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CUTTING-EDGE TECHNOLOGY

Double Kissing Inflation Outside the Stent Versus Jailed Balloon Technique for Coronary Bifurcation Lesions

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ABSTRACT

Side branch (SB) occlusion remains challenging in bifurcation percutaneous coronary intervention. We have introduced a novel method to protect SB named double kissing inflation outside the stent (DKo), which features twice inflation of protective balloon kissing with stent and postdilation balloon. This study compared protective effects of DKo vs jailed balloon technique (JBT) for bifurcation. This retrospective, single-center study enrolled 875 consecutive bifurcation lesions receiving either DKo (n = 209) or JBT (n = 666). At the 12-month follow-up, major adverse cardiac event occurred less in DKo (6.7% vs 12.0%; $P = 0.042$), even in 1:2 propensity score matching analysis (6.4% vs 12.3%; $P = 0.034$). Rewiring and transient SB loss occurred also less in DKo (0.5% vs 13.8% [$P < 0.001$]; 0.5% vs 4.8% [$P = 0.003$]). Similar results were observed in matching analysis. This study demonstrated DKo protected SB better than JBT in bifurcation percutaneous coronary intervention. (JACC: Asia 2023;3:678-682) © 2023 The Authors. Published by Elsevier on behalf of the American College of Cardiology Foundation. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

Coronary bifurcation lesions account for 15% to 20% in percutaneous coronary intervention, in which provisional stenting technique is preferred.[1] Side branch (SB) compromise in provisional technique has not been resolved completely.[2] Guidewire protection is first used, but it serves as a marker of rewiring rather than prevents occlusion. The jailed balloon technique (JBT) improves SB patency and decreases occlusion owing to higher occupation of balloon.[3] However, residual occlusion risk remains a challenge after balloon removal, mainly triggered by rewiring, postdilation, and/or severe dissection.[4,5]

We have introduced double kissing inflation outside the stent (DKo) for bifurcation with long-term protection of inflated balloon, which pushed vessel wall outward, diminished residual occlusion, and thus secured SB without rewiring.[6] We compared DKo vs JBT for bifurcation in a large sample size.

METHODS

STUDY POPULATION. This retrospective, single-center study was conducted in Zhongshan Hospital between February 2019 and January 2021. Excluding SB vessel diameter of >2.5 mm, bifurcation percutaneous coronary intervention history, guidewire protection, 2-stent strategies, balloon-only strategy, or stenting not crossed bifurcation, coronary bifurcation lesions with a visually estimated diameter stenosis of ≥70% involving the main vessel (MV) and ≥50% involving the SB ostium receiving balloon protection

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The authors attest they are in compliance with human studies committees and animal welfare regulations of the authors' institutions and Food and Drug Administration guidelines, including patient consent where appropriate. For more information, visit the Author Center.

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were screened. This study was conducted in accordance with the guidelines of the Declaration of Helsinki and approved by ethics committees.

INTERVENTION. DKo is schematically illustrated (Figure 1A). After sufficient preparation with balloon, DKo starts with simultaneous inflation of stent (10-16 atm) and SB balloons (sized a little bit smaller than reference vessel diameter). The key point of DKo is prolonged protection, as the balloon is inflated once again kissing with postdilation balloon based on main branch (MB) size at the bifurcation core (up to 16-20 atm). After withdrawing the SB balloon, a proximal optimization technique (POT) with another short noncompliant balloon based on MV size is performed (up to 16-22 atm) strictly not exceeding the bifurcation, accurately positioned by stent boost and angiography.[6] JBT starts with stent implantation in MV accompanied by the jailed balloon under stent, with either inflation as active protection or deflation as passive protection. Then, the jailed balloon is removed. A POT with a short balloon is performed immediately after jailed balloon removal to correct stent malapposition in the MV proximally to SB takeoff. If the SB compromises, rewiring, final kissing balloon inflation, and even rescue stenting are performed. The bifurcation lesion was divided into 3 segments, the MV, MB, and SB.[1]

OUTCOMES. The primary endpoint is major adverse cardiac event, a composite of death, myocardial infarction, or ischemia-driven revascularization at 12 months. The secondary endpoints are rewiring and transient SB loss during the procedure, defined as TIMI flow grade 0/1 after balloon removal.[7]

