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Randomized Comparisons Between Different Stenting Approaches for Bifurcation Coronary Lesions With or Without Side Branch Stenosis

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ABSTRACT

OBJECTIVES This study sought to evaluate the optimal percutaneous coronary intervention techniques using drug-eluting stents for bifurcation coronary lesions.

BACKGROUND The optimal bifurcation stenting technique needs to be evaluated.

METHODS The trial included 2 randomization studies separated by the presence of side branch (SB) stenosis for patients having non-left main bifurcation lesions. For 306 patients without SB stenosis, the routine final kissing balloon or leave-alone approaches were compared. Another randomization study compared the crush or single-stent approaches for 419 patients with SB stenosis.

RESULTS Between the routine final kissing balloon and leave-alone groups for nondiseased SB lesions, angiographic restenosis occurred in 17.9% versus 9.3% ($p = 0.064$), comprising 15.1% versus 3.7% for the main branch ($p = 0.004$) and 2.8% versus 5.6% for the SB ($p = 0.50$) from 214 patients (69.9%) receiving 8-month angiographic follow-up. Incidence of major adverse cardiac events including death, myocardial infarction, or target vessel revascularization over 1 year was 14.0% versus 11.6% between the routine final kissing balloon and leave-alone groups ($p = 0.57$). In another randomization study for diseased SB lesions, 28.2% in the single-stent group received SB stents. From 300 patients (71.6%) receiving angiographic follow-up, between the crush and single-stent groups, angiographic restenosis rate was 8.4% versus 11.0% ($p = 0.44$), comprising 5.2% versus 4.8% for the main branch ($p = 0.90$) and 3.9% versus 8.3% for the SB ($p = 0.12$). One-year major adverse cardiac events rate between the crush and single-stent groups was 17.9% versus 18.5% ($p = 0.84$).

CONCLUSIONS Angiographic and clinical outcomes were excellent after percutaneous coronary intervention using drug-eluting stents with any stent technique for non-left main bifurcation lesions once the procedure was performed successfully. (J Am Coll Cardiol Intv 2015;8:550–60) © 2015 by the American College of Cardiology Foundation.

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Among the percutaneous coronary intervention (PCI) techniques proposed for drug-eluting stents (DES), the optimal stenting technique for bifurcation coronary lesions is still under debate (1). Most clinical trials, such as CACTUS (Coronary Bifurcations: Application of the Crushing Technique Using Sirolimus-Eluting Stents) (2), NORDIC (Nordic Bifurcation Stent Technique Study) I, II, and III (3–5), and BBC ONE (British Bifurcation Coronary Study) (6), failed to show the superior outcomes of a unique stent technique over others. These studies were also limited in generalizability due to the heterogeneity of the inclusion criteria, operator experience, study protocol, and enrolled population across the studies.

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To enhance our understanding for bifurcation interventions, we planned a trial to enroll all bifurcation lesions whether they have side branch (SB) stenosis or not. However, due to the varying indications of diverse stenting techniques, a single randomization study could not possess multiple comparisons. Therefore, we designed a trial consisting of 2 parallel randomization studies separated according to the presence of SB stenosis. The 2 randomizations were nominated as different abbreviated names to highlight different indications and interventional approaches. This study, therefore, consecutively enrolled all potential candidates having non-left main bifurcation lesions with or without SB stenosis at the same sites by the same investigators. One study of the trial was the CROSS (Choice of Optimal Strategy for Bifurcation Lesions With Normal Side Branch) study, which compared the role of routine final kissing balloon (FKB) inflation to the selective use of FKB for bifurcations without SB stenosis. The PERFECT (Optimal Stenting Strategy for True Bifurcation Lesions) study was the other study, which compared the crush technique to the single-stent technique for bifurcations with SB stenosis.

METHODS

STUDY DESIGN. The trial consisted of the randomization studies of the CROSS and PERFECT studies, which were prospective, open-label, randomized studies conducted in 14 centers across Korea. The 2 parallel studies were designed to include all comers of patients having bifurcation coronary lesions with or without SB stenosis from the same investigating sites. Patients were eligible for the studies if they were 18 to 75 years old and had angina with bifurcation coronary disease requiring protection, with a reference diameter ≥2.5 mm in the main branch (MB), a lesion length ≤50 mm, and a reference diameter ≥2.0 mm in the SB. Exclusion criteria were left main disease, in-stent restenosis, graft lesions, chronic total occlusion, ST-segment elevation myocardial infarction (MI) within 2 weeks, decreased SB flow, renal failure, left ventricular ejection fraction ≤35%, and serious comorbidities with a life expectancy <1 year. If patients met the inclusion criteria, SB stenosis by visual estimation determined potential inclusion in the CROSS study for patients with SB stenosis <50% or in the PERFECT study, for patients with SB stenosis ≥50% and a lesion length <20 mm. All patients provided written informed consent. The study was approved by the Institutional Review Board at each hospital.

