CLINICAL STUDY

Necessity and proper way of intermediate kissing balloon dilation for culotte stenting: further insights from bench testing

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Abstract

Objective: The aim of this study was to investigate whether intermediate kissing balloon dilation (IKBD) is necessary during mini-culotte stenting (MCS) and how it can be properly conducted.

Methods: MCS was emulated in a bifurcation model with a branch diameter difference (BDD) in three-step sizes of 0.50, 0.75 and 1.00 mm, and with intermediate balloon dilation (IBD) in three treatments of routine intermediate solo balloon dilation (rISBD), concurrent IKBD (cIKBD) or sequential IKBD. Microcomputed tomography was performed to assess stent under-expansion (SUE) around the polygon of confluence (POC), residual ostial stenosis (ROS) at the ostial side-branch (SB) and main-branch (MB) and stent cell distortion (SCD) in the bifurcation segments.

Results: There were both main and interactive effects of IBD and BDD on ROS at the ostial SB and SCD in the ostial SB, but there were only main effects of IBD or BDD on SUE around the POC, ROS at the ostial MB and SCD in the ostial MB. Analysis of the main effects showed that SUE around the POC or ROS at the ostial SB was significantly different between sIKBD and rISBD and between cIKBD and rISBD. There was also a significant difference in SCD in the ostial SB between sIKBD and rISBD and between sIKBD and cIKBD. Analysis of the interactive effects showed that ROS at the ostial SB or SCD in the ostial SB was affected by all IBD treatments in all BDD step-sizes. Moreover, increasing the BDD step-sizes significantly increased ROS at the ostial SB as treated by rISBD and SCD in the ostial SB as treated by rISBD or cIKBD.

Conclusions: SIKBD was shown to be essential and superior to rISBD or cIKBD, resulting in better bifurcated stent expansion and coverage when using MCS.

Keywords: coronary bifurcation; culotte stenting; intermediate kissing dilation

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Conflict of interest: The authors declare that they have no conflict of interest.

Funding: This study was conducted with the support of the National Natural Science Foundation of China (Grant No. 81370311) and the Key Program of Social Development of Fujian Science and Technology Department (Grant No. 2013Y0043).

Ethical approval: Not applicable.

Informed consent: Not applicable.

Journal of Interventional Medicine **2018**, Vol. 1, No. 4, pp. 212–220

INTRODUCTION

Percutaneous coronary intervention of bifurcation lesions remains a challenge. While a simple interventional strategy is preferred for most bifurcation lesions (1-4), a complex strategy is considered optional or mandatory for the treatment of complex bifurcation lesions (5,6).

Classic culotte stenting, introduced by Chevalier et al. (7), has undergone several modifications to improve its procedural safety and clinical efficacy (8-11). Mini-culotte stenting (MCS) has become one of the most commonly used two-stent techniques (11). However, if there is a bigger branch diameter difference (BDD) between the side-branch (SB) and main-branch (MB), incomplete stent expansion (ICSE) and incomplete stent coverage (ICSC) may occur in the bifurcation connecting domain (BCD). ICSE causes stent under-expansion (SUE), stent mal-apposition in the polygon of confluence (POC) and residual ostial stenosis (ROS) near the SB or/and MB ostium, while ICSC exhibits itself by stent cell distortion (SCD) or a big gap near the branch ostia (8-11). Theoretically, both ICSE and ICSC increase the risks of in-stent thrombosis and restenosis. Recently, we proposed a novel MCS procedure for double kissing mini-culotte stenting (DK-MCS), in which intermediate kissing balloon dilation (IKBD) was conducted prior to MB stenting. Our study showed that DK-MCS was more efficient in the reduction of the SB restenosis and in target vessel/lesion revascularization in the treatment of true bifurcation lesions compared to provisional SB stenting (8). Nevertheless, previous studies on the culotte-stenting techniques have generally paid more attention to ICSE but little to no attention to ICSC.

Despite the roles of IKBD having been confirmed in the DKCRUSH-1 study (12), the requirement for and the proper way of conducting IKBD are uncertain when using culotte stenting. By performing bench testing in a bifurcation model with a 2×3 factorial design by considering the effects of three step-sizes of BDD and three treatments of intermediate balloon dilation (IBD) on the bifurcated stent morphology, we examined whether IKBD is necessary and how IKBD can be appropriately conducted when using MCS for coronary bifurcation intervention.

METHODS

MCS procedure

All procedural steps were adopted according to the previous description of the inverted MCS (11), except for the replacement of routine intermediate solo balloon dilation (rISBD) with concurrent IKBD (cIKBD) or sequential IKBD (sIKBD) prior to MB stenting to pretreat the proximal SB stent that protruded into the parent main vessel (PMV). This resulted in three IBD treatments: rISBD, cIKBD and sIKBD (Figure 1).

Materials

The bifurcation model, consisting of polyvinyl alcohol based on Murray's law, had a distal bifurcation angle of ~60° and BDD step-sizes of 0.50, 0.75 and 1.00 mm, which were generated through a combination of an MB caliber of 3.5 mm and an SB caliber of 3.00, 2.75 and 2.50 mm, respectively.

