Observational Study

Medicine

OPEN

Balloon-stent kissing technique versus jailed wire technique for interventional treatment of coronary bifurcation lesions

Comparison of short- and long-term clinical outcomes

Zhe Jin, MD[a], Linlin Song, MS[b], Zhenguo Zheng, MD[c,*], Shuying Zhang, MD[c], Meilan Wang, BS[c]

Abstract

Side-branch occlusion is a serious complication of provisional one-stent strategies used to treat coronary bifurcation lesions. The aim of the study was to compare the short- and long-term clinical outcomes between the balloon-stent kissing technique (BSKT) and jailed wire technique (JWT) in patients with non-left coronary bifurcation lesions.

This prospective, double-blinded, randomized controlled study enrolled 89 consecutive patients (aged 18–85 years) with 90 true bifurcation lesions (hemadostenosis ≥70%; bifurcation angle <90°; Medina classification 1.1.1, 1.0.1, or 0.1.1) who underwent percutaneous coronary intervention (PCI) at the Zhongshan Hospital Affiliated to Dalian University (China) between January 2013 and May 2016. The patients were randomly divided into the BSKT (44 patients, 45 lesions) and JWT (45 patients, 45 lesions) groups. The intervention was conducted according to technical requirements using a single-stent strategy. Operative success rate, occurrence of complications, postoperative quantitative coronary angiography, and incidence of perioperative and long-term major adverse cardiovascular events (MACEs) were compared between groups.

The intervention success rate was 100% in both groups. After main-branch stenting, the BSKT was associated with significantly lower rates of side-branch occlusion (0% vs 15.6%, $P<.05$) and side-branch post-processing (8.9% vs 26.7%, $P<.05$) than the JWT. The BSKT was associated with significantly lower degrees of postoperative proximal main-branch residual stenosis (6.1 ± 5.1% vs 9.6 ± 8.6%, $P<.05$) and side-branch ostial stenosis (51.6 ± 20.6% vs 70.3 ± 20.8%, $P<.05$) than the JWT. The incidence of perioperative MACEs was significantly lower in the BSKT group than in the JWT group (0% vs 13.3%, $P<.05$). Patients were followed for a mean duration of 19.0 ± 6.1 months. The occurrence rates of long-term MACEs, angina of Canadian Cardiovascular Society grade ≥2, and severe heart failure were not significantly different between groups.

The BSKT is a safe and effective technique that may have advantages over the JWT with regard to protection of the side-branch during PCI for bifurcation lesions.

Abbreviations: BSKT = balloon-stent kissing technique, CHD = coronary heart disease, FKB = final kissing balloon, JBT = jailed balloon technique, JWT = jailed wire technique, LVEF = left ventricular ejection fraction, MACEs = major adverse cardiovascular events, NYHA = New York Heart Association, PCI = percutaneous coronary intervention, POT = proximal optimizing technique, RCT = randomized controlled trial, TIMI = thrombolysis in myocardial infarction.

Keywords: balloon-stent kissing technique, coronary bifurcation lesions, jailed wire technique, side-branch occlusion

Editor: Stefano Omboni.

The authors have no funding and conflicts of interest to disclose.

[a] Department of Cardiology, the Hunchun Hospital, Jilin, [b] Department of Cardiology, the Affiliated Xinhua Hospital of Dalian University, [c] Department of Cardiology, the Affiliated Zhongshan Hospital of Dalian University, Zhongshan, Dalian, China.

[*] Correspondence: Zhenguo Zheng, Department of Cardiology, the Affiliated Zhongshan Hospital of Dalian University, No. 6 Jiefang street, Zhongshan, Dalian 116001, China (e-mail: kzzg@sina.com).

Medicine (2019) 98:20(e15633)

Received: 31 October 2018 / Received in final form: 26 March 2019 / Accepted: 18 April 2019

http://dx.doi.org/10.1097/MD.0000000000015633

1. Introduction

Coronary heart disease (CHD) is a major cause of mortality and was responsible for >8 million deaths worldwide in 2013.[1] The prevalence of CHD in 2010 was estimated to be 7% in those aged 45 to 64 years and >20% in those aged over 65 years.[2] In China, the incidence of CHD has progressively risen in recent years.[3] A variety of options are available for the management of CHD, including coronary artery bypass grafting and percutaneous coronary intervention (PCI).[4]

