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Modified Flower Petal Technique

A New Technique for the Treatment of Medina Type 1.1.1 Coronary Bifurcation Lesions

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Objectives This study sought to propose a new technique for the treatment of Medina type 1.1.1 bifurcation lesions.

Background Although there are many different 2-stent techniques, the optimal strategy for patients with Medina type 1.1.1 bifurcation lesions has not yet been determined.

Methods The authors selected 30 patients who had Medina type 1.1.1 coronary bifurcation lesions. The most important characteristics of this new technique are complete coverage of the side branch (SB) ostium by stent struts and lower metallic burden at carina region. All procedures were performed using drug-eluting stents. All patients were followed up to 9 months after the intervention. Quantitative coronary angiography (QCA) analyses were performed for both the main and the side branches at baseline, after stent implantation, and at 9-month follow-up.

Results Procedural success rate was 100%. Final kissing balloon inflation could be performed in all patients. There was no major adverse cardiac events during hospital stay. Clinical and angiographic QCA follow-up was available in 28 patients (93.4%). There was no death, myocardial infarction, or stent thrombosis at 9 months follow-up. In-stent restenosis requiring reintervention was noted at the SB ostium in only 1 patient.

Conclusions This new "modified flower petal" technique has several advantages for stent implantation of Medina type 1.1.1 bifurcation lesions over the available techniques: complete coverage of the SB ostium, lower metallic burden at the carina, and excellent immediate and midterm clinical outcomes. (J Am Coll Cardiol Intv 2013;6:516–22) © 2013 by the American College of Cardiology Foundation

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Bifurcation lesions are frequent in routine practice and occur in approximately 15% of percutaneous coronary interventions (PCIs) (1,2). PCI of bifurcation lesions still represents a technical challenge. Despite the introduction of drug-eluting stents, it has been associated with low procedural success and high complication and restenosis rates (3).

Most true bifurcation lesions need 2 stents. Especially in cases of significant side branch (SB) stenosis with a large area supplied by the SB or a large SB vessel, the implantation of 2 stents at Medina type 1.1.1. bifurcation lesions should be considered (3,4). There are many different two-stent techniques, for instance, crush technique, culotte technique, T-stenting, modified T-stenting, simultaneous kissing stenting. The choice of technique depends on the angulation of the SB, the diameter of the SB and the main vessel (MV), and the lesion morphology. However, the outcomes of these stenting techniques were not shown to be superior to the provisional SB stenting (5). The optimal strategy for patients with Medina type 1.1.1 bifurcation lesions has not yet been determined. We propose a new technique for the treatment of Medina type 1.1.1 true bifurcation lesions.

Methods

Patient selection. Between January 2011 and October 2011, we selected 30 patients (17 male, 13 female; mean age 55.6 ± 11.6 years) who had Medina type 1.1.1 coronary bifurcation lesions (6). The vessel size had to be ≥2.5 mm in MV and ≥2.25 mm in SB by visual estimation in coronary angiography. Patients with acute myocardial infarction, in-stent restenotic lesions, heavily calcified lesions, high bifurcation angle (>70°), chronic total occlusion, or contraindications to prolonged use of antiplatelet agents were excluded. The local ethics committee approved the study.

Written informed consents for both the PCI procedure and participation in the study were obtained from all patients. All the patients were brought back for angiography at 9 months, which was considered part of the study method; and this information was part of the informed consent of the study.

Procedure. We have developed a new technique for the treatment of Medina type 1.1.1 true coronary bifurcation lesions, derived from flower petal stenting that was firstly defined by Kinoshita et al. (7). The most important characteristics of our technique are complete coverage of the SB ostium by stent struts and the lower metallic burden at the carina region. A large (7- or 8-F) and strong back-up support guiding catheter must be selected for this technique. Steps of this technique are illustrated in Figures 1 and 2.

The procedure starts with wiring both branches. It is necessary to pre-dilate all significantly stenosed branches. After the pre-dilation, the SB stent–MV balloon system is prepared outside of the guiding catheter. First, the plastic stent cover is pulled back slightly to expose the final proximal stent strut (Fig. 1A), and the stent delivery system balloon is inflated to 5 to 6 atm and then deflated to expand the final proximal stent strut (Fig. 1B). The MV wire is then passed through the now expanded, final proximal stent strut (Fig. 1C).