Open-cell stents with excellent side-hole expandability (Excel™, JW Medical Inc., Shandong, China; Resolute™, Metronic Co., Minnesota, USA) were used for testing. A pair of stents of the same brand was assigned to stent the SB and MB in each test.

Experimental protocol

In the bifurcation model, a 2×3 factorial experiment was designed by considering 2 key factors with 3 BDD levels with 3 step-sizes of 0.50, 0.75 and 1.00 mm and IBD with 3 treatments of rISBD, cIKBD and sIKBD). The BDD was achieved by using stents of 3.5 mm versus 3.0 mm, 2.75 mm and 2.5 mm to stent the MB and SB, respectively, which resulted in BDD step-sizes of 0.50, 0.75 and 1.00 mm. Prior to MB stenting, one of the IBD treatments was added to the MCS procedure. As a result, 9 tests were achieved per 3 step-sizes of BDD and 3 treatments of IBD in a testing run, with a total of 72 tests resulting from 8 repeat test runs (Figure 2).

Morphological analysis

Each procedural step was observed visually and recorded with a high-resolution digital video recorder (L-1ex/TT02RX, ELMO, Japan). The final results were examined through microcomputed tomography (mCT) (SkyScan 1176, SkyScan, Belgium). The bifurcation was divided into 4 segments of PMV, MB, SB and POC (Figure 3A), and the analysis of ICSE or

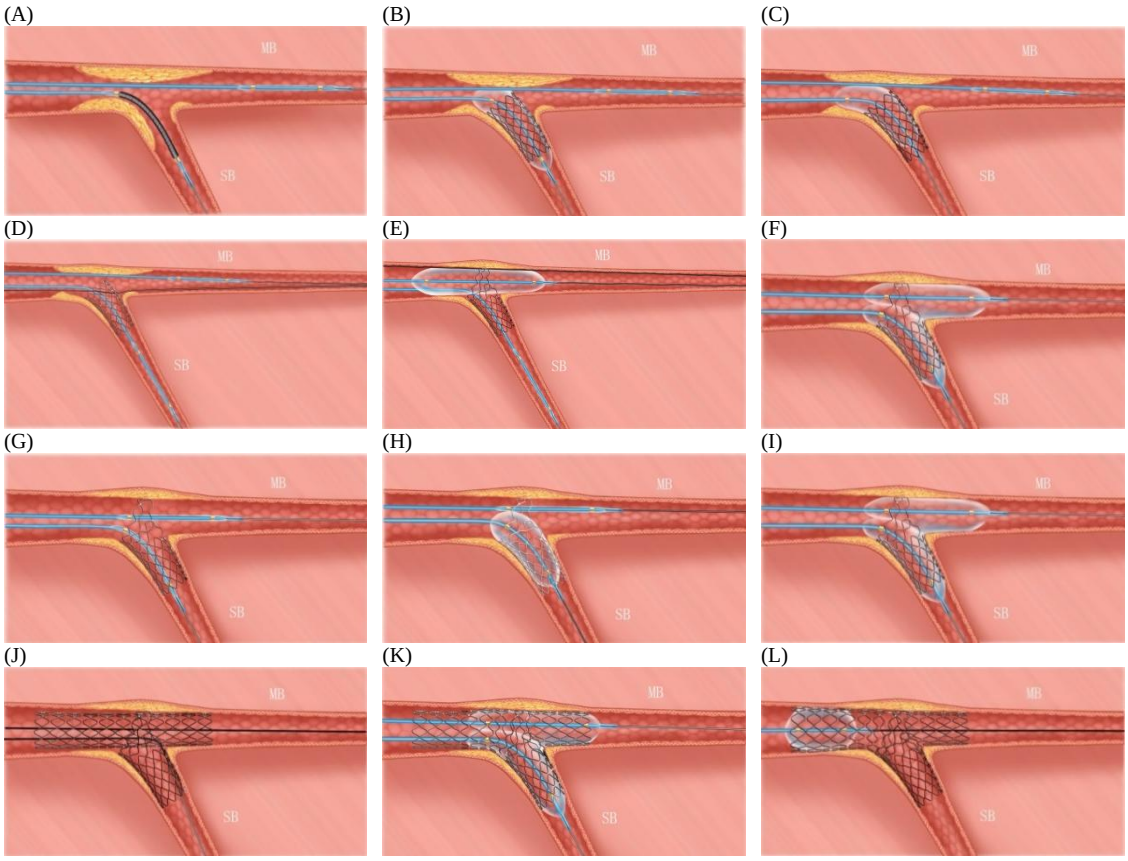

Figure 1. The MCS procedural steps with different IBD treatments. A. After wiring the SB and MB, pre-embed a balloon in the MB (if necessary) and insert the SB stent with mini-protrusion of 1–2 mm into the PMV or POC. B-C. Deploy the SB stent with nominated pressure, and then slightly withdraw the SB balloon with higher pressure re-inflation (≥12 AMT); D. Advance the SB balloon deeply, and rewire the MB close to the carina. E-I. Prior to MB stenting, dilate the side-hole and protruded segment of the SB stent by either rISBD (E), cIKBD (F) or sIKBD (G-I). J. Stent the MB and then rewire the SB close to the carina. K. Perform final kissing balloon dilation with 2 non-compliance balloons; L. End the procedure using the proximal optimization technique. Abbreviations: cIKBD, concurrent intermediate kissing balloon dilation; IBD, intermediate balloon dilation; MB, main-branch; MCS, mini-culotte stenting; PMV, parent main vessel; POC, polygon of confluence; rISBD, routine intermediate solo balloon dilation; SB, side-branch; sIKBD, sequential intermediate kissing balloon dilation.