Around 15% to 20% of PCIs are carried out for coronary bifurcation lesions.[5,6] PCI for coronary bifurcation lesions has a lower postoperative success rate, higher restricture rate (as assessed by radiography), and more frequent complications than PCI for non-bifurcation lesions, resulting in poorer clinical outcomes.[7–9] Thus, an important focus of current research is the development of safe and effective treatment strategies for bifurcation lesions. The provisional one-stent strategy (i.e., stenting of the main-branch with additional stenting of the side-branch if necessary) is currently the preferred choice for bifurcation lesions, although various 2-stent intentional techniques are also available.[6,10,11] Nevertheless, an important complication of the provisional one-stent strategy is side-branch occlusion after main-branch stenting, which can occur due to shifting of the main-branch plaque or a change in the location of the carina.[12,13] In 2011, our center initiated the use of the balloon-stent kissing technique (BSKT), an innovative provisional stenting strategy that protects the side-branch by minimizing shifts of the carina and plaque.[14] We found that the use of the BSKT resulted in a high postoperative success rate (Thrombolysis In Myocardial Infarction [TIMI] grade 3 flow in both the main-branch and side-branch in all 60 patients), preservation of the bifurcation angle, no instances of side-branch occlusion and a low occurrence of perioperative adverse events.[14] Nevertheless, the BSKT has yet to be directly compared with other stenting strategies for bifurcation lesions.

We hypothesized that the BSKT would result in a lower rate of side-branch occlusion than the jailed wire technique (JWT), an alternative provisional stenting strategy used for bifurcation lesions. Therefore, the aim of the present study was to compare the postoperative success rate, side-branch occlusion rate, proximal main-branch residual stenosis and major adverse cardiovascular events (MACEs) between the BSKT and the JWT.

2. Methods

2.1. Study participants

This prospective, double-blinded, randomized controlled trial (RCT) enrolled 89 consecutive patients with 90 true bifurcation lesions who underwent PCI at Zhongshan Hospital Affiliated to Dalian University (Dalian, China) between January 2013 and May 2016. All patients underwent coronary angiography to confirm true bifurcation lesions and received PCI. The inclusion criteria were: aged 18 to 85 years; stable or unstable angina pectoris or old or acute myocardial infarction; coronary arteriography revealed the primary vascular lesions and target lesion in the main-branch; non-left main coronary artery bifurcation lesions; true bifurcation lesions (defined as a vessel with ≥50% stricture); hemadostenosis ≥70%; bifurcation angle <90°; Medina classification 1.1.1, 1.0.1, or 0.1.1[15]; and requiring ≤4 stents. The exclusion criteria were: currently enrolled in another clinical trial; stent restenosis; severely calcified lesions or excessively tortuous lesions; left main bifurcation lesions; lesions in coronary artery bypass grafts; serious heart failure (New York Heart Association [NYHA] class IV); severe impairment of renal function (serum creatinine >2.0 mg/dL); increased risk of bleeding (active peptic ulcer or history of cerebral hemorrhage); contraindications to anti-platelet or anticoagulant therapy; and life expectancy <12 months.

The study was conducted in accordance with the principles of the Declaration of Helsinki and was approved by the ethics committee of Zhongshan Hospital Affiliated to Dalian University (no. 2014012). All patients provided informed written consent for all procedures and inclusion in the study. This trial is registered at clinicaltrials.gov (NCT03429634).

2.2. Interventional treatment

The patients were randomly divided into the BSKT (44 patients, 45 lesions) and JWT (45 patients, 45 lesions) groups using sequentially numbered, opaque, sealed envelopes. All patients received preoperative oral aspirin (300 mg loading dose), clopidogrel (300 mg loading dose), or ticagrelor (180 mg loading dose), intraoperative intravenous injection of heparin (100–150 IU/kg), postoperative aspirin (100 mg/d), a long-term statin-related drug, and clopidogrel (75 mg/d), or ticagrelor (90 mg/dose bid) for at least 1 year. All bifurcation lesions were treated with a single-stent strategy (stent placement in the main-branch) with additional stent implantation in the side-branch when necessary. The use of side-branch protection techniques was determined intraoperatively by the surgeon. The methods used for the BSKT and JWT techniques were as follows:

BSKT: The main-branch and side-branch were accessed using standard 0.014" coronary guidewires (transfemoral or trans-radial approach with 6–7 Fr coronary guiding catheters). When necessary, pre-dilatation of the main-branch was performed using a standard Ryujin balloon. A standard coronary stent was advanced into the main-branch so as to cover all the main lesions; meanwhile, a monorail balloon (angiographically sized to the side-branch vessel diameter; generally 1.5–2.5 mm) was advanced into the side-branch vessel and pre-dilatation of the side-branch was performed. The side-branch balloon was expanded to an appropriate pressure (6–10 ATM), and the main-branch stent was then deployed to nominal pressure so that the side-branch balloon and main-branch stent "kissed." The stent balloon and side-branch balloon were simultaneously deflated. The position of the main-branch stent balloon was maintained while the side-branch balloon was removed; the side-branch guidewire was left in place and removed after main-branch stent optimization. The main-branch stent balloon was fully expanded to high pressure to optimize stent apposition and rectify any stent deformation, and the side-branch guidewire was then retracted. Coronary angiography was performed to determine the need for post-processing of the side-branch (see below).