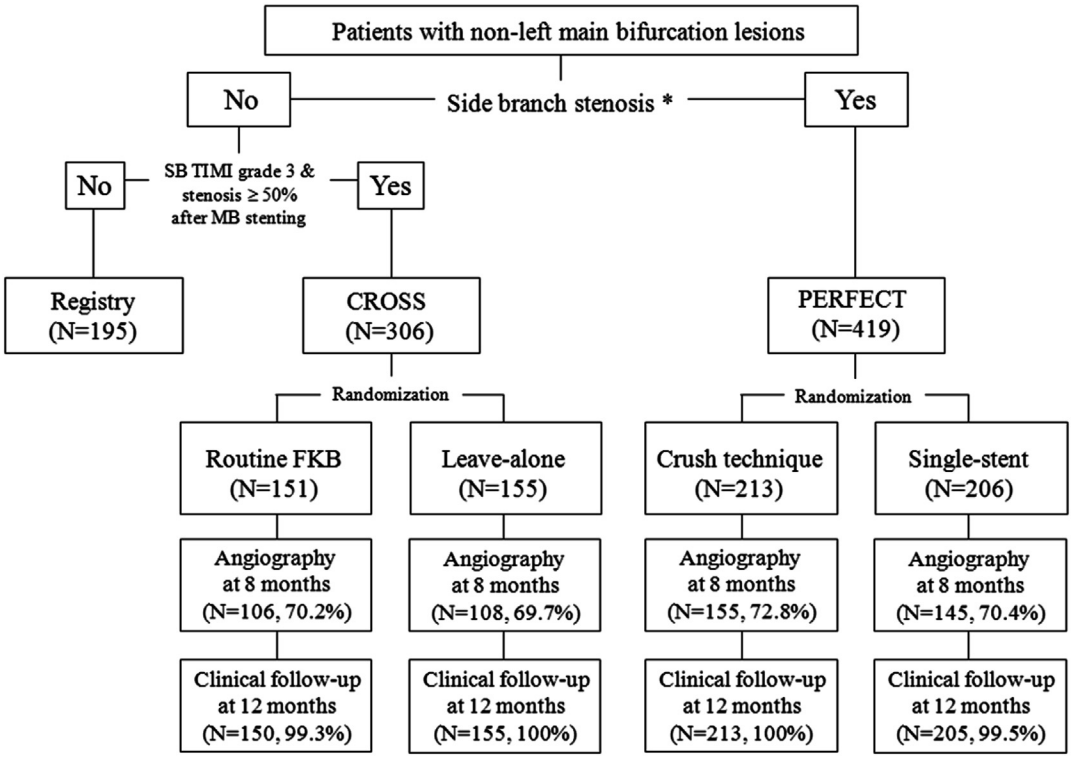
ABBREVIATIONS AND ACRONYMS

DES = drug-eluting stent
FKB = final kissing balloon
IVUS = intravascular ultrasound
MACE = major adverse cardiac events
MB = main branch
MI = myocardial infarction
PCI = percutaneous coronary intervention
SB = side branch
TIMI = Thrombolysis In Myocardial Infarction

Study participants were randomly assigned to the stenting technique groups in a 1:1 ratio, using an interactive web-based response system. For the CROSS study, after MB stenting, patients with SB stenosis ≥50% and good flow and those with TIMI (Thrombolysis In Myocardial Infarction) flow grade 3 were randomly assigned to either the routine FKB or the leave-alone group as shown in **Figure 1**. Patients with SB stenosis <50% or decreased TIMI flow grade ≤2 after MB stenting were not randomized but were referred to the registry group. For the PERFECT study, after successful wire placement in both the MB and SB, patients were randomized to the crush and single-stent technique groups. The randomization sequence was computer-generated and stratified according to the participating center and stent type used.

STENTING TECHNIQUES. All procedures were performed using standard techniques for PCI (7). Intravascular ultrasound (IVUS) evaluation of both branches was recommended for all patients. To standardize the stenting techniques, the study protocol specified procedural steps for each stenting technique as shown in Online Figure 1. Pre-dilation of the SB was not recommended in the CROSS study, but it was performed at the discretion of the operator in the PERFECT study. For patients in the CROSS study, FKB was routinely performed in the routine FKB group but discouraged in the leave-alone group. Fractional flow reserve was used to assess functional ischemia in the MB at the discretion of the operator. Because the purpose of the study was to assess the outcome of routine FKB, fractional flow reserve for the SB was not used to guide the procedure. If the SB showed decreased flow, serious dissection, or suboptimal results with stenosis ≥70% after FKB, provisional-T stenting was selectively performed (8).

FIGURE 1 Study Flow



The flow chart depicts how patients were assigned to the registry and studies and how the studies were randomized. *≥2mm diameter and ≥50% stenosis. CROSS = Choice of Optimal Strategy for Bifurcation Lesions With Normal Side Branch; FKB = final kissing balloon; PERFECT = Optimal Stenting Strategy for True Bifurcation Lesions; SB = side branch; TIMI = Thrombolysis In Myocardial Infarction.

In the PERFECT study, stenting with the crush technique was performed as previously described (8,9). In brief, before SB crushing, the SB stent was minimally retracted to the MB to avoid excessive overlap of metal struts in the proximal MB. Crushing of the SB stent was performed with an MB stent or balloon. In the single-stent group, when a serious SB complication occurred after pre-dilation, the patient was moved to the crush group to receive SB stenting first. For stent optimization, FKB was routinely attempted in all patients who underwent 2-stent techniques, such as crush or provisional-T. During crush stenting, 2-step FKB, in which post-dilations in the SB and MB were followed by FKB, was performed (10).

Antithrombotic therapy consisted of standard dual antiplatelet therapy with 100 mg/day of aspirin and 75 mg/day of clopidogrel for at least 12 months after all procedures.

STUDY ENDPOINTS AND ANGIOGRAPHIC EVALUATION. The primary endpoints of the CROSS and PERFECT studies were in-segment percentage diameter stenosis on the SB and overall restenosis rate on both MB and SB at the 8-month angiography, respectively. Therefore, all patients were asked to receive an angiographic follow-up at 8 months post-procedure or earlier if angina symptoms occurred. Quantitative angiographic analysis of the MB and SB were performed within the stented segment (in-stent) and over the entire segment (in-segment), including the stent and within 5 mm of the proximal and distal margins in an angiographic core laboratory of the CardioVascular Research Foundation (Seoul, Korea) using dedicated bifurcation angiographic software (CAAS-5.4, Pie Medical, Maastricht, the Netherlands) (11). The reference diameter was determined by interpolation. Binary restenosis was defined as ≥50% stenosis on follow-up angiography. Bifurcation classifications were made according to the Medina classification (12).