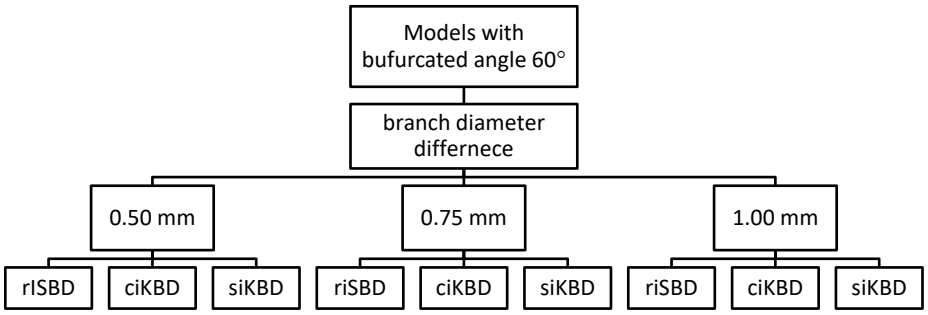

Figure 2. Experimental protocol with factorial design.

ICSC focused on the bifurcated connecting domain (BCD), which comprised the POC and its adjacent three segments (5 mm proximal to the POC and 5 mm distal to the SB or MB ostium; Figure 3B).

For the ICSE analysis, mCT was used to measure the reference area (A_{REF}), the minimal area (A_{MIN}) of the stent lumen in each segment and the ostial area (A_{OST}) of the MB (A_{MBO}) and the SB (A_{SBO}) (Figure 3A) (13). Briefly, the A_{REF} of the PMV, the MB or the

SB was measured along each segment at its proximal, middle and distal point, and then averaged, respectively. The A_{MIN} of the PMV, the MB or the SB was measured at its narrowest site, and the A_{OST} of the MB or the SB was measured at its ostium. In bench testing, the A_{MIN} of the PMV was usually located in the stent-overlapping segment, and the A_{MIN} of the MB or the SB was located at its ostium (~A_{OST}). Based on the basic measurements, SUE at the PMV (ROS at PMV) was calculated using the equation $100 \times (A_{REF} - A_{MIN})/A_{REF}$. ROS at the MB was calculated using the equation: $100 \times (A_{REF} - A_{MBO})/A_{REF}$. ROS at the SB was calculated using the equation $100 \times (A_{REF} - A_{SBO})/A_{REF}$.

For ICSC, mCT was used to measure the ring-to-ring distance (D_1) along the stent long axis in BCD (Figure 3B), which was normalized by the standard ring-to-ring distance (D_0) provided by manufacturers (D_1/D_0). A cell with $D_1/D_0 \geq 1.5$ was considered to be significantly distorted. In each BCD segment, the total number of stent cells (N_t) and distorted stent cells (N_d) were counted, and SCD as a percentage was calculated using the equation $100 \times N_d/N_t$.

Statistical analysis

All analyses were performed with statistical software packages (SSPS 17.0, Chicago, IL). Data were expressed as mean ± SD for continuous variables. A univariate general linear model with a 2×3 factorial design was adopted to analyze the main effects of IBD or BDD and the interaction effects between IBD and BDD on ICSE and ICSC. The interaction effects between IBD and BDD on ICSE and ICSC (if any) were analyzed through two-way ANOVA; otherwise, the main effects of IBD or BDD on ICSE and ICSC (if any) were analyzed through one-way ANOVA. The LSD test following one- or two-way ANOVA was finalized as appropriate. A p value < 0.05 was considered to be statistically significant.