Abbreviations and Acronyms

MLD = minimal lumen diameter

MV = main vessel

PCI = percutaneous coronary intervention

QCA = quantitative coronary angiography

SB = side branch

TLR = target lesion revascularization

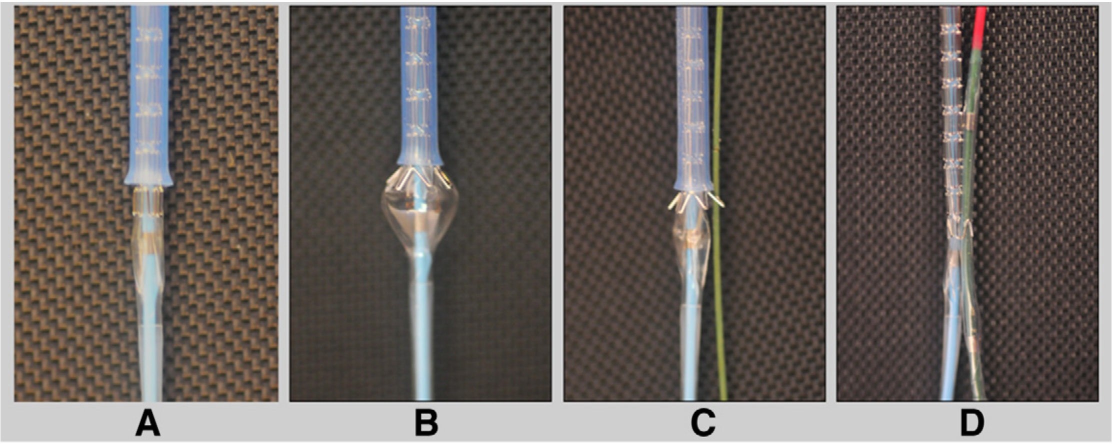

Figure 1. Preparation of the SB Stent–MV Balloon System

(A) The plastic stent cover is pulled back slightly to expose the final proximal stent strut. **(B)** The stent delivery system balloon is inflated to 5 to 6 atm and deflated. **(C)** The main vessel (MV) wire is passed through the final proximal stent strut. **(D)** The stent cover is removed and another balloon is loaded on the MV wire and centered on the last proximal stent strut. The final proximal strut of the stent is then recrimped firmly by hand. SB = side branch.

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Figure 2. Schematic Model Presentation of This New Technique

(A) The prepared side branch stent–main vessel balloon system is advanced through the guiding catheter to the lesion localization until the main vessel (MV) balloon stopped the stent. **(B)** The stent balloon is inflated and deflated. **(C)** MV balloon is inflated to provide the protruding strut contacts the wall on the opposite side. **(D)** First kissing balloon inflation is performed. **(E)** Both balloons and the side branch wire are withdrawn. **(F)** Another stent is positioned in the MV. **(G)** The MV stent is inflated. **(H)** The side branch is rewired, and final kissing balloon inflation is performed (Online Video 1).

The stent cover is removed and another, compliant balloon is loaded on the MV wire and centered on the last proximal stent strut. The final proximal strut of the stent, which was slightly dilated before, is then recrimped firmly between the index finger and the thumb (Fig. 1D). It is especially important that the operator ensures the last proximal stent strut is between the markers of the MV balloon, and the operator must be sure that there will be no slippage of the balloon as it passes through the guide. The SB stent–MV balloon system is now ready to be advanced into the lesion location. Balloon and stent sizes are selected according to the distal reference vessel size. The prepared SB stent–MV balloon system is advanced through the guiding catheter to the lesion location until MV balloon stops the advancement of the SB stent (Fig. 2A, Online Video 1). In this way, the MV balloon can prevent excessive stent advancement into the SB and provides complete coverage of the SB ostium by the stent struts. Firstly, the stent balloon is inflated and deflated (Fig. 2B). Secondly, the MV balloon is inflated (Fig. 2C). Thus, the protruding final proximal strut contacts the opposite side of the main vessel wall without breakage or deformation (Fig. 3). The first kissing balloon is then performed by simultaneously inflating the SB and the MV balloons (Fig. 2D). Both balloons and the SB wire are withdrawn (Fig. 2E), and another stent is positioned in the MV (Fig. 2F). The MV stent is inflated and deflated (Fig. 2G). The wire and balloon can easily pass through the SB ostium, because there is only 1 layer of stent strut at the SB ostium. The procedure is completed by final kissing balloon inflation (Fig. 2H).

