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Interventional cardiology

Culotte stenting vs. TAP stenting for treatment of de-novo coronary bifurcation lesions with the need for side-branch stenting: the Bifurcations Bad Krozingen (BBK) II angiographic trial

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Aims In percutaneous coronary intervention for de-novo coronary bifurcation lesions, the optimal technique for provisional side-branch stenting is still a matter of debate. We tested whether in this setting culotte stenting reduces the incidence of restenosis as compared with T-and-protrusion (TAP) stenting.

Methods and Results This trial included 300 patients with a coronary bifurcation lesion requiring a side-branch stent. Patients were randomly assigned to culotte stenting or TAP stenting using drug-eluting stents in a 1:1 fashion. Primary endpoint was maximal per cent diameter stenosis of the bifurcation lesion at 9-month angiographic follow-up. As clinical endpoints we assessed target lesion re-intervention (TLR) and target lesion failure (composite of cardiac death, target vessel myocardial infarction, and TLR).

Angiographic follow-up was available in 91% of the patients. After culotte stenting, the maximum per cent diameter stenosis in the treated bifurcation lesion was 21 ± 20% as compared with 27 ± 25% after TAP stenting ($P = 0.038$). The respective corresponding binary restenosis rates were 6.5 and 17% ($P = 0.006$). The 1-year incidence of TLR was 6.0% after culotte stenting vs. 12.0% after T-stenting ($P = 0.069$). Target lesion failure occurred in 6.7% of the culotte group and in 12.0% of the TAP group ($P = 0.11$). Only one patient of the culotte group incurred a definite stent thrombosis during 1-year follow-up.

Conclusions Compared with the TAP stenting, culotte stenting was associated with a significantly lower incidence of angiographic restenosis.

Keywords Coronary disease • Bifurcations • Culotte stenting • TAP stenting • Drug-eluting stents • Restenosis

Introduction

In percutaneous coronary intervention (PCI) for bifurcation lesions, single stenting of the main branch is the preferred approach and stenting of the side branch is only recommended for inadequate results of the side branch.[1] With this strategy, double stenting of both, the main and the side branch, is currently still needed in 5–36% of bifurcation procedures.[2,3,4,5] Various techniques have been developed for this purpose, which are now used in daily routine.[6,7,8,9,10] Among these techniques, T-and-protrusion (TAP) stenting and

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culotte stenting are the two approaches that are compatible with the recommended strategy of provisional side-branch stenting. A recent consensus document mentions some form of T-stenting, including TAP, in the first place.[1] Nevertheless, there has been no randomized study comparing TAP stenting with culotte stenting in patients requiring side-branch stenting.

To fill this gap in evidence we performed the randomized 'Bifurcations Bad Krozingen' (BBK) II trial comparing the 9-month angiographic results of TAP stenting with those of culotte stenting. In addition, we assessed 1-year clinical outcomes of both techniques.

Methods

Patient selection

The BBK II trial was designed as a prospective, randomized, non-blinded, and single centre trial. During the study period, we screened patients with an indication for PCI of a de-novo bifurcation lesion. Bifurcation lesions were treated according to the strategy of provisional side-branch stenting. For inclusion in BBK II, a reference diameter of the main branch between 2.5 and 4.0 mm on visual estimation was required as well as a reference diameter of the side branch that was at least 2.25 and $\leq$ 1.0 mm smaller that of the main branch. Patients were not eligible in case of intraluminal thrombus, heavy calcification, severe tortuosity, or if there was a contraindication to dual antiplatelet therapy, intravenous anticoagulants, the stent alloy or—limus drugs. Additional exclusion criteria included acute ST-elevation myocardial infarction, hemodynamic instability, and a history of bleeding diathesis or coagulopathy.

This trial, carried out according to the Declaration of Helsinki, was approved by the Ethics Committee of the medical faculty of the University of Freiburg, Germany. All patients gave written informed consent before any study procedure. This trial was registered at ClinicalTrials.gov (identifier: NCT01267838).

Randomization, technical approach, and follow-up

If after lesion preparation or after placement of the main branch stent and subsequent kissing balloon inflation, the operator decided that a side-branch stent was needed, the patient could be eligible for randomization. Pre-specified criteria for side-branch stenting either before or after main branch stenting were extensive dissection or impaired flow (< TIMI grade 3), or residual stenosis of the side branch $\geq$ 75% on visual estimation. Patients were randomized to culotte stenting or TAP stenting using sealed envelopes based on a computer generated random sequence with a block size of 20.

