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A Randomized Clinical Study Comparing Double Kissing Crush With Provisional Stenting for Treatment of Coronary Bifurcation Lesions

Results From the DKCRUSH-II (Double Kissing Crush versus Provisional Stenting Technique for Treatment of Coronary Bifurcation Lesions) Trial

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Objectives The present study aimed to investigate the difference in major adverse cardiac events (MACE) at 12 months in patients with coronary bifurcation lesions after double kissing double crush (DK crush) or provisional stenting (PS) techniques.

Background Provisional side branch (SB) stenting is preferable to DK crush because it has been associated with fewer complications. It is unknown which strategy would provide the best results.

Methods From April 2007 to June 2009, 370 unselected patients with coronary bifurcation lesions from 7 Asian centers were randomly assigned to either the DK or the PS group. Additional SB stenting in PS was required if final results were suboptimal. The primary end point was the occurrence of MACE at 12 months, including cardiac death, myocardial infarction, or target vessel revascularization (TVR). Secondary end point was the angiographic restenosis at 8 months.

Results There were 3 procedural occlusions of SB in the PS group. At 8 months, angiographic restenosis rates in the main vessel and SB were significantly different between the DK (3.8% and 4.9%) and the PS groups (9.7% and 22.2%, $p = 0.036$ and $p < 0.001$, respectively). Additional SB stenting in the PS group was required in 28.6% of lesions. TVR was 6.5% in the DK group, occurring significantly less often than in the PS group (14.6%, $p = 0.017$). There were nonsignificant differences in MACE and definite stent thrombosis between the DK (10.3% and 2.2%) and PS groups (17.3%, and 0.5%, $p = 0.070$ and $p = 0.372$, respectively).

Conclusions DK crush was associated with a significant reduction of TLR and TVR in this unselected patient population. However, there was no significant difference in MACE between DK and the PS groups. (Randomized Study on DK Crush Technique Versus Provisional Stenting Technique for Coronary Artery Bifurcation Lesions; ChicTR-TRC-00000015) (J Am Coll Cardiol 2011;57:914–20) © 2011 by the American College of Cardiology Foundation

Percutaneous coronary intervention for coronary bifurcation lesions still remains a hotly debated topic (1). Several studies (2–4) have concluded that stenting the main vessel (MV) with provisional stenting (PS) of side branches (SB) is preferable in the great majority of bifurcation lesions. However, the difference in study design does not allow us to translate these studies into everyday practice. As a result, we designed this prospective, randomized DKCRUSH-II (Double Kissing Crush versus Provisional Stenting Technique for Treatment of Coronary Bifurcation Lesions) trial

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to address the clinical relevance of double kissing double crush (DK crush) and PS in our "unselected" patient population.

Methods

Patient selection. The DKCRUSH-II study was conducted in 7 Asian centers after the protocol was approved by the ethics committee, and signed informed consent was obtained from all patients.

Patients ≥18 years of age with a diagnosis of documented silent ischemia, angina, or acute myocardial infarction (AMI) (<12 h proceeding to an emergent percutaneous coronary intervention procedure) after the restoration of blood flow in 2 branches, were considered eligible for enrollment. Patients with chronic total occlusion in the MV or SB immediately after successful recanalization, and unprotected distal left main bifurcation lesions involving both ostia of the left anterior descending and left circumflex coronary arteries, without chronic total occlusion in the right coronary artery, were also enrolled. An additional eligibility criterion was the presence of only 1 coronary bifurcation lesion (Medina [5] classification 1,1,1 and 0,1,1) per patient, defined as a diameter stenosis of >50% in both vessels with a reference vessel diameter between 2.5 and 4.0 mm by visual estimation. The maximum treatable lesion length by visual estimation for each individual branch had to be completely covered by 2 EXCEL stents (JW Medical System, Weihai, China) (6).

Exclusion criteria included liver dysfunction, expected lifespan <12 months, heavy calcification requiring rotational atherectomy, pregnancy, contraindication, or suspected intolerance to one of the study drugs.

