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The modified balloon crush technique

A simplified approach to optimizing final kissing balloon inflation

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Abstract

This study aimed to investigate the feasibility and safety of the modified balloon crush technique.

The conventional crush technique accompanies difficult and suboptimal final kissing balloon inflation (FKI)

In a single-center percutaneous coronary intervention registry, 515 patients with 515 bifurcation lesions were treated with the modified balloon technique (n = 70) or the conventional crush technique (n = 445). In contrast to the conventional crush technique, where the implanted side branch (SB) stent is crushed by expansion of the main branch (MB) stent, the modified balloon crush technique uses balloon crushing and additional SB ballooning across the crushed SB stent before MB stenting to facilitate FKI. The primary outcome of interest was major adverse cardiovascular event (MACE), a composite of all-cause death, spontaneous myocardial infarction, and target vessel revascularization.

Baseline clinical and angiographic characteristics were similar between the 2 treatment groups. FKI had comparable success rates in both groups (97.1% for the modified balloon group and 98.4% for the conventional crush group; $P = .35$). There were no differences in procedure time, fluoroscopic time, or contrast amount between the 2 groups. At 1-year follow up, the cumulative MACE incidences were comparable between the 2 groups (7.3% vs 8.8%; $P = .73$). The incidence of target lesion revascularization (TLR) was significantly lower after the modified balloon crush technique compared with the conventional crush technique (0% vs 5.6%; $P = .048$).

The modified balloon crush technique appears to be a feasible and safe alternative to the conventional crush technique with the potential to reduce the revascularization rate.

Abbreviations: CI = confidence interval, DK-crush technique = double kissing crush technique, FKI = final kissing balloon inflation, HR = hazard ratio, IVUS = intravascular ultrasound, MACE = major adverse cardiovascular event, MB = main branch, PCI = percutaneous coronary intervention, SB = side branch, TLR = target lesion revascularization, TVR = target vessel revascularization.

Keywords: coronary bifurcation lesion, crush technique, final kissing balloon inflation

1. Introduction

Despite the current consensus on the single-stent technique as the default treatment strategy for a coronary bifurcation lesion, double-stenting techniques are still considered a viable option for lesions with significantly diseased side branches (SBs).[1] Among the various double-stenting techniques currently in clinical use, the crush technique is widely employed because of its technical simplicity and good coverage of the SB ostium.[2] Nonetheless, the crush technique inevitably generates a multi-layer strut covering the SB ostium, resulting in a difficult and suboptimal final kissing balloon inflation (FKI).[3,4] To overcome this weakness, the double kissing (DK)-crush technique was recently introduced and showed feasibility and efficacy in previous studies.[5,6] However, the additional kissing balloon inflation might complicate the procedure and limit its dissemination.

To optimize FKI, a modified balloon crush technique was introduced previously by Collins et al,[7] which used additional SB ballooning across the crushed SB stent before main branch (MB) stenting. However, because of the small number of subjects enrolled in the study (10 patients), the results derived from it needs to be validated. Against this background, we analyzed and compared cohorts of patients treated with the modified balloon and conventional crush techniques in our tertiary academic hospital.

2. Methods

2.1. Study patients

We identified 515 patients with 515 coronary bifurcation lesions treated with the crush technique between January 2007 and