JWT: First and second steps were the same as for the BSKT group. The main-branch stent was located and then released using a nominal pressure. Coronary angiography was performed to determine the need for post-processing of the side-branch. If post-processing was not required then the guidewire was retracted followed by re-expansion of the main-branch stent balloon under high pressure.

Post-processing of the side-branch: The 2 techniques described above were used to protect the side-branch. If coronary angiography showed ≥75% stricture of the side-branch opening or TIMI flow grade <3 in the side-branch and the reference vessel diameter was ≥2 mm after main-branch stent placement, then a wire was placed through the stent mesh into the side-branch, the side-branch was dilated with a compliant balloon, and finally a kissing balloon was formed. Coronary angiography was repeated and if the side-branch opening stenosis was ≥75% and the reference vessel diameter was ≥2.5 mm, coronary stenting was performed on the side-branch followed by formation of a kissing balloon; otherwise, the operation was considered completed.

2.3. Outcome measures

2.3.1. Intraoperative/perioperative outcomes. The intervention success rate was recorded for both groups; intervention success was defined as the stent completely covering the target lesion, residual stenosis of the main-branch <20%, and blood flow of TIMI grade 3. Any intraoperative complications, including side-branch occlusion (defined as side-branch blood flow of TIMI grade <3), coronary artery dissection, thrombosis, and coronary artery rupture, were also recorded. Any post-processing of the side-branch, including balloon dilation or stent implantation, was noted. Any perioperative MACEs, including cardiac death, perioperative myocardial infarction, and target lesion revascularization, were recorded.

2.3.2. Coronary angiography. The bifurcation angle and length of the main-branch lesion were measured by an investigator blinded to the grouping. The primary side-branch reference vessel diameter and minimum vessel diameter were measured preoperatively and postoperatively.

2.3.3. Long-term outcomes. The patients were followed postoperatively for 6 to 24 months. Any occurrence of MACEs, angina pectoris of Canadian Cardiovascular Society (CCS) grade ≥2 and severe heart failure (NYHA class IV) were recorded.

2.4. Statistical analysis

All data were analyzed using SPSS 22.0 (IBM Corp., Armonk, NY). Measurement data are presented as the mean ± standard deviation and were compared between groups using Student *t* test. Count data are presented as n (%) and were compared between groups using the chi-squared test or Fisher exact probability method. Survival was analyzed by the Kaplan–Meier method and the log-rank test. $P<.05$ was considered to be statistically significant.

3. Results

3.1. Baseline characteristics of the study participants

The baseline clinical characteristics of the patients are shown in Table 1. There were no significant differences between groups in sex, age, diagnosis of CHD, history of chronic myocardial infarction, history of PCI, hypertension, diabetes mellitus, hyperlipidemia, smoking status or left ventricular ejection fraction (LVEF).

3.2. Lesion characteristics and operative characteristics

There were no significant differences between the 2 groups in the distribution of the bifurcation lesion positions, the distribution of the Medina classifications, the bifurcation angle or the main-branch lesion length (Table 2). Stent diameter, total stent length, number of stents implanted, and type of stent implanted also showed no significant differences between groups (Table 2). The intervention success rate was 100% in both groups. After placement of the main-branch stent, occlusion of the side-branch occurred in 7 cases (15.6%) in the JWT group, of which 3 (6.7%) were completely occluded (TIMI grade 0) and 4 (8.9%) exhibited partial flow (TIMI grade 1 or 2). By contrast, there were no cases of side-branch occlusion in the BSKT group ($P<.05$ vs JWT group). The rate of side-branch dissection was comparable between the JWT group (3 cases, 6.7%) and BSKT group (1 case, 2.2%). There were no instances of coronary artery rupture, blood clots, wire breakage, or balloon entrapment in both groups. The rate of side-branch post-processing was significantly lower in the BSKT group than in the JWT group ($P<.05$). Post-processing of the side-branch was needed in 12 cases (26.7%) in the JWT group (including stent insertion in 1 case; 2.2%) and 4 cases (8.9%) in the BSKT group (none of which required stent insertion).

Table 1

Baseline clinical characteristics.