Table 1 Baseline Clinical Characteristics

	DK Group (n = 185)	PS Group (n = 185)	p Value
Age, yrs	63.9 ± 11.1	64.6 ± 9.9	0.542
Male	146 (78.9)	141 (76.2)	0.618
Diabetes	36 (19.5)	44 (23.8)	0.377
Hypertension	121 (65.4)	112 (60.5)	0.403
Hyperlipidemia	63 (34.1)	53 (28.6)	0.336
Current smoking	57 (30.8)	44 (23.8)	0.315
Serum creatinine >2.5 mg/dl	10 (5.41)	17 (9.19)	0.360
Previous MI	32 (17.3)	26 (14.1)	0.475
Previous PCI	39 (21.1)	38 (20.5)	1.000
Previous CABG	0 (0)	1 (0.5)	0.500
Acute MI	30 (16.2)	31 (16.8)	1.000
ST-segment elevation MI	25 (13.5)	22 (11.9)	0.755
Non–ST-segment elevation MI	5 (2.7)	9 (4.9)	0.415
Unstable angina	123 (66.5)	126 (68.1)	0.557
Stable angina	29 (15.7)	21 (11.4)	0.287
Silent ischemia	3 (0.8)	7 (1.9)	0.296
LVEF <40%	28 (15.1)	21 (11.4)	0.333

Values are mean ± SD or n (%).

CABG = coronary artery bypass graft; DK = double kissing; LVEF = left ventricular ejection fraction; MI = myocardial infarction; PCI = percutaneous coronary intervention; PS = provisional stenting.

Procedure. Patients were randomly assigned in a 1:1 ratio to the DK crush (DK group) or the PS group. DK crush, as described previously (7), was performed as follows: stenting SB, balloon crush, first kissing balloon inflation, stenting MV, and final kissing balloon inflation (FKBI). Another key step in the procedure is the alternative inflation with a noncompliant balloon at high pressure (≥16 atm) for the SB before each kissing. In the PS group, a "safety" wire prior to MV stent placement was used in all cases. Criteria for treatment of SB following MV stent placement were: diameter stenosis >50%, dissection type >B, or decreased Thrombolysis In Myocardial Infarction (TIMI) flow. If balloon dilation was not successful, then the T stent technique was performed, followed by FKBI. Intravascular ultrasound pre-dilation and the administration of glycoprotein IIb/IIIa inhibitors were left to the operator's discretion.

All patients were pretreated with aspirin and clopidogrel. A 300-mg loading dose of clopidogrel was administered before the index procedure if patients were not pretreated. Intravenous unfractionated heparin was used to maintain an activated clotting time between 250 and 300 s through the whole procedure. Total creatine kinase (CK) and CK-MB were dynamically measured until 72 h post-procedure. After discharge, aspirin therapy was continued indefinitely (100 mg/day for life), and clopidogrel (75 mg/day) was continued for at least 12 months.

Follow-up. Clinical follow-up was performed with visits or telephone contact at 1, 6, 8, and 12 months. Adverse events were monitored throughout the entire study period. Follow-up coronary angiography was scheduled at 8 months after the indexed procedure unless clinical reasons indicated earlier.

Quantitative coronary angiographic measurements. Matched orthogonal views were used for quantitative coronary analysis (QCA) before, post-procedure, and at follow-up after intracoronary injection of nitroglycerin (~100 to 200 μg). Angiograms were analyzed offline with a validated automated edge-detection coronary bifurcation system (CAAS version 5.7, Pie Medical Imaging, Maastricht, the Netherlands). Vessel segments involving bifurca-

Abbreviations and Acronyms

AMI = acute myocardial infarction
DK crush = double kissing double crush
DS = diameter stenosis
FKBI = final kissing balloon inflation
ISR = in-stent restenosis
KUS = unsatisfactory kissing
MACE = major adverse cardiac events
MI = myocardial infarction
MLD = minimal lumen diameter
MV = main vessel
POC = polygon of confluence
PS = provisional stenting
QCA = quantitative coronary analysis
SB = side branch
ST = stent thrombosis
TIMI = Thrombolysis In Myocardial Infarction
TLR = target lesion revascularization
TVR = target vessel revascularization

