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Clinical Outcome After Crush Versus Culotte Stenting of Coronary Artery Bifurcation Lesions

The Nordic Stent Technique Study 36-Month Follow-Up Results

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Objectives The aim of the study was to compare long-term follow-up results of crush versus culotte stent techniques in coronary bifurcation lesions.

Background The randomized Nordic Stent Technique Study showed similar 6-month clinical and 8-month angiographic results with the crush and culotte stent techniques of de novo coronary artery bifurcation lesions using sirolimus-eluting stents. Here, we report the 36-month efficacy and safety of the Nordic Stent Technique Study.

Methods A total of 424 patients with a bifurcation lesion were randomized to stenting of both main vessel and side branch with the crush or the culotte technique and followed for 36 months. Major adverse cardiac events—the composite of cardiac death, myocardial infarction, stent thrombosis, or target vessel revascularization—were the primary endpoint.

Results Follow-up was complete for all patients. At 36 months, the rates of the primary endpoint were 20.6% versus 16.7% ($p = 0.32$), index lesion restenosis 11.5% versus 6.5% ($p = 0.09$), and definite stent thrombosis 1.4% versus 4.7% ($p = 0.09$) in the crush and the culotte groups, respectively.

Conclusions At 36-month follow-up, the clinical outcomes were similar for patients with coronary bifurcation lesions treated with the culotte or the crush stent technique. (Nordic Bifurcation Study. How to Use Drug Eluting Stents [DES] in Bifurcation Lesions? NCT00376571) (J Am Coll Cardiol Intv 2013;6:1160–5) © 2013 by the American College of Cardiology Foundation

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In percutaneous coronary intervention (PCI), the use of drug-eluting stents has improved the short- and long-term outcomes of bifurcation lesion treatment (1). However, the optimal technique for treatment of this complex lesion subset remains a matter of debate. In the Nordic Bifurcation Study, the simple technique of main vessel stenting and provisional stenting of the side branch (SB) yielded clinical results as good as those of the more complex 2-stent techniques, with less procedure time, less radiation time, and smaller volume of contrast media (2,3). Therefore, the provisional SB stenting strategy can be recommended in most cases. However, in situations where the SB has a large diameter, has significant disease at the ostium, or has a long lesion, complete lesion coverage may be considered by stenting both the main vessel and the SB. In the randomized Nordic Stent Technique Study, we compared the crush and the culotte bifurcation stenting techniques and observed similar 6-month clinical outcome and slightly improved 8-month angiographic SB results in the culotte group (4). Previous data on the safety of 2-stent techniques are limited, and concern has been raised about long-term clinical safety outcomes, particularly stent thrombosis (ST) (5). The aim of the present study was to evaluate the 36-month clinical results in patients with coronary artery bifurcation lesions treated with the crush or the culotte stent techniques. The outcomes of patients with left main coronary artery (LM) bifurcation lesions were assessed in a subgroup analysis.

Methods

Study design and study population. The Nordic Bifurcation Stent Technique Study was a nonblinded randomized trial that was designed to compare the crush and the culotte coronary bifurcation stent techniques. The flow diagram of the study is shown in Figure 1 (4). There was a clinical 6-month visit in all patients and an 8-month angiographic follow-up, stratified at randomization, in 160 and 164 patients in the crush and culotte groups, respectively. The primary endpoint of the primary publication was the number of 6-month major adverse cardiac events (MACE). The clinical follow-up was scheduled up to 36 months. The study was a multicenter trial conducted at 13 centers in Denmark, Finland, Latvia, and Norway (Online Appendix). It was approved by the national ethics committees of the participating centers, and written informed consent was obtained from all patients. From August 1, 2005 through February 28, 2007, 424 patients were included. In brief, patients were eligible if they had stable or unstable angina pectoris or silent ischemia, attributable to a de novo coronary bifurcation lesion defined according to Lefèvre et al. (6). For inclusion, the diameter of the main vessel had to be ≥3.0 mm and the SB ≥2.5 mm by visual estimation. Patients with both true and nontrue bifurcation lesions were included. The criteria for exclusion have been described previously (4). After providing written informed consent, patients were randomly assigned to the study groups in a 1:1 fashion before any balloon dilation was performed. The sirolimus eluting stent Cypher Select + (Cordis/Johnson & Johnson, Miami Lakes, Florida) was used. The main treatment principles of the crush and the culotte techniques have been reported (4). Per protocol, the operators were required to attempt a final kissing balloon dilation (FKBD) at the end of the procedure. After PCI, the recommended treatment time for clopidogrel was 6 to 12 months and lifelong for aspirin (≥75 mg/day).