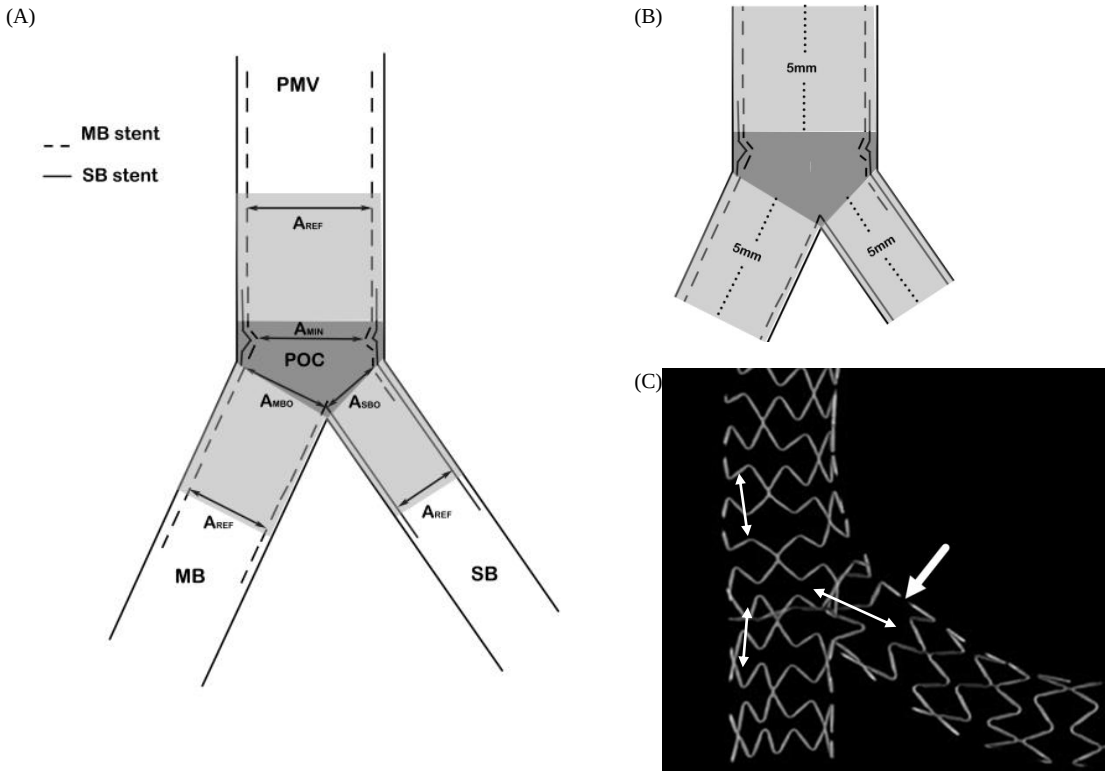

Figure 3. Bifurcation segmentation and morphological analysis. **A**: Segmentation of bifurcation into the PMV, POC, MB and SB. Measurements of A_{REF}, A_{MIN}, A_{MBO} and A_{SBO} at their respective measuring sites for calculation of SUE and ROS. **B**: Definition of the BCD as the POC with its proximal 5 mm segment, SB and MB ostium with its distal 5 mm segments (upper panel). Measurement of the ring-to-ring distance axially (white double-headed arrow) in the BCD with mCT (lower panel) for calculation of the severity of SCD.

Abbreviations: A_{MBO}, area of the MB ostium; A_{MIN}, minimal area; A_{REF}, reference area; A_{SBO}, area of the SB ostium; BCD, bifurcation connecting domain; MB, main-branch; PMV, proximal main vessel; POC, polygon of confluence; ROS, residual ostial stenosis; SB, side-branch; SCD, stent cell distortion; SUE, stent under-expansion.

RESULTS

Representative examples of rISBD, cIKBD and sIKBD with a BDD of 1.0 mm are shown in Figure 4. The bifurcated stent morphology in each IBD treatment and BDD step-size is listed in Table 1. Overall, a univariate general linear model showed not only the main effects that IBD or BDD had on ICSE or ICSC, but it also showed the interaction effects between IBD and BDD on ICSE or ICSC in the ostial SB. Only the main effects of IBD or BDD on ICSE or ICSC were shown in other segments of the BCD (Table 2).

ICSE among 3 IBD treatments and 3 BDD step-sizes

SUE around POC

Only main effects of IBD or BDD on SUE around the POC were observed (P = 0.03). A comparison of the main effects between IBD treatments or BDD step-sizes showed that there were significant differences in SUE between sIKBD and rISBD (P = 0.001) and between cIKBD and rISBD (P = 0.040), but there were insignificant differences between sIKBD and cIKBD (P = 0.139). Moreover, there were significant differences in SUE between a BDD of 1.0