CLINICAL FOLLOW-UP AND OUTCOMES. Clinical follow-up was performed at 1, 3, 6, and 12 months, and annually thereafter for 5 years. The clinical endpoints were major adverse cardiac events (MACE)

comprising death, MI, and target vessel revascularization with its individual components. Deaths were considered cardiac unless an unequivocal, noncardiac cause was established. MI was defined as an increase in creatine kinase-myocardial band concentration to >3× the upper limit of the normal range, with ischemic symptoms or new ischemic electrocardiographic changes. Target lesion revascularization was defined as repeat revascularization with PCI or coronary artery bypass surgery for restenosis of the entire segment involving the implanted stent and within 5 mm of the distal and proximal margins of the stent. Target vessel revascularization was defined as any repeat revascularization in the treated vessel and was considered clinically driven when the treated vessels had at least 50% stenosis in the presence of ischemic signs or symptoms.

STATISTICAL ANALYSIS. The primary analysis in the CROSS study was a noninferiority comparison between routine FKB and leave-alone groups for the primary endpoint. Angiographic in-segment percentage diameter stenosis on the SB was the primary endpoint and was assumed to be 30% in the routine FKB group (13,14). The sample size of 90 randomized patients in each group was calculated with a noninferiority margin of 15% and a statistical power of 90%, a 1-sided significant alpha of 0.05, and a follow-up loss of 20%. For the PERFECT study, the hypothesis was that the crush technique was superior to the single-stent technique in terms of the overall restenosis rate of the MB or SB at the 8-month angiographic follow-up. A sample size of 240 patients in each group was calculated with the assumption of an overall restenosis rate of 11% in the crush group and 23% in the provisional-T stent group, a power of 90%, a drop-out of 15%, and a 2-sided significant alpha of 0.025 (2,15,16). After reaching 90% of the target number in the PERFECT study, the data safety monitoring board decided to terminate the study due to a delay in enrollment. Because the 2 parallel studies were performed during the same study period, 306 and 419 patients were finally enrolled in the CROSS and PERFECT studies between April 2007 and January 2013, respectively (**Figure 1**).

All analyses were performed in accordance with an intention-to-treat principle. Differences in baseline clinical, angiographic, and procedural characteristics were compared using the Student *t* test for continuous variables and the chi-square or Fisher exact test for categorical variables, as appropriate. The Kaplan-Meier method was used to estimate survival rates in the 2 groups. For clinical endpoints, patients were censored at 1 year or when the endpoint occurred. SAS software (version 9.1, SAS Institute, Cary, North Carolina) was used for statistical analyses.

RESULTS

STUDY POPULATION. Baseline clinical characteristics were well matched between the 2 treatment groups in the CROSS and PERFECT studies (**Table 1**). Procedural characteristics are shown in **Table 2**. The majority of patients received IVUS guidance. There was no difference in the type, number, and length of the MB stents between the 2 treatment groups in the CROSS and PERFECT studies. SB stents were rarely implanted in the CROSS study. In the PERFECT study, 28.2% of patients in the single-stent group received SB stenting due to the suboptimal or impending occlusion of SB. The incidence of peri-procedural MI were 8.4% in the leave-alone and 5.3% in the routine FKB groups in the CROSS study ($p = 0.29$) and 14.1% in the single-stent group and 14.1% in the crush groups in the PERFECT study ($p = 0.98$).

ANGIOGRAPHIC FINDINGS. Angiographic characteristics at baseline and after the procedure are shown in **Table 3**. Baseline angiographic characteristics were similar between the 2 groups in the CROSS and PERFECT studies. Significant SB stenosis, which was represented by a Medina classification of 1.0.1., 1.1.1., 0.1.1., or 0.0.1., was observed in 25.9% of patients in the CROSS study and in 89.8% of patients in the PERFECT study. After the procedure, for the MB, in-stent minimal lumen diameter was comparable between the 2 treatment groups in the CROSS study, but it was smaller in the crush group than in the single-stent group in the PERFECT study. For the SB, ostial minimal lumen diameter was greater in the routine FKB group in the CROSS study and in the crush group in the PERFECT study.

Follow-up angiography was performed in 214 patients (69.9%) in the CROSS study and 300 patients (71.6%) in the PERFECT study as shown in **Table 4**. For the primary endpoints, in the CROSS study, 8-month in-segment percentage SB stenosis was not inferior in the leave-alone group compared with that of the routine FKB group (p for noninferiority < 0.001 and superiority $= 0.074$). Overall angiographic restenosis in analysis segment, as the primary endpoint of the PERFECT study, was not different between the crush and the single-stent groups. In the MB, the in-segment restenosis rate was higher in the routine FKB group than in the leave-alone group in the CROSS study, but it was comparable between the 2 groups in the PERFECT study. The in-segment SB restenosis rate was comparable between the 2 treatment groups

TABLE 1 Baseline Characteristics of Patients

	CROSS Study			PERFECT Study		
	Routine-FKB (n = 151)	Leave-Alone (n = 155)	p Value	Crush (n = 213)	Single-Stent (n = 206)	p Value
Age, yrs	61.0 ± 9.2	61.0 ± 7.9	0.98	60.9 ± 8.9	61.1 ± 8.8	0.86
Male	107 (70.9)	104 (67.1)	0.48	160 (75.1)	155 (75.2)	1.0
Body mass index, kg/m^2	24.7 ± 3.0	24.9 ± 2.6	0.75	24.9 ± 2.8	24.9 ± 3.0	0.86
Current smoking	50 (33.1)	39 (25.2)	0.13	54 (25.4)	67 (32.5)	0.11
Diabetes mellitus	46 (30.5)	45 (29.0)	0.78	55 (25.8)	60 (29.1)	0.45
Hypertension	84 (55.6)	91 (58.7)	0.59	118 (55.4)	114 (55.3)	0.99
Hyperlipidemia	71 (47.0)	77 (49.7)	0.64	132 (62.0)	118 (57.3)	0.33
Family history of coronary disease	10 (6.6)	19 (12.3)	0.092	30 (14.1)	26 (12.6)	0.66
Previous coronary angioplasty	8 (5.3)	15 (9.7)	0.15	20 (9.4)	11 (5.3)	0.11
Renal dysfunction	4 (2.6)	0 (0.0)	0.058	1 (0.5)	1 (0.5)	1.0
Congestive heart failure	0 (0.0)	0 (0.0)		0 (0.0)	2 (1.0)	0.24
Previous myocardial infarction	3 (2.0)	6 (3.9)	0.5	9 (4.2)	9 (4.4)	0.94
Clinical manifestation			0.64			0.43
Stable or asymptomatic angina	74 (49.0)	84 (54.2)		130 (61.3)	127 (62.0)	
Unstable angina	66 (43.7)	62 (40.0)		74 (34.9)	65 (31.7)	
Recent myocardial infarction	11 (7.3)	9 (5.8)		8 (3.8)	13 (6.3)	
Left ventricular ejection fraction, %	60.9 ± 7.0	62.2 ± 5.7	0.098	60.4 ± 6.8	59.5 ± 7.2	0.2