Study endpoints and definitions. The pre-specified study endpoints were the occurrence of total death, cardiac death, myocardial infarction (MI), target lesion revascularization (TLR), definite ST and MACE (cardiac death, nonprocedural MI, ST, target vessel revascularization by PCI or coronary artery surgery), index lesion restenosis, and Academic Research Consortium–defined definite, probable, and possible ST (7) at 36-month follow-up. Blinded outcome assessment was performed by an independent clinical event committee.

Abbreviations and Acronyms

FKBD = final kissing balloon dilation
LM = left main coronary artery
MACE = major adverse cardiac events
MI = myocardial infarction
PCI = percutaneous coronary intervention
SB = side branch
ST = stent thrombosis
TLR = target lesion revascularization

Nonprocedural MI was defined as a rise of biochemical markers exceeding the decision limit of MI (above the 99th percentile including <10% CV) associated with either typical symptoms and/or electrocardiographic changes (4).

Statistical analysis. Differences in categorical variables between the 2 groups were analyzed using the chi-square test or Fisher exact test. We used the 2-tailed *t* test to compare continuous variables. Time-to-event data were analyzed using the Kaplan-Meier method and the log-rank test. All tests were 2-sided and statistical significance was set at 5%.

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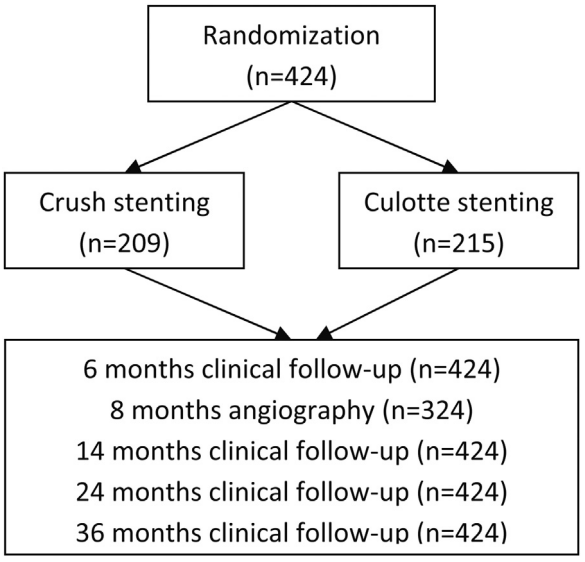

Figure 1. Flow Diagram

The 36-month patient flow diagram of the Nordic Stent Technique Study.

Table 1. Baseline Clinical Characteristics of the Nordic Stent Technique Study

	Crush (n = 209)	Culotte (n = 215)	p Value
Age, yrs	65 ± 10	65 ± 11	0.64
Male	149 (71)	154 (71)	1.00
Current smoker	42 (20)	58 (27)	0.11
Hypercholesterolemia	176 (84)	159 (74)	0.01
Hypertension	130 (62)	129 (60)	0.69
Diabetes mellitus	28 (13)	31 (15)	0.78
Family history	118 (57)	134 (62)	0.28
Previous PCI	84 (40)	72 (34)	0.16
Previous CABG	8 (4)	11 (5)	0.64
Indication			
Stable angina pectoris	162 (78)	155 (72)	0.22
Unstable angina pectoris	43 (21)	54 (26)	0.30
Silent ischemia	4 (2)	6 (3)	0.75
Antiplatelet therapy			
Aspirin	207 (99.0)	214 (99.5)	0.61
Clopidogrel	208 (99.5)	215 (100)	0.49
GP IIb/IIIa inhibitors	106 (51)	105 (51)	0.92

Values are mean ± SD or n (%).
CABG = coronary artery bypass graft; GP = glycoprotein; PCI = percutaneous coronary intervention.