Sirolimus-, everolimus-, biolimus-, and zotarolimus-eluting stents were allowed in this study. Stable patients were loaded with 600 mg of clopidogrel at least 2 h before intervention. Patients with acute coronary syndrome were loaded with 60 mg of prasugrel or 180 mg of ticagrelor. In the catheterization laboratory, patients received an intra-arterial dose of 100 U/kg heparin or adequate dose of bivalirudin plus intravenous aspirin, 500 mg, if not on chronic treatment with aspirin. Glycoprotein IIb/IIIa inhibitors were only used for bail-out situations.

In patients assigned to TAP stenting, we generally performed proximal optimization (POT) of the main branch stent with non-compliant balloon inflation before proceeding with side-branch stenting. Thereafter, we placed the second stent in the side branch and advanced a balloon in the main branch at the orifice of the side branch. In the next step, the stent in the side branch was meticulously positioned, taking care that the marker band and about the first half millimetre of the stent were within the main-branch stent. When the optimal position of the side-branch stent was achieved, we deployed the side-branch stent by a kissing balloon manoeuvre, first inflating the side-branch balloon with the stent and immediately afterwards the main-branch balloon.[11] Thereafter, we first deflated the main-branch balloon; the side-branch balloon was always deflated last to prevent crushing the protruding struts.

In patients assigned to culotte stenting, we removed the wire in the main branch after POT and placed the second stent from the main branch, overlapping with the first stent, into the side branch. After rewiring of the main branch, a final kissing balloon manoeuvre was performed. In patients in whom the need for a two-stent approach became apparent immediately after lesion preparation (e.g. for extensive dissection), the first stent could be placed in the direction of the side branch. This was followed by POT, placement of the main branch stent and final kissing balloon inflation.

After PCI, we recommended lifelong aspirin ($\geq$ 100 mg per day) and clopidogrel (75 mg per day) for 6 months, prasugrel or ticagrelor for 12 months in patients treated for acute coronary syndrome.

Plasma concentrations of cardiac troponin, creatine kinase and its MB isoenzyme were systematically measured 24 h after the intervention. We obtained at least three ECG recordings during that time. Patients returned to the hospital for routine angiographic re-study and clinical evaluation at 9 months. We also performed an interview at 30 days, 6 months, and 1 year. For patients reporting cardiac symptoms, at least one clinical and electrocardiographic examination was performed in the outpatient clinic or by the referring physician. All available information derived from contingent hospital readmission records or provided by the referring physician or by the outpatient clinic was entered into the computer database.[11]

Quantitative coronary angiography

Bifurcation lesions were characterized according to the Medina classification. For quantitative coronary angiography (QCA), angiograms obtained at baseline, at completion of the intervention, and at 9-month follow-up were analysed with a computer-based system dedicated to bifurcation analysis (Qangio XA version 7.3, Medis, Leiden, Netherlands), according to the standard operating procedure of our certified angiographic core laboratory.[11] We obtained QCA measurements of the three segments of the bifurcation lesion: the proximal and distal segment of the main branch and the side branch. We always performed measurements in the stented portion of the vessel (in-stent).

Study endpoints and definitions

Primary endpoint of the study was the maximal in-stent per cent diameter stenosis of the bifurcation lesion (the highest QCA estimated in-stent stenosis from proximal, distal, and the side-branch segment) at 9-month follow-up. Secondary endpoints included the binary restenosis rate defined as any target lesion diameter stenosis $\geq$50%.

We also assessed 1-year clinical outcomes. The definitions for clinical events were the same as in BBK I study and previously published.[11] Clinically indicated target lesion re-intervention (TLR) was defined as coronary artery bypass surgery or repeat PCI involving the stented segment and performed for symptoms or signs of ischemia in the presence of angiographic restenosis or for high grade (>70%) angiographic restenosis irrespective of the clinical presentation. Finally, we assessed target-lesion failure, defined as a composite of death from cardiac causes, any myocardial infarction (not clearly attributable to a non-target vessel), or target lesion revascularization. We determined the incidence of stent thrombosis according to the Academic-Research-Consortium (ARC) criteria. All events were classified and adjudicated by two physicians not involved in the follow-up process. Clinical data entry and QCA were double checked by trained study personnel.