Characteristic	JWT group (N=45 patients)	BSKT group (N=44 patients)	*P* value
Gender (male)	30 (66.7%)	31 (70.5%)	.700
Age, y	65.4±10.4	66.0±8.8	.771
Diagnosis of CHD			.239
SA or UA	23 (51.1%)	27 (61.4%)	
NSTEMI	14 (31.1%)	7 (15.9%)	
STEMI	8 (17.8%)	10 (22.7%)	
Chronic MI	6 (13.3%)	4 (9.1%)	.766
History of PCI	3 (6.7%)	4 (9.1%)	.975
Hypertension	33 (73.3%)	25 (56.8%)	.102
Diabetes mellitus	16 (35.6%)	18 (40.9%)	.603
Smoker	17 (37.8%)	22 (50.0%)	.245
Hyperlipidemia	13 (28.9%)	11 (25.0%)	.679
LVEF (%)	59.2±10.1	60.4±8.0	.570

Data presented as mean±standard deviation or n (%). BSKT=balloon-stent kissing technique, CHD=coronary heart disease, JWT=jailed wire technique, LVEF=left ventricular ejection fraction, MI=myocardial infarction, NSTEMI=non-ST-elevation myocardial infarction, PCI=percutaneous coronary intervention, SA=stable angina, STEMI=ST-elevation myocardial infarction, UA=unstable angina.

Table 2

Lesion characteristics and operative characteristics.

Characteristic	JWT group (N=45)	BSKT group (N=45)	*P* value
Lesion location			.390
LAD	34 (75.6%)	37 (82.2%)	
LCX	4 (8.9%)	5 (11.1%)	
RCA	7 (15.6%)	3 (6.7%)	
Medina classification			.696
1.1.1	29 (64.4%)	27 (60.0%)	
1.0.1	6 (13.3%)	9 (20.0%)	
0.1.1	10 (22.2%)	9 (20.0%)	
Bifurcation angle, °	56.0±22.0	55.0±17.0	.814
Main-branch lesion length, mm	27.5±12.7	25.8±9.4	.526
Stent diameter, mm	2.99±0.39	2.98±0.36	.897
Total stent length, mm	31.9±15.0	31.4±12.7	.892
Number of stents	1.33±0.48	1.27±0.45	.554
Stent type			.462
Rapamycin-eluting stent	32 (71.1%)	36 (80.0%)	
Paclitaxel-eluting stent	12 (26.7%)	9 (20.0%)	
Adjuvant tamoxifen-eluting stent	1 (2.2%)	0 (0%)	
Surgical success rate	100%	100%	–
Postoperative side-branch flow			.016
TIMI grade 3	38 (84.4%)	45 (100%)	
TIMI grade 2	2 (4.4%)	0 (0%)	
TIMI grade 1	2 (4.4%)	0 (0%)	
TIMI grade 0	3 (6.7%)	0 (0%)	
Side-branch occlusion (TIMI grade <3)	7 (15.6%)	0 (0%)	.018
Side-branch dissection	3 (6.7%)	1 (2.2%)	.609
Side-branch post-processing	12 (26.7%)	4 (8.9%)	.027
Side-branch stenting	1 (2.2%)	0 (0%)	1.000

Data presented as mean±standard deviation or n (%). BSKT=balloon-stent kissing technique, JWT=jailed wire technique, LAD=left anterior descending artery, LCX=left circumflex artery, RCA=right coronary artery, TIMI=thrombolysis in myocardial infarction.

3.3. Quantitative analysis of coronary angiography findings

Preoperatively, there were no significant differences between groups in reference vessel diameter, minimal blood vessel diameter, or diameter stenosis for the proximal main-branch vessel, distal main-branch vessel, and side-branch opening (Table 3). However, postoperative assessment of the side-branch

Table 3

Quantitative analysis of coronary angiography findings.