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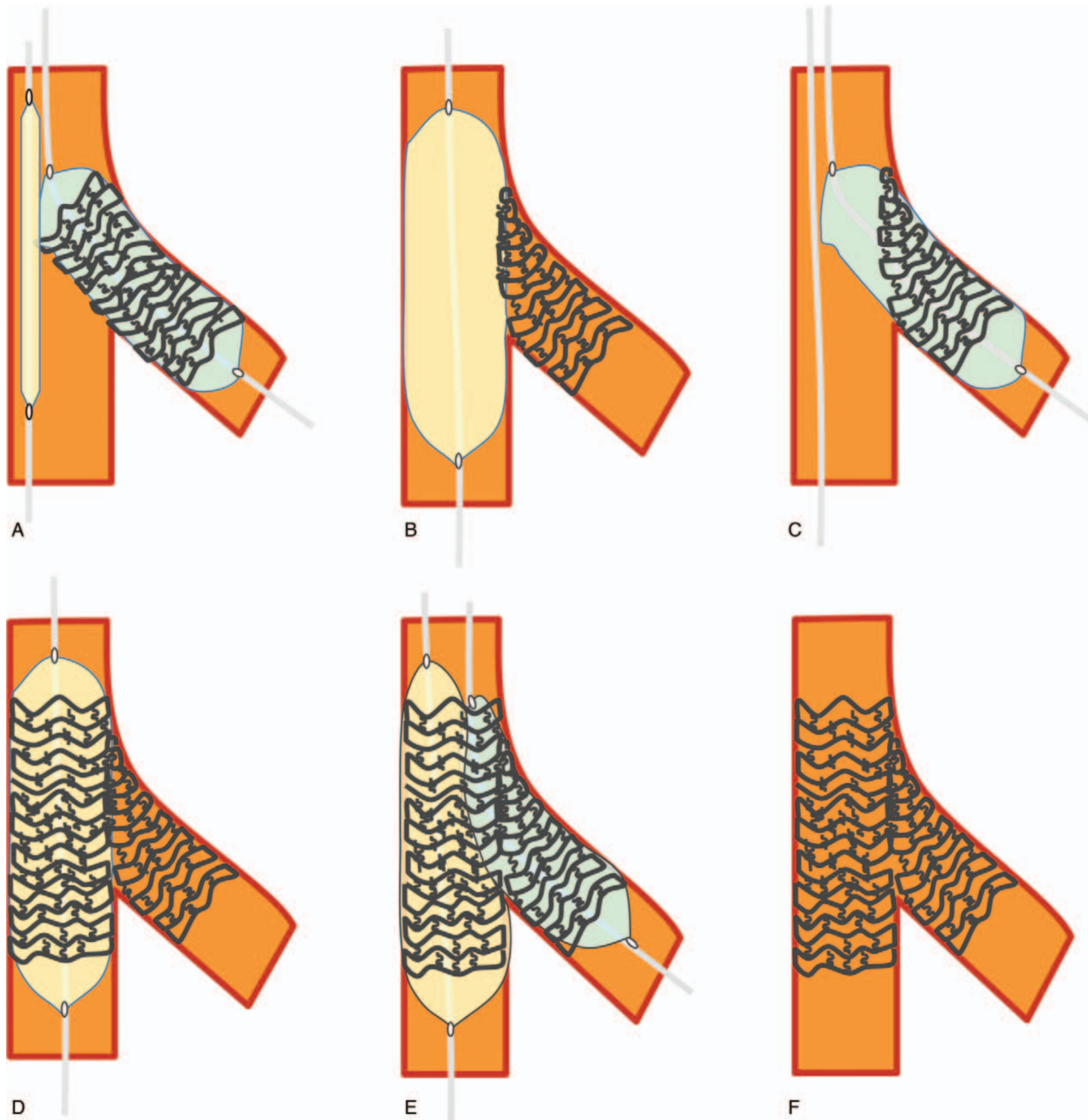

Figure 1. Modified balloon crush technique. A, After predilation of the main branch (MB) and side branch (SB), the stent is placed in the SB with the balloon catheter loaded in the MB. B, After deployment of the SB stent, it is crushed by the inflated MB balloon. C, The SB ostium is re-opened by balloon inflation. D, The stent is implanted in the MB. E–F, The procedure is completed with final kissing balloon inflation.

October 2011 from the prospective percutaneous coronary intervention (PCI) registry of a tertiary academic hospital. Of these patients, the modified balloon technique was performed in 70 cases and the conventional crush technique was performed on 445 patients. Demographic and procedural data were collected from the electronic case reporting forms. This study was approved by the institutional review board of our hospital, and informed consent to be enrolled was obtained from all patients.