Table 2 Lesion Characteristics

	DK Group (n = 185)	PS Group (n = 185)	p Value
Number of diseased vessels			0.066
1-vessel disease	56 (30.3)	64 (34.6)	
2-vessel disease	75 (40.5)	51 (27.6)	
3-vessel disease	54 (29.1)	70 (37.8)	
Lesion site			0.746
LAD-LCX	33 (17.8)	29 (15.7)	
LAD-diagonal	112 (60.5)	110 (59.5)	
LCX-obtuse marginal	23 (12.4)	30 (16.2)	
Distal right coronary artery	17 (9.2)	16 (8.6)	
Medina stratification			0.187
1,1,1	155 (83.8)	144 (77.8)	
0,1,1	30 (16.2)	41 (22.2)	
Main vessel TIMI flow grade			0.414
0~2	26 (14.1)	31 (16.8)	
3	159 (85.9)	154 (83.2)	
Lesions in main vessel			
In-stent restenosis	2 (1.1)	5 (2.7)	0.449
Chronic total occlusion	8 (4.3)	16 (8.6)	0.138
Thrombus-containing	10 (5.4)	5 (2.7)	0.292
Severe tortuous	17 (9.2)	20 (10.8)	0.729
Severe calcification	2 (1.1)	5 (2.7)	0.449
Concentric	13 (7.0)	11 (5.9)	0.680
Lesions in side branch			
In-stent restenosis	3 (1.6)	5 (2.7)	0.504
Chronic total occlusion	3 (1.6)	3 (1.6)	1.000
Thrombus-containing	6 (3.2)	3 (1.6)	0.332
Severe tortuous	25 (13.5)	31 (16.8)	0.469
Severe calcification	2 (1.1)	5 (2.7)	0.449
Concentric	17 (9.2)	15 (8.1)	0.854
Side branch TIMI flow grade			0.610
0~2	11 (6.0)	13 (7.1)	
3	174 (94.1)	172 (93.0)	
Type C lesions			
Main vessel	119 (64.3)	126 (68.1)	0.584
Side branch	46 (24.9)	45 (24.3)	0.141

Values are n (%).
LAD = left anterior descending coronary artery; LCX = left circumflex coronary artery; TIMI = Thrombolysis In Myocardial Infarction; other abbreviations as in Table 1.

tion lesions (8) were divided into proximal MV, distal MV, and SB segments within 5 mm proximal or distal to the stent, and polygon of confluence (POC). QCA variables included reference vessel diameter, minimal lumen diameter (MLD), acute gain, late lumen loss, and net gain. QCA analysis was performed by an independent core laboratory (CCRF [China Cardiovascular Research Foundation], Beijing, China).

Study end points and definitions. The primary end point was the occurrence of major adverse cardiac events (MACE) at 12 months, included cardiac death, myocardial infarction (MI), or target vessel revascularization (TVR). The clinical study end points were analyzed by members of an independent committee who were blinded to the treatment allocation. Secondary angiographic end points were restenosis in the MV and SB at 8 months. MI was diagnosed if the plasma level of CK-MB increased to >1 times the pre-value immediately before stenting in AMI patients. MI in non-AMI patients, cardiac death, in-stent restenosis (ISR), target lesion revascularization (TLR), TVR, angiographic and procedural success, and stent thrombosis (ST) were defined according to Nordic criteria (2) and the Academic Research Consortium (ARC) definitions (9). Unsatisfactory kissing (KUS) was defined as the difference between vessel/stent diameter and balloon diameter used for FKBI ≥0.5 mm or the presence of residual stenosis ≥20% during FKBI by visual estimation. Lesion specificities were defined according to American Heart Association/American College of Cardiology criteria (10). Angiographic patterns of ISR were defined by Mehran's classification (11) and classified by Class I to IV.