Characteristic	JWT group (N=45)	BSKT group (N=45)	*P* value
Preoperative values for the proximal main-branch			
Reference vessel diameter, mm	2.98±0.39	3.00±0.35	.842
Minimal lumen diameter, mm	1.03±0.86	1.02±0.83	.970
Diameter stenosis (%)	65.2±28.6	65.5±29.6	.971
Preoperative values for the distal main-branch			
Reference vessel diameter, mm	2.63±0.32	2.58±0.27	.458
Smallest blood vessel diameter, mm	0.80±0.49	0.80±0.60	1.000
Diameter stenosis (%)	69.1±19.1	68.8±23.1	.938
Preoperative values for the side-branch			
Reference vessel diameter, mm	1.93±0.38	1.98±0.25	.478
Smallest blood vessel diameter, mm	0.69±0.31	0.61±0.29	.216
Diameter stenosis (%)	64.1±15.3	69.1±13.9	.102
Postoperative values for the proximal main-branch			
Reference vessel diameter, mm	2.99±0.38	3.00±0.34	.817
Smallest vessel diameter, mm	2.69±0.38	2.82±0.35	.094
Diameter stenosis (%)	9.6±8.6	6.1±5.1	.019
Postoperative values for the distal main-branch			
Reference vessel diameter, mm	2.64±0.33	2.60±0.27	.444
Smallest blood vessel diameter, mm	2.46±0.38	2.44±0.28	.754
Diameter stenosis (%)	7.0±7.2	6.0±5.0	.419
Postoperative values for the side-branch			
Reference vessel diameter, mm	1.94±0.37	1.98±0.25	.533
Smallest blood vessel diameter, mm	0.60±0.47	0.98±0.46	<.001
Diameter stenosis (%)	70.3±20.8	51.6±20.6	<.001
Change in diameter stenosis (%)	6.3±21.3	–17.5±19.4	<.001

Data presented as mean±standard deviation. BSKT=balloon-stent kissing technique, JWT=jailed wire technique. Change in diameter stenosis of the side-branch=postoperative diameter stenosis–preoperative diameter stenosis.

revealed that the BSKT group had a significantly larger minimal vessel lumen (0.98±0.46 vs 0.60±0.47, $P<.001$) and a significantly smaller diameter stenosis (51.6±20.6 vs 70.3±20.8, $P<.001$) than the JWT group.

3.4. Perioperative and long-term MACEs

The occurrence rates of perioperative and long-term MACEs are shown in Table 4. The rate of perioperative MACEs was significantly higher ($P<.05$) in the JWT group (6 cases, 13.3%) than in the BSKT group (no cases). Perioperative MACEs in the JWT group included 5 cases of myocardial infarction and 1 case of cardiac death. The average postoperative follow-up duration was 19.0±6.1 months. There were no significant differences in the occurrence of MACEs, angina pectoris, or severe heart failure between the 2 groups, but the total major adverse events rate occurring in-hospital and during postoperative follow-up was significantly lower in the BSKT group than in the JWT group. The total 24-month survival rate was comparable between the 2 groups (BSKT 97.7% vs JWT 91.1%, $P=.18$) (Table 4), but the Kaplan–Meier analysis indicated that the 2 survival curves were significantly apart ($P<.001$, log-rank test) (Fig. 1).

Table 4

Perioperative and long-term major adverse cardiac events.

Adverse event	JWT group (N=45 patients)	BSKT group (N=44 patients)	*P* value
Perioperative adverse events			
Major adverse cardiac events	6 (13.3%)	0 (0.0%)	.037
Cardiac death	1 (2.2%)	0 (0.0%)	1.000
Myocardial infarction	5 (11.1%)	0 (0.0%)	.069
Target lesion revascularization	0 (0.0%)	0 (0.0%)	–
Long-term adverse events			
Major adverse cardiac events	5 (11.1%)	3 (6.8%)	.736
Cardiac death	3 (6.7%)	1 (2.3%)	.625
Myocardial infarction	1 (2.2%)	2 (4.5%)	.984
Target lesion revascularization	1 (2.2%)	0 (0.0%)	1.000
Angina pectoris (CCS ≥2)	9 (20.0%)	6 (13.6%)	.423
Severe heart failure	4 (8.9%)	1 (2.3%)	.371

Data presented as n (%). CSS=Canadian Cardiovascular Society grade.

4. Discussion

The main findings of the present study were that the use of the BSKT to treat coronary bifurcation lesions resulted in significantly lower rates of side-branch occlusion and side-branch post-processing than the use of the JWT. Furthermore, the BSKT was associated with significantly lower degrees of postoperative proximal main-branch residual stenosis and side-branch ostial stenosis, as compared with the JWT. Moreover, the incidence of perioperative MACEs was significantly lower in the BSKT group than in the JWT group, while the long-term incidences of MACEs, angina (CCS grade ≥2) and severe heart failure were comparable between groups. The novel data presented in this study indicate that the BSKT is a safe and effective technique that may have advantages over the JWT with regard to side-branch protection during PCI for bifurcation lesions.