2.2. Stenting technique

All procedures for PCI were performed in compliance with standard guidelines.[8,9] Use of adjunctive devices and drugs, such as cutting balloons, rotablators, and glycoprotein IIb/IIIa inhibitors, was left to operator discretion. Evaluation of both branches by intravascular ultrasound (IVUS) was recommended for all patients. The conventional crush technique was performed as previously described.[2,10] Briefly, after predilation of the MB and SB, 2 stents were placed in each branch, with the SB stent minimally retracted into the MB. Next, the SB stent was deployed and its balloon and wire were removed. The MB stent was then inflated, flattening the protruding cells of the SB stent against the MB wall. After wire re-crossing and balloon-dilation of the SB, the procedure was completed with FKI. The modified balloon crush technique is depicted in Figure 1, and a representative case is presented in Figure 2. After predilation of both branches, the

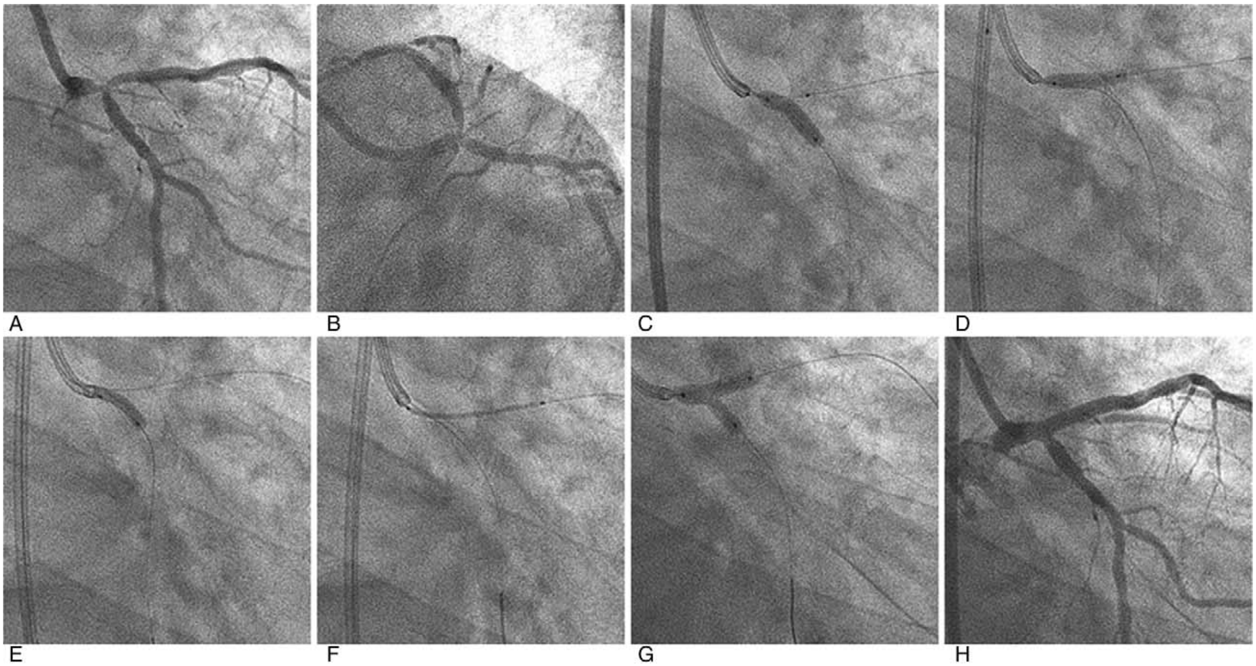

Figure 2. A representative case treated with the modified balloon crush technique. A patient with distal left main bifurcation stenosis was successfully treated with the modified balloon crush technique. A–B, Initial angiography shows significant stenosis involving the distal left main bifurcation. C, The stent in the left circumflex coronary artery (LCX) was deployed with the balloon catheter placed in the left anterior descending coronary artery (LAD). D, The protruding portion of the LCX stent was flattened by inflation of the LAD balloon. E, The LCX ostium was reopened by balloon inflation. F, The left main coronary artery and LAD were stented. G, The procedure was completed with final kissing balloon inflation. H, The procedure was found to have been successful on the final angiography.

balloon catheter was loaded into the MB instead of the stent to crush the protruded SB stent. Before the MB stent was deployed, the existing SB stent was rewired and dilated with the balloon catheter, which was positioned across the crushed cells of the SB stent. The remaining steps were identical to the conventional crush technique.

