JACC: CARDIOVASCULAR INTERVENTIONS
VOL. 6, NO. 11, 2013

ISSN 1936-8798/$36.00
PUBLISHED BY ELSEVIER INC.
http://dx.doi.org/10.1016/j.jcin.2013.06.009

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%.

Practice, Oulu University Hospital, Oulu, Finland. The study was supported by an unrestricted grant from the Cordis/Johnson & Johnson Company. Dr. Holm has received research grants and honoraria from Cordis Corp.; research grants, speaking fees, and honoraria from St. Jude Medical; speaking fees and honoraria from Terumo; and research grants from Medtronic. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose. The authors have full access to the data of the study and take full responsibility for its integrity.

Manuscript received December 18, 2012; revised manuscript received May 17, 2013, accepted June 6, 2013.