The best interventional treatment for coronary bifurcation lesions in the era of drug-eluting stents remains unclear. A RCT comparing single-stent and two-stent techniques for the treatment of coronary bifurcation lesions found that the 2-stent technique

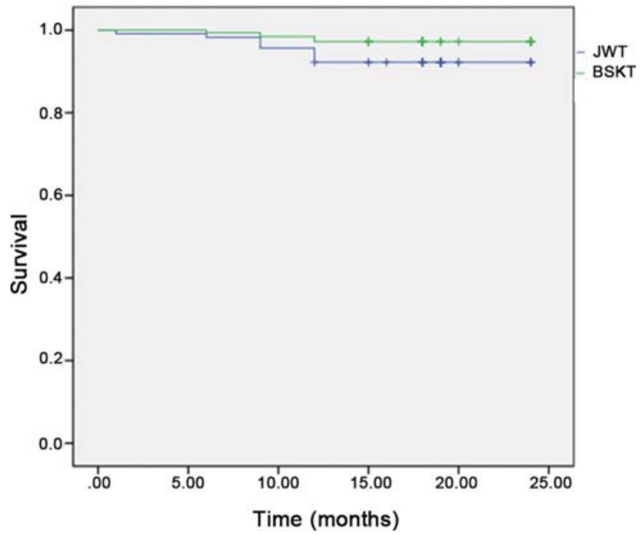

Figure 1. Kaplan–Meier analysis of the survival during follow-up after the balloon-stent kissing technique (BSKT) and jailed wire technique (JWT) in patients with non-left coronary bifurcation lesions. $P<.001$, log-rank test.

was associated with higher rates of in-hospital mortality, myocardial infarction, and 9-month adverse outcomes (a composite of death, myocardial infarction, and target vessel failure).[10] The Nordic bifurcation study found no significant differences in outcomes between a provisional one-stent strategy and an intentional two-stent strategy at 6 months[16] and 5 years,[17] although the provisional one-stent strategy was associated with shorter procedure and fluoroscopy durations. Therefore, the more simple single-stenting technique is currently the preferred strategy.

Occlusion of a primary side-branch after main-branch stenting can lead to potentially fatal arrhythmias and perioperative myocardial infarction, resulting in adverse clinical outcomes.[9] The Korean Coronary bifurcation stent (COBIS II) study[18] found that, compared with false bifurcation lesions, true bifurcation lesions had a higher incidence of side-branch occlusion (10.5% vs 3.9%) and a greater risk of MACEs (hazard ratio: 1.39). Side-branch protection to prevent side-branch occlusion is a very important step during the provisional stenting technique, particularly for true bifurcation lesions where the risk of occlusion is higher. In the COBIS II study,[9] the side-branch occlusion rate was 8.4% even with the use of a JWT. Singh et al[19] recommended the use of jailed balloon technology to protect the side-branch ostium, whereby the side-branch balloon can be used for angioplasty of the side-branch if necessary after deployment of the main-branch stent to nominal pressure; the side-branch balloon is then retracted before full re-expansion of the main-branch stent balloon. Traditional wire protection techniques cannot effectively prevent side-branch occlusion, whereas the jailed balloon technique (JBT) can reduce side-branch occlusion rates as well as the long-term incidence of MACEs. The BSKT is an innovative improvement of the JBT that appears to further enhance its beneficial effect.

This study was a RCT that ensured baseline data homogeneity in the 2 groups. An important finding was that the side-branch occlusion rate was significantly lower in the BSKT group than in the JWT group (0% vs 15.6%, $P<.05$). There were 7 cases of side-branch occlusion in the JWT group, of which only 2 cases had successful intervention for the side-branch after main-branch stenting; 2 cases required no further treatment because of the small size of the branch, while 3 cases had unsuccessful reintervention because of side-branch rewiring failure and no reflow. Although post-processing can correct severe stenosis or ostial occlusion, it will increase the operation time and amount of contrast agent used, and the success rate is low. Notably, the BSKT significantly reduced the rate of side-branch post-processing (8.9% vs 26.7%, $P<.05$) and decreased side-branch diameter stenosis after intervention (by $17.5\pm19.4\%$).

The COBIS II study[20] found that the use of the final kissing balloon (FKB) technique with a one-stent strategy resulted in a lower incidence of MACEs and lower rates of target lesion revascularization for both vessels after a median of 36 months of follow-up, as compared with a non-FKB approach. The BSKT will increase the proximal main-branch minimal lumen diameter, thereby reducing the risk of subsequent target lesion revascularization of the main-branch due to ischemia. The J-REVERSE study[21] used optical coherence tomography to show that the FKB technique can increase the average lumen size of the main-branch and produce a more uniform distribution of the vascular intima. The present study found that the BSKT was more effective than the JWT at increasing the diameter of the main-branch and reducing residual stenosis ($6.1\pm5.1\%$ vs $9.6\pm8.6\%$, $P<.05$). There is a major difference between the BSKT and the JBT (a non-kiss type balloon protection technology). BSKT involves embedding the proximal balloon without any special requirements (because the blood vessel walls have a degree of elasticity) and simultaneous extraction of a double balloon. The embedded proximal balloon should optimally reach or go slightly beyond the main-branch proximal stent in order to achieve the best effect of the kiss. A larger compliant balloon (usually >0.5 mm of the main stent diameter) may be needed for main branch expansion with the use of a proximal optimizing technique (POT)[22] to ensure complete expansion and adherence of the main-branch stent.