Preparations and follow-up. All patients were pre-treated with aspirin 300 mg and clopidogrel 300-mg loading dose, followed by 75 mg daily, at least 1 day before the index procedure. During the procedure, an intra-arterial bolus of unfractionated heparin was administered at the dosage of 70 U/kg. All procedures were performed by using zotarolimus-eluting stents (Endeavor, Medtronic, Minneapolis, Minnesota), paclitaxel-eluting stents (Coraxel, Alvi Medica, Istanbul, Turkey), and sirolimus-eluting stents (Coracto, Alvi Medica). After the procedures, all patients were advised to stay on dual antiplatelet therapy for at least 1 year. Up to 9 months, all patients were followed with outpatient clinic visits or telephone contact. All patients adhered to dual antiplatelet therapy during the study period.

Definitions and clinical endpoints. Procedure success was defined as successful implantation of 2 stents in the MV and SB, causing a final residual stenosis ≤30%. Major adverse

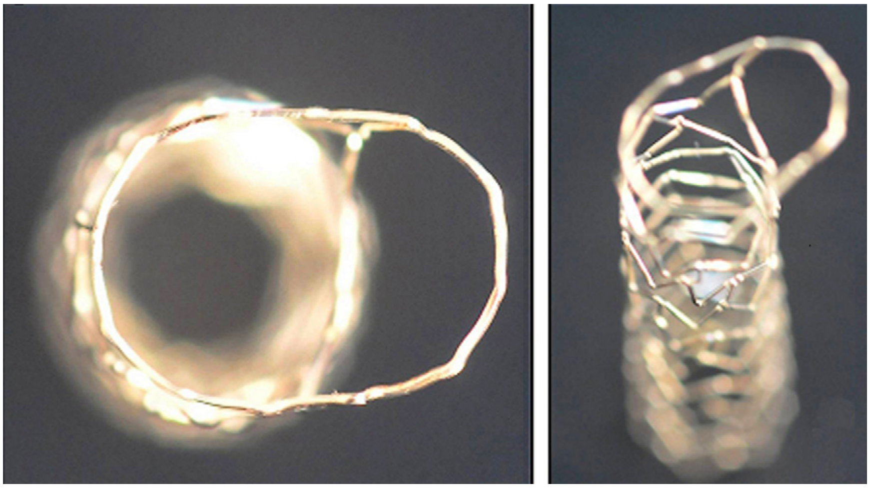

Figure 3. The Appearance of the SB Stent

The final proximal strut of the side branch (SB) stent is opened widely. There is no distortion at SB stent.

cardiac events were defined as cardiac death, acute myocardial infarction, and target lesion revascularization (TLR). TLR was defined as a repeat revascularization with a stenosis ≥50% within the stent or the 5-mm proximal or distal segments adjacent to the stent. Stent thrombosis was defined as any of the following: angiographic demonstration of stent closure or intrastent thrombosis; unexplained sudden death; or myocardial infarction without concomitant documentation of a patent stent.

Quantitative coronary angiography analysis. Quantitative coronary angiography (QCA) analyses were performed for both the main and the SB at baseline, after stent implantation and at 9-month follow-up using the computer-based edge-detection Coronary Angiography Analysis System (CAAS II, Pie Medical, the Netherlands). All analyses were performed in consensus by 2 experienced interventional cardiologists (M.G. and Z.E.) who were blinded to the patients' characteristics. Interpolated reference vessel diameter, minimal lumen diameter (MLD), and percent diameter stenosis were obtained using the guiding catheter as a scaling device from the QCA system. Late lumen loss was calculated as post-intervention minus follow-up MLD. Quantitative angiographic measurements of target lesions were made at "in-stent" zone and "in-segment" zone, which includes both stented segment and margins 5 mm proximal and distal to the stent. Binary restenosis was defined as >50% diameter stenosis of the target lesion (8).

Statistical analysis. All calculations were performed with the Statistical Package for the Social Sciences version 13.0 (SPSS, Chicago, Illinois). Continuous variables were expressed as mean ± SD and compared with paired Student *t* test. Categorical variables were presented as counts and percentages and compared by the McNemar test. A p value <0.05 was considered significant.