2.3. Angiographic evaluation

For all stented branches, quantitative angiographic analysis was performed over the entire segment (in-segment), which consisted of the stented segment (in-stent) and the non-stented segments 5 mm proximal and distal. This analysis was performed in the angiographic core laboratory of the CardioVascular Research Foundation, Seoul, Korea using dedicated software for bifurcation lesions (CAAS-5.4, Pie-Medical, the Netherlands).[11] The reference diameter, minimal lumen diameter, and percentage diameter stenosis were measured using this technique. The reference diameter was estimated by interpolation of the diameters of the normal segments proximal and distal to the lesion. Bifurcation classifications were made according to the MEDINA classification.[12] Follow-up angiography was not routinely recommended and only performed at the discretion of the attending physicians. Binary restenosis was defined as ≥ 50% stenosis on follow-up angiography, and late luminal loss was measured over the entire segment.

2.4. Clinical follow-up and outcomes

Clinical follow-up was performed at 1, 3, 6, and 12 months, and annually thereafter, at a clinical visit or through a telephone interview. The primary outcome of interest was major adverse cardiovascular event (MACE), a composite of death from any cause, spontaneous myocardial infarction, and target vessel revascularization (TVR). The individual components of MACE, death from cardiac and non-cardiac causes, peri-procedural myocardial infarction, clinically driven TVR, target lesion revascularization (TLR), and stent thrombosis were also compared. Deaths were considered cardiac unless an unequivocal, noncardiac cause was established. Peri-procedural myocardial infarction was defined as creatine kinase MB or troponin I concentration more than 5 times the upper limit of the normal range within 24 hours of the procedure. Spontaneous myocardial infarction was defined as creatine kinase MB or troponin I concentration above the normal range more than 24 hours after the procedure, if occurring unrelated with the index procedure. TLR was defined as repeat revascularization of the entire segment involving the implanted stent and areas within 5 mm of the distal and proximal stent margins with PCI or coronary artery bypass surgery for restenosis. TVR was defined as any repeat revascularization for 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. Stent thrombosis was defined as clinical presentation of an acute coronary syndrome with documentation of a flow-limiting thrombus within or adjacent to a successfully treated lesion.

2.5. Statistical analysis

Results of descriptive analysis are presented as mean ± standard deviation or number (proportion). Continuous variables were compared with a *t*-test or Wilcoxon rank sum test, and categorical variables were compared with χ^2 statistics or a Fisher exact test, as appropriate. The number of events and their

Table 1

Baseline characteristics of the study patients.

Variables	Modified balloon crush N=70	Conventional crush N=445	P
Age, y	64.6±10.9	63.5±10.0	.42
Male	50 (71.4)	342 (76.9)	.32
Body mass index, kg/m^2	24.9±2.6	24.9±2.8	.85
Diabetes mellitus	25 (35.7)	160 (36.0)	.97
Insulin-dependent	1 (4.0)	15 (9.4)	.70
Hypertension	43 (61.4)	278 (62.5)	.87
Hyperlipidemia	46 (65.7)	326 (73.3)	.19
Current smoking	18 (25.7)	137 (30.8)	.39
Prior coronary angioplasty	7 (10.0)	75 (16.9)	.15
Prior myocardial infarction	4 (5.7)	20 (4.5)	.55
Congestive heart failure	1 (1.4)	1 (0.2)	.25
Renal dysfunction	2 (2.9)	10 (2.2)	.67
Peripheral artery disease	3 (4.3)	21 (4.7)	>.99
Chronic pulmonary disease	0	13 (2.9)	.23
Acute coronary syndrome	25 (35.7)	162 (36.4)	.91
Family history of coronary disease	5 (7.1)	67 (15.1)	.076
Electrocardiographic findings			
Sinus rhythm	69 (98.6)	431 (96.9)	.70
Atrial fibrillation	1 (1.4)	6 (1.3)	
Other	0	8 (1.8)	
Left ventricular ejection fraction, %	59.5±8.9	60.2±6.9	.50

Values are presented as number (percentage) or mean±SD.

cumulative incidence are presented as number (percentage), with the latter estimated using the Kaplan–Meier method and compared between the 2 groups using the log-rank test of the time to the first event after the index procedure. All statistical analyses were performed using IBM SPSS version 21 (IBM, Chicago, IL). A 2-tailed *P*-value of <.05 was considered statistically significant.

