

## The EBC TWO Study (European Bifurcation Coronary TWO)

### A Randomized Comparison of Provisional T-Stenting Versus a Systematic 2 Stent Culotte Strategy in Large Caliber True Bifurcations

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**Background**—For the treatment of coronary bifurcation lesions, a provisional strategy is superior to systematic 2-stent techniques for the most bifurcation lesions. However, complex anatomies with large side branches (SBs) with significant ostial disease length are considered by expert consensus to warrant a 2-stent technique upfront. This consensus view has not been scientifically assessed.

**Methods and Results**—Symptomatic patients with large caliber true bifurcation lesions (SB diameter  $\geq 2.5$  mm) and significant ostial disease length ( $\geq 5$  mm) were randomized to either a provisional T-stent strategy or a dual stent culotte technique. Two hundred patients aged  $64 \pm 10$  years, 82% male, were randomized in 20 European centers. The clinical presentations were stable coronary disease (69%) and acute coronary syndromes (31%). SB stent diameter ( $2.67 \pm 0.27$  mm) and length ( $20.30 \pm 5.89$  mm) confirmed the extent of SB disease. Procedural success (provisional 97%, culotte 94%) and kissing balloon inflation (provisional 95%, culotte 98%) were high. Sixteen percent of patients in the provisional group underwent T-stenting. The primary end point (a composite of death, myocardial infarction, and target vessel revascularization at 12 months) occurred in 7.7% of the provisional T-stent group versus 10.3% of the culotte group (hazard ratio, 1.02; 95% confidence interval, 0.78–1.34;  $P=0.53$ ). Procedure time, x-ray dose, and cost all favored the simpler procedure.

**Conclusions**—When treating complex coronary bifurcation lesions with large stenosed SBs, there is no difference between a provisional T-stent strategy and a systematic 2-stent culotte strategy in a composite end point of death, myocardial infarction, and target vessel revascularization at 12 months.

**Clinical Trial Registration**—URL: <http://www.clinicaltrials.gov>. Unique identifier: NCT 01560455.

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**Key Words:** acute coronary syndrome ■ confidence interval ■ coronary disease ■ myocardial infarction ■ stent

Treatment of bifurcation coronary lesions remains a difficult area, in which best practice is yet to be fully established. Randomized trials of all-comer bifurcation lesions have demonstrated that there is no advantage to systematic dual drug-eluting stent strategies. However, these trials included a high proportion of patients with no disease in the side branch (SB) or relatively small SB vessels.<sup>1–10</sup>

#### See Editorial by De Luca

Expert consensus suggests that large caliber bifurcation lesions with significant ostial SB disease probably warrant an upfront 2-stent strategy, but this consensus has not been tested.<sup>11</sup> This trial was designed to assess the hypothesis that large true bifurcations with significant SB ostial disease are

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### WHAT IS KNOWN

- For the treatment of coronary bifurcation lesions, a provisional strategy is superior to systematic 2 stent techniques for the most bifurcation lesions.
- However, complex anatomies with large side branches with significant ostial disease length are considered by expert consensus to warrant a 2-stent technique upfront.

### WHAT THE STUDY ADDS

- When treating complex coronary bifurcation lesions with large side branches and significant ostial disease, there is no difference between a provisional T-stent strategy and a systematic 2-stent culotte in a composite end point of death, myocardial infarction, and target vessel revascularization at 12 months.

better treated with a systematic culotte technique than with the provisional T-stent approach (hereafter referred to as provisional-T).

### Methods

The study was an investigator-led prospective randomized multi-centre trial devised by and run through the European Bifurcation Club ([www.bifurc.net](http://www.bifurc.net)) in 6 European countries. The trial was administered and overseen by a Clinical Research Organization (Cardiovascular European Research Center) and the data were seen, assessed, and adjudicated by a Clinical Events Committee and a Data and Safety Monitoring Board. The study protocol was approved by the relevant authorities in all countries involved in the study. The trial was registered on [clinicaltrials.gov](http://clinicaltrials.gov) (NCT01560455).