STATISTICAL ANALYSIS. Continuous variables were reported as mean ± SD or median (IQR) according to the distribution. Categorical variables were presented as number (%). The Student's *t*-test, Wilcoxon rank-sum, chi-square, and Fisher exact tests were used when appropriate. Exploratory multivariable logistic regression analysis by means of an enter algorithm was performed to select independent predictors of transient SB occlusion (including DKo, baseline characteristics, baseline angiogram, jailed pressure, active protection, and maximum postdilation pressure). Data were analyzed using R software (version 4.1.3). *P* values of <0.05 were considered statistically significant.

ABBREVIATIONS AND ACRONYMS

DKo = double kissing inflation outside the stent

JBT = jailed balloon technique

MB = main branch

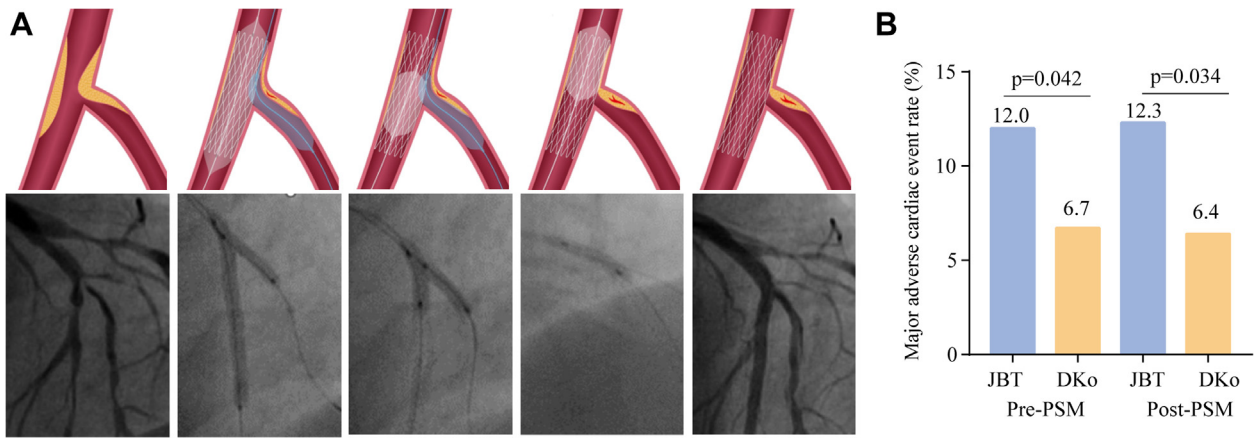
MV = main vessel

SB = side branch

RESULTS

BASELINE CHARACTERISTICS AND ANGIOGRAM. During the study period, 875 cases fulfilling the inclusion and exclusion criteria were enrolled in the study, 209 of whom underwent a DKo procedure. Table 1 shows comparable characteristics between groups except gender. Coronary angiogram showed similar percentages of Medina type 1.1.1 lesions and bifurcation angles. More serious lesion of the MV and MB was observed in the DKo group.

FIGURE 1 Procedure and Clinical Outcomes



(A) Schematic and coronary angiographic illustration of key steps of DKo technique. **(B)** Incidence of major adverse cardiac events. DKo = double kissing inflation outside the stent; JBT = jailed balloon technique; PSM = propensity scoring matching.