3. Results

3.1. Study patients

Baseline clinical characteristics were well balanced between the 2 study groups (Table 1). Procedural characteristics are shown in Table 2. The majority of procedures were performed under IVUS guidance. The trans-radial approach was used more frequently in the modified balloon crush group. For SB treatment, predilation and use of the cutting balloon were significantly higher in the modified balloon crush group. There were no differences in the number, size, and length of the implanted stents between the 2 groups, but the proportion of first-generation drug-eluting stents was higher in the conventional crush group. Most procedures were successfully completed with FKI, with higher applied pressure in the conventional crush group. Procedure time, fluoroscopic time, and contrast amount were comparable between the 2 groups.

3.2. Angiographic characteristics

Table 3 lists the angiographic characteristics before and after the procedure. The proportion of true bifurcation was higher in the conventional crush group (81.4% vs 90.1%, $P=.04$), but the SB was more severely diseased in the modified balloon crush group. The quantitative parameters for postprocedural angiography indicated that the procedures were equally successful in both groups despite the differences in the baseline severity of SB disease. Follow-up angiography was performed on 17 (24.3%) and 231 (51.9%) patients of the modified balloon and conventional crush groups, respectively ($P<.001$) and did not show any differences in the binary restenosis rate (11.8% vs 13.4%; $P>.99$) or any other angiographic parameter (data not shown).

3.3. Clinical outcomes

Most patients completed a 1-year follow up (92.9% and 95.5% of the modified balloon and conventional crush groups, respectively; $P=.37$). Over the first 12 months post-treatment, there was no difference in the cumulative incidence of MACE and its individual components, as indicated in Table 4 and Figure 3. However, the patients of the modified balloon crush group experienced less TLR than those of the conventional crush group.

4. Discussion

To optimize FKI without the use of complex procedures, the balloon crush technique was modified by adopting additional SB ballooning across the crushed SB stent strut before MB stenting. The feasibility and safety of this technique were investigated in 515 patients from a single center PCI registry, whose bifurcation lesions were treated with the modified balloon crush or conventional crush technique. FKI was comparably successful in the majority of patients from both groups. Overall angiographic and clinical outcomes were also comparable between the 2 groups. However, a TLR rate was significantly lower after the modified balloon crush technique.

Theoretically, the modified balloon crush technique has several potential advantages over the conventional crush technique. First, opening the SB ostium before MB stenting might facilitate FKI and improve its result. In contrast to the conventional crush technique, in which the guidewire and balloon catheter must re-cross a double-layer metal strut over the SB ostium, the additional

Table 2

Procedural characteristics of the study patients.