Values are mean ± SD or n (%).
CROSS = Choice of Optimal Strategy for Bifurcation Lesions With Normal Side Branch; FKB = final kissing balloon; PERFECT = Optimal Stenting Strategy for True Bifurcation Lesions.

in the CROSS and PERFECT study. Figure 2 shows the location of restenosis according to the treatment groups.

CLINICAL OUTCOMES. Table 5 shows the 1-year clinical outcomes of patients. There was no difference in the rate of MACE and individual components of MACE comprising death, MI, or target vessel revascularization between the 2 treatment groups in the CROSS and PERFECT studies. Figure 3 shows the Kaplan-Meier incidence curves of 1-year MACE.

DISCUSSION

Our trial included 2 randomized studies evaluating the optimal stent strategy for non-left main bifurcation coronary lesions. They showed that any bifurcation stenting using current DES might achieve excellent long-term results once the procedure is performed successfully. In the CROSS study, for bifurcations without SB stenosis, the selective FKB strategy was not inferior to routine FKB after MB stenting for angiographic and clinical outcomes. For true bifurcations with SB stenosis in the PERFECT study, the crush technique failed to achieve better angiographic outcomes than the single-stent technique did. Of interest, the 1-year incidence of death, spontaneous MI, or target vessel revascularization was in single-digit numbers in all groups in both randomized studies.

Because of different inclusion criteria of previous randomization studies for bifurcation lesions, interpretation of these comparative results should be done carefully (2–6). It is common knowledge that outcomes of bifurcation PCI are dependent on baseline lesion complexity (17). In addition, due to the diversity of the bifurcation techniques proposed (18), the study protocol must prespecify the individual steps of the stenting techniques to assess the real benefits of each stenting technique. In this regard, we stratified bifurcations into 2 different groups according to the presence of baseline SB stenosis. We then compared 2 commonly used stenting techniques for each patient group of the CROSS and PERFECT study. Moreover, to minimize the impact of procedural inhomogeneity across operators, individual steps for each stenting technique were detailed in the protocol and approved by the operators (10). The use of new-generation DES strengthened this study by representing current practices of PCI compared with previous randomized studies using first-generation DES (17,19). With the strengths, this report of a trial including 2 randomized studies may help physicians to understand the outcomes of diverse stenting techniques.

In the CROSS study, enrolling bifurcations without significant SB stenosis, the selective use of FKB in the leave-alone group was not inferior to the routine use of FKB after MB stenting. In our study, although only

TABLE 2 Procedural Characteristics of Patients

	CROSS Study			PERFECT Study		
	Routine-FKB (n = 151)	Leave-Alone (n = 155)	p Value	Crush (n = 213)	Single-Stent (n = 206)	p Value
Treated vessels			0.54			0.62
1	111 (73.5)	109 (70.3)		159 (74.6)	145 (70.4)	
2	35 (23.2)	43 (27.7)		46 (21.6)	52 (25.2)	
3	5 (3.3)	3 (1.9)		8 (3.8)	9 (4.4)	
Target bifurcation lesions			0.69			0.33
Left anterior descending artery	137 (90.7)	137 (88.4)		200 (93.9)	190 (92.2)	
Left circumflex artery	11 (7.3)	12 (7.7)		10 (4.7)	15 (7.3)	
Right coronary artery	3 (2.0)	6 (3.9)		3 (1.4)	1 (0.5)	
Transradial approach	56 (37.1)	55 (35.5)	0.77	25 (11.7)	25 (12.1)	0.90
Procedure time, min	40.8 ± 18.5	32.8 ± 16.2	<0.001	52.5 ± 21.0	48.7 ± 21.2	0.065
Fluoroscopic time, min	21.4 ± 10.3	17.9 ± 8.1	0.001	29.3 ± 14.1	25.9 ± 12.7	0.013
Contrast amount, cc	287.4 ± 127.7	273.3 ± 110.4	0.31	349.6 ± 145.0	347.0 ± 124.5	0.85
Treatment of main branch						
Noncompliant balloon	95 (62.9)	87 (56.1)	0.23	141 (66.2)	97 (47.1)	<0.001
Cutting balloon	0 (0.0)	1 (0.6)	1.00	6 (2.8)	2 (1.0)	0.29
Intravascular ultrasound	139 (92.1)	149 (96.1)	0.13	204 (95.8)	197 (95.6)	0.94
Pre-dilation	148 (98.0)	149 (96.1)	0.50	208 (97.7)	202 (98.1)	1.0
Stent implantation	151 (100)	155 (100)		213 (100)	206 (100)	
Number of stents	1.3 ± 0.5	1.2 ± 0.4	0.61	1.4 ± 0.5	1.4 ± 0.5	0.76
Mean stent diameter, mm	3.5 ± 2.2	3.3 ± 0.3	0.23	3.3 ± 0.3	3.3 ± 0.3	0.49
Length of stents, mm	33.2 ± 13.1	33.0 ± 14.8	0.94	37.3 ± 14.7	36.9 ± 15.3	0.76
Maximal pressure applied, atm	19.2 ± 4.4	18.5 ± 4.6	0.18	18.7 ± 4.1	15.9 ± 4.7	<0.001
Used stents			0.58			0.98
Sirolimus-eluting stents	47 (31.1)	36 (23.2)		127 (59.6)	118 (57.3)	
Paclitaxel-eluting stents	17 (11.3)	21 (13.5)		2 (0.9)	3 (1.5)	
Everolimus-eluting stents	33 (21.9)	36 (23.2)		59 (27.7)	59 (28.6)	
Zotarolimus-eluting stents	44 (29.1)	53 (34.2)		19 (8.9)	19 (9.2)	
Others	10 (6.6)	9 (5.8)		6 (2.8)	7 (3.4)	
Treatment of side branch						
Noncompliant balloon	18 (11.9)	2 (1.3)	<0.001	116 (54.5)	26 (12.6)	<0.001
Cutting balloon	0 (0.0)	1 (0.6)	1.00	2 (0.9)	0 (0.0)	0.50
Intravascular ultrasound	73 (48.3)	51 (32.9)	0.006	195 (91.5)	164 (79.6)	<0.001
Pre-dilation	5 (3.3)	6 (3.9)	0.79	177 (83.1)	76 (36.9)	<0.001
FKB inflation	144 (95.4)	7 (4.5)	<0.001	204 (95.8)	163 (79.1)	<0.001
Stent implantation	3 (2.0)	1 (0.6)	0.37	208 (97.7)	58 (28.2)	<0.001
Number of stents	1	1	–	1.0 ± 0.2	1.0 ± 0.2	0.66
Mean stent diameter, mm	2.6 ± 0.1	2.8	0.42	2.7 ± 0.2	2.7 ± 0.2	1.00
Length of stents, mm	24.7 ± 2.9	30.0	0.25	21.4 ± 6.7	21.5 ± 6.9	0.93
Maximal pressure applied, atm	15.7 ± 5.1	17.0	0.84	18.0 ± 4.2	15.1 ± 4.0	<0.001
Stenting technique			0.75			<0.001
Crush	0 (0.0)	0 (0.0)		206 (99.0)	15 (25.9)	
Provisional-T	2 (66.7)	1 (100)		1 (0.5)	43 (74.1)	
Others	1 (33.3)	0 (0.0)		1 (0.5)	0 (0.0)	
Used stents			0.50			0.85
Sirolimus-eluting stents	2 (66.7)	0 (0.0)		126 (60.6)	34 (58.6)	
Paclitaxel-eluting stents	0 (0.0)	0 (0.0)		2 (1.0)	0 (0.0)	
Everolimus-eluting stents	1 (33.3)	0 (0.0)		54 (26.0)	19 (32.8)	
Zotarolimus-eluting stents	0 (0.0)	1 (100)		18 (8.7)	4 (6.9)	
Others	0 (0.0)	0 (0.0)		8 (3.8)	1 (1.7)	