Results

The mean age of patients was 55.6 ± 11.6 years, and 17 (56.7%) of patients were male. The most common PCI indication was stable angina (86.7%), and 14 (46.7%) patients had diabetes mellitus. The lesion localization was distal left main coronary artery in 2 (6.7%), the left anterior descending artery–diagonal branch level in 26 (86.7%), and the circumflex artery–obtuse marginal branch level in 2 (6.7%). The bifurcation angle in all patients was under 70°. Table 1 shows baseline clinical and angiographic characteristics of patients.

Table 2 shows procedural characteristics. Pre-dilation of MV and SB was performed in 17 (56.7%) and 21 (70%) patients, respectively. The final kissing balloon inflation could be performed in all patients. Procedural success rate of the modified flower petal technique was 100%. There was no major adverse cardiac event during hospital stay. In 4 (13.4%) patients, we could not advance the SB stent–MV balloon system to the lesion location because the wires were twisted together. In those patients, advancement of the SB stent–MV balloon system was stopped, and the SB wire was pulled back until the tip of the stent balloon to untwist the wires and recross into the SB. The SB stent–MV balloon system could then be successfully advanced to the lesion location in all patients.

Angiographic QCA follow-up was available in 28 patients (93.4%). QCA analysis results for both the MV and the SB at baseline, after procedure and 9 months follow-up are summarized in Table 3.

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Table 1. Baseline Clinical and Angiographic Characteristics of Patients (N = 30)

Age, yrs	55.6 ± 11.6
Sex	
Male	17 (56.7)
Female	13 (43.3)
Hypertension	19 (63.4)
Diabetes	14 (46.7)
Hypercholesterolemia	16 (53.4)
Smoking	16 (53.4)
Family history of CAD	11 (36.7)
Prior myocardial infarction	2 (6.7)
Prior PCI	4 (13.4)
Prior bypass surgery	0 (0.0)
PCI indication	
Unstable angina	4 (13.4)
Stable angina	26 (86.7)
Lesion location	
LMCA	2 (6.7)
LAD-D	26 (86.7)
CX-OM	2 (6.7)
Bifurcation angle <70°	30 (100.0)

Values are mean ± SD or n (%).
CAD = coronary artery disease; CX-OM = circumflex coronary artery and obtuse marginal branch; LAD-D = left anterior descending coronary artery and diagonal branch; LMCA = left main coronary artery; PCI = percutaneous coronary intervention.

Clinical follow-up at 9 months was available in 28 (93.4%) of patients. There was no death, myocardial infarction, or subacute or late stent thrombosis at 9 months follow-up. In 1 patient, in-stent restenosis requiring reintervention was noted at the SB ostium (Fig. 4). That patient also had exertional angina. Thus, only 1 patient showed major adverse cardiac event and TLR by PCI (Table 4).

Table 2. Procedural Characteristics (N = 30)

Pre-dilation	
Main vessel	17 (56.7)
Side branch	21 (70.0)
Main vessel stent	
Zotarolimus-eluting stent	11 (36.7)
Paclitaxel-eluting stent	14 (46.7)
Sirolimus-eluting stent	5 (16.7)
Side branch stent	
Zotarolimus-eluting stent	8 (26.7)
Paclitaxel-eluting stent	15 (50.0)
Sirolimus-eluting stent	7 (23.3)
Stent diameter, mm	
Main vessel	3.36 ± 0.27
Side branch	2.74 ± 0.33
Stent length, mm	
Main vessel	23.6 ± 5.4
Side branch	15.3 ± 5.3
Final kissing balloon inflation	30 (100.0)
Procedural success	30 (100.0)
Periprocedural myocardial infarction	0 (0.0)
Acute stent thrombosis (%)	0 (0.0)
In-hospital major adverse cardiac event (%)	0 (0.0)

Values are mean ± SD or n (%).