Variables	Modified balloon crush N=70	Conventional crush N=445	P
Treated vessels			.79
1 vessel	28 (40.0)	169 (38.0)	
2 vessels	37 (52.9)	233 (52.4)	
3 vessels	5 (7.1)	43 (9.7)	
Target bifurcation lesions			.22
Left main coronary artery	25 (35.7)	195 (43.8)	
Left anterior descending artery	43 (61.4)	238 (53.5)	
Left circumflex artery	1 (1.4)	11 (2.5)	
Right coronary artery	1 (1.4)	1 (0.2)	
Trans-radial approach	6 (8.6)	3 (0.7)	<.001
Procedure time, min	79.8±25.6	77.2±28.4	.47
Fluoroscopic time, min	33.0±13.8	31.6±15.4	.49
Contrast amount, cc	400.3±149.6	398.9±166.1	.95
Treatment of main branch			
Non-compliant balloon	53 (75.7)	263 (59.1)	.008
Cutting balloon	3 (4.3)	13 (2.9)	.47
Intravascular ultrasound	69 (98.6)	443 (99.6)	.36
Predilation	68 (97.1)	404 (90.8)	.074
Stent implantation			
Number of stents	1.5±0.6	1.5±0.6	.84
Mean stent diameter, mm	3.3±0.3	3.4±0.3	.072
Length of stents, mm	40.7±17.5	41.3±16.9	.79
Maximal pressure applied, atm	12.8±4.0	14.0±4.2	.026
Used stents			.006
Sirolimus-eluting stents	15 (21.4)	159 (35.7)	
Paclitaxel-eluting stents	0	2 (0.4)	
Everolimus-eluting stents	30 (42.9)	209 (47.0)	
Zotarolimus-eluting stents	22 (31.4)	63 (14.2)	
Biolimus-eluting stents	3 (4.3)	10 (2.2)	
Others	0	2 (0.4)	
Treatment of side branch			
Non-compliant balloon	24 (34.3)	197 (44.3)	.12
Cutting balloon	6 (8.6)	12 (2.7)	.025
Intravascular ultrasound	63 (90.0)	429 (96.4)	.026
Predilation	65 (92.9)	371 (83.4)	.041
Stent implantation			
Number of stents	1.0±0.2	1.1±0.3	.13
Mean stent diameter, mm	2.8±0.3	2.9±0.3	.39
Length of stents, mm	23.1±9.1	23.7±9.4	.63
Maximal pressure applied, atm	12.2±3.6	12.7±3.7	.26
Final kissing balloon inflation	68 (97.1)	438 (98.4)	.35
Main branch			
Non-compliant balloon	50 (73.5)	302 (68.9)	.45
Size of balloon	3.3±0.3	3.4±0.3	.075
Applied pressure	9.6±3.7	11.2±3.8	.002
Side branch			
Non-compliant balloon	34 (50.0)	251 (57.3)	.26
Size of balloon	2.7±0.3	2.8±0.3	.19
Applied pressure	9.8±4.0	11.0±3.6	.014

Values are presented as number (percentage) or mean±SD.

SB ballooning in the modified balloon crush technique leaves only a single-layer metal strut to be re-crossed, potentially improving the success rate of FKI. Moreover, a single-layer strut more easily cleared by FKI results in a wider metallic SB ostium compared with the double-layer strut in the conventional crush technique. Given the importance of FKI in terms of improving outcomes after the crush technique,[13,14] the lower TLR rate in the modified balloon crush group can be partially explained by this hypothesis. Second, because simultaneous introduction of 2 stents in not needed, the modified balloon crush technique is compatible with a 6-Fr guiding catheter, enabling a trans-radial approach. Finally, separate positioning and implantation of individual stents makes handling easier during this technique.

The DK-crush technique is also useful for facilitating and optimizing FKI. It has been shown to generate better scaffolding at the polygon of confluence on IVUS examinations compared with the conventional crush technique.[15] Its feasibility and efficacy has also been shown in several clinical studies.[5,6] However, the modified balloon crush technique might represent a simplified alternative to the DK- or conventional crush technique

Table 3

Angiographic Characteristics of the Lesions Before and After the Indicated Procedure.

Variables	Modified balloon crush N=70	Conventional crush N=445	P
Baseline			
Medina classification			.047
0.0.0	1 (1.4)	0	
0.0.1	5 (7.1)	11 (2.5)	
0.1.0	3 (4.3)	8 (1.8)	
0.1.1	13 (18.6)	64 (14.4)	
1.0.0	1 (1.4)	5 (1.1)	
1.0.1	6 (8.6)	35 (7.9)	
1.1.0	3 (4.3)	20 (4.5)	
1.1.1	38 (54.3)	302 (67.9)	
Main branch			
Severe calcification	12 (17.1)	79 (17.8)	.90
Severe tortuosity	0	1 (0.2)	>.99
TIMI flow grade			.071
0 or 1	6 (8.6)	15 (3.4)	
2	3 (4.3)	37 (8.3)	
3	61 (87.1)	393 (88.3)	
Proximal reference diameter, mm	4.0±0.7	4.0±0.5	.84
Distal reference diameter, mm	2.6±0.5	2.7±1.3	.73
Lesion length, mm	32.4±15.5	30.3±13.3	.25
Minimal lumen diameter, mm	1.1±0.5	1.2±0.5	.33
Diameter stenosis, %	65.6±16.6	64.2±14.6	.46
Side branch			
Severe calcification	4 (5.7)	17 (3.8)	.51
Severe tortuosity	0	2 (0.4)	>.99
TIMI flow grade			.004
0 or 1	7 (10.0)	11 (2.5)	
2	3 (4.3)	35 (7.9)	
3	60 (85.7)	399 (89.7)	
Distal reference diameter, mm	2.4±0.6	2.4±0.5	.70
Lesion length, mm	14.8±8.9	13.5±9.7	.28
Minimal lumen diameter, mm	1.0±0.5	1.2±0.5	.037
Diameter stenosis, %	63.6±14.7	58.4±16.3	.012
Post-procedure			
Main branch			
Stent length, mm	36.5±14.6	37.0±13.5	.77
Minimal luminal diameter, mm			
In-stent	2.6±0.4	2.7±0.4	.46
In-segment	2.2±0.5	2.3±0.5	.15
Diameter stenosis, %			
In-stent	10.8±7.5	10.3±8.6	.62
In-segment	21.4±11.5	19.5±10.9	.19
Side branch			
Stent length, mm	17.5±8.8	16.5±8.5	.38
Minimal luminal diameter, mm			
In-stent	2.3±0.4	2.4±0.4	.66
In-segment	2.0±0.5	2.0±0.4	.22
Diameter stenosis, %			
In-stent	12.7±9.4	13.0±10.2	.81
In-segment	20.7±11.5	19.4±10.9	.36