Statistical analysis. We hypothesized that the rate of concurrent MACE between the 2 arms would be significantly different, favoring the DK crush ($\pi = 12\%$) versus the PS ($\sigma = 24\%$) approach. A total sample size of 316 was needed to detect a 50% reduction in the MACE rate (80% power, $\alpha = 0.05$, 2-sided [tailed]). To accommodate a 15% (n = 47) loss and because of considerable uncertainty about

Table 3 Procedural Characteristics

	DK Group (n = 185)	PS Group (n = 185)	p Value
Intravascular ultrasound used	85 (45.9)	88 (47.6)	0.655
Glycoprotein IIb/IIIa inhibitor used	8 (4.3)	2 (1.1)	0.105
Pre-dilation			
Main vessel	78 (42.2)	105(56.8)	0.007
Side branch	82 (44.3)	68 (36.8)	0.169
Pre-dilation using KBI	25 (13.5)	16 (8.6)	0.185
No. patients stratified by no. stent			
Main vessel			0.475
1 stent	141 (76.2)	142 (76.8)	
2 stents	42 (22.7)	38 (20.5)	
3 stents	2 (1.1)	5 (2.7)	
Side branch			<0.001
0 stents	0 (0)	132 (72.4)	
1 stent	174 (94.1)	52 (28.1)	
2 stents	10 (5.4)	1 (0.5)	
3 stents	1 (0.5)	0 (0)	
Post-dilation for stents			
Main vessel	185 (100.0)	162 (87.6)	0.008
Inflation pressure, atm*	14.43 ± 2.13	14.47 ± 2.25	1.000
Side branch	185 (100.0)	70 (37.8)	<0.001
Inflation pressure, atm*	12.21 ± 2.17	12.28 ± 2.15	0.904
Final kissing balloon inflation	185 (100.0)	147 (79.5)	<0.001
Unsatisfactory kissing	15 (8.1)	47 (25.4)	<0.001
Angiographic success			
Main vessel	184 (99.5)	181 (97.8)	0.372
Side branch	185 (100.0)	177 (95.7)	0.007
Complete revascularization	171 (92.4)	176 (95.1)	0.390
Procedural time, min	37.66 ± 20.04	36.59 ± 30.01	0.688
Total fluoroscopy time, min	23.09 ± 18.14	22.48 ± 17.68	0.781
Contrast volume, ml	148.71 ± 88.19	137.46 ± 94.97	0.238

Values are n (%) or mean ± SD. *Indicates the pressure during final kissing balloon inflation.
KBI = kissing balloon inflation; other abbreviations as in Table 1.

Table 4 QCA in Entire Cohort of Patients

	Main Vessel			Side Branch		
	DK (n = 185)	PS (n = 185)	p Value	DK (n = 185)	PS (n= 185)	p Value
Pre-procedure						
RVD, mm	2.86 ± 0.31	2.82 ± 0.37	0.555	2.38 ± 0.32	2.29 ± 0.35	0.329
MLD, mm	0.94 ± 0.35	0.86 ± 0.36	0.264	0.89 ± 0.30	0.84 ± 0.30	0.413
DS, %	67.2 ± 14.5	69.5 ± 16.9	0.436	62.8 ± 14.7	63.4 ± 14.2	0.762
Lesion length, mm	28.4 ± 12.9	28.7 ± 15.5	0.884	15.4 ± 11.3	14.9 ± 12.5	0.842
Post-procedure						
RVD, mm	2.97 ± 0.44	2.89 ± 0.41	0.226	2.49 ± 0.38	2.36 ± 0.35	0.036
MLD, mm	2.72 ± 0.51	2.58 ± 0.44	0.036	2.18 ± 0.43	1.63 ± 0.46	0.003
DS, %	9.7 ± 3.7	11.9 ± 6.3	0.485	12.3 ± 8.6	28.6 ± 13.8	0.027
Acute gain, mm	1.59 ± 0.49	1.56 ± 0.56	0.365	1.48 ± 0.51	0.99 ± 0.51	0.048
At 8-month follow-up						
RVD, mm	2.98 ± 0.42	2.91 ± 0.47	0.976	2.43 ± 0.35	2.38 ± 0.36	0.010
MLD, mm	2.47 ± 0.56	2.35 ± 0.55	0.746	1.85 ± 0.47	1.43 ± 0.53	0.002
DS, mm	17.3 ± 10.5	20.6 ± 12.1	0.907	22.9 ± 13.0	32.2 ± 18.6	0.011
Late loss, mm	0.10 ± 0.43	0.09 ± 0.47	0.809	0.22 ± 0.41	0.18 ± 0.45	0.496
Net gain, mm	1.48 ± 0.55	1.37 ± 0.64	0.675	1.37 ± 0.59	0.87 ± 0.63	0.019
Restenosis	7 (3.8)	18 (9.7)	0.036	9 (4.9)	4 1 (22.2)	<0.001