Statistical methods

According to the published data,[11] we assumed a maximal per cent diameter stenosis of 32 ± 20% in the bifurcation lesion after provisional TAP stenting. To achieve 90% power to detect a 25% relative reduction in maximal per cent in-stent diameter stenosis in the bifurcation lesion treated by culotte stenting as compared with TAP-stenting at a level of significance of 5%, a sample size of 266 patients was needed. To compensate for potential losses to angiographic follow-up, we aimed for 300 patients. We performed a modified intention-to-treat analysis of angiographic outcome measures, including the primary endpoint, which was restricted to patients with follow-up angiography. Clinical endpoints were analysed according to the intention-to-treat principle.

For all statistical analyses, we used the SPSS software package, version 18 (SPSS Inc., Chicago, Illinois). Discrete variables were reported as counts (percentages) and continuous variables as mean ± standard deviation. For discrete variables, we tested differences between groups with the χ^2 test or Fisher exact test when expected cell sizes were less than five. The two-tailed *t*-test was used to compare continuous variables. As a sensitivity analysis, we also performed analysis of covariance with pertinent baseline variables as covariates, to corroborate our primary analysis. All tests were two-sided and statistically significance was set at 5%.

Results

Study cohort and procedural outcome

The flow diagram of the BBK II trial is shown in *Figure 1*. Between 2010 and 2015, we enroled 300 patients; 150 were assigned to culotte stenting and 150 to TAP stenting. The 9-month angiographic follow-up was obtained in 139 patients of the culotte group after a median of 336 days (interquartile range 295–377 days) and 135