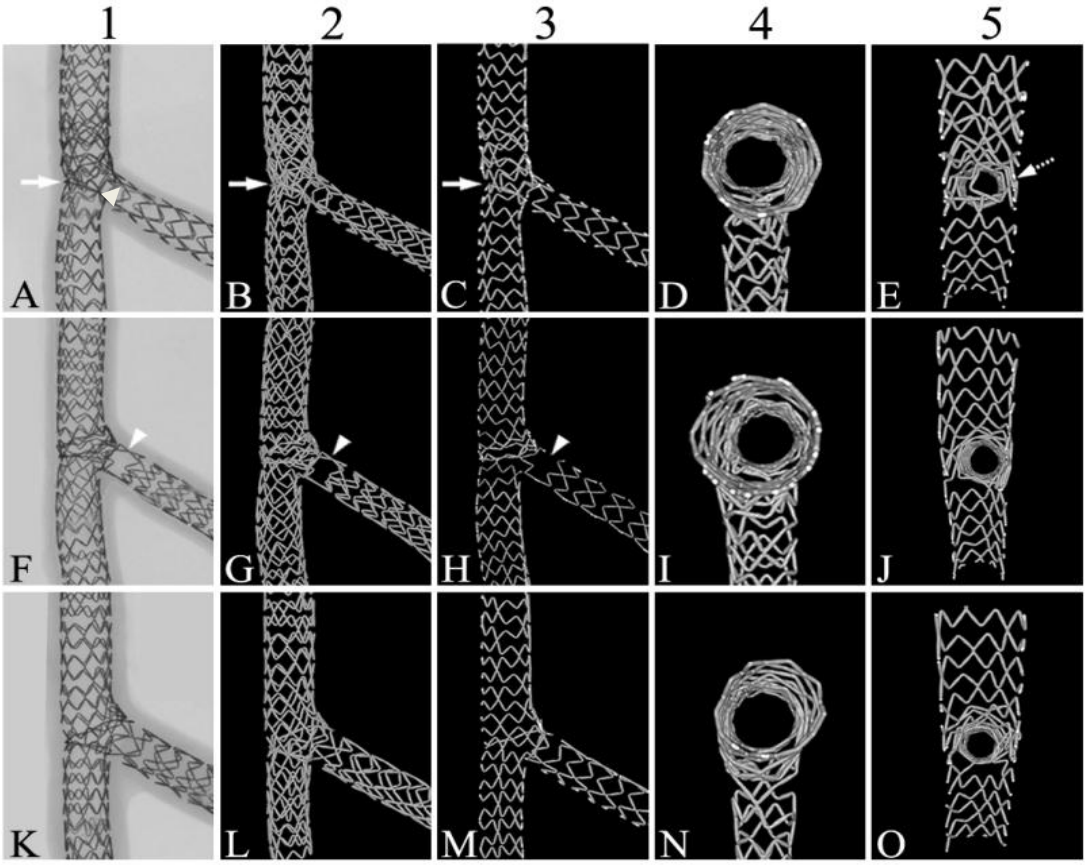

Figure 4. Comparison of bifurcated stent morphologies among IBD treatments. The high-definition photographs (1st row) and fully reconstructed 3D images of mCT (2nd row) with the different electronically cut 3D-images, the half-cut images through the bifurcation coronal plane (3rd row), the transverse-cut images through PMV (4th row) and the longitudinally sagittal-cut images through PMV-MB (5th row), are shown to compare the resultant bifurcated morphologies among the three IBD treatments of rISBD (upper panels), rIKBD (middle panels) and sIKBD (lower panels). For rISBD, there is SUE presenting as a remarkable napkin-ring band in the stent-overlapped segment around the POC (A, B and C, arrow), SCD as slight SB stent deformation in the proximal two cells near the ostia SB (A, B and C, arrowhead) and ROS as a smaller ostial SB area free of struts (E, dotted arrow); for cIKBD, SCD is much more severe than for the rISBD or sIKBD, forming big gaps near the ostial SB (F, G and I, arrowhead) despite no significant SUE (F, G and H) or ROS (J); for sIKBD, no more SUE (K, L and M), SCD (K, L and M) or ROS (P) is observed. Stents of 3.5 and 2.5 mm were used to treat the MB and SB in three cases, respectively. Abbreviations are given in Figures 1 and 3.

Table 1 Comparisons of bifurcated stent morphologies among different BDDs and IBDs

	BDD 0.5 mm			BDD 0.75 mm			BDD 1.0 mm		
	rISBD	cIKBD	sIKBD	rISBD	cIKBD	sIKBD	rISBD	cIKBD	sIKBD
ICSE									
SUE, POC (%)	6.7±2.4	6.2±2.6	5.0±1.9	9.5±3.3	7.9±2.3	6.5±2.2	13.1±6.4	8.8±3.4	6.8±2.4
ROS, SB (%)	13.3±3.3	11.5±3.3	8.8±2.9	22.5±7.7	14.5±4.2	11.4±3.1	29.5.±8.2	18.7±8.3	12.9±4.2
ROS, MB (%)	9.5±3.9	9.1±3.8	8.1±3.2	11.1±4.4	10.4±3.8	10.8±3.7	16.1±5.6	12.8±1.7	11.4±1.7
ICSC									
SCD, POC (%)	0.8±2.4	0.8±2.4	0.8±2.4	1.7±3.1	1.7±3.1	2.5±3.5	2.5±5.0	2.5±3.5	3.3±5.0
SCD, SB (%)	14.2±6.6	11.7±4.7	3.3±5.0	20.8±6.6	19.2±6.6	4.2±5.0	28.3±3.1	20.8±6.6	5.0±4.7
SCD, MB (%)	3.3±5.0	0.8±2.4	0.8±2.4	9.2±6.1	5.8±7.5	3.3±3.6	11.7±6.9	7.5±7.5	4.2±5.0

Abbreviations: BDD = branch diameter difference; IBD = intermediate balloon dilation; cIKBD/sIKBD = concurrent/sequential intermediate kissing balloon dilation; ICSC = incomplete stent coverage; ICSE = incomplete stent expansion; MB = main-branch; POC = polygon of confluence; ROS = residual ostial stenosis; rISBD = routine intermediate solo balloon dilation; SB = side-branch; SCD = stent cell distortion; SUE = stent under-expansion. The same abbreviations used in following tables were used in this table unless noted otherwise.