Values are mean ± SD or n (%).
DS = diameter stenosis; MLD = minimal lumen diameter; QCA = quantitative coronary analysis; RVD = reference vessel diameter; other abbreviations as in Table 1.

expected end point rates, it was decided to extend the enrollment to 370 patients. The treatment-group differences were evaluated with analysis of variance or Wilcoxon rank sum scores for continuous variables. When ordinal tests were required for continuous variables, medians and quartiles were used as the descriptive statistics. The chi-square test or the Fisher exact test was used to analyze categorical variables. Survival rate free from events was generated by Kaplan-Meier analysis. Statistical significance was taken as a 2-sided p value <0.05. All analyses were performed with the use of the statistical program SPSS 16.0 (SPSS Institute Inc, Chicago, Illinois).

Results

Baseline characteristics. From April 17, 2007, to June 23, 2009, 370 patients (average age 64.32 ± 10.46 years) with true bifurcation lesions were enrolled and randomly assigned to the DK (n = 185) and PS (n = 185) groups. Baseline clinical and lesion characteristics (including the number of diseased vessels, lesion location, stratification of lesions, and TIMI flow grade 0 to 2) were well matched between the 2 groups (Tables 1 and 2).

Procedural characteristics. In the PS group, 121 (65.4%) SB received balloon angioplasty only, 11 (5.9%) SB did not receive any therapy, and in 53 (28.6%) SB, additional stents were required. A significant reduction in angiographic success was observed in the SB between the DK and PS groups (p = 0.007) (Table 3). The procedural time, total fluoroscopy, and contrast volume in the DK group were nonsignificant compared with the PS group. KUS was more frequently in PS (25.4%) group, compared with 8.1% in DK group (p < 0.001).

QCA analysis. Repeat angiogram at 8 months (average 249.51 ± 52.41 days) was available in 339 (91.6%) patients. There were no significant differences in terms of the baseline characteristics between the 2 groups (Table 4). DK crush was associated with increased post-stenting MLD in the MV, POC, and SB (Tables 4 and 5). This resulted in a significant reduction of diameter stenosis (DS), an increase in acute gain, and an increased net gain in POC and SB relative to the PS group, with the exception of the MV.

The overall restenosis rates in the MV and SB were 3.8% and 4.9% in the DK group, respectively, compared with 9.7% (p = 0.036) and 22.2% (p < 0.001) in the PS group.

Table 5 Quantitative Coronary Analysis for POC Area

	DK Group (n = 185)	PS Group (n = 185)	p Value
Pre-procedure			
RVD, mm	2.72 ± 0.49	2.70 ± 0.50	0.162
MLD, mm	0.86 ± 0.38	0.83 ± 0.35	0.692
DS, %	67.3 ± 11.5	69.3 ± 13.5	0.576
Post-procedure			
RVD, mm	2.85 ± 031	2.78 ± 0.30	0.754
MLD, mm	2.12 ± 0.36	1.98 ± 0.38	0.003
DS, %	20.0 ± 14.5	23.2 ± 12.7	0.235
Acute gain, mm	1.18 ± 0.44	1.14 ± 0.48	0.309
At 8 months			
RVD, mm	2.67 ± 0.40	2.68 ± 0.51	0.962
MLD, mm	2.07 ± 0.56	1.87 ± 0.55	0.001
DS, %	22.5 ± 14.5	30.2 ± 17.4	0.003
Late loss, mm	0.06 ± 0.48	0.12 ± 0.50	0.023
Net gain, mm	1.13 ± 0.52	1.02 ± 0.54	0.007
Restenosis	8 (4.3)	36 (19.5)	<0.001

Values are mean ± SD or n (%).
Abbreviations as in Tables 1 and 4.