Results

At 36-month follow-up, mortality, MACE, restenosis, and ST data were available in all 424 patients. Baseline clinical (Table 1) and procedural characteristics (Table 2) of the 2 groups were well matched. In the majority of patients, the index bifurcation lesion location was the left anterior descending artery. A total of 41 (10%) patients had LM lesions. According to the Medina classification, true bifurcation lesions (Medina 1,1,1; 1,0,1; 0,1,1) were more common in the culotte than the crush stenting group (82% vs. 73%, respectively, p = 0.03).

We found no significant differences in clinical outcome between the 2 study groups. At 36-month follow-up, the cumulative incidences of MACE were 20.6% in the crush group and 16.7% in the culotte group (p = 0.32). The rates of event-free survival of MACE are shown in Figure 2. Table 3 provides cardiac/noncardiac death, MI, restenosis, and ST data. The outcomes in the 2 study groups were similar, albeit there was a trend to a higher rate of index lesion restenosis in the crush group and a higher rate of definite ST in the culotte group.

The success rate of FKBD was lower in the crush than in the culotte group (84.3% vs. 91.6%, p = 0.02). The rates of MACE tended to be decreased (18% vs. 24%, p = 0.3), and a significant decrease was found in nonprocedural MI (5% vs. 18%, p = 0.001) and in definite ST (2% vs. 8%, p = 0.04) in patients with successful FKBD versus unsuccessful FKBD.

A total of 41 patients (10%) had a LM coronary bifurcation lesion. Of these patients, 20 were randomized to stenting with the crush technique and 21 with the culotte technique. At 36 months, the rates of MACE were 45% (n = 9) vs. 9.5% (n = 2) (p = 0.01), respectively. The individual endpoints in LM patients are shown in Table 4.

Discussion

The Nordic Stent Technique Study is the only randomized comparison of crush versus culotte stent technique in coronary bifurcation lesions. At 3-year follow-up, we did not observe significant differences in the rates of MACE, all-cause death, cardiac death, MI, TLR, or target vessel revascularization between the study groups, but we did detect a trend to less restenosis after culotte stenting and less definite ST after crush stenting. FKBD was associated with lower rates of MACE, MI, and ST.

In our study, a control angiography was performed at 8 months in 76% of the patients (Fig. 1). At the time of the control angiography, and probably in part induced by the angiography, an increase in MACE was observed in both stent technique groups (Fig. 2). At 8-month follow-up, there were more incidents of angiographic SB in-stent restenosis in the crush group than in the culotte group (9.8% vs. 3.8%, p < 0.05) (1). At 36 months, there was a trend to increased restenosis in the crush group, but this did not translate into increased TLR.

Table 2. Procedural Characteristics of the Patients in the Nordic Stent Technique Study

	Crush (n = 209)	Culotte (n = 215)	p Value
LVEF, %	57 ± 11	57 ± 12	1.00
Lesion location			
Left anterior descending artery	132 (63)	142 (66)	0.54
Circumflex artery	42 (20)	43 (20)	1.00
Right coronary artery	15 (7)	9 (4)	0.21
Left main stem	20 (10)	21 (10)	1.00
True bifurcation lesion: Medina 1,1,1; 1.0.1; 0,1,1	153 (73)	177 (82)	0.03
Mean lesion length, mm*			
Main vessel	17.4 ± 10.3	17.4 ± 10.1	0.93
Side branch	7.3 ± 5.8	7.5 ± 6.0	0.76
Mean stent length, mm*			
Main vessel	23.5 ± 9.3	23.6 ± 9.1	0.93
Side branch	10.6 ± 5.6	10.6 ± 5.8	0.96
Proximal reference diameter, mm*			
Main vessel	3.38 ± 0.38	3.32 ± 0.33	0.07
Side branch	2.78 ± 0.33	2.77 ± 0.33	0.77
Main vessel stented	209 (100)	213 (99.1)	0.50
Side branch stented	207 (99.0)	210 (97.7)	0.45
Stents, n			
Main vessel	1.23 ± 0.44	1.20 ± 0.47	0.50
Side branch	1.03 ± 0.24	1.04 ± 0.28	0.61
Pre-dilation			
Main vessel	151 (72)	158 (74)	0.82
Side branch	123 (59)	147 (68)	0.04
Final kissing balloon dilation	177 (85)	197 (92)	0.03
Treatment according to randomization	202 (97)	208 (97)	1.00
Procedural success†	205 (98)	210 (98)	1.00

Values are mean ± SD or n (%). *By visual estimate. †Residual main vessel stenosis ≤30% and normal side branch flow.