### Study Population

Patients requiring percutaneous coronary intervention (PCI) were eligible for the study if they were aged  $\geq 18$  years and had true bifurcation coronary artery disease (both main vessel [MV] and SB  $>50\%$  narrowed) in which both the MV and SB reference diameters were  $\geq 2.5$  mm, with SB ostial disease  $\geq 5$  mm in length. These were therefore patients in whom the SB could be (1) capable of causing angina and (2) a potential target for intervention. Main exclusion criteria were unprotected left main stem narrowing  $\geq 50\%$ , acute ST elevation myocardial infarction (MI), cardiogenic shock, chronic total occlusion of either vessel, additional type C lesion requiring PCI, left ventricular ejection fraction  $\leq 20\%$ , platelet count  $\leq 50 \times 10^9/\text{mm}^3$ , and patient life expectancy  $< 12$  months or known relevant allergies. Patients who consented to the study were randomized via a secure website using standard random number generation methodology with stratification by center. All patients gave informed consent.

### Revascularization Procedure

Patients were assessed for angina status (Canadian Cardiovascular Society [CCS]) and antianginal medications. Aspirin 75 to 160 mg daily was continued if the patient was established ( $>3$  days) on this medication. If not, oral aspirin 300 mg was

given  $\geq 3$  hours before PCI. Clopidogrel 75 mg daily was continued if the patient was established ( $>3$  days) on this medication. If not, clopidogrel 600 mg was given  $\geq 3$  hours before PCI. Intravenous unfractionated heparin 70 IU/kg was given at the start of the procedure with additional dosing as necessary to maintain the activated clotting time  $\geq 200$  s during the procedure. Additional antiplatelet agents could be used at the discretion of the operator. Blood for serum creatine kinase and troponin levels was taken at the start of the procedure. PCI was undertaken via the access site of choice of the operator. NOBORI biolimus-eluting stents (Terumo Corporation) were used. Minimum operator volume was 150 PCI per annum. Hemostasis technique and use of vascular closure devices were at the discretion of the operator. Creatine kinase and troponin were taken 16 to 22 hours post PCI. Aspirin 75 to 160 mg daily and clopidogrel 75 mg daily were given for a minimum of 12 months.

### Provisional-T Group

Patients randomized to the provisional-T arm of the study followed an algorithm determining the procedural steps:

Coronary guide wires were passed to the MV and SB. MV preparation was at the operator's discretion. SB predilatation was discouraged unless considered essential. The MV was stented with a wire jailed in the SB. Stent diameter was chosen according to the diameter of the distal MV segment. Proximal optimization treatment of the MV stent with a balloon size according to the proximal MV diameter was encouraged but was not mandatory. The SB vessel was then rewired, aiming for a distal cell crossing, after which a kissing balloon dilatation was performed with two, ideally noncompliant, balloons size appropriately for the SB and distal MV. Finally, the proximal stented portion of the MV was postdilated either with the kissing balloon pair to low pressure or with a short noncompliant balloon of the correct size. After these steps, the SB was not treated further unless one of the following conditions existed:

- $<$ thrombolysis in myocardial infarction 3 flow in the SB
- $>90\%$  ostial pinching of the SB
- threatened SB vessel closure
- SB vessel dissection  $>$ type A

Under these conditions, the operator was free to implant a second stent in the SB as a T-stent, such that there was no, or minimal, stent strut overhang into the MV. Other techniques were not permitted. After T-stenting, repeat kissing balloon inflation was mandatory.

### Culotte Group

Patients randomized to the culotte arm of the study followed an algorithm determining the procedural steps:

The MV and SB were both wired. Lesion preparation in both vessels was according to operator preference. The SB was then ideally stented first, from before the bifurcation in the MV, to beyond the diseased segment of the SB, with a wire jailed in the MV. After an optional proximal optimization treatment, the MV was then rewired (through a distal stent strut where possible) and after the removal of the jailed wire, balloon dilatation was made to open the stent struts. The SB wire was then removed (to prevent metal-to-metal jail) and the MV was stented from before the bifurcation to beyond the diseased segment in the MV, according

to the diameter of the distal vessel. After a further optional proximal optimization treatment, the SB was then rewired, and high pressure (eg, 20 atm) individual noncompliant balloon inflations were made in each vessel at the bifurcation point according to the diameter of the branch vessel to ensure good stent strut separation. Finally, a lower pressure kissing inflation was made at the bifurcation. A final proximal optimization treatment in the stented segment proximal to the bifurcation was optional.

### Follow-Up

Adverse event tracking began at randomization and continued to the end of the 12-month follow-up period in a cohort block. Patients underwent either telephone or hospital follow-up at 6 and 12 months. At 12 months, CCS grade and antianginal medication were also assessed.