Table 6 Clinical Outcome

	DK Group (n = 185)	PS Group (n =185)	p Value
Intra-procedural			
Acute closure	0 (0)	3 (1.6)	0.248
Cardiac death	0 (0)	0 (0)	1.000
Emergent CABG	0 (0)	0 (0)	1.000
Needing IABP	0 (0)	0 (0)	1.000
MI	0 (0)	3 (1.6)	0.248
In-hospital			
Cardiac death	1 (0.5)	0 (0)	0.500
MI	6 (3.2)	4 (2.2)	0.751
CABG	0 (0)	0 (0)	1.000
TLR	1 (0.5)	1 (0.5)	1.000
TVR	1 (0.5)	1 (0.5)	1.000
MACE	6 (3.2)	4 (2.2)	0.751
Stent thrombosis definite	4 (2.2)	1 (0.5)	0.372
Procedural success	179 (96.8)	173 (93.5)	0.217
At 6-month			
Cardiac death	1 (0.5)	2 (1.1)	1.000
MI	6 (3.2)	4 (2.2)	0.751
CABG	0 (0)	1 (0.5)	0.500
TLR	2 (1.1)	6 (3.2)	0.284
TVR	3 (1.6)	8 (4.3)	0.220
MACE	6 (3.2)	11 (5.9)	0.321
Stent thrombosis definite	4 (2.2)	1 (0.5)	0.372
At 12-month			
Cardiac death	2 (1.1)	2 (1.1)	1.000
MI	6 (3.2)	4 (2.2)	0.751
CABG	0 (0)	1 (0.5)	0.500
TLR	8 (4.3)	24 (13.0)	0.005
TVR	12 (6.5)	27 (14.6)	0.017
MACE	19 (10.3)	32 (17.3)	0.070
Stent thrombosis	5 (2.7)	2 (1.1)	0.449
Definite	4 (2.2)	1 (0.5)	0.372
Possible	1 (0.5)	1 (0.5)	1.000

Values are n (%).
IABP = intra-aortic balloon pumping; MACE = major adverse cardiac event(s); TLR = target lesion revascularization; TVR = target vessel revascularization; other abbreviations as in Table 1.

Restenosis at the SB ostium and POC in the PS and DK groups were as follows: 18.4% versus 3.8% ($p < 0.001$), and 19.5% versus 4.3% ($p < 0.001$). Class I ISR in MV and SB were seen in 82% and 88%, with Class II, III, and IV in 11% and 6%, 3% and 2%, and 4% and 4%, respectively. The presence of KUS predicted the occurrence of ISR in MV (hazard ratio [HR]: 4.007, 95% confidence interval [CI]: 1.640 to 10.110, p = 0.025) and SB (HR: 0.491, 95% CI: 0.243 to 0.991, p = 0.037).

Clinical outcome. SB occlusion immediately after MV stent placement occurred 3 times (1.6%) in the PS group (Table 6). There were no significant differences in procedural success rate and cumulative MACE and ST rate at 6 months between the 2 groups (Table 6).

At 12 months, the rates of cardiac death and MI in the DK and PS groups were comparable. TLR in the DK group (4.3%) occurred significantly less often than in the PS group (13.0%, p = 0.005) (Fig. 1A), with clinically driven TLR in