LVEF = left ventricular ejection fraction.

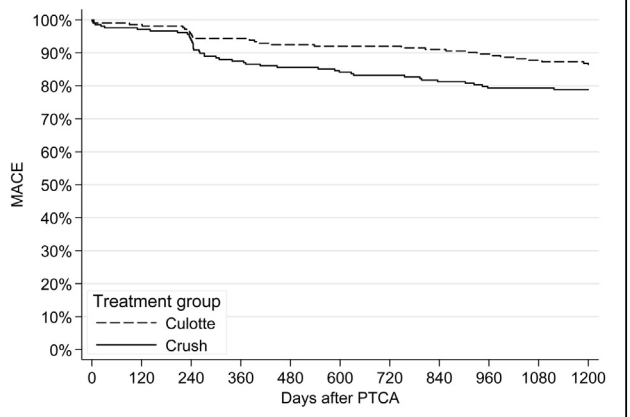

Figure 2. 3-Year MACE-Free Survival

Major adverse cardiac event (MACE)-free survival (cardiac death, myocardial infarction not related to percutaneous coronary intervention, target vessel revascularization) during 36 months of follow-up of the Nordic Stent Technique Study. PTCA = percutaneous transluminal coronary angioplasty.

In our long-term 36-month follow-up, the rates of definite ST were 1.4% and 4.7% (p = 0.09) in the crush and culotte groups, respectively. However, the difference between the 2 groups was less prominent after including probable and possible ST in the analysis (crush 5.3% vs. culotte 7.9%). Also, the higher definite ST rate was not reflected in higher rates of cardiac death and MI in culotte-treated patients.

The numerically higher restenosis rate in crush-treated patients concurs with our earlier finding of increased angiographic restenosis after crush stenting. A nonrandomized trial of 80 patients (8) compared culotte techniques with T-stenting. After 9-month follow-up, the culotte group had a lower TLR rate than the T-stenting group did (8.9% vs. 27.3%, respectively). In this study, the ST rate was 2.2% in the culotte group at 9 months (8). This is in line with a recent prospective registry study in which 100 patients with coronary bifurcation lesions were treated with the crush technique using paclitaxel-eluting stents. After 36-month follow-up, the rate of ST was 3% (9). In a recent Italian retrospective registry study (10), including more than 4,000 patients with bifurcation lesions treated with various techniques, the 24-month ST rate of 2.9% was not associated with the use of 2-stent techniques. The ST rates for patients treated with crush or culotte techniques were not reported specifically. Overall, the data from these studies suggest that the rate of ST is around 3% on a long-term basis for bifurcation lesions treated with a 2-stent technique.

We found a favorable effect of both 2-stent techniques on the long-term rate of restenosis with a need for TLR in only 6% of patients at 36 months (Table 3), whereas it was 10% after 12 months in a recent study using a T-stent technique and sirolimus-eluting stents (11). Another study using the crush technique with paclitaxel-eluting stents observed an 8% rate of TLR at 36-month follow-up (9). Although speculative, due to the lack of randomized data, the lower long-term TLR rates with culotte and crush techniques as compared to the T-stenting technique might reflect a beneficial effect of the complete carina coverage that may be achieved using these techniques.

