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CLINICAL RESEARCH

CORONARY

Optimal Strategy for Provisional Side Branch Intervention in Coronary Bifurcation Lesions

3-Year Outcomes of the SMART-STRATEGY Randomized Trial

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ABSTRACT

OBJECTIVES This study compared the long-term follow-up results of conservative versus aggressive strategies for provisional side branch (SB) intervention in coronary bifurcation lesions.

BACKGROUND The appropriate criteria for provisional SB ballooning or stenting have not been established.

METHODS A total of 258 patients with a large bifurcation lesion were randomized to a conservative or aggressive SB intervention strategy. Different criteria applied for the initiation of SB intervention after main vessel stenting in the conservative and aggressive groups were Thrombolysis In Myocardial Infarction flow grade lower than 3 versus a stenosis diameter >75% for non-left main bifurcations, and a stenosis diameter >75% versus a stenosis diameter >50% for left main bifurcations. The primary endpoint was target vessel failure (TVF), defined as a composite of cardiac death, spontaneous myocardial infarction, or target vessel revascularization at 3 years.

RESULTS At 3 years, TVF occurred in 11.7% of the conservative group versus 20.8% of the aggressive group ($p = 0.049$). Although no significant differences were observed in the incidence of TVF between groups at 1 year (9.4% vs. 9.2%; $p = 0.97$), landmark analysis between 1 and 3 years showed significantly less TVF in patients assigned to the conservative strategy (2.6% vs. 12.7%; $p = 0.004$). The crossover to the 2-stent technique was an independent predictor of TVF (hazard ratio: 5.42, 95% confidence interval: 2.03 to 14.5; $p < 0.001$). There was no interaction between left main bifurcation and treatment effects for TVF (p for interaction = 0.8).

CONCLUSIONS A conservative strategy compared with an aggressive strategy for provisional SB intervention is associated with long-term benefits for patients with a large bifurcation lesion. (Optimal Strategy for Side Branch Stenting in Coronary Bifurcation Lesion; NCT00794014) (J Am Coll Cardiol Intv 2016;9:517–26) © 2016 by the American College of Cardiology Foundation.

Provisional side branch (SB) intervention after main vessel (MV) stenting is the default strategy for most bifurcation lesions in real-world practice (1,2). However, the appropriate criteria for provisional SB ballooning or stenting after MV stenting have not been established. Previous studies found that the rate of crossover to a 2-stent technique during provisional SB intervention was highly variable,

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ABBREVIATIONS AND ACRONYMS

DES = drug-eluting stent(s)

IVUS = intravascular ultrasound

LM = left main

MI = myocardial infarction

MV = main vessel

PCI = percutaneous coronary intervention

SB = side branch

TBR = target bifurcation revascularization

TLR = target lesion revascularization

TVF = target vessel failure

TVR = target vessel revascularization

ranging from 2% to 30%, depending on the criteria for the SB stenting (3-7). In the randomized SMART-STRATEGY (SMart Angioplasty Research Team-Optimal STRATEGY for Provisional Side Branch Intervention in Coronary Bifurcation Lesions) trial, different strategies for provisional SB intervention were compared in patients undergoing percutaneous coronary intervention (PCI) for bifurcation lesions. The trial results demonstrated that a conservative strategy for provisional SB intervention was associated with a lower rate of crossover to the 2-stent technique and a lower incidence of procedure-related myocardial necrosis compared with an aggressive strategy but had similar short-term clinical outcomes (8). The aim of the present study was to compare 3-year clinical outcomes in patients with coronary bifurcation lesions treated with a conservative or an aggressive strategy for provisional SB intervention.

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METHODS

STUDY DESIGN AND PATIENTS. This prospective, randomized, nonblinded, single-center trial enrolled patients with coronary bifurcation lesions who underwent PCI with drug-eluting stents (DES) from July 2007 to December 2010. The protocol was approved by the local institutional review board, and written informed consent was obtained from all participants. The design, exclusion and inclusion criteria, and data collection methods of the SMART-STRATEGY trial were previously described (8). In brief, patients with stable coronary artery disease or non-ST-segment elevation acute coronary syndrome and a de novo coronary bifurcation lesion including an unprotected left main (LM) bifurcation lesion were included. The MV diameter was ≥2.5 mm, and the SB diameter was ≥2.3 mm by visual estimation. Patients with hemodynamic instability, left ventricular ejection fraction <25%, and primary PCI were excluded.

Patients were stratified by the presence or absence of an LM bifurcation lesion and were randomized 1:1 to a conservative or aggressive strategy for provisional SB intervention after MV stenting (**Figure 1**). For LM bifurcation lesions, the conservative strategy was SB ballooning followed by kissing ballooning for an SB stenosis diameter >75% after MV stenting and SB stenting for an SB stenosis diameter >50% or type B or greater dissection after SB ballooning. The aggressive strategy was SB ballooning followed by kissing ballooning for an SB stenosis diameter >50% after MV stenting and SB stenting for an SB stenosis diameter >30% or type B or greater dissection after SB ballooning. For non-LM bifurcation lesions, the conservative strategy was SB ballooning followed by kissing ballooning for Thrombolysis In Myocardial Infarction flow grade lower than 3 in the SB after MV stenting and SB stenting for Thrombolysis In Myocardial Infarction flow grade lower than 3 in the SB after SB ballooning. The aggressive strategy was SB ballooning followed by kissing ballooning for an SB stenosis diameter >75% after MV stenting and SB stenting for an SB stenosis diameter >50% after SB ballooning. For all cases of SB stenting, the T-stenting and small protrusion technique (9) was used exclusively, and final kissing balloon inflation was mandatory. All procedures were performed under intravascular ultrasound (IVUS) guidance whenever possible (see the Online Appendix for details).

STUDY ENDPOINTS AND FOLLOW-UP. The primary endpoint was the occurrence of target vessel failure (TVF), defined as a composite of cardiac death, spontaneous myocardial infarction (MI), or target vessel revascularization (TVR) at 3-year follow-up. Secondary endpoints included the individual components of the primary endpoint, all-cause death, stent thrombosis, target lesion revascularization (TLR), and target bifurcation revascularization (TBR) at 3-year follow-up. All deaths were considered cardiac unless a definite noncardiac cause could be established. Spontaneous MI was defined as elevated cardiac enzymes (troponin or myocardial band fraction of creatine kinase) greater than the upper limit of the normal that occurred along with ischemic symptoms or electrocardiography findings indicative of ischemia unrelated to the index procedure. TVR was defined as repeat revascularization of the target vessel by PCI or bypass graft surgery. TLR was defined as repeat PCI of the lesion within 5 mm of stent deployment or bypass graft surgery of the target vessel. TBR was defined as repeat revascularization with a stenosis diameter ≥50% within 5 mm proximal or distal to carina of bifurcation. Stent thrombosis was assessed according to the definitions of the Academic Research Consortium as definite, probable, or possible stent thrombosis (10).

Data on all-cause death, cardiac death, spontaneous MI, stent thrombosis, TLR, TBR, TVR, and TVF were obtained through office visits or telephone contact at 1, 3, 9, and 12 months after the index procedure and every 6 months thereafter. For validation, information about vital status was obtained through