### End Points

#### Primary End Points

The primary end point of the study was a composite of all-cause death, MI, and target vessel revascularization at 12 months.

#### Secondary End Points

These were the individual components of the primary end point, angina status (CCS), and angina medication.

#### Procedural End Points

These were procedural success, completion of kissing balloon inflations per protocol, in-hospital major adverse cardiac event, procedure duration, fluoroscopy time, x-ray dose, and estimated cost.

### Definitions

#### Myocardial Infarction

Typical rise and fall of biochemical markers of myocardial necrosis with ischemic symptoms or ECG changes as per European Society of Cardiology/ American College of Cardiology guidelines.<sup>12</sup> Periprocedural MI is arbitrarily defined by the elevation of cTn values ( $>5\times 99$ th percentile URL) in patients with normal baseline values ( $\leq 99$ th percentile URL) or a rise of cTn values  $>20\%$  if the baseline values are elevated and are stable or falling. In addition, either (1) symptoms suggestive of myocardial ischemia, (2) new ischemic ECG changes, or (3) angiographic findings consistent with a procedural complication or (4) imaging demonstration of new loss of viable myocardium or new regional wall motion abnormality are required.<sup>13</sup>

#### Target Vessel Revascularization

This comprised target vessel revascularization by PCI or coronary artery bypass graft of either the MV or the SB or target vessel inadequacy— $<$ thrombolysis in myocardial infarction 3 flow in either MV or SB after appropriate vasodilators on a repeat angiogram, without attempted repeat intervention.

#### Procedural Success

Thrombolysis in myocardial infarction 3 flow and  $<30\%$  residual stenosis in the MV and thrombolysis in myocardial infarction 3 flow in the SB.

#### In-Hospital Major Adverse Cardiac Event

Death, MI, or target vessel revascularization during the index admission.

#### Procedure Duration

Time from initial infiltration of local anesthetic to removal of guiding catheter.

#### Procedure Fluoroscopy Time

Duration of x-ray screening and acquisition.

#### Diamentor

x-ray dose area product ( $\text{cGy}\cdot\text{cm}^2$ ).

#### Procedure Cost

The difference in procedural cost was assessed using a composite of the number of guidewires, balloons and stents opened or used, and procedural time.

#### Angina Index

Angina medication scoring system, scoring 1 for GTN spray, oral nitrate,  $\beta$ -blocker, calcium antagonist, nicorandil (max score 5).

#### Medina Classification

This classification attributes a score of 0 or 1 to the 3 segments of a bifurcation lesion—proximal MV, distal MV, and SB—as a binary function dependent on an angiographic stenosis of  $>50\%$  (score 1) or  $<50\%$  (score 0) in each location.<sup>14</sup>

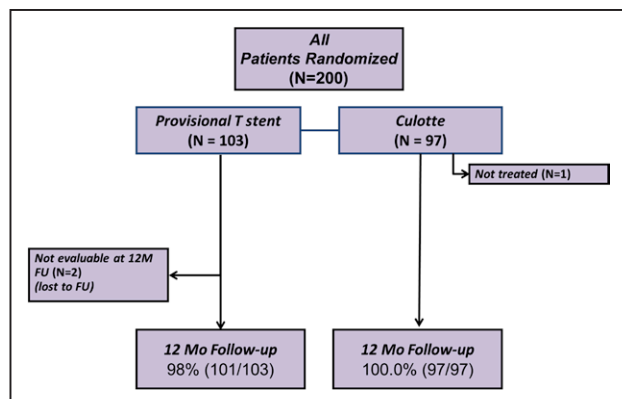
### Statistical Methods

The NORDIC (The Nordic Bifurcation Study), BBC ONE (British Bifurcation Coronary: Old, New, and Evolving Strategies) and CACTUS (Coronary Bifurcations: Application of the Crushing Technique Using Sirolimus-Eluting Stents) trials combined yielded a rate of death, MI, or target vessel revascularization of  $\approx 10\%$  for the provisional T-stent strategy at 1 year.<sup>1,7,10</sup> For the larger caliber bifurcations with ostial SB disease included in this study, the rate of this composite primary end point at 12 months was expected to be 25% using a provisional-T technique. The complete lesion coverage culotte technique was anticipated to result in a lower rate of death, MI, or target vessel revascularization of 10%, based on previous understanding of the technical aspects of stent implantation. Using these estimates, a 2-sided significance ( $1-\alpha$ ) of 95% and 80% power, a sample size of 200 patients was required.