Table 3. Quantitative Coronary Angiographic Analysis of Patients

	Main Vessel	Side Branch	*p* Value
Baseline (N = 30)			NS
RVD, mm	3.38 ± 0.33	2.72 ± 0.26	
MLD, mm	0.82 ± 0.41	0.80 ± 0.36	
Diameter stenosis, %	76.1 ± 12.2	70.8 ± 13.0	
Post-procedure (N = 30)			
RVD, mm	3.34 ± 0.32	2.67 ± 0.30	<0.001
MLD, mm	2.89 ± 0.25	2.20 ± 0.23	<0.001
Diameter stenosis, %	12.8 ± 3.1	17.4 ± 4.9	
Acute gain, mm	2.07 ± 0.48	1.40 ± 0.35	
Follow-up (n = 28)			
RVD, mm	3.39 ± 0.31	2.65 ± 0.31	<0.001
MLD, mm	2.68 ± 0.33	1.87 ± 0.36	<0.001
Diameter stenosis, %	20.8 ± 6.5	29.2 ± 9.4	NS
Late lumen loss, mm	0.21 ± 0.10	0.33 ± 0.24	
Restenosis	0 (0.0)	1 (3.6)	

Values are mean ± SD or n (%).
MLD = minimum lumen diameter; RVD = reference vessel diameter.

Discussion

The most important characteristics of the modified flower petal technique were complete coverage of the SB ostium, lower metallic burden at carina, high success rate of the final kissing balloon inflation, and easy to apply. This study also showed that the modified flower petal technique offered high immediate procedural success and excellent 9-month outcome in patients with true bifurcation lesion (Medina type 1.1.1).

Despite the widespread application of drug-eluting stents, restenosis at the ostium of the SB is still unresolved regardless of the variety of bifurcation stenting methods. One of the most important reasons of SB ostial restenosis is incomplete coverage (8,9). Current techniques such as conventional T-stenting often result in incomplete coverage of the SB ostium, which may impair outcome (10). Colombo et al. (11) described the crush technique, which offers complete coverage of the SB ostium, in 2003. Using this technique, the SB restenosis was reduced to about 17% from 26% (12,13). However, the 3 stent layers in the proximal part of the bifurcation lesion in the crush technique predispose to incomplete stent apposition, potentially leading to thrombotic complications. Furthermore, the success of the crush technique depends on achieving final kissing balloon inflation, which is potentially difficult because the wire and the balloon have to cross double layers of stent at the SB orifice. The rate of final kissing balloon inflation in this

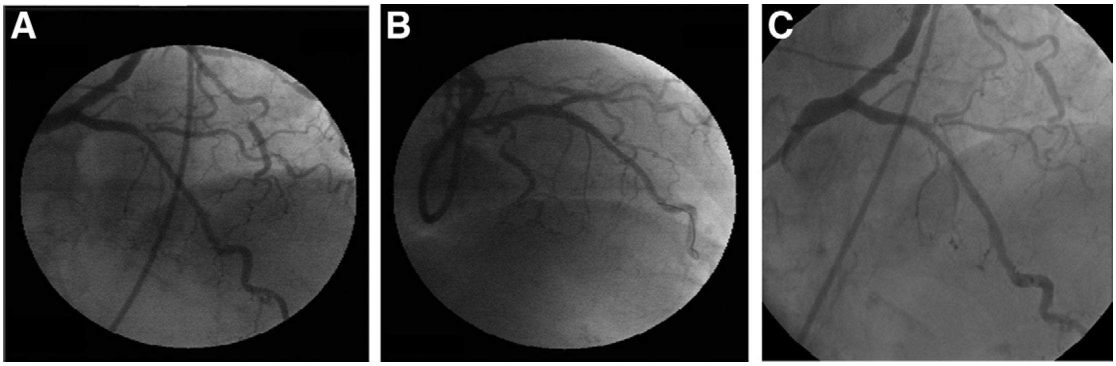

Figure 4. Serial Angiographic Appearance of Patient With Side Branch Restenosis

(A) Baseline coronary angiography. There is a severe lesion in the mid-left anterior descending coronary artery and a significant lesion in the diagonal branch. **(B)** Final result after kissing balloon dilation. **(C)** The 9-month angiographic follow-up. There is a significant stent restenosis in the ostium of the diagonal branch.

technique varies between 64% and 75% (13–15). Early and long-term results after PCI are not satisfactory in patients with failure of final kissing balloon inflation (13). To overcome this problem, the minicrush stenting was devised to improve the success rate of final kissing balloon inflation. Although significantly improved, the success rate of final kissing balloon inflation using minicrush stenting still cannot be accomplished in some patients (16). In the modified flower petal technique, first, the SB stent is positioned and inflated, but excessive stent advancement into the SB is prevented by the MV balloon (anchor balloon) (Fig. 2A). In this way, complete coverage of the SB ostium by stent struts is provided. The MV balloon is then inflated, and the protruding strut contacts the wall on the opposite side. Another stent is positioned and inflated in the MV (Fig. 2E). Due to only 1 layer of stent struts at the SB ostium, we could perform a final kissing balloon inflation in all cases without difficulty.