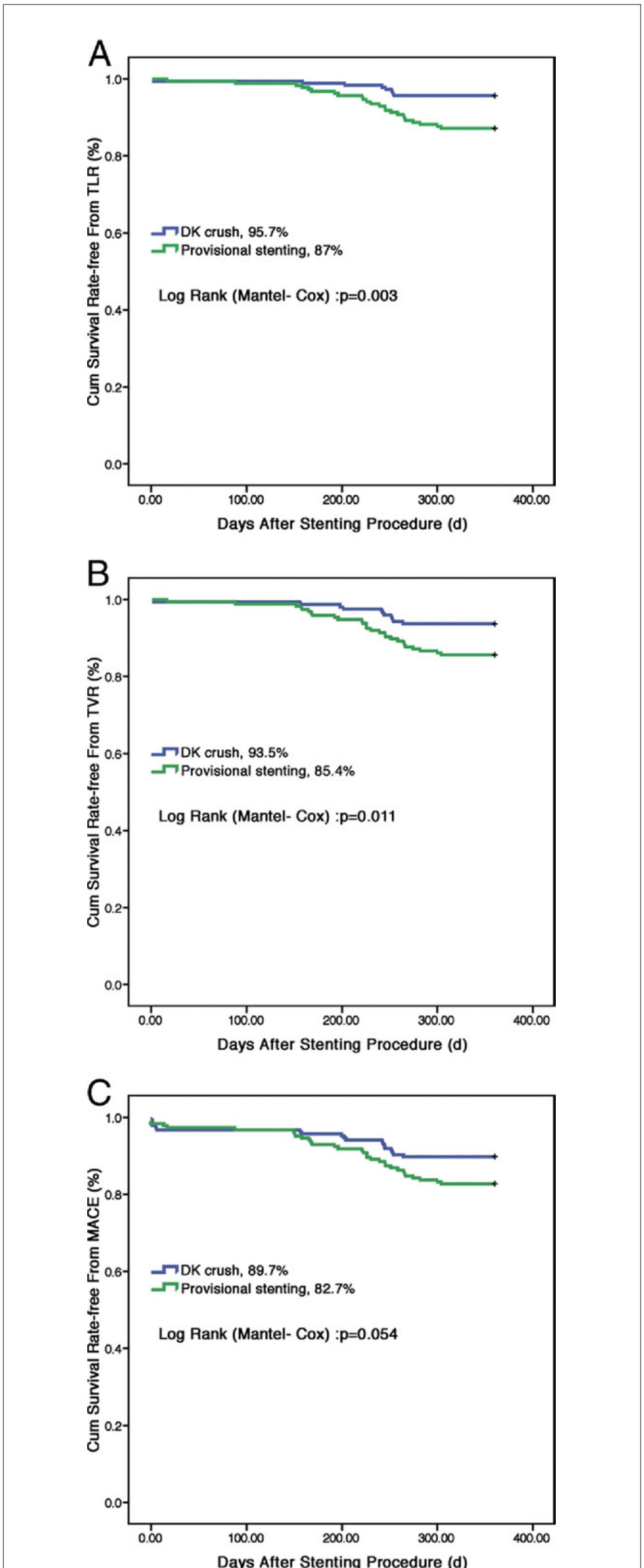

Figure 1 Comparison of Survival Rate Free From TLR, TVR, and MACE Between DK Crush and PS Groups

(A) Target lesion revascularization (TLR), **(B)** target vessel revascularization (TVR), and **(C)** major adverse cardiac events (MACE). PS = provisional stenting.

Table 7 Patients With ST

	Patient (Technique)						
	1 (PS)	2 (DK)	3 (DK)	4 (DK)	5 (DK)	6 (PS)	7 (DK)
ARC definition	Definite	Definite	Definite	Definite	Definite	Possible	Possible
Days from PCI	17	5	1	2	6	182	205
Location of ST	MV	SB	MV	SB	SB	Unknown	Unknown
DPT	Yes	Yes	Yes	Yes	Yes	Yes	No stopped on day 195
No. of stents	3/1	2/1	1/1	1/1	1/1	1/1	1/1
Stent length, mm	123	84	46	60	50	66	36
Diabetes	Yes	Yes	No	No	No	No	No
Diseased vessels	3	2	2	2	2	3	3
Lesion location	LAD-LCX	LAD-D	LAD-D	LAD-LCX	LAD-D	LAD-LCX	LAD-LCX
Calcification	Yes	No	Yes	No	Yes	Yes	Yes
IVUS used	Yes	No	Yes	Yes	No	Yes	Yes
FKBI	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Inflation pressure during FKBI, atm	14 + 10	14 + 10	8 + 8	14 + 14	14 + 14	16 + 16	12 + 12
Clinical consequence	QMI + TLR	QMI + TLR	QMI + TLR	QMI + TLR	Death	NQMI	Death

D = diagonal; DPT = dual antiplatelet therapy; FKBI = final kissing balloon inflation; IVUS = intravascular ultrasound; MV = main vessel; NQMI = non–Q-wave myocardial infarction; QMI = Q-wave myocardial infarction; SB = side branch; ST = stent thrombosis; other abbreviations as in Tables 1, 2, and 6.