The primary composite end point was compared using a hazard ratio and 95% confidence interval from a Cox regression model with the treatment group as the only covariate. Differences in categorical variables between the 2 groups were analyzed with the  $\chi^2$  test or Fisher exact test. Continuous variables were analyzed with the Student t test, and treatments were compared with a log-rank test and Kaplan–Meier survival curve. Individual components of the primary end point and secondary end points were summarized by the treatment group. Analyses were done on an intention-to-treat basis using SAS 9.4 software.

### Results

Between April 2011 and January 2014, 200 patients were randomized to the trial across 20 European centers in 6 countries (Figure 1). One hundred three patients were randomized to the provisional-T group and 97 patients to the culotte group. One patient in the culotte group did not undergo treatment because



**Figure 1.** Flow of patients through the trial. FU indicates follow up.

a pressure wire study at the time of the procedure confirmed that the stenosis in the MV was not significant.

Patient demographics and clinical features are shown in Table 1. Most patients had an elective presentation. There was a high prevalence of diabetes mellitus in both the groups.

Procedure characteristics are shown in Table 2. In the provisional-T group, 16% of patients underwent SB T-stent implantation. Two patients in the culotte group only had a stent placed in the MV. One patient in the provisional-T group lost antegrade flow in the SB. Mean SB stent diameter was significantly greater than 2.5 mm confirming investigator adherence to protocol. Procedural success was high, as was completion of kissing balloons in both the groups. Procedure duration, fluoroscopy time, and estimated consumable costs all favored the provisional-T approach.

Quantitative coronary angiography results from an independent core laboratory are shown in Table 3. SB lesion length averaged over 10 mm in both the groups, confirming good adherence to inclusion criteria. Diameter stenosis was significantly less after culotte stenting in both the SB (Table 3).

Follow-up was complete for 98% and 100% of patients in the provisional-T and culotte groups, respectively.

The primary end point outcomes are shown in Table 4 and Figure 2. There was no statistical difference between the 2 groups for the primary composite end point of death, MI, or target vessel revascularization: 7.7% in the provisional-T group versus 10.3% in the culotte group (hazard ratio, 1.02; 95% confidence interval, 0.78–1.34;  $P=0.53$ ). There was also no significant difference in the rates of the components of the primary end points between the 2 groups. There were over twice as many periprocedural infarctions in the culotte group as in the provisional group. Stent thrombosis was also numerically more frequent in the culotte group.

CCS grade was  $\geq 2$  in 66.5% of patients preprocedure and improved to 6% in both the groups at 12-month follow-up with no intergroup difference (provisional-T 6.0% versus culotte 6.2%;  $P=0.99$ ). Similarly, the mean ( $\pm$ SD) angina index was  $1.37\pm 0.99$  preprocedure and  $1.03\pm 0.06$  at 12-month follow-up ( $P<0.01$ ), with no intergroup difference (provisional-T 1.00 versus culotte 1.06;  $P=0.80$ ).

## Discussion

In this randomized trial of true bifurcations (involving large SBs with significant length ostial disease), we found no difference in the composite end point of death, MI, or target vessel

revascularization at 12 months between a provisional T-stent approach and a systematic 2 stent culotte strategy.

Regardless of randomized technique allocated, freedom from major adverse cardiovascular events at 1 year was good, and both techniques were effective at relieving angina, as has been noted previously.<sup>15</sup>

**Table 1. Patient Characteristics and Clinical Features**

	Provisional-T (n=103)	Culotte (n=97)
Age, y mean (SD)	62.9 (10.8)	63.5 (12.1)
Male (%)	87 (85%)	76 (78%)
Diabetes mellitus	26 (25%)	30 (31%)
Hypertension	65 (63%)	66 (68%)
Smoking	58 (56%)	49 (50%)
Family history	49 (48%)	48 (49%)
Hypercholesterolaemia	72 (70%)	70 (70%)
Creatinine >200 mmol/L	0 (0%)	1 (1%)
Previous MI	40 (39%)	40 (41%)
Previous PCI	41 (40%)	40 (41%)
Peripheral vascular disease	6 (6%)	8 (8%)
Left ventricular function		
Unknown	25 (24%)	10 (10%)
Good (EF >50%)	59 (57%)	65 (67%)
Moderate (30%–50%)	18 (17%)	20 (21%)
Poor (<30%)	1 (1%)	2 (2%)
Presentation		
Stable coronary disease	71 (69%)	66 (68%)
ACS	32 (31%)	31 (32%)
Diseased territories >70%		
Single vessel	77 (76%)	61 (65%)
Two vessel	18 (17%)	27 (29%)
Three vessel	6 (6%)	5 (5%)
Site of bifurcation disease		
LAD	80 (78%)	75 (77%)
Circumflex	16 (15%)	18 (19%)
RCA	6 (6%)	4 (4%)
Bifurcation lesion characteristics		
True bifurcation	103 (100%)	97 (100%)
Type (Medina classification)		
1,1,1	83 (81%)	66 (68%)
1,0,1	6 (6%)	7 (7%)
0,1,1	12 (12%)	23 (24%)
Adverse lesion features		
Calcification $\geq$ moderate	20 (19%)	17 (17%)
Tortuosity $\geq$ moderate	10 (10%)	15 (15%)