Table 2 Main and interactive effects of BDDs and IBDs on bifurcated stent morphologies

	SUE, POC		ROS, SB		ROS, MB	
	F	P	F	P	F	P
Corrected model	4.362	<0.001	11.545	<0.001	3.202	0.004
IBDs	7.770	0.001	23.877	<0.001	1.946	0.151
BDDs	7.316	0.001	16.838	<0.001	9.110	<0.001
IBDs × BDDs	1.181	0.328	2.733	0.037	0.876	0.484
	SCD, POC		SCD, SB		SCD, MB	
	F	P	F	P	F	P
Corrected model	0.545	0.818	20.103	<0.001	3.628	0.002
IBDs	0.203	0.817	61.085	<0.001	5.670	0.005
BDDs	1.877	0.162	13.641	<0.001	7.942	0.001
IBDs × BDDs*	0.051	0.995	2.842	0.031	0.450	0.772

Note: * represents interactive effects of CBSs and BDDs

Table 3 Main effects of IBDs and BDDs on bifurcated stent morphologies by one-way ANOVA

Variables	IBDs			
	rISBD	cIKBD	sIKBD	P
ICSE				
SUE, POC (%)	9.8±4.9	7.6±2.9*	6.1±2.2*	0.003
ROS, SB (%)	21.8±9.3	14.9±6.2*	11.0±3.7*	<0.001
ROS, MB (%)	12.2±5.3	10.8±3.5	10.1±3.2	0.212
ICSC				
SCD, POC (%)	1.7±3.5	1.7±2.9	2.2±3.8	0.812
SCD, SB (%)	21.1±8.0	17.2±7.1	4.2±4.8*#	<0.001
SCD, MB (%)	8.1±6.8	4.7±6.7	2.8±3.9*	0.011
Variables	BDDs			
	0.5 mm	0.75 mm	1.0 mm	P
ICSE				
SUE, POC (%)	6.0±2.3	8.0±2.8	9.5±5.0*	0.004
ROS, SB (%)	11.2±3.5	16.1±7.0*	20.4±9.8*#	<0.001
ROS, MB (%)	8.9±3.5	10.7±3.8	13.4±3.9*#	<0.001
ICSC				
SCD, POC (%)	0.8±2.3	1.9±3.1	2.8±4.4	0.138
SCD, SB (%)	9.7±7.1	14.7±9.6	18.1±11.0*	0.011
SCD, MB (%)	1.7±3.5	6.1±6.2*	7.8±7.0*	0.001

Note: Due to too many p-values in the final LSD test, the table shows only the values of P<0.05; other P-values are specifically noted in the results section if applicable.

For comparison between IBDs: vs. riSBD, * P<0.05; vs. cIKBD, # P<0.05. For comparison between BDDs: vs. BDD 0.5 mm, * P<0.05; vs. BDD 0.75 mm, # P<0.05.

mm and 0.50 mm (P = 0.001) and insignificant differences between a BDD of 0.75 mm and 0.50 mm (P = 0.058) and between a BDD of 1.0 mm and 0.75 mm (P = 0.126). This indicated that SUE around the POC could be determined by IBD or BDD (Table 3).

ROS at ostial SB

There were both main and interactive effects of IBD or BDD on ROS. A comparison of the main effects between IBD treatments or BDD step-sizes showed that there were significant differences in ROS between sIKBD and rISBD (P < 0.001) and between cIKBD and rISBD (P = 0.001) and insignificant differences between sIKBD and cIKBD (P = 0.056). Moreover, there were significant differences in ROS between a BDD of 1.0 mm and 0.50 mm (P < 0.001), 1.0 mm and 0.75 mm (P = 0.048) and 0.75 mm and 0.50 mm (P = 0.022). This indicated that ROS at the ostial SB could be determined by IBD or BDD (Table 3). Further analysis of the interaction effects of IBD and BDD by two-way (2×3) factorial ANOVA showed that ROS was significantly affected by IBD treatments at all BDD step-sizes (P = 0.030, = 0.001, < 0.001, respectively). Moreover, as BDD step-sizes increased, ROS increased significantly if treated by rISBD (P = 0.001) and insignificantly if treated by cIKBD (P = 0.060), by sIKBD (P = 0.079). This indicated that

ROS at the ostial SB was also co-determined by the combination of IBD and BDD and could be reduced partly by cIKBD and almost completely by sIKBD (Table 4 and Figure 5A).

ROS was found to be similar among IBD treatments. Comparing BDD step-sizes, we found that there were significant differences in ROS between a BDD of 1.0 mm and 0.50 mm (P < 0.001) and 1.0 mm and 0.75 mm (P = 0.014). However, there were insignificant differences in ROS between a BDD of 0.75 mm and 0.50 mm (P = 0.097), which indicated that ROS at the ostial MB was mainly determined by the BDD (Table 3).