TABLE 1 Baseline Characteristics and Procedural and Clinical Outcomes

	Total			PSM		
	JBT (n = 666)	DKo (n = 209)	*P* Value	JBT (n = 406)	DKo (n = 203)	*P* Value
Baseline characteristics						
Male	526 (79.0)	181 (86.6)	0.02	352 (86.7)	175 (86.2)	0.97
Age, y	63.2 ± 10.4	64.0 ± 10.3	0.35	64.0 ± 10.3	63.9 ± 10.2	0.92
Acute coronary syndrome	277 (41.6)	91 (43.5)	0.68	188 (46.3)	91 (44.8)	0.80
Diabetes mellitus	192 (28.8)	62 (29.7)	0.88	122 (30.0)	62 (30.5)	0.98
Hypertension	406 (61.0)	136 (65.1)	0.32	267 (65.8)	136 (67.0)	0.83
Hypercholesterolemia	67 (10.1)	23 (11.0)	0.79	45 (11.1)	23 (11.3)	0.41
Smoking	274 (41.1)	93 (44.5)	0.44	180 (44.3)	93 (45.8)	0.80
Prior PCI	154 (23.1)	58 (27.8)	0.20	104 (25.6)	58 (28.6)	0.50
Baseline angiogram						
Medina type 1.1.1	481 (72.2)	166 (79.4)	0.05	317 (78.1)	161 (79.3)	0.94
Bifurcation angle, °	50.0 (30.0-70.0)	50.0 (40.0-70.0)	0.70	50.0 (30.0-70.0)	50.0 (40.0-70.0)	0.60
MV stenosis, %	70.0 (54.5-84.6)	79.3 (60.0-87.9)	0.001	75.3 (57.1-89.2)	79.3 (60.0-87.8)	0.68
MB stenosis, %	74.2 (57.6-86.7)	80.6 (60.0-90.0)	0.003	80.0 (60.8-90.2)	80.0 (60.0-90.0)	0.89
SB stenosis, %	71.4 (52.0-83.3)	71.4 (53.8-85.0)	0.26	73.3 (53.3-85.0)	71.4 (53.6-85.0)	0.85
Propensity score	-	-	-	0.3 ± 0.1	0.3 ± 0.1	0.75
Procedure						
Active protection	534 (80.2)	209 (100.0)	<0.001	317 (78.1)	203 (100.0)	<0.001
Jailed pressure, atm	6.0 (2.0-10.0)	8.0 (6.0-10.0)	<0.001	6.0 (2.0-10.0)	8.0 (6.0-10.0)	<0.001
Postdilation pressure, atm	16.0 (16.0-18.0)	18.0 (16.0-20.0)	<0.001	16.0 (16.0-18.0)	18.0 (16.0-20.0)	<0.001
Rewiring	92 (13.8)	1 (0.5)	<0.001	65 (16.0)	1 (0.5)	<0.001
Transient SB occlusion	32 (4.8)	1 (0.5)	0.003	23 (5.7)	1 (0.5)	<0.001
Final angiogram						
MV stenosis, %	10.0 (8.3-12.1)	10.0 (7.9-11.8)	0.12	10.0 (8.2-12.1)	10.0 (7.9-11.8)	0.27
MB stenosis, %	9.1 (6.7-11.1)	8.6 (6.7-10.7)	0.11	9.1 (6.7-11.1)	8.6 (6.7-10.7)	0.24
SB stenosis, %	46.7 (25.0-70.0)	40.0 (25.0-46.7)	<0.001	46.9 (28.1-71.3)	40.0 (25.0-46.7)	<0.001

Values are n (%), mean ± SD, or median (IQR).

DKo = double kissing inflation outside the stent; JBT = jailed balloon technique; MB = main branch; MV = main vessel; PCI = percutaneous coronary intervention; PSM = propensity score matching; SB = side branch.

PROCEDURAL AND CLINICAL OUTCOMES. Active protection was performed in 100% of DKo group, but only in 80.3% of JBT group ($P < 0.001$). In the DKo group, the maximum pressure of protective balloon and postdilation in the MV was higher (8 atm vs 6 atm [$P < 0.001$]; 18 atm vs 16 atm [$P < 0.001$], respectively). Rewiring and transient SB loss occurred less in the DKo group (0.5% vs 13.8% [$P < 0.001$]; 0.5% vs 4.8% [$P = 0.003$], respectively). A final angiogram showed comparable results in MV and MB. However, the DKo technique alleviated SB lesion presented as lower residual stenosis (40.0% vs 46.7%; $P < 0.001$). In a 1:2 propensity score matching analysis, similar superiority was observed in DKo (Table 1).

At the 12-month follow-up, major adverse cardiac events occurred less often in the DKo group (6.7% vs 12.0%; $P = 0.042$). Even in a 1:2 propensity-score matching analysis (including baseline characteristics and angiogram), similar clinical superiority was observed in DKo group (Figure 1B).