ACS indicates acute coronary syndrome; Cx, circumflex; EF, ejection fraction; LAD, left anterior descending; MI, myocardial infarction; PCI, percutaneous coronary intervention; and RCA, right coronary artery.

**Table 2. Procedure Characteristics**

	Provisional-T (n=103)	Culotte (n=97)	P Value
Access site			
Femoral	38 (37%)	42 (43%)	0.335
Radial	65 (63%)	55 (57%)	
Sheath gauge			
6F	75 (73%)	63 (65%)	0.539
≥7F	28 (27%)	33 (34%)	
Glycoprotein inhibitor use	4 (4%)	7 (7%)	0.302
Main vessel stent	103 (100%)	96 (99%)	0.485
Mean stent diameter (mm, SD)	3.06 (0.32)	3.03 (0.33)	0.393
Stent length (mm, SD)	23.4 (4.8)	22.9 (5.1)	0.352
Side branch stent	16 (16%)	94 (97%)	<0.001
Mean stent diameter (mm, SD)	2.61 (0.29)	2.72 (0.25)	0.125
Stent length (mm, SD)	19.9 (6.8)	20.7 (5.5)	0.606
Total stented length (mm, SD)	33.6 (17)	51.8 (20)	<0.001
Total no. of stents (SD)	1.6 (0.8)	2.5 (0.7)	<0.001
Kissing balloons inflation	97 (94%)	93 (96%)	0.749
Procedural success	100 (97%)	95 (98%)	1
Procedure time (min, SD)	67.8 (25.6)	82.5 (38.8)	<0.001
Fluoroscopy time (min, SD)	20.1 (10.1)	26.6 (17.1)	<0.001
Diamantor (cGy·cm <sup>2</sup> , SD)	11 447 (8866)	18 362 (31 779)	0.035
Contrast volume (mL, SD)	245.9 (98.8)	269.3 (120.3)	0.13
Procedural cost (Euros)	2257	3263	<0.001

Procedural success was higher than in previously reported trials of complex stenting techniques.<sup>8</sup> In the combined BBC ONE and NORDIC trials, the technical success among complex patients was 94% and kissing balloon success was 75%. The reason for the higher rate of success in this study probably relates to several factors—first, the SBs were larger and this may have facilitated recrossing; second, use of the culotte rather than the crush technique; and third, the expertise of the operators who all have a special interest in bifurcation treatment.

In terms of consumables, the culotte strategy was associated with increased procedural time, x-ray dose, and cost. This replicates findings from previous studies.<sup>1–8</sup> Periprocedural MI was numerically more prevalent after culotte stenting. This probably relates to repeat instrumentation and dilatation of vessels in the more complex procedure. Whether small degrees of cardiac enzyme release are prognostically important is debated.<sup>16</sup>

Most previous bifurcation trials have favored the provisional approach but have included lesions with small or non-diseased SB.<sup>1–10</sup> In the DK-CRUSH-II study (Double Kissing Crush Versus Provisional Stenting Technique for Treatment of

Coronary Bifurcation Lesions), the provisional strategy compared with the DK Crush technique had higher rates of both MV and SB restenosis at 8-month angiographic follow-up but no increase in major adverse cardiac event at 12 months. Nearly 30% of the provisional strategy patients received a SB stent, and this group had significantly lower rates of final kissing inflation.<sup>17</sup> Expert consensus opinion has suggested that complex lesions (large SB with significant length ostial disease) are best treated with a planned 2 stent strategy.<sup>11</sup> In the EBC TWO trial (European Bifurcation Coronary TWO), this hypothesis was tested in these complex lesions using contemporary practice. Even with these complex lesions, only 16% of the provisional group received a SB stent. This reflects good adherence to the provisional-T strategy protocol. It also confirms that the provisional SB stent rate remains low using a stepwise provisional approach with noncompliant kissing balloon inflations, even among patients in whom the SB is large and the disease length is significant.<sup>1,7,9,10,18,19</sup>