Values are presented as number (percentage) or mean±SD.

due to its feasibility, efficacy, and similar influence on FKI performance.

Both the modified balloon and conventional crush techniques showed excellent outcomes in our study, compared with the crush techniques investigated in previous studies. Over a 1-year follow-up, TVR and MACE rates were 4.4% to 7.5% and 7.3% to 8.8%, respectively. In previous studies, angiographic restenosis rates were reported to range from 11.5% to 28.0%, and 6-month/9-month MACE rates from 13.0% to 26.5%.[10,14,16–19] The low MACE rates in our present study might be explained by the optimized procedures resulting from IVUS guidance and a high FKI success rate. This finding is supported by the recent randomized CROSS and PERFECT studies that emphasized the importance of stent-optimization in the performance of bifurcation stenting.[20]

Several limitations to our study should be acknowledged. First, the small number of subjects enrolled in the modified balloon crush group underpowered our analyses of differences in

Table 4

Clinical Outcomes in the Study Patients.

Variables	Modified balloon crush N=70	Conventional crush N=445	*P*
Death	1 (1.5)	6 (1.4)	.97
Cardiac	1 (1.5)	3 (0.7)	.51
Non-cardiac	0	3 (0.7)	.49
Periprocedural myocardial infarction	15 (21.4)	79 (17.8)	.56
Spontaneous myocardial infarction	2 (2.9)	14 (3.3)	.91
Q-wave	0	0	–
Non-Q wave	2 (2.9)	14 (3.3)	.91
Repeat revascularization	3 (4.4)	32 (7.5)	.38
Target vessel revascularization	3 (4.4)	32 (7.5)	.38
Clinically driven	0	5 (1.2)	.37
Target lesion revascularization	0	24 (5.6)	.048
Stent thrombosis	0	1 (0.2)	.69
Target lesion	0	1 (0.2)	.69
Non-target lesion	0	0	–
Major adverse cardiac events	5 (7.3)	38 (8.8)	.73

Values are number and incidences calculated using Kaplan–Meir methods. *P* values were analyzed using the log-rank test.

angiographic and clinical outcomes. Second, routine follow-up angiography was not mandatory, which might have led to over- or underestimation of angiographic restenosis rates. Third, post-procedural intravascular imaging data, such as intravascular ultrasound or optical coherence tomography, were not available in our data, which otherwise would have delineated difference in strut status between the 2 groups and the mechanism for increased TLR in the conventional crush group. Finally, our findings need to be further confirmed by a randomized study, as a non-randomized design can introduce unmeasured confounders.