Values are n (%) or mean ± SD. Dash indicates that data were unavailable.

Abbreviations as in Table 1.

TABLE 3 Angiographic Characteristics of Lesions Before and After Procedure

	CROSS Study			PERFECT Study		
	Routine-FKB (n = 151)	Leave-Alone (n = 155)	p Value	Crush (n = 213)	Single-Stent (n = 206)	p Value
Baseline*						
Medina classification			0.18			0.012
1.0.0.	18 (12.2)	15 (9.8)		2 (1.0)	4 (2.0)	
1.1.0.	52 (35.1)	74 (48.4)		5 (2.4)	22 (10.9)	
1.0.1.	8 (5.4)	4 (2.6)		18 (8.7)	18 (8.9)	
1.1.1.	28 (18.9)	24 (15.7)		137 (65.9)	126 (62.4)	
0.1.0.	34 (23.0)	25 (16.3)		4 (1.9)	5 (2.5)	
0.1.1.	6 (4.1)	4 (2.6)		39 (18.8)	25 (12.4)	
0.0.1.	1 (0.7)	3 (2.0)		3 (1.4)	2 (1.0)	
0.0.0.	1 (0.7)	4 (2.6)		0 (0.0)	0 (0.0)	
Main branch						
Severe calcification	7 (4.7)	8 (5.2)	0.84	25 (12.0)	25 (12.4)	0.91
Severe tortuosity	1 (0.7)	0 (0.0)	0.49	0 (0.0)	0 (0.0)	–
TIMI flow grade			0.14			0.43
0 or 1	4 (2.7)	5 (3.3)		3 (1.4)	6 (3.0)	
2	4 (2.7)	0 (0.0)		14 (6.7)	10 (5.0)	
3	140 (94.6)	148 (96.7)		191 (91.8)	186 (92.1)	
Proximal reference diameter, mm	3.5 ± 0.6	3.4 ± 0.5	0.24	3.6 ± 0.4	3.7 ± 0.5	0.039
Distal reference diameter, mm	2.5 ± 0.4	2.5 ± 0.4	0.86	2.6 ± 0.4	2.6 ± 0.4	0.67
Lesion length, mm	28.3 ± 12.9	27.1 ± 12.8	0.42	28.9 ± 14.6	27.8 ± 13.1	0.43
Minimal lumen diameter, mm	1.2 ± 0.4	1.1 ± 0.4	0.20	1.1 ± 0.4	1.1 ± 0.4	0.75
Diameter stenosis, %	60.5 ± 11.8	61.8 ± 13.4	0.36	64.4 ± 12.3	65.9 ± 11.7	0.21
Side branch						
Severe calcification	0 (0.0)	0 (0.0)	–	5 (2.4)	4 (2.0)	1.0
Severe tortuosity	0 (0.0)	0 (0.0)	–	0 (0.0)	1 (0.5)	0.49
TIMI flow grade			0.84			1.0
0 or 1	2 (1.4)	4 (2.6)		1 (0.5)	1 (0.5)	
2	1 (0.7)	1 (0.7)		16 (7.7)	15 (7.4)	
3	145 (98.0)	148 (96.7)		191 (91.8)	186 (92.1)	
Distal reference diameter, mm	2.1 ± 0.4	2.1 ± 0.4	0.069	2.2 ± 0.4	2.2 ± 0.4	0.17
Lesion length, mm	2.3 ± 4.3	1.4 ± 3.1	0.026	10.3 ± 8.2	8.3 ± 7.3	0.009
Minimal lumen diameter, mm	1.6 ± 0.4	1.7 ± 0.4	0.24	1.1 ± 0.4	1.2 ± 0.4	0.25
Diameter stenosis, %	29.4 ± 13.4	29.0 ± 15.7	0.82	57.2 ± 14.5	53.3 ± 16.5	0.012
Post-procedure*						
Main branch						
Stent length, mm	31.5 ± 12.0	30.9 ± 11.7	0.66	34.0 ± 13.5	34.7 ± 13.4	0.64
Minimal luminal diameter, mm						
In-stent	2.6 ± 0.4	2.6 ± 0.4	0.68	2.6 ± 0.4	2.7 ± 0.4	0.041
In-segment	2.2 ± 0.4	2.2 ± 0.4	0.53	2.2 ± 0.4	2.3 ± 0.5	0.13
Diameter stenosis, %						
In-stent	11.6 ± 6.6	12.8 ± 7.2	0.12	13.5 ± 7.2	13.0 ± 6.9	0.48
In-segment	20.3 ± 8.7	20.7 ± 8.3	0.70	22.1 ± 10.0	20.7 ± 8.7	0.12
Side branch						
Stent length, mm	15.3 ± 8.1	24.6	0.42	15.4 ± 7.1	16.4 ± 6.6	0.32
Minimal luminal diameter, mm						
Ostium	1.7 ± 0.4	1.6 ± 0.5	0.053	2.3 ± 0.4	1.9 ± 0.6	<0.001
In-segment	1.6 ± 0.4	1.5 ± 0.4	0.15	1.8 ± 0.4	1.6 ± 0.4	<0.001
Diameter stenosis, %						
Ostium	25.8 ± 15.0	32.2 ± 18.2	0.001	13.7 ± 11.1	25.7 ± 17.8	<0.001
In-segment	28.7 ± 13.3	34.2 ± 16.6	0.002	21.0 ± 10.7	31.1 ± 15.0	<0.001