Another technique that provides complete coverage of the SB ostium is the culotte technique. The culotte technique offers the advantage over the crush technique of having only 2 stent layers in the proximal part of the bifurcation lesion, potentially leading to a lower risk of incomplete stent apposition. In addition, due to 1 layer of stent struts at the SB orifice, final kissing balloon inflation is easier after the culotte technique than after the crush technique (17). Culotte stenting has better long-term results (17,18). However, an important limitation of the culotte technique is its dependence on maximal stent cell diameter. In this technique, if closed-cell stents are used for bifurcation lesion with a larger SB (>3 mm), the inner stent cannot be fully expanded, leading to narrowing, like a napkin ring; therefore, open-cell stents must be preferred for the culotte technique (19,20). Other disadvantages of the culotte technique are a high concentration of metal with a double-stent layer at the carina and in the proximal part of the bifurcation, and the necessary rewiring of both branches through the stent struts can be difficult and time consuming. In the modified flower petal technique, open-cell stents must also be preferred for preventing the "napkin ring" phenomenon. This technique offers advantages over the culotte technique, such as lower metallic burden with only 1 stent layer in the proximal part of the bifurcation and the need to rewire only the SB through the stent struts.

Recently, Kinoshita et al. (7) devised a new technique for stenting bifurcation lesions, flower petal stenting. This technique was initially very difficult and complex, and then it was relatively simplified by the authors. The most important advantages of flower petal stenting are complete coverage of the SB ostium and the lower metallic burden in the proximal part of the bifurcation lesion, which contains only 1 layer of stent struts. One of the most important differences between our technique and flower petal stenting is the number of guidewires. The flower petal technique necessitates 3 guidewires (2 in the MV and 1 in the SB), and twisting of the guidewires within the anatomy frequently occurs. Therefore, advancement of the SB stent–MV balloon system to the bifurcation region together can be prevented by twisted wires (7). It is possible to resolve this problem by withdrawing 1 of the guidewires inside the balloon and then going back into the SB. But this process

Table 4. Clinical Follow-Up at 9 Months (n = 28)

Death	0 (0.0)
Myocardial infarction	0 (0.0)
Subacute stent thrombosis	0 (0.0)
Late stent thrombosis	0 (0.0)
Target lesion revascularization	1 (3.6)
Cumulative major adverse cardiac events	1 (3.6)

Values are n (%).

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can prolong or complicate the procedure. In our technique, we used only 2 wires (1 in the MV and another 1 in the SB), and the incidence of twisting of guidewires is probably lower in our technique than in flower petal stenting. In this study, twisting of wires was noted in only 4 (9.8%) patients. The number of balloons and steps of the procedure were also lower in our technique. Thus, the cost, time, and complexity of the procedure are lower in our technique than in flower petal stenting.

In our experience, the other important disadvantage of our technique and flower petal stenting is decreased flexibility of SB stent during advancement of both SB stent and MV balloon together. Therefore, these techniques are not suitable for tortuous lesions.

Study limitations. It is a single-center experience with a relatively small sample size and was not compared with provisional stenting or other 2-stent bifurcation techniques, such as culotte stenting, minicrash, or sleeve techniques.

Conclusions

This new "modified flower petal" technique has several advantages for stent implantation of Medina type 1.1.1 bifurcation lesions over the conventional techniques and flower petal stenting: much easier, complete coverage of the SB ostium; lower metallic burden at carina; high success rate of the final kissing balloon inflation; and excellent immediate and midterm clinical outcomes. The modified flower petal technique appears to be a feasible and safe novel technique in treating Medina type 1.1.1 bifurcation lesions. A multicenter prospective randomized study comparing our technique with other techniques would be necessary to confirm the initial very promising results obtained in this single-center study.

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Key Words: bifurcation lesions ■ side branch ■ two-stent techniques.

APPENDIX

For accompanying videos, please see the online version of this article.