29 (7 in the DK, 22 in the PS groups), and ischemia-driven TLR in 3 (1 in the DK and 2 in PS groups) patients. This translated into an increased rate of TVR in the PS group (14.6% vs. 6.5%, p = 0.017) (Fig. 1B). However, there was no difference in the cumulative MACE between the DK (10.3%) versus PS (17.3%, p = 0.070) groups (Fig. 1C). The overall and definite ST in DK were 2.7% and 2.2%, all nonsignificant with respect to PS group (1.1% and 0.5%, respectively). The timing, baseline, and procedural characteristics of patients in whom ST occurred are summarized in Table 7.

Discussion

The major findings of the present study were: 1) 28.6% of patients in the PS group were transferred to the 2-stent subgroup; and 2) DK crush had a lower rate of TLR and TVR at 12 months in this unselected patient population, with 91.6% having repeat angiograms at 8 months.

Comparison with previous studies. The rate of PS with SB stenting varied mainly depending on the study design. When stenting of the SB was limited to the cases with severely impaired blood flow (2,12), this rate was around ~2% to 4%. If residual stenosis >50% was considered as one of the criteria, stenting the SB was required in 22% (13) and 31.3% of cases (4), respectively, similar to our results (28.6%). By PS, acute closure of the SB might be life threatening or could result in MI, as occurred in 1.6% of patients in the DKCRUSH-II and in 1.14% of patients in CACTUS (Coronary Bifurcations: Application of the Crushing Technique Using Sirolimus-Eluting Stents) (1.14%) studies (4). On the other hand, smaller SB did not result in any significant clinical events even if they were occluded, as occurred in the BBC ONE (BBC ONE–British Bifurcation Coronary Study) and Nordic study (2,3). The lack of any angiographic core laboratory evaluation, >26% lesions not defined as true bifurcation lesions, and no study monitoring would likely result in underreporting of MACE. Therefore, results from those highly selected patients could not guide our everyday clinical practices.

Differences between DK, classical crush, and PS. Studies comparing a complex versus a simple approach for bifurcation lesions have studied different 2-stent techniques (2,12,14–16). Of these techniques, classical crush was extensively accepted at its early stage. The performance of FKBI is a crucial step in reducing restenosis, ST, and MACE (17–19). The quality of FKBI should not be ignored when crush stenting was used. Conceptually, classical crush with 2-step kissing is easily confused with DK crush. The former method introduces the first kissing inflation by the MV balloon and side stent without rewiring the SB, resulting in no real difference from the original crush. DK crush, focusing on the performance and quality of each kissing inflation using a noncompliant balloon in the SB, was associated with a significant reduction of TVR in the MV and SB (19,20).

On the other hand, the routine use of FKBI after the 1-stent technique for simple bifurcations would not carry any advantage over that without FKBI (21), but without functional assessment (22). The present study reported a 2.6-fold increase of ISR in MV by PS, which might reflect the importance of the quality of FKBI even after the 1-stent technique.

Comparison of safety end points. The 2-stent technique seems also to have a detrimental impact on the occurrence of ST (1,4,10,23), varying from 0.2% to 4.5%. However, the presence of procedural SB occlusion in the PS group in the DKCRUSH-II and CACTUS studies indicated that a jailed wire in the SB could not improve the procedural safety in bigger SB with a heavy plaque burden.

The clinical implication of the present study is that DK crush stenting would be superior to PS for complex/high-risk bifurcation lesions.

Study limitations. The present study reported clinical results at 12 months. We could not address the difference in clinical outcome when follow-up was extended. Another limitation is the lack of functional assessment by fractional flow reserve. Finally, sample sizes were probably inadequate for the analysis of ST risk in 2 groups.

Conclusions

This DKCRUSH-II study for unselected patients with coronary bifurcation lesions indicates that implantation of sirolimus-eluting stents was associated with a lower rate of overall restenosis in the MV. DK crush reduced the occurrence of restenosis in both the MV and SB, resulting in a reduction of TLR and TVR.

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