In this trial, culotte was the planned 2-stent strategy. This technique has been compared with other 2-stent strategies and represents contemporary practice.<sup>20,21</sup> There are theoretical advantages of the culotte over a provisional-T strategy in lesions with large SB, such as SB protection and full ostial coverage.<sup>22–24</sup> In left main bifurcation, lesions culotte technique has compared favorably with the provisional strategy but was associated with increased major adverse cardiac event (mainly because of increased target vessel revascularization) when compared with the DK crush technique.<sup>21,25,26</sup> The 2 kissing balloon inflations intrinsic to the DK crush technique may improve ostial SB stent apposition resulting in less restenosis. In our trial, quantitative coronary analysis in the culotte group showed greater acute gain in both the SB and the MB, possibly because of less stent distortion in the

**Table 3. Quantative Coronary Analysis of the Lesions**

	Provisional-T (n=103)	Culotte (n=97)	P Value
Lesion length			
Main vessel (mm, SD)	18 (6.7)	18 (8.8)	0.972
Side branch (mm, SD)	9.7 (7.1)	10.8 (7.3)	0.310
Diameter stenosis			
Main vessel Pre (%), (SD)	51.3 (21.1)	47.7 (20.5)	0.220
Main vessel Post (%), (SD)	10.8 (7.6)	8.0 (8.3)	0.572
Side branch Pre (%), (SD)	54.1 (15.6)	54.8 (13.9)	0.734
Side branch Post (%), (SD)	31.2 (13.8)	25.1 (11.1)	<0.001
Minimal lumen diameter			
Main vessel Pre (mm, SD)	1.1 (0.50)	1.10 (0.49)	0.758
Main vessel Post (mm, SD)	2.46 (0.46)	2.33 (0.38)	0.022
Main vessel acute gain (mm, SD)	1.34 (0.61)	1.23 (0.51)	0.170
Side branch Pre (mm, SD)	0.96 (0.37)	0.93 (0.31)	0.543
Side branch Post (mm, SD)	1.53 (0.43)	2.03 (0.35)	0.981
Side branch acute gain (mm, SD)	0.57 (0.5)	1.10 (0.39)	0.980

**Table 4. Trial End Points**

	Provisional-T (n=103)	Culotte (n=97)	P Value
<b>Primary end point</b>			
Death, myocardial infarction or target vessel failure at 12 mo	8 (7.7%)	10 (10.3%)	0.530
<b>Secondary end points</b>			
Death	2 (2.0%)	1 (1.1%)	0.596
Periprocedural (inpatient)	0	0	
Subsequent	2	1	
Myocardial infarction	5 (4.9%)	10 (10.3%)	0.143
Periprocedural (inpatient)	4	10	
Subsequent	1	0	
In-hospital MACE	5 (4.9%)	10 (10.3%)	0.143
Target vessel revascularization	3 (2.9%)	1 (1.0%)	0.621
<b>Stent thrombosis</b>			
Definite/Probable (ARC)	1	2	0.357
Possible	0	1	

ARC indicates Academic Research Consortium; and MACE, major adverse cardiac event.

MB and less recoil in the SB. However, the culotte technique was associated with increased procedural time, x-ray dose, cost, and periprocedural MI. Despite quantitative coronary analysis superiority and these initial procedural investments, there did not seem to be any long-term advantage with the culotte as there was no difference in the composite end point at 12 months (Figure 2).