There are certain technical characteristics of the BSKT that merit specific mention. First, the side-branch balloon should be expanded before deployment of the main-branch stent, as this can effectively prevent displacement of the main-branch stent due to plaques or vascular crest excursion and avoid aggravation of side-branch stricture or occlusion of the side-branch. Second, as a kissing-balloon technique, the double balloon must always match the main-branch diameter to fully expand proximal lesions and severely stenotic lesions. Third, the ostial plaque of the side-branch should be fixed during the initial expansion of the main-branch stent, so that the final expansion of the main-branch stent balloon does not cause obvious side-branch plaque shift.

Chen et al[23] found that perioperative myocardial infarction was associated with an increased long-term risk of death in patients with coronary bifurcation lesions treated with drug-eluting stents. In the present study, we also found that the BSKT group had a lower rate of myocardial infarction and MACEs than the JWT group during follow-up, as well as a significantly lower rate of perioperative MACEs than the JWT group. Although the survival rate was comparable between the 2 groups, additional research is merited to establish whether the lower incidence of perioperative MACEs in the BSKT group may improve the long-term prognosis of patients treated with this technology. Indeed, the Kaplan–Meier analysis suggests that the 2 survival curves were significantly apart, hinting towards a possible difference over the long-term.

This study has certain limitations. First, this was a single center study with a small sample size, so the generalizability of the findings is unknown. Second, the patients were clinically followed for a maximum of only 24 months, and there was no angiographic follow-up so the assessment of longer-term and angiographic outcomes was not possible. Third, only one comparator group was included (JWT), so comparisons of the BSKT with other provisional one-stent or intentional two-stent strategies were not made. Future studies with larger sample sizes, longer follow-up durations, and additional comparator groups are required to confirm our findings.

In conclusion, the BSKT is a safe and effective technique that appears to have certain advantages over the JWT with regard to side-branch protection during PCI for bifurcation lesions. In particular, the BSKT was associated with lower rates of side-branch occlusion, side-branch post-processing, and perioperative MACEs than the JWT, while the long-term incidence of MACEs was comparable between groups. Due to the high difficulty and cost of the technique, we do not recommend the BSKT as a routine procedure for bifurcation lesions. Instead, we recommend that the BSKT be reserved for patients at high risk of side-branch occlusion, as assessed using the recently published RESOLVE scoring system.[24]

Author contributions

Conceptualization: Zhenguo Zheng.
Data curation: Zhe Jin, Linlin Song, Shuying Zhang, Meilan Wang.
Formal analysis: Zhe Jin, Linlin Song, Shuying Zhang, Meilan Wang.
Investigation: Linlin Song, Shuying Zhang.
Methodology: Zhe Jin, Linlin Song, Shuying Zhang.
Project administration: Linlin Song, Zhenguo Zheng, Shuying Zhang, Meilan Wang.
Resources: Linlin Song, Meilan Wang.
Software: Meilan Wang.
Supervision: Meilan Wang.
Writing – original draft: Zhe Jin.
Writing – review & editing: Zhe Jin, Linlin Song, Zhenguo Zheng, Shuying Zhang, Meilan Wang.