DISCUSSION

Our study confirms DKo presents better procedural and clinical outcomes than JBT for bifurcation.

DKo improves clinical outcomes and decreases transient SB loss. Approximately 4.8% of transient SB occlusion incidence in JBT is comparable with or slightly higher than other studies.[5,8] Transient SB loss frequently occurs in JBT, but it may be less reported owing to massive salvage through rewiring, balloon inflation and stenting. Our study indicates transient SB loss was mainly triggered by rewiring (21/32) and postdilation (8/32). Even though efforts greatly restored the SB in JBT (24/32), recanalization is highly dependent on personal experience and unreproducible. Prolonged balloon protection in DKo may keep the SB ostium open and avoid massive rewiring. Non-flow-limiting dissection and mild to moderate stenosis of the ostial SB often exists, and most of them are of no clinical significance.[9] Therefore, rewiring is

rarely necessary. DKo protects SB simply and reproducibly; therefore, we strongly recommend DKo in provisional stenting techniques.

Additional exploratory logistic regression analysis indicates DKo was the only protector against transient SB loss (OR: 0.08; 95% CI: 0.01-0.59; $P = 0.013$). Previous study indicates that SB ostial stenosis, SB lesion length, diffuse atherosclerotic plaque in the SB ostium, proximal MV stenosis, and bifurcation angle are independently predictive of SB occlusion in provisional stenting technique.[10] A possible explanation for this discrepancy between these studies and ours is the protective method. Wiring in the SB is associated with recovery of the occluded SB rather than prevention of SB occlusion, which is just performed in partial lesions. Unlike that, occupation of balloon in either JBT or DKo prevents SB occlusion owing to carina shift and plaque shift with MV stenting, so traditional predictors of SB occlusion become meaningless in balloon protection. Impact factors focus on the residual risk of SB occlusion in JBT, including postdilation and rewiring. The second inflation of the protective balloon in DKo may push the vessel wall outward, maintain a patent SB during postdilation, heal mild dissection, and alleviate stenosis of the ostial SB. Most important, as patent blood flow and mild to moderate stenosis of the ostial SB are always of no clinical significance, there is no need to rewire and related complications can be avoided. Therefore, a second kissing inflation, as the only difference between DKo and JBT, is uniquely predictive of SB occlusion in this study.

Although DKo is simple to operate and possibly generalized broadly, there are some technical issues. First is stent malapposition. In theory, occupation of the protective balloon in DKo allows aggressive postdilation of the bifurcation core, which contributes to stent apposition, especially distal segment beyond bifurcation. Additionally, decreased stenosis and occlusion risk of SB enables aggressive POT even exceeding bifurcation core in DKo, which facilitates amending stent malapposition. In contrast, no balloon occupation and potential occlusion risk in JBT may result in insufficient postdilation and POT, which increases stent malapposition. Finally, intravascular ultrasound examination shows comparable stent apposition between the proximal and distal segments of stents in DKo in our prior study.[6] Hence, there is no need to worry about the adverse effect of balloon on stent apposition during postdilation. No device trap in our study may be related to the following technical details: shrinking of the deflated balloon profile is conducive to balloon withdrawal; and the postdilation balloon in the MV should not exceed the upper edge of the SB balloon, which can effectively reduce withdrawal resistance. We still need to be vigilant in specific situations, such as severe calcified and/or high-angulated lesions, distal bifurcations, and large profile of drug-coated balloon. Until now, we have not encountered device entrapment in DKo, but attention should be paid.

Although most clinical and lesion characteristics are matched, the observational study is lack of balancing undetected confounding factors and impacted by physician's preference. There is the potential for selection bias of excessive balloon protection based on personal preference in our center. Intravascular imaging and functional testing have not been used routinely to examine lesion details. Drug-coated balloons may be applied in SB to improve long-term outcomes. Some lesions with nonsignificant SB (<2.5 mm) were included owing to their potential importance.

CONCLUSIONS

We demonstrate that DKo provides preferable outcomes for bifurcation lesions compared with JBT. It may be reasonable to reduce SB deterioration and simplify bifurcation percutaneous coronary intervention, which seems to be worth generalizing broadly.

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