Values are n (%) or mean ± SD. Dashes indicate that data were unavailable. *Quantitative angiographic analysis in the core laboratory was available in 148 lesions (98.0%) in the routine-FKB and 153 lesions (98.7%) in the leave-alone groups of the CROSS study and 208 lesions (97.7%) in the crush and 202 lesions (98.1%) in the single-stent groups of the PERFECT study.

TIMI = Thrombolysis In Myocardial Infarction; other abbreviations as in Table 1.

TABLE 4 Angiographic Characteristics of Lesions at Follow-Up

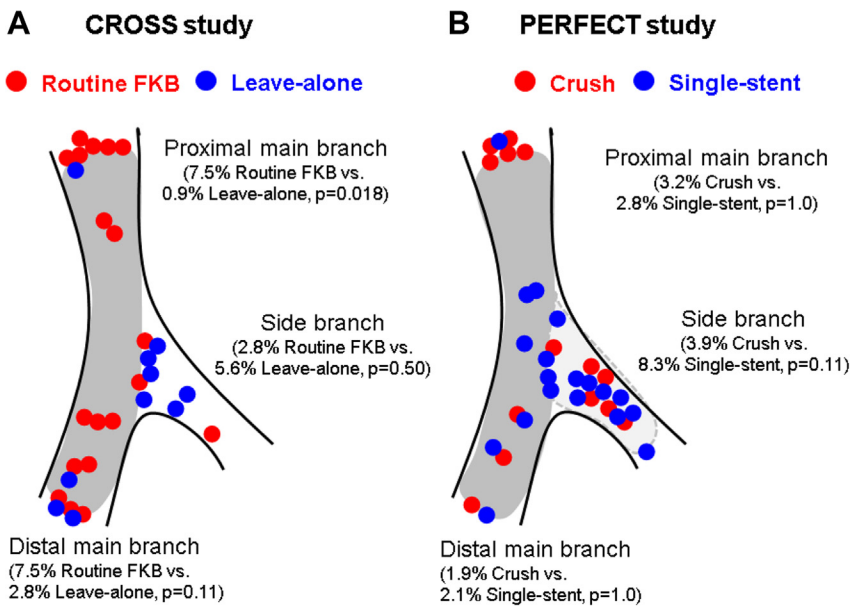
	CROSS Study			PERFECT Study		
	Routine-FKB (n = 106)	Leave-Alone (n = 108)	p Value	Crush (n = 155)	Single-Stent (n = 145)	p Value
Overall restenosis, %*	19 (17.9)	10 (9.3)	0.064	13 (8.4)	16 (11.0)	0.44
Main branch						
Minimal luminal diameter, mm						
In-stent	2.2 ± 0.6	2.3 ± 0.5	0.32	2.4 ± 0.4	2.4 ± 0.5	1.0
In-segment	1.9 ± 0.6	2.1 ± 0.4	0.071	2.1 ± 0.4	2.2 ± 0.5	0.44
Diameter stenosis, %						
In-stent	22.8 ± 16.2	20.5 ± 13.4	0.24	19.8 ± 10.6	21.3 ± 13.3	0.26
In-segment	29.7 ± 17.3	25.7 ± 13.1	0.064	26.8 ± 13.1	26.1 ± 12.4	0.65
Late luminal loss, mm						
In-stent	0.4 ± 0.5	0.3 ± 0.4	0.13	0.2 ± 0.3	0.3 ± 0.4	0.036
In-segment	0.2 ± 0.5	0.1 ± 0.4	0.094	0.1 ± 0.4	0.2 ± 0.4	0.24
Restenosis						
In-stent	8 (7.5)	1 (0.9)	0.018	2 (1.3)	5 (3.4)	0.27
Proximal edge	6 (5.7)	1 (0.9)	0.064	5 (3.2)	1 (0.7)	0.22
Distal edge	3 (2.8)	2 (1.9)	0.68	1 (0.6)	1 (0.7)	1.0
In-segment	16 (15.1)	4 (3.7)	0.004	8 (5.2)	7 (4.8)	0.90
Restenosis pattern			1.0			1.0
Focal	10 (62.5)	2 (50.0)		5 (62.5)	4 (57.1)	
Diffuse	6 (37.5)	2 (50.0)		3 (37.5)	3 (42.9)	
Side branch						
Minimal luminal diameter, mm						
Ostium	1.6 ± 0.4	1.5 ± 0.5	0.17	2.0 ± 0.4	1.6 ± 0.5	<0.001
In-segment	1.5 ± 0.4	1.5 ± 0.4	0.73	1.7 ± 0.4	1.4 ± 0.4	<0.001
Diameter stenosis, %						
Ostium	27.5 ± 15.9	33.3 ± 16.9	0.010	23.2 ± 15.1	34.3 ± 18.9	<0.001
In-segment†	31.1 ± 14.5	34.9 ± 15.8	0.074	27.7 ± 13.2	37.7 ± 17.1	<0.001
Late luminal loss, mm						
Ostium	0.1 ± 0.4	0.1 ± 0.4	0.59	0.3 ± 0.4	0.3 ± 0.5	0.15
In-segment	0.1 ± 0.4	0.1 ± 0.4	0.88	0.1 ± 0.3	0.2 ± 0.3	0.36
Restenosis						
Ostium	2 (1.9)	4 (3.7)	0.68	1 (0.6)	4 (2.8)	0.20
In-segment	3 (2.8)	6 (5.6)	0.50	6 (3.9)	12 (8.3)	0.12
Restenosis pattern			0.33			0.52
Focal	2 (66.7)	6 (100)		6 (100)	9 (75.0)	
Diffuse	1 (33.3)	0 (0.0)		0 (0.0)	3 (25.0)	