Postprocedural cardiac enzyme data were available for 94% of patients. As seen in previous trials, the rate of

periprocedural MI was increased in the culotte group, reflecting the increased procedural complexity.<sup>1,7</sup> Whether it is necessary or sensible to include periprocedural MI in a composite end point alongside is controversial.<sup>27</sup>

Stent thrombosis rates were low overall, although there was a nonsignificant increase in the culotte group in keeping with previous studies.<sup>7,8,10</sup> Even with the high rates of final kissing balloon inflation and 12 months of dual antiplatelet therapy, the risk of stent thrombosis in bifurcations persists.<sup>28</sup>

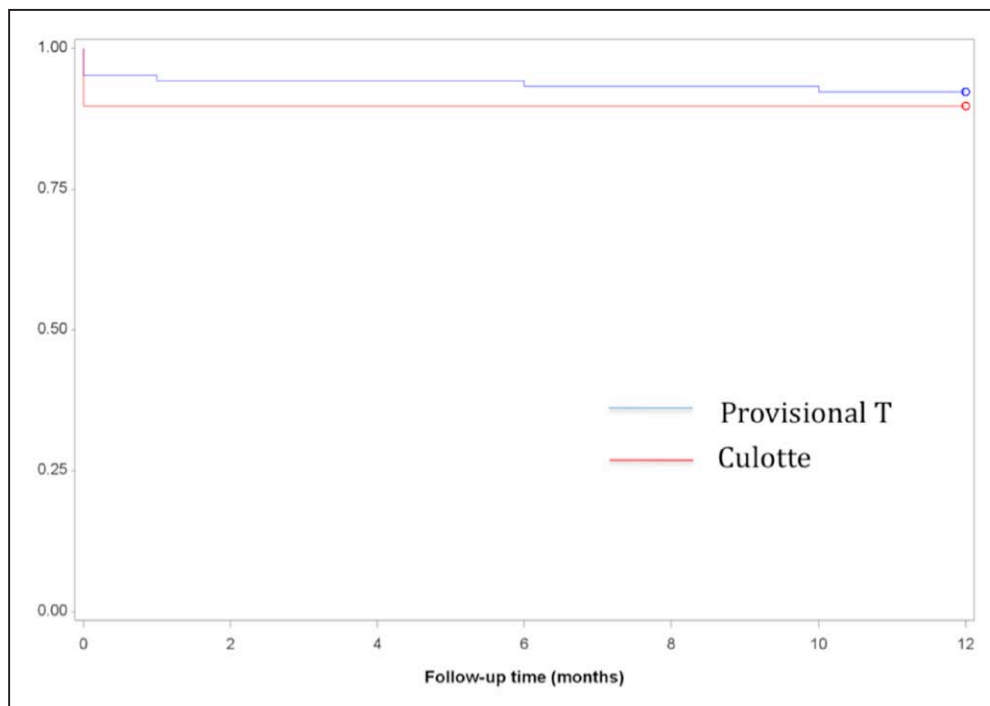
Revascularization rates were numerically higher in the provisional-T group, but remained infrequent in either group despite the complex bifurcation lesions studied.

Nobori stent is stainless steel with biolimus A9 drug and biodegradable polymer, coated only on the abluminal side only. The stent has compared favorably to second-generation everolimus-eluting stents.<sup>29,30</sup>

### Study Limitations

The study is underpowered (our clinical event rates were low: we had expected a 25% rate in the provisional arm). The null hypothesis that the 2 groups are the same was not disproven. We have aimed to answer an important clinical question in a group of patients with lesion characteristics that are difficult to recruit. For the study to be powered adequately, larger numbers of patients would need to be recruited.

This trial had an open design that meant the operators, and patients were aware of received treatment. This could have led to theoretical bias in interpreting clinical outcomes. Telephone follow-up was complete, but it is possible that it did not correctly identify all clinical end points. By using clinical follow-up alone, the trial reflects current clinical practice but lacks angiographic follow-up data. Follow-up in this trial was only to 12 months, so it is not possible to comment on long-term outcomes from these treatment strategies.



**Figure 2.** Primary end point at 12 months.

All patients received a combination of aspirin and clopidogrel antiplatelet therapy. Current guidelines suggest that the patients with acute coronary syndrome might have been treated with the newer agents (ticagrelor or prasugrel).

## Conclusions

For the treatment of coronary bifurcation lesions with large SB ( $\geq 2.5$  mm) with significant length ostial disease ( $\geq 5$  mm), a systematic 2 stent culotte technique compared with a provisional-T strategy is associated with increased procedural time, x-ray dose, cost, and periprocedural MI. In addition, there is no difference between the groups in terms of the composite end point of death, MI, or target vessel revascularization at 12 months. The provisional T-stent strategy remains the technique of choice for bifurcation lesions of all types.

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## Disclosures

Dr David Hildick-Smith has served on an Ad Board for Terumo and is a member of the Cardiovascular European Research Center (CERC).

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