An important finding in our study was that FKBD reduced the long-term rates of MACE, nonprocedural MI, and ST. In a previous report of patients treated with the crush technique, the absence of FKBD was a predictor for TLR at 9 months (12). Thus, the present results give further evidence that FKBD should be performed, whenever possible, in complex bifurcation lesions requiring 2 stents (1). Interestingly, the rate of FKBD was significantly higher in culotte- versus crush-treated patients, possibly because of

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Table 3. MACE, Mortality, Restenosis, and ST at 36-Month Follow-Up of the Nordic Stent Technique Study

	Crush (n = 209)	Culotte (n = 215)	p Value
MACE	43 (20.6)	36 (16.7)	0.32
All-cause death	10 (4.8)	14 (6.5)	0.53
Cardiac death	7 (3.3)	7 (3.3)	1.00
Noncardiac death	3 (1.4)	7 (3.3)	0.34
MI	14 (6.7)	13 (6.0)	0.84
TLR	13 (6.2)	13 (6.1)	0.94
TVR	25 (12.0)	21 (9.8)	0.47
Index lesion restenosis	24 (11.5)	14 (6.5)	0.09
Definite ST	3 (1.4)	10 (4.7)	0.09
Probable ST	3 (1.4)	1 (0.5)	0.37
Possible ST	5 (2.4)	6 (2.8)	1.00
Definite and probable ST	6 (2.9)	11 (5.1)	0.32
Definite, probable, and possible ST	11 (5.3)	17 (7.9)	0.33

Values are n (%). MACE is a composite of cardiac death, MI, TVR, and ST.
MACE = major adverse cardiac events; MI = myocardial infarction; ST = stent thrombosis; TLR = target lesion revascularization; TVR = target vessel revascularization.

SB wiring problems in the multiple stent layers of the crush technique. The observed lower success rate of FKBD in the crush group, however, did not result in high ST rates. This may be explained by the fact that the overall number of patients with definite ST (n = 13) was low, and only few definite ST (n = 4) occurred in the relatively small group of 50 patients, where FKBD had been unsuccessful.

In patients with LM stenosis, both crush and culotte techniques yielded good 36-month safety results with low rates of death or MI. However, stenting with the crush technique seemed to be associated with a higher rate of TLR than was the culotte technique. The optimal PCI treatment strategy for true bifurcation lesions with a large SB, such as in LM disease, is currently unknown. In our study, the number of LM patients was small and no definitive conclusions can be drawn. However, the results suggest that culotte might be an acceptable technique in distal LM lesions when a 2-stent strategy is needed.

Table 4. Mortality, MACE, and ST at 36-Month Follow-Up in Patients With Left Main Bifurcation Lesion Stenting

	Crush (n = 20)	Culotte (n = 21)	p Value
All-cause death	1 (5.0)	1 (4.8)	0.51
Cardiac death	1 (5.0)	0 (0.0)	0.49
MI	2 (10.0)	0 (0.0)	0.14
TLR	7 (35.0)	2 (9.5)	0.049
TVR	7 (35.0)	2 (9.5)	0.049
ST	1 (5.0)	0 (0.0)	0.49
MACE	8 (40.0)	3 (14.0)	0.01

Values are n (%). MACE is a composite of cardiac death, MI, TVR, and ST.
Abbreviations as in Table 3.

In the ISAR-LEFT MAIN (Intracoronary Stenting and Angiographic Results: Drug-Eluting Stents for Unprotected Coronary Left Main Lesions) study (13), where 98% of distal LM lesions were treated with culotte stenting, the 1-year MACE was 16% in patients treated with sirolimus-eluting stents. A recent randomized study compared culotte stenting to a modified crush technique, double kissing crush, for LM bifurcation lesions (14). It showed that the MACE rate was higher with the culotte technique (16.3 vs. 6.2%) at 1 year. Thus, the double kissing crush also seems to be a promising technique in LM stenting.

According to our study and the previous data, there is no specific 2-stent technique that may generally be recommended for the treatment of coronary artery bifurcation lesions. Therefore, the operator may choose technique according to the coronary anatomy and personal experience.

Study limitations. The Nordic Stent Technique Study had an open design, and operators and patients were aware of the technique used. This might introduce bias in the interpretation of symptoms at follow-up.

Conclusions

At 36-month follow-up, the clinical outcomes were similar for patients with coronary bifurcation lesions treated with the culotte or crush stent technique.

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Key Words: angioplasty ■ balloon ■ bifurcation lesions ■ coronary artery disease ■ drug-eluting stents ■ restenosis.

APPENDIX

For information regarding the Nordic-Baltic PCI Study Group, please see the online version of this paper.