Values are n (%) or mean ± SD. *The primary endpoints of the PERFECT study. †The primary endpoints of CROSS study.
Abbreviations as in Table 1.

4.5% of patients finally received FKB in the leave-alone group, angiographic and clinical outcomes were excellent and comparable to those in patients receiving routine FKB. On the other hand, MB restenosis was higher in the routine FKB group due to the potential distortion of the MB stent strut (20,21). Otherwise, greater barotrauma in the MB due to FKB might have resulted in more frequent restenosis at the proximal part of stents in our study. Absence of angiographic or clinical benefits using routine FKB was in line with the results of the NORDIC III study (5). Previous studies evaluating ischemia of the SB using fractional flow reserve, partly explained the mechanism by which a few SB after MB stenting were functionally compromised for bifurcations with nondiseased SB (22–24). Given these results, in the case of planned single-stent treatment for non-left main bifurcation lesions, FKB needs to be conservatively performed for selected patients with decreased flow or impending occlusion of the SB after MB stenting.

The PERFECT study confirmed the current consensus that the single-stent technique yields comparable clinical outcomes to the 2-stent technique (1). At follow-up angiography, the crush technique had no benefits over the single-stent technique in terms of angiographic and clinical restenosis. Instead, the procedural time and contrast amount

FIGURE 2 Locations of Restenoses Between the 2 Treatments in the CROSS and PERFECT Studies



Locations of restenoses between the 2 treatments in the CROSS **(A)** and PERFECT **(B)** studies on an intention-to-treat analysis basis. Abbreviations as in Figure 1.

TABLE 5 Clinical Outcomes of Patients

	CROSS Study			PERFECT Study		
	Routine-FKB (n = 151)	Leave-Alone (n = 155)	p Value	Crush (n = 213)	Single-Stent (n = 206)	p Value
Death	2 (1.3)	0 (0.0)	0.15	3 (1.4)	2 (1.0)	0.68
Cardiac	2 (1.3)	0 (0.0)	0.15	2 (0.9)	1 (0.5)	0.58
Noncardiac	0 (0.0)	0 (0.0)		1 (0.5)	1 (0.5)	0.98
Myocardial infarction	9 (6.0)	13 (8.4)	0.42	30 (14.1)	29 (14.1)	0.98
Q-wave	0 (0.0)	1 (0.6)	0.32	0 (0.0)	0 (0.0)	
Non-Q-wave	9 (6.0)	12 (7.7)	0.55	30 (14.1)	29 (14.1)	0.98
Target vessel revascularization	11 (7.4)	5 (3.2)	0.11	6 (2.9)	7 (3.4)	0.73
Clinically driven	4 (2.7)	1 (0.6)	0.16	1 (0.5)	3 (1.5)	0.30
Target lesion revascularization	10 (6.7)	4 (2.6)	0.088	4 (1.9)	7 (3.4)	0.33
Percutaneous coronary intervention	10 (6.7)	4 (2.6)	0.088	4 (1.9)	6 (2.9)	0.48
Main branch	9 (6.0)	3 (1.9)	0.067	4 (1.9)	6 (2.9)	0.48
Side branch	2 (1.3)	2 (1.3)	0.97	2 (1.0)	2 (1.0)	0.97
Coronary artery bypass graft	0 (0.0)	0 (0.0)		0 (0.0)	1 (0.5)	0.31
Main branch				0 (0.0)	1 (0.5)	0.31
Side branch				0 (0.0)	0 (0.0)	
Stent thrombosis	0 (0.0)	1 (0.6)	0.33	1 (0.5)	0 (0.0)	0.32
Target lesion	0 (0.0)	0 (0.0)	–	0 (0.0)	0 (0.0)	–
Nontarget lesion	0 (0.0)	1 (0.6)	0.33	1 (0.5)	0 (0.0)	0.32
Major adverse cardiac events	21 (14.0)	18 (11.6)	0.57	38 (17.8)	38 (18.5)	0.85