References

[1] GBD 2013 Mortality and Causes of Death CollaboratorsGlobal, regional, and national age-sex specific all-cause and cause-specific mortality for 240 causes of death, 1990–2013: a systematic analysis for the Global Burden of Disease Study 2013. Lancet 2015;385:117–71.
[2] Centers for Disease Control, Prevention CPrevalence of coronary heart disease–United States, 2006–2010. MMWR Morb Mortal Wkly Rep 2011;60:1377–81.
[3] Hu SS, Kong LZ, Gao RL, et al. Outline of the report on cardiovascular disease in China, 2010. Biomed Environ Sci 2012;25:251–6.
[4] Kappetein AP, van Mieghem NM, Head SJ. Revascularization options: coronary artery bypass surgery and percutaneous coronary intervention. Cardiol Clin 2014;32:457–61.
[5] Myler RK, Shaw RE, Stertzer SH, et al. Lesion morphology and coronary angioplasty: current experience and analysis. J Am Coll Cardiol 1992;19:1641–52.
[6] Lassen JF, Holm NR, Stankovic G, et al. Percutaneous coronary intervention for coronary bifurcation disease: consensus from the first 10 years of the European Bifurcation Club meetings. EuroIntervention 2014;10:545–60.
[7] Sharma SK, Sweeny J, Kini AS. Coronary bifurcation lesions: a current update. Cardiol Clin 2010;28:55–70.
[8] Latib A, Colombo A. Bifurcation disease: what do we know, what should we do? JACC Cardiovasc Interv 2008;1:218–26.
[9] Hahn JY, Chun WJ, Kim JH, et al. Predictors and outcomes of side branch occlusion after main vessel stenting in coronary bifurcation lesions: results from the COBIS II Registry (COronary BIfurcation Stenting). J Am Coll Cardiol 2013;62:1654–9.
[10] Hildick-Smith D, de Belder AJ, Cooter N, et al. Randomized trial of simple versus complex drug-eluting stenting for bifurcation lesions: the British Bifurcation Coronary Study: old, new, and evolving strategies. Circulation 2010;121:1235–43.
[11] Dash D. Recent perspective on coronary artery bifurcation interventions. Heart Asia 2014;6:18–25.
[12] Kang SJ, Mintz GS, Kim WJ, et al. Preintervention angiographic and intravascular ultrasound predictors for side branch compromise after a single-stent crossover technique. Am J Cardiol 2011;107:1787–93.
[13] Koo BK, Waseda K, Kang HJ, et al. Anatomic and functional evaluation of bifurcation lesions undergoing percutaneous coronary intervention. Circ Cardiovasc Interv 2010;3:113–9.
[14] Jin Z, Li L, Wang M, et al. Innovative provisional stenting approach to treat coronary bifurcation lesions: balloon-stent kissing technique. J Invasive Cardiol 2013;25:600–4.
[15] Medina A, Suarez de Lezo J, Pan M. [A new classification of coronary bifurcation lesions]. Rev Esp Cardiol 2006;59:183.
[16] Steigen TK, Maeng M, Wiseth R, et al. Randomized study on simple versus complex stenting of coronary artery bifurcation lesions: the Nordic bifurcation study. Circulation 2006;114:1955–61.
[17] Maeng M, Holm NR, Erglis A, et al. Long-term results after simple versus complex stenting of coronary artery bifurcation lesions: Nordic Bifurcation Study 5-year follow-up results. J Am Coll Cardiol 2013;62:30–4.
[18] Park TK, Park YH, Song YB, et al. Long-term clinical outcomes of true and non-true bifurcation lesions according to Medina Classification-results from the COBIS (COronary BIfurcation Stent) II Registry. Circ J 2015;79:1954–62.
[19] Depta JP, Patel Y, Patel JS, et al. Long-term clinical outcomes with the use of a modified provisional jailed-balloon stenting technique for the treatment of nonleft main coronary bifurcation lesions. Catheter Cardiovasc Interv 2013;82:E637–46.
[20] Yu CW, Yang JH, Song YB, et al. Long-term clinical outcomes of final kissing ballooning in coronary bifurcation lesions treated with the 1-Stent technique: results from the COBIS II Registry (Korean Coronary Bifurcation Stenting Registry). JACC Cardiovasc Interv 2015;8:1297–307.
[21] Takahashi H, Otake H, Shinke T, et al. Impact of final kissing balloon inflation on vessel healing following drug-eluting stent implantation: insight from the optical coherence tomography sub-study of the J-REVERSE trial. J Cardiol 2016;68:504–11.
[22] Finet G, Derimay F, Motreff P, et al. Comparative analysis of sequential proximal optimizing technique versus kissing balloon inflation technique in provisional bifurcation stenting: fractal coronary bifurcation bench test. JACC Cardiovasc Interv 2015;8:1308–17.
[23] Chen SL, Zhang JJ, Ye F, et al. Periprocedural myocardial infarction is associated with increased mortality in patients with coronary artery bifurcation lesions after implantation of a drug-eluting stent. Catheter Cardiovasc Interv 2015;85(suppl):696–705.
[24] Dou K, Zhang D, Xu B, et al. An angiographic tool for risk prediction of side branch occlusion in coronary bifurcation intervention: the RESOLVE score system (Risk prEdiction of Side branch OccLusion in coronary bifurcation interVEntion). JACC Cardiovasc Interv 2015;8 (1 pt A):39–46.