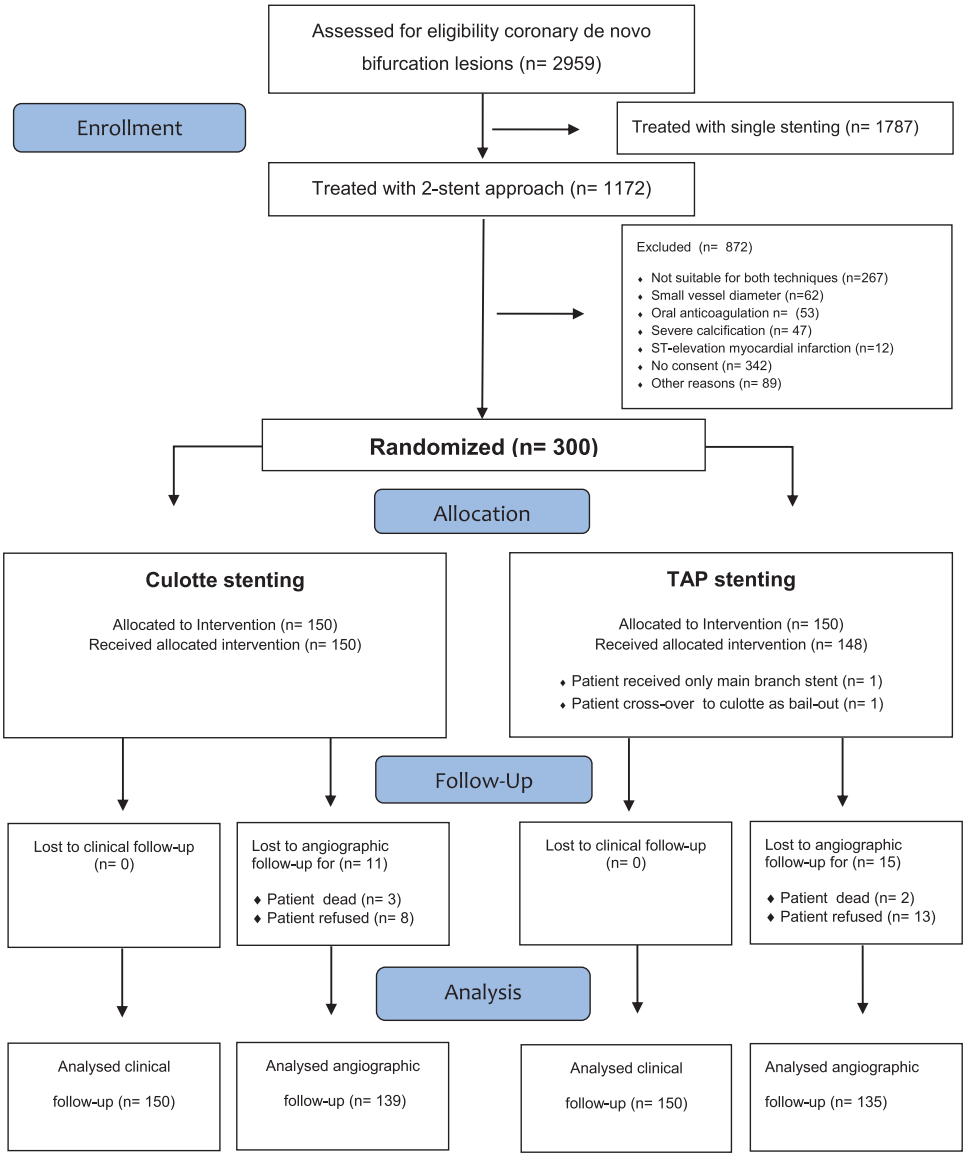

Figure 1 Flow diagram of the Bad Krozingen Bifurcation Study II.

patients of TAP group after a median of 335 days (interquartile range 291–378 days, $P = 0.97$ for difference between groups). Overall, angiographic follow-up was available in 91% of the study population. Reasons for missing follow-up angiography were death in 5 patients and patient refusal in 21 cases. One-year clinical follow-up was complete in all surviving patients.

The baseline demographic and clinical characteristics of the study population are shown in *Table 1*. Patients of the culotte group were 2.8 years (95% confidence interval: 0.4–5.1 years) younger than patients of the TAP group ($P = 0.02$). Otherwise there were no significant differences between the two study groups.

Table 2 and Supplementary material online, *Table S1* summarize the angiographic and procedural characteristics. Baseline angiographic variables were well balanced between the two groups except for lesion length in the side branch, which was slightly longer in the TAP group [mean difference 1.7 mm (95% confidence interval 0.1–3.2 mm), $P = 0.033$], and bifurcation angle, which was slightly larger in the culotte group [mean difference 6.3° ([95% confidence interval 0.6–12.0°), $P = 0.032$]. The distribution of stent types was not significantly different between the two study groups.

All patients assigned to culotte stenting could be treated successfully with the culotte approach. In the TAP group, the side-branch stent could not be placed in one patient, and one patient crossed over to culotte stenting because of abrupt closure of the side branch before placement of the main-branch stent. Final kissing balloon dilatation was performed in all study patients.

Angiographic results

As shown in *Figure 2*, the primary endpoint, maximal in-stent per cent diameter stenosis at the bifurcation lesion at angiographic follow-up, was 21 ± 20% after culotte stenting as compared with 27 ± 25% after TAP stenting ($P = 0.038$). The difference in maximal per cent diameter stenosis was 5.7% (95% confidence interval 0.3–11.2%). This resulted in a binary restenosis rate of 6.5% ($N = 9$) after culotte stenting and 17% ($N = 23$) after TAP stenting ($P = 0.006$). The difference in primary endpoint between the two study groups was similar after adjustment for age, lesion length in the side branch and bifurcation angle [6.7% (95% confidence interval 1.2–12.3%), $P = 0.017$]. The result for the primary endpoint was largely driven by the side-branch result (in-stent per cent diameter stenosis after culotte stenting in 16.2 ± 20.5 and in 22.4 ± 26.0 after TAP stenting; $P = 0.029$, *Figure 3*). The proximal and distal segments of the main branch did not show any significant differences between the two study groups (average in-stent per cent diameter stenosis at follow-up ranged between 9 and 13%; Supplementary material online, *Table S2*). There was no interaction between side-branch stent type and the effect of randomized treatment on the primary angiographic endpoint ($P_{int} = 0.36$).

Consistent with the data on per cent diameter stenosis, minimal luminal diameter in the side branch at angiographic follow-up was significantly larger after culotte stenting (Supplementary material online, *Table S2*). Both, acute gain and late loss were similar in the main branch. However, in the side branch we found a significant difference in late lumen loss in favour of culotte stenting (Supplementary material online, *Table S2*).

