

CORONARY

Impact of the Complexity of Bifurcation Lesions Treated With Drug-Eluting Stents



The DEFINITION Study (Definitions and impact of complex bifurcation lesions on clinical outcomes after percutaneous coronary intervention using drug-eluting stents)

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ABSTRACT

OBJECTIVES The present study established criteria to differentiate simple from complex bifurcation lesions and compared 1-year outcomes stratified by lesion complexity after provisional stenting (PS) and 2-stent techniques using drug-eluting stents.

BACKGROUND Currently, no criterion can distinguish between simple and complex coronary bifurcation lesions. Comparisons of PS and 2-stent strategies stratified by lesion complexity have also not been reported previously.

METHODS Criteria of bifurcation complexity in 1,500 patients were externally tested in another 3,660 true bifurcation lesions after placement of drug-eluting stents. The primary endpoint was the occurrence of a major adverse cardiac event (MACE) at 12 months. The secondary endpoint was the rate of stent thrombosis (ST).

RESULTS Complex ($n = 1,108$) bifurcation lesions were associated with a higher 1-year rate of MACE (16.8%) compared with simple ($n = 2,552$) bifurcation lesions (8.9%) ($p < 0.001$). The in-hospital ST and 1-year target lesion revascularization rates after 2-stent techniques in the simple group (1.0% and 5.6%, respectively) were significantly different from those after PS (0.2% [$p = 0.007$] and 3.2% [$p = 0.009$], respectively); however, 1-year MACE rates were not significantly different between the 2 groups. For complex bifurcation lesions, 2-stent techniques had lower rates of 1-year cardiac death (2.8%) and in-hospital MACE (5.0%) compared with PS (5.3%, $p = 0.047$; 8.4%, $p = 0.031$).

CONCLUSIONS Complex bifurcation lesions had higher rates of 1-year MACE and ST. The 2-stent and PS techniques were overall equivalent in 1-year MACE. However, 2-stent techniques for complex lesions elicited a lower rate of cardiac death and in-hospital MACE but higher rates of in-hospital ST and revascularization at 1 year for simple lesions. (J Am Coll Cardiol Intv 2014;7:1266–76) © 2014 by the American College of Cardiology Foundation.

Percutaneous coronary intervention of bifurcation lesions is technically challenging and is often associated with higher rates of in-stent restenosis. The ostial side branch (SB) is the most common site of in-stent restenosis (1,2) after placement of a drug-eluting stent. Patients with bifurcation lesions do not benefit from systematic 2-stent strategies, but provisional stenting (PS) using a jailed wire in the SB has been widely accepted as the gold standard in the majority of bifurcation lesions (1-6). This is based on several clinical trials (1-6); however, these trials have an important limitation of not being stratified according to the Medina classification (7). Inclusion of lesion complexity as a parameter in previous studies might have otherwise led to different stenting strategies, and consequently, the final clinical results might have been different (8-11).

Most importantly, current classifications do not provide more information about the complexity of bifurcation lesions (10). Therefore, it is too early to conclude that PS can be considered a final solution for coronary bifurcation lesions (10-12). Accordingly, the present DEFINITION (Definitions and impact of complex bifurcation lesions on clinical outcomes after percutaneous coronary intervention using drug-eluting stents) study was designed to establish a practical, easy-to-use classification to differentiate simple from complex bifurcation lesions and analyze the effect of bifurcation complexity on clinical results after PS and 2-stent techniques.

METHODS

STUDY DESIGN AND PATIENT POPULATION. Between January 2004 and July 2012, 5,160 patients with at least 1 Medina 1,1,1 and 0,1,1 coronary bifurcation lesion (7) were prospectively registered. For 1,500 patients from January 2004 to June 2006 (training group), confounding factors for composite major adverse cardiac events (MACE) were selected by logistic regression analysis. The rate of MACE stratified by each confounding factor and combinations of several confounding factors were calculated. Definitions of

complex and simple bifurcation lesions were then established according to the predictive value of the confounding factors.

Finally, these definitions were externally tested in 3,660 patients (study group) between July 2006 and July 2012. Patients in the study group were divided into 2 pre-specific subgroups according to the criteria established from the training group: the simple and complex groups. The ethics committee of each participating center approved the study protocol, and each patient provided written consent.

INCLUSION/EXCLUSION CRITERIA. Only Medina 1,1,1 and 0,1,1 coronary bifurcation lesions with an SB diameter ≥ 2.5 mm by visual estimation were included in the training and study groups. The following exclusion criteria were included: 1) SB diameter < 2.5 mm; 2) ST-segment elevation myocardial infarction (MI) < 1 week; 3) cardiogenic shock; 4) a history of coronary artery bypass grafting; 5) use of bare-metal stent; 6) in-stent restenotic lesions; 7) lesions being treated by classic crush stenting or the kissing stenting technique; and 8) patients who were already included in any other clinical study.

STENTING PROCEDURES. The selection of stenting techniques and of the transradial versus transfemoral approach was left to the physician's discretion. Stents for all implanted lesions were limus-eluting stents, including the Cypher (Cordis, Johnson & Johnson, Miami Lakes, Florida); Firebird or Firebird-2 (Microport Co., Shanghai, China); EXCEL, BIOMATRIX FLEX (Biosensor/Jiwei Co., Shandong, China); Partner (Lepu Med, Beijing, China); Xience or Xience Prime (Abbott Vascular, Santa Clara, California); and Endeavor or Endeavor Resolute (Medtronic, Minneapolis, Minnesota). Use of intravascular ultrasound was left to the physician's discretion. Stenting techniques have been described previously (3,4,12). Briefly, final kissing balloon inflation was recommended after all 2-stent strategies. Kissing balloon inflation was only used after PS if there were any of the following indications in the SB: Thrombolysis in

ABBREVIATIONS AND ACRONYMS

DK	= double kissing
DS	= diameter stenosis
MACE	= major adverse cardiac event(s)
MI	= myocardial infarction
PS	= provisional stenting
SB	= side branch
ST	= stent thrombosis
TLR	= target lesion revascularization
TVR	= target vessel revascularization

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