, there was a trend to more stent thrombosis with the single stent (3.0% vs 1.5%). We found an equally low stent thrombosis rate of 0.6% with the Tryton® stent. Five year follow up of the Axxess® stent system (Biosensors® Europe SA, Rue de Lausanne 29, 1110 Morges, Switzerland) has also been published, showing total MACE rates of 22.3% with routine side branch stenting [16]. However, there should be caution in direct comparisons as MACE definitions vary and these trials use hierarchical MACE rates.

The non-hierarchical MACE rate of 9.8% and MACCE of 13.9% we demonstrated at 5 years are therefore very favourable. The relatively low rates may be partly attributed to collecting centres being high volume centres, with dedicated bifurcation specialists with significant experience of using Tryton® stents. However, the definition of peri-procedural MI did have a large influence on MI rates and so overall MACE. Older studies, including the Tryton FIM, defined it by the presence of new pathological Q waves or a rise in CK >2×ULN with a rise in CK-MB. Other trials have used a rise in CK-MB >3×ULN [3,11]. We have used the same criteria as in the original FIM whenever CK-MB was available to the collecting centre, or the newer SCAI criteria where the traditional CK-MB used in earlier trials was superseded by troponins [13]. Consequently a much higher cut-off of CK-MB ≥10×ULN or Troponin ≥70×ULN, or new Q waves/LBBB with CK-MB ≥5×ULN or Troponin ≥35×ULN was employed for the majority our data collection. This significantly affected the MI detection rates as has been previously noted [18]. Indeed, analysis of peri-procedural MI rates in the Tryton® Pivotal trial showed that rates using the protocol definition of >3×ULN CK-MB were 10× higher than if the SCAI criteria were used [19]. Taking this into account, it should also be pointed out that even though the Tryton® stent is a BMS, it is combined with a DES in the main vessel branch, and additionally the results of the recent NORSTENT trial demonstrated no difference in rates of all cause death or MI at 5 year follow-up for BMS in comparison to DES [17].

Oddly, the diameter of the side branch in our 5 year data did not seem to influence the MACE rate, in contrast to the Tryton® IDE study at 9 month follow-up. In the IDE study 60% of the side branches treated were smaller than the intended study population of side branch vessels of 2.25 mm diameter or greater by Quantitative Coronary Analysis (QCA). This influenced the results such that clinically driven target vessel revascularization in the Tryton® was 4.7% compared to 3.6% seen with the provisional technique. Hence Tryton®, compared to the provisional arm of the study, did not meet the non-inferiority clinical endpoint of target vessel failure

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Table 4
Stent thrombosis case characteristics.

Age	Events	Time to events	Type of thrombosis	Side-branch size	MEDINA	Diameter stenosis side-branch	Diameter stenosis main-branch	Medication
73	STEMI and TLR	782 days	Very late (definite)	2.5 mm	1,1,1	100%	100%	Aspirin

Key: STEMI = ST Elevation Myocardial Infarction, TLR = Target Lesion Revascularization.

(TVF) and this was driven in large part by peri-procedural CK-MB elevations (Tryton® 17.4%; Provisional 12.8%). When post hoc subgroup analysis of the intended study population (>2.25 mm) was undertaken Tryton® outperformed the provisional arm of the study in TVF (Tryton® 11.3%; Provisional 15.6%) but also had a reduction in percent diameter stenosis (Tryton® 30.4%; Provisional 40.6%; $p = 0.004$) [11,12]. It is not surprising therefore that in our study, by using the SCAI criteria together with a cut off of 2.5 mm diameter for the side branch, we found no difference between small and larger diameters ($p = 0.979$). It should be noted however that in our study side branch size was assessed by visual analysis rather than QCA.

As expected the diabetic population had higher event rates ($p < 0.001$) together with more cardiac and non-cardiac deaths (5.9% and 20.8%). There was notably more TLR (14.7% vs 4.4%, $p = 0.046$) even though the MI rates were not significantly different. The only one recorded definitive stent thrombosis was seen in a non-diabetic patient presenting with a STEMI at 782 days after implantation, with a true bifurcation with a 2.5 mm side branch. The very low 0.6% stent thrombosis rate is comparable to that for the 2nd generation DES but was unusually low for that observed in other bifurcation studies.

4.1. Limitations

Data was unfortunately unable to be collected from all eligible centres. However, the follow-up rate form responding centres was 98%. The non-hierarchical MACE makes comparison difficult. We did not use QCA, hence operator's visual assessment of the side branch size could have led to errors. It was a retrospective study that was non-randomized for direct comparison with other 5 year data. Data missing from non-responding centres may have led to a positive bias. There was no angiographic follow-up, thus silent side branch restenosis cannot be ruled out. There was a change in the MI definition used during the course of this study period.

5. Conclusions

The Tryton® Side-Branch Stent has good safety and efficacy at 5 year follow-up, with low rates of non-hierarchical MACE and MACCE. Only 1 case of stent thrombosis occurred, and this was very late. Results are favourable in comparison to other complex bifurcation strategies. Further larger scale follow-up is needed to confirm these results.

6. Impact on daily practice

The Tryton® Side-Branch Stent has good safety and efficacy at 5 year follow-up, with low rates of non-hierarchical MACE and MACCE. Results are favourable in comparison to other complex bifurcation strategies.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.carrev.2018.06.023.

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