Table 1 Baseline clinical characteristics

	Culotte stenting $n = 150$	TAP stenting $n = 150$	P
Age (yrs)	66.3 ± 10.6	69.1 ± 10.3	0.02
Male (%)	107 (71.3)	114 (76.0)	0.36
Diabetes mellitus (%)	41 (27.3)	42 (28.0)	0.90
Current smoker (%)	17 (11.3)	17 (11.3)	1.0
Hypertension (%)	132 (88)	128 (85.3)	0.49
Positive family history (%)	61 (40.7)	59 (39.3)	0.81
LDL-Cholesterol (mg/dl)	119 ± 42	127 ± 53	0.16
Creatinine (mg/dl)	1.08 ±0.87	1.07 ± 0.55	0.89
Previous MI (%)	24 (16.0)	32 (21.3)	0.24
History of PCI (%)	57 (38)	48 (32)	0.28
History of CABG (%)	9 (6.0)	10 (6.7)	0.81
Patients with ACS (%)	32 (21.3)	29 (19.3)	0.67
Ejection fraction (%)	56 ± 7.3	57 ± 6.0	0.26

CABG, coronary artery bypass grafting; LDL, low density lipoprotein; MI, myocardial infarction; PCI, percutaneous coronary intervention; ACS, acute coronary syndrome.

Clinical outcome

Table 3 summarizes the 1-year clinical outcome. As compared with TAP stenting, culotte stenting was associated with a lower TLR with borderline statistical significance (6 vs. 12%, $P = 0.069$). TLR was always clinically indicated. This difference between the two study groups, was largely driven by a difference in the need for side-branch TLR. We also noticed a trend towards lower target lesion failure in the culotte group as compared with the TAP group (*Table 3*). Cardiac death and target vessel myocardial infarction were infrequent in both groups. During the entire follow-up, there was only one case of definite acute stent thrombosis in the culotte group.

Discussion

To the best of our knowledge, this is the first randomized trial comparing TAP vs. culotte stenting in patients with de-novo coronary bifurcation lesions requiring side-branch stenting. As the main result we found that in this setting an interventional approach using culotte stenting is more efficacious than TAP stenting in preventing restenosis. This is demonstrated by a significantly lower maximum per cent diameter stenosis at the bifurcation lesion after culotte stenting as compared with that after TAP stenting and a lower binary restenosis rate. These angiographic differences between the two stenting techniques translated into a 50% lower rate of TLR.

Thorough analysis of the QCA data revealed that the acute angiographic result was similar between the two techniques as shown by comparable acute gain and residual stenosis after PCI in both the side branch and the main branch. Whereas in the main branch, the late lumen loss was similar irrespective of the stenting technique, the average late lumen loss in the side branch was more than doubled after TAP stenting as compared with culotte stenting. Thus, the result in the side branch was the main driver of the primary and secondary endpoints of the study. This may be attributed to the advantage of culotte stenting that it achieves an optimal and complete coverage of

Table 2 Baseline angiographic and procedural characteristics

	Culotte stenting $n = 150$	TAP stenting $n = 150$	*P*
Number of vessels affected (%)			0.22
1 vessel	21 (14)	15 (10)	
2 vessels	41 (27.3)	54 (36.0)	
3 vessels	88 (58.7)	81 (54.0)	
Multi vessel PCI (%)	62 (41.3)	73 (48.7)	0.20
Location of bifurcation (%)			0.81
Distal Left Main	28 (18.7)	23 (15.3)	
LAD territory	82 (54.7)	83 (55.3)	
LCX territory	36 (24.0)	38 (25.3)	
RCA territory	4 (2.7)	6 (4.0)	
True bifurcations (111; 101; 011) *n*, (%)	147 (98)	143 (95.3)	0.20
Lesion length by QCA estimation (mm)			
Main branch	23.9 ± 7.6	22.7 ± 7.3	0.15
Side branch	13.8 ± 6.6	15.5 ± 6.9	0.03
Bifurcation angle (°) pre PCI	57.8 ± 29.9	51.5 ± 19.6	0.03
Bifurcation angle (°) post-PCI	54.0 ± 19.7	52.0 ± 17.0	0.35
Bifurcation angle (°) 9 months post-PCI	53.3 ± 20.9	50.3 ± 17.3	0.21
Stent type in side branch, *n* (%)			0.50
Sirolimus (Cypher)	12 (8.0)	15 (10.0)	
Everolimus (Xience pro)	13 (8.7)	15 (10.0)	
Everolimus (Promus; P. element)	43 (28.7)	49 (32.7)	
Zotarolimus (Resolute; R. Integrity)	54 (36.0)	46 (30.7)	
Sirolimus (Orsiro)	17 (11.3)	21 (14.0)	
Olimus (Synergy; Biomatrix)	11 (7.3)	5 (3.3)	
Contrast volume (mL)	229 ± 104	245 ± 138	0.25
Fluoroscopy time (min)	23.1 ± 15.0	20.4 ± 11.7	0.09
Radiation exposure (μGym^2)	6439 ± 6226	6309 ± 4382	0.84
Radial access (%)	53 (35.3)	56 (37.3)	0.72