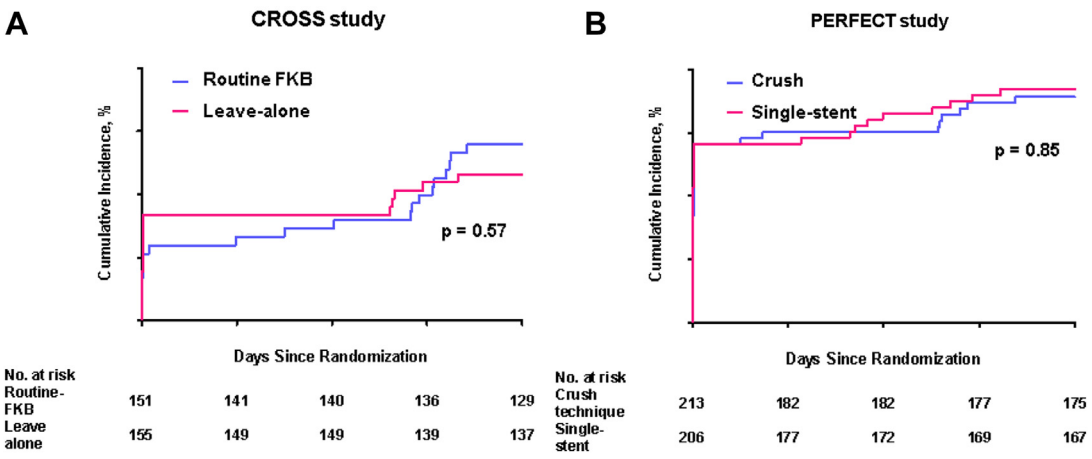
Values are n (%) using Kaplan-Meier methods. The p values were analyzed using the log-rank test. Dashes indicate that data were unavailable.

Abbreviations as in Table 1.

used were significantly greater after the crush technique. This finding was in line with previous studies showing that the systemic use of the 2-stent technique may not be appropriate, even for true bifurcations (2,3,6,17). However, it should be noted that 28% of patients in the single-stent group eventually received the 2-stent technique because of suboptimal results or impending occlusion of the SB before or after MB stenting. This finding suggests that the planned 2-stent technique can also be a reasonable approach when SB occlusion is strongly anticipated.

When periprocedural MI was excluded, the 1-year incidence of MACE was a single-digit number after using any of the stent techniques in the CROSS and PERFECT studies. Angiographic restenosis rates ranged from 16.0% to 28.0% in the CACTUS (14) and NORDIC (3) studies, but from 8.4% to 11.0% in our PERFECT study. The low event rate may be partly due to refinement of the stenting technique with successful performance or improved devices. For instance, in our study, the systemic use of IVUS in more than 90% of patients may have improved long-term clinical outcomes for bifurcation coronary lesions (25). In addition, after stent crushing, 95.8% of patients received successful FKB, which may have subsequently contributed to the low event rate (10,15). Recent use of new-generation DES might also improve prognosis (19). Given this finding, we can conclude that PCI for

FIGURE 3 Kaplan-Meier Incidence Curves of MACE in the CROSS and PERFECT Studies



Kaplan-Meier incidence curves of major adverse cardiac events (MACE) comprising death, myocardial infarction, or target vessel revascularization over 1 year in the CROSS **(A)** and PERFECT **(B)** studies on an intention-to-treat analysis basis. Abbreviations as in Figure 1.

bifurcation lesions using DES appears to lead to an excellent prognosis once the procedure is performed optimally, according to the standard guidelines.

STUDY LIMITATIONS. First, our studies were still underpowered to compare clinical outcomes between 2 different treatments. Moreover, angiographic follow-up was limitedly performed in 70% of patients. In particular, unexpectedly low restenosis rate and early termination make a drawback of the PERFECT study in the comparison of 2 stent techniques. However, given the difficulty in enrolling true bifurcations in randomized trials, comparably low angiographic and clinical event rates between 2 stent techniques in the PERFECT study may still provide valuable information. Second, due to the unexpectedly long study enrollment period, there might be temporal changes in the standard treatments, such as use of DES and adjunctive medications. For instance, new-generation DES were used for approximately one-half of the patients. Third, although consecutive patients were prospectively enrolled, not all patients with bifurcations were recruited due to any reason. Moreover, because we excluded patients with true bifurcations when both wires could not be successfully inserted in the MB and SB, it is likely that patients with very complex bifurcation morphology were excluded from our study. In addition, because enrollment was performed by visual assessment of investigators, relatively simple lesions were also included. True bifurcations with diffuse SB stenosis were also excluded. Therefore, event rates in our study may have been under-reported compared with real-world practices. Fourth, because SB diameter was relatively small with the mean reference of 2.1 mm, bifurcations with big SB may have different outcomes. Fifth, the outcomes of our studies may not be applicable to all practices. The penetration rate of IVUS during PCI is still <30% in the United States (26). Finally, only 1 2-stent technique was evaluated in our study. Other 2-stent techniques, such as culotte, kissing, or a modified crush technique, may have a different prognosis (18). However, given the previous NORDIC II study, which showed comparable outcomes between crush and culotte stenting, the findings of the PERFECT study may represent general outcomes between single- and 2-stenting techniques.

CONCLUSIONS

The CROSS and PERFECT studies demonstrated that outcomes of PCI for bifurcation lesions were comparably safe and effective with any stenting technique, even for true bifurcation lesions. Of importance is that the procedures must be done with a careful functional and anatomical evaluation.

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PERSPECTIVES

The present cohort comprises 2 randomized trials—CROSS and PERFECT—aimed to assess the outcomes of bifurcation stenting with comparisons of diverse techniques using new devices. The CROSS study highlighted that routine final kissing balloon inflation, which had been considered necessary to restore the side branch flow, may lead to poor angiographic and subsequent clinical outcomes due to higher restenosis rate in the main branch. The PERFECT study indicated that either the double-stent or single-stent technique with provisional side branch treatment results in excellent clinical outcomes once the procedure is optimally performed for true bifurcation lesions. Future research needs to investigate the optimized technique or device for each individual patient.

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KEY WORDS bifurcation, coronary artery disease, restenosis, stent

APPENDIX For a supplemental figure, please see the online version of this article.