ICSC among three IBD treatments and three BDD step-sizes

SCD in POC

No SCD occurred as treated by any IBD at any BDD (Table 3).

SCD in ostial SB

There were both main and interaction effects of IBD or BDD on SCD. A comparison of the main effects between IBD treatments or BDD step-sizes showed that there were significant differences in SCD between sIKBD and rISBD (P < 0.001) and between sIKBD and cIKBD (P = < 0.001) and insignificant differences between cIKBD and rISBD (P = 0.050). Moreover, there were significant differences in SCD between a BDD of 1.0 mm and 0.50 mm (P = 0.003) and insignificant differences between a BDD of 1.0 mm and 0.75 mm (P = 0.223) and 0.75 mm and 0.50 mm (P = 0.069), which indicated that SCD in the ostial SB could be determined by IBD or BDD (Table 3). Further analysis of the interaction effects of IBD and BDD by two-way (2×3) factorial ANOVA showed that SCD was significantly affected by IBD treatments at all BDD step-sizes (P = 0.020, < 0.001 and < 0.001). As BDD step-sizes increased, SCD also increased significantly if treated by rISBD (P < 0.001) or by cIKBD (P = 0.014), and it increased insignificantly if treated by sIKBD (P = 0.796). This indicated that SCD in the ostial SB was co-determined by a combination of IBD and BDD, and that it could be reduced partly by cIKBD and almost completely by sIKBD (Table 4 and Figure 5B).

SCD in ostial MB

There were only main effects of IBD or BDD on SCD. A comparison of the main effects between IBD treatments and BDD step-sizes showed that there were significant differences in SCD between sIKBD and rISBD (P = 0.003) and insignificant differences in SCD between sIKBD and cIKBD (P = 0.261) and between cIKBD and rISBD (P = 0.056). Moreover, there were significant differences in SCD between a BDD of 1.0 mm and 0.50 mm (P < 0.001) and 0.75 mm and 0.50 mm (P = 0.009), and there were insignificant differences between a BDD of 1.0 mm and 0.75 mm (P = 0.320). This indicated that SCD in the ostial MB could be determined by IBD or BDD (Table 3).

DISCUSSION

As one of the most commonly used two-stent techniques, MCS offers several advantages, including fewer overlapping struts, higher final kissing dilation success (11) and better clinical outcomes as shown in Nordic studies comparing MCS with crush stentings (3,14). Nevertheless, the need for similar branch sizes still limits the broad clinical utilities of MCS. Modification of the MCS procedure reduced ICSE markedly, but incompletely, when it was conducted at higher BDD values (>0.5 mm) (9-11). Additionally, ICSC remains an unsolved issue when using MCS. Accordingly, how to effectively reduce ICSE and ICSC has become a major focus in the further improvement of the MCS procedure.

Table 4 Interactive effects of BDDs and IBDs on bifurcated stent morphologies by two-way ANOVA

Variables	ROS, SB (%)			
	rISBD	cIKBD	sIKBD	P
BDD 0.5 mm	13.3±3.3	11.5±3.3	8.8±2.9*	0.030
BDD 0.75 mm	22.5±7.7a	14.5±4.2*	11.4±3.1*	0.001
BDD 1.0 mm	29.5±8.2a	18.7±8.3*	12.9±4.2*	<0.001
P	<0.001	0.060	0.079	
Variables	SCD, SB (%)			
	riSBD	ciKBD	siKBD	P
BDD 0.5 mm	14.2±6.6	11.7±4.7	3.3±5.0*#	0.002
BDD 0.75 mm	20.8±6.6a	19.2±6.6a	4.2±5.0*#	<0.001
BDD 1.0 mm	28.3±3.1ab	20.8±6.6*a	5.0±4.7*#	<0.001
P	<0.001	0.014	0.796	

Note: Due to too many p-values in the final LSD test, the table shows only the values of P<0.05; other p-values are specifically noted in the results section if applicable.

For comparison between IBDs under different BDDs: vs. riSBD, *P<0.05; vs. ciKBD, #P<0.05. For comparison between BDDs with different IBDs: vs. BDD 0.5 mm, [a]P<0.05; vs. BDD 0.75 mm, [b]P<0.05.ROS at ostial MB.