LAD, left anterior descending coronary artery; LCX, left circumflex coronary artery; RCA, right coronary artery; PCI, percutaneous coronary intervention; DES, drug eluting stents.

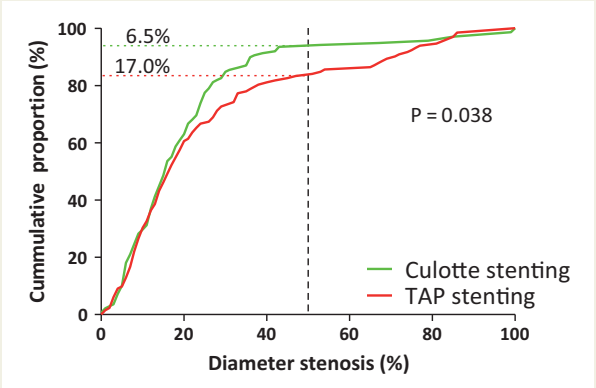

Figure 2 Cumulative frequency of maximal per cent diameter stenosis of the bifurcation lesion at 9-month angiographic follow-up in patients assigned to Culotte stenting (green) or TAP stenting (red). The broken lines indicate the percentage of lesions with (above the line) and without (below the line) restenosis (per cent diameter stenosis ≥50%). *P* value by two-tailed *t*-test.

the side-branch ostium. In contrast, TAP stenting can result in gap, protrusion into the main branch or stent distortion within the side branch. It might be speculated that the smoother transition of the stented area from the main into the side branch using the culotte technique might result in less irritation of the vessel wall at the side branch thus resulting in lower neointima formation. Moreover with TAP, there is larger probability of creating more metal burden at the carina, which can negatively influence the flow dynamics and finally lead to higher neointima proliferation or faster progression of atherosclerosis during long-term follow-up.[12]

Our findings do not suggest any safety issue with either TAP or culotte stenting. During 1-year follow-up, cardiac death, target vessel myocardial infarction, and stent thrombosis were infrequent and not significantly different between both groups. Nevertheless, driven mainly by TLR, the rate of target lesion failure favoured culotte stenting over TAP stenting, albeit without reaching statistical significance. BBK II, however, was not powered to evaluate clinical outcome. In this respect, the currently available data from registries are reassuring. In the BBK registry,[5] the 1-year incidence of definite/probable stent thrombosis after TAP stenting of the side branch was 2.2% with

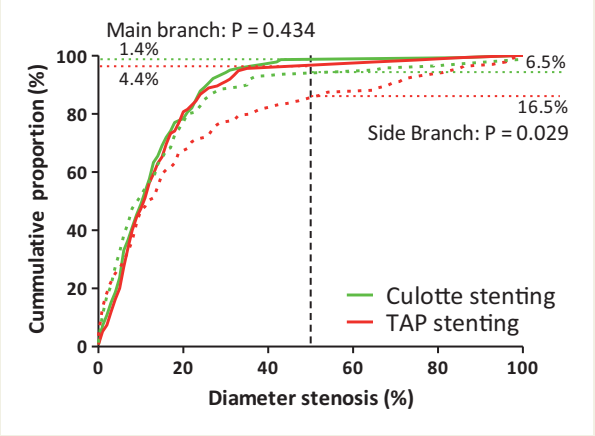

Figure 3 Cumulative frequency of maximal per cent diameter stenosis of the main branch (continuous lines) and side branch (dashed lines) at 9-month angiographic follow-up in patients assigned to Culotte stenting (green) or TAP stenting (red). The numbers represent the proportions of patients with per cent diameter stenosis ≥50%. *P* value by two-tailed *t*-test. The restenosis of the side branch was located ostially in 44% of the binary restenoses after culotte stenting and in 81% after TAP stenting.