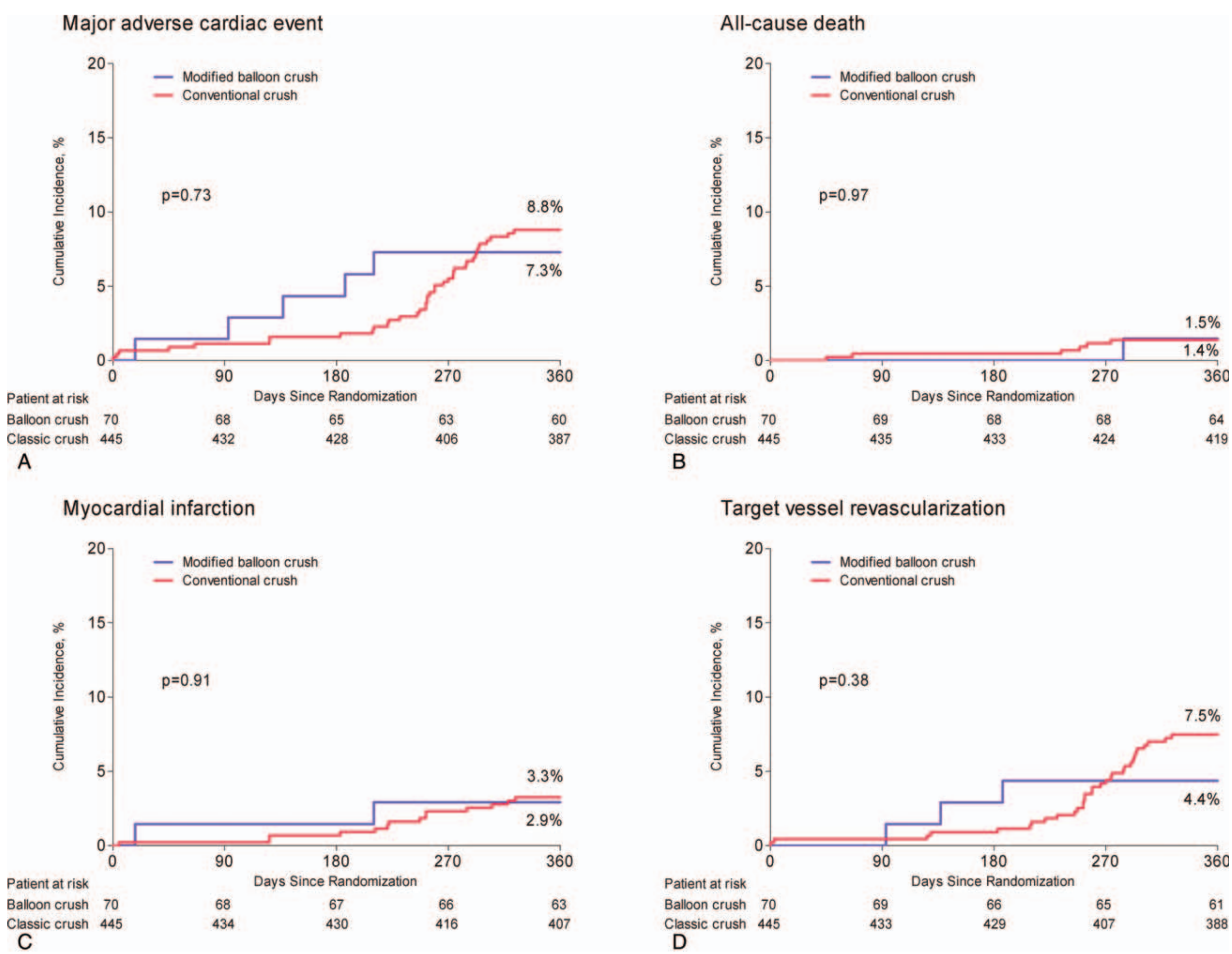

Figure 3. Cumulative incidence of major adverse cardiovascular event and its individual components over 1 year. MACE=major adverse cardiac event.

Nonetheless, our present data suggest that the modified balloon crush technique might be a feasible alternative to the conventional crush technique and improve procedural completeness and clinical outcomes.

5. Conclusion

The modified balloon crush technique, which uses additional SB ballooning across the crushed SB stent, is a feasible and safe procedure and shows the potential to improve outcomes.

Author contributions

Conceptualization: Jae-Hyung Roh, Young-Hak Kim.
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