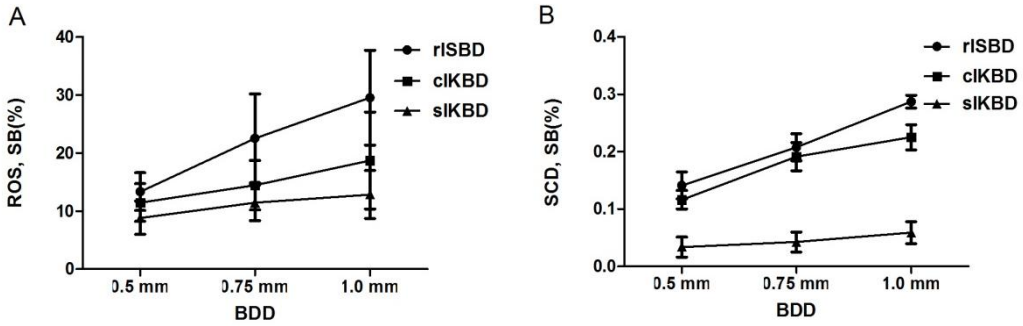

Figure 5. Interaction effect of IBDs and BDDs on ROS and SCD at ostial SB. A: Two-way factorial analysis shows that ROS was significantly affected by IBD treatments in all BDD step-sizes; moreover, as BDD step-sizes increased, ROS increased significantly if treated by rISBD and increased insignificantly if treated by cIKBD or sIKBD. B: Two-way factorial analysis shows that SCD was significantly affected by IBD treatments in all BDD step-sizes; moreover, as BDD step-sizes increased, SCD increased significantly if treated by rISBD or cIKBD and increased insignificantly if treated by sIKBD. Abbreviations are given in Figure 4.

New findings in this study

This study, which used a 2×3 factorial experiment, was the first to show that adding sIKBD to MCS could reduce ICSE (SUE, ROS) without inducing ICSC (SCD) in each BCD segment. Our major findings were as follows:

1) SUE around the POC, ROS at the ostial SB and SCD in the ostial SB were significantly different among different IBD treatments or BDD step-sizes.

2) ROS at the ostial SB or SCD in ostial SB were co-affected by IBD treatments, BDD step-sizes or their combination. Moreover, increasing BDD significantly increased ROS at the ostial SB as treated by rISBD and SCD in the ostial SB as treated by rISBD or cIKBD.

3) Compared to rISBD, cIKBD partly reduced ICSE and induced ICSC, whereas sIKBD nearly completely reduced ICSE and ICSC at greater BDD values.

Requirement for and correct way of conducting IKBD when using culotte stentings

RISBD is necessary for culotte stenting to open the side-hole of the initially implanted stent in order to pass the subsequently implanted stent. In scenarios involving greater BDD values (≥0.5 mm), if using rISBD only, SUE occurs in the stent-overlapped segment, resulting in significant ICSE manifested by SUE around the POC and ROS at the ostial SB/MB. By performing cIKBD rather than rISBD before MB stenting, DK-MCS could effectively reduce SUE and ROS but introduce another dilemma of ICSC, in particular, SCD at the ostial SB (8-11). In this study, sIKBD was found to eradicate not only ICSE but also ICSC when used in scenarios involving greater BDD values of up to 1.0 mm. These results strongly suggest that sIKBD is an essential step and the correct way to eliminate a bifurcated stent, both under-expansion and deformation.

Mechanisms of sIKBD for morphological improvement

For inverted culotte stentings, there is a tighter connection between two stents because conducting SB stenting followed by MB stenting creates a scenario in which the bigger MB stent is inside the smaller SB stent in the stent-overlapped segment. This intertwined connection creates an interaction between two stents in several culotte-stenting steps (e.g., dilating the stent side-hole by a single balloon dilation, stenting MB and performing intermediate or final kissing balloon dilation), all of which forcibly tear stents, resulting in culotte-associated stent deformation or even a larger gap in BCD segments. As demonstrated in our study, ICSC, particularly SCD in ostial SB, occurred frequently when using rISBD or cIKBD, and it could be eradicated through sIKBD whenever used in scenarios with a BDD of 1.0 mm.

SIKBD is characterized by sequential instead of simultaneous IKBD, or to be more exact, by inflating the SB balloon first with higher pressure followed by inflating the MB balloon with lower pressure. SIKBD plays important roles in the maintenance of the bifurcated stent configurations through the following

mechanisms: (1) inflating the SB balloon first with higher pressure firmly fixes the ostial or proximal struts of the SB stent and maintain the SB ostial geographic configuration, thus avoiding stent distortion or ICSC caused by subsequent inflation of the MB balloon during IKBD, MB stenting or final kissing balloon dilation; (2) fully expanding the side-hole of the SB stent and its protruded segment into the PMV diminishes SUE or ROS. In fact, sIKBD, although a minor step, has the ability to prevent culotte-associated ICSE and ICSC, which is clinically important as it would enable us to broaden the use of MCS for bifurcation intervention.

Limitations

Although we controlled wiring and ballooning techniques that might have affected the results of our study, there were several limitations to our study. First, the bench testing we used might not exactly represent clinical situations, particularly those involving complex anatomic or lesion characteristics. Second, although a strict, 2×3 two-way factorial design was adopted in the study after considering the most important factor (BDD), another anatomic factor (the bifurcated angulation) was not included. Finally, the selection of stent platforms with excellent side-hole expandability for testing does not represent all stent brands because poorer outcomes may occur if stents with suboptimal expandability are used. The findings should be considered alongside these limitations, and clinical studies are warranted to further confirm our observations.

CONCLUSIONS

When compared to rISBD or cIKBD, sIKBD conducted prior to MB stenting when using MCS was associated with better bifurcated stent morphologies in terms of stent expansion and coverage even in the case of greater BDD values. Therefore, sIKBD should be considered an essential step for and the proper way to optimize culotte stenting.

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