Table 3 One-year clinical outcomes

	Culotte stenting *n* = 150	TAP stenting *n* = 150	*P*
Target lesion revascularization *n*, (%)	9 (6.0)	18 (12.0)	0.069
TLR only in side branch *n*, (%)	7 (4.7)	13 (8.7)	0.16
Target lesion failure *n*, (%)	10 (6.7)	18 (12.0)	0.11
Death, any cause *n*, (%)	3 (2.0)	4 (2.7)	0.70
Cardiac *n*, (%)	1 (0.7)	1 (0.7)	1.0
Non-cardiac *n*, (%)	2 (1.3)	3 (2.0)	0.65
Target vessel myocardial infarction *n*, (%)	2 (1.3)	1 (0.7)	0.56
ARC definite/probable Stent thrombosis *n*, (%)	1 (0.7)	0 (0)	0.32

ARC, Academic Research Consortium.

the first-generation sirolimus-eluting stent and 0.7% with second-generation DES. In a registry of culotte stenting[13] using mainly first-generation DES, the 1-year rate of definite/probable stent thrombosis was 1.5%. Even better results may be expected with new-generation DES.[14] Thus, consistent with our current findings, registry data do not suggest any safety issue with either TAP or culotte stenting during the first year following PCI. Nevertheless, additional data on long-term outcome are needed. In the NORDIC stent technique study with first-generation DES,[15] the 3-year incidence of definite stent thrombosis following culotte stenting was 4.7% and it was 3.4% in the DKCRUSH-III trial with new-generation DES.[16]

TAP stenting is currently the preferred approach of side-branch stenting with the recommended strategy of provisional side-branch stenting. Thus far, culotte stenting has only been compared with two crush stenting techniques that are not compatible with the strategy of provisional side-branch stenting. The NORDIC stent technique study[17] was the first randomized comparison of culotte stenting with classic crush stenting. Although there was no significant difference in the primary study endpoint of major adverse cardiac events, this trial showed a significantly reduced in-stent restenosis with culotte stenting as compared with crush stenting. The DKCRUSH-III trial[18] compared culotte stenting with the double-kissing crush technique in patients with unprotected distal left main stenosis. During 3-year follow-up, culotte stenting was associated with higher incidence of major adverse cardiac events including stent thrombosis. It is uncertain whether the favourable results of double-kissing crush obtained in the left main can be transferred to bifurcations of smaller vessels. Neither the NORDIC stent technique study nor the DK-CRUSH-III trials are applicable to the critical setting with the strategy of provisional side-branch stenting, when after placement of the main-branch stent an additional side-branch stent is needed. In this setting, for which classic or double-kissing crush technique are not suitable, the present trial might offer new guidance.

Limitations

The BBK II trial was designed as an angiographic study. Thus, the study is underpowered for clinical and safety endpoints.

Our study could not be blinded which could potentially have biased the results. To limit this potential bias in assessment of the primary endpoint and other angiographic variables, a computerized quantitative analysis system with only minimal operator interference was used. There was no external event adjudication committee. Thus, methodologically the study may be open to assessment bias. To minimize this problem, the clinical endpoints of the trial were adjudicated by investigators blinded to the assigned treatment.

The lack of a full intention-to-treat analysis for the angiographic endpoints may be considered as another limitation. Nevertheless, our rate of angiographic follow-up of > 90% does not suggest a meaningful bias.

Only a proportion of our patients with bifurcation lesions treated with a two-stent approach could be included in this study. Apart from the various exclusion criteria and patient refusal, the lesion characteristics had to be suitable for both stenting techniques. Thus, our results pertain to a specific subset of bifurcation lesions with appropriate angle and size of both branches.

Clinical implications

According to expert consensus based on currently available evidence, provisional side-branch stenting is the recommended strategy for most bifurcation lesions. If side-branch stenting is needed, the results of the BBK II study reported here suggest considering culotte stenting. Nevertheless, before culotte stenting can be established as the technique of first choice in this setting, a dedicated multicentre study powered for clinical endpoints is needed. Compared with the more commonly used TAP stenting, culotte stenting reduces the risk of clinically relevant restenosis. It needs to be considered, however, that the feasibility of culotte stenting is limited to suitable anatomy.

Moreover, culotte stenting is technically more challenging than TAP stenting and, thus, requires specific expertise and continuous training.

Supplementary material

Supplementary material is available at *European Heart Journal* online.

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