

# Double Kissing Mini-Culotte Stenting in Unprotected Distal Left Main Bifurcation Under Optical Coherence Tomography Guidance: Immediate and Short-Term Outcomes



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Culotte stenting is an effective strategy for left main coronary artery bifurcation lesions. Increased side branch ostial restenosis is the main drawback of culotte stenting. This is due to a napkin ring or potential gap produced at the ostium of the side branch. A bench study by Toth et al<sup>11</sup> has shown that additional sequential kissing balloon dilation before main vessel stenting can prevent this deformity. We report immediate and short-term results of double kissing (DK) mini-culotte stenting with a 1-year angiographic follow-up. Between March 2020 and December 2022, 45 patients with distal left main (LM) disease underwent DK mini-culotte stenting at our center under optical coherence tomography guidance. Of 45 patients (male: 35 (77.77%); mean age:  $63.67 \pm 4.94$  years), chronic coronary artery syndrome was present in 26 (57.8%) and unstable angina in the remainder. All lesions were Medina (1,1,1), (0,1,1), or (1,0,1), with a median Synergy between Percutaneous Coronary Intervention with Taxus and Cardiac Surgery (SYNTAX) score of 28 (interquartile range 23 to 29). All procedures were technically successful with no adverse clinical events (death, myocardial infarction, or stent thrombosis). Under optical coherence tomography guidance, adequate minimal stent area of  $13.28 \pm 0.77$  mm<sup>2</sup>,  $8.25 \pm 0.29$  mm<sup>2</sup>, and  $7.54 \pm 0.45$  mm<sup>2</sup> was achieved in LM, left anterior descending, and left circumflex, respectively. Adequate stent expansion of >80% was achieved in all cases. At the end of 1 year, the incidence of major adverse cardiovascular events was 2.2%. Furthermore, restenosis of the side branch developed in 1 patient (2.2%), which was managed conservatively. DK mini-culotte stenting in the distal LM bifurcation has shown promising results and is effective in preventing side branch stent deformation and its sequelae of in-stent restenosis. © 2024 Elsevier Inc. All rights are reserved, including those for text and data mining, AI training, and similar technologies. (Am J Cardiol 2024;229:47–55)

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Bifurcation percutaneous coronary intervention (PCI) remains a significant challenge for interventional cardiologists, and it comprises approximately 15% to 20% of all coronary interventions.<sup>1</sup> Despite advancements in stenting techniques, determining the best approach remains a complex decision because each bifurcation lesion has its characteristics and unique morphology.<sup>2,3</sup>

Provisional stenting is still regarded as the treatment of choice for simple coronary artery bifurcation lesions.<sup>2–4</sup> However, its effectiveness might be limited in more

complex coronary artery anatomies, for which an upfront 2-stent strategy is considered a better option.<sup>5,6</sup>

Double kissing (DK) crush is considered a preferred technique for distal left main (LM) true bifurcation lesion.<sup>7,8</sup> The major drawback of the culotte technique that causes the superiority of the DK-crush technique was increased incidence of in-stent restenosis (ISR) at the ostium of the side branch (SB) on follow-up, necessitating target lesion revascularization (TLR).<sup>7,8</sup> Bench testing and intravascular ultrasound (IVUS) analysis have suggested that napkin ring formation or potential gap at the ostial SB leads to increased ISR and TLR.<sup>9,10</sup> Toth et al<sup>11</sup> in a bench study have shown that additional sequential kissing balloon dilation before the main vessel (MV) stenting can prevent these deformities and probably its sequelae of increased SB ostial restenosis.

We report immediate and short-term results of DK mini-culotte stenting of distal LM performed at our institute under optical coherence tomography (OCT) guidance with 1-year angiographic follow-up results.

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## Methods

This is a single-center prospective cohort study conducted from March 2020 to December 2022. After institutional ethical clearance, patients with unprotected distal LM bifurcation disease underwent DK mini-culotte stenting with a predefined protocol, as mentioned later, and were followed up prospectively for 1 year. The study complied with the Declaration of Helsinki. The inclusion criteria were (1) patient aged  $\geq 18$  years, (2) diameter narrowing  $\geq 50\%$  in both left anterior descending artery (LAD) and left circumflex artery (LCx), (3) Medina class 1,1,1; 0,1,1; or 1,0,1, (4) vessel size  $\geq 2.75$  mm in the LAD and  $\geq 2.5$  mm in the LCx by visual estimation on coronary artery angiography, (5) SB stenosis  $\geq 70\%$  with lesion length  $\geq 10$  mm, (6) difference between 2 daughter vessels of  $\leq 0.5$  mm, and (7) LM carina angle of  $\leq 70^\circ$ . The exclusion criteria were (1) severe left ventricular dysfunction with ejection fraction  $< 30\%$ , (2) acute myocardial infarction (MI) within 24 hours, (3) cardiogenic shock, (4) patient with LM disease having significant thrombus, (5) contraindications to prolonged use of dual antiplatelet drugs, (6) life expectancy  $< 1$  year, and (7) having any clinical conditions that would interfere with medication compliance on long-term follow-up. All patients provided informed consent for the procedure, and subsequent data were collected and analyzed.

We used the femoral access in all cases. All patients received a loading dose of aspirin (300 mg) and clopidogrel/ticagrelor/prasugrel (300 mg/180 mg/60 mg)  $\geq 2$  hours before the procedure. After the procedure, all patients continued aspirin (75 mg) and clopidogrel (75 mg) or ticagrelor (90 mg twice daily) or prasugrel (10 mg) for  $\geq 12$  months according to American College of Cardiology/American Heart Association guidelines.<sup>12</sup> Drug-eluting stents such as Xience Prime (Abbott Vascular, California) (everolimus-eluting) stents or Ultimaster (Terumo, Shizuoka, Japan) (sirolimus-eluting) stents were deployed as per the availability. After a coronary artery angiogram, preprocedural OCT was performed using a Dragonfly Optis catheter (Abbott Vascular) to assess the morphology of the lesion, length of the lesion, minimum luminal area (MLA), and diameter of the normal vessel distal to the diseased segment. The external elastic lamina (EEL)-to-EEL diameter of the distal reference segment of the artery was assessed, and the size of the stent was rounded down to the nearest whole number.<sup>13</sup> If the distal reference EEL cannot be identified, the stent diameter should be chosen using the mean luminal diameter at the distal reference, rounded up to the next stent size. We defined achieving optimal coverage of coronary artery lesions as ensuring that the 5-mm edge zones neighboring the stent exhibited  $\leq 30\%$  stenosis. Moreover, these zones should not display major lipid plaque or plaque rupture and should be free from any visible edge dissection observed on angiography. The major steps of DK mini-culotte stenting were as follows (Figure 1): (1) both the vessels LAD and LCx were wired; (2) baseline OCT assessment was performed before predilation (if OCT catheter was not able to negotiate, OCT was performed after predilation); (3) both the vessels were predilated; (4) the first stent was deployed from the LCx to the LM, with

minimal protrusion of 2 to 3 mm into the LM; (5) the first proximal optimization technique (POT) of the stent in LM was performed; (6) the LAD was entered after crossing the previously implanted stent at the most distal strut, and it was confirmed with OCT. If required, the struts were opened with a smaller balloon; (7) next, the first sequential kissing dilation was performed using balloons fitted to the diameter of the distal branches. First, the LCx balloon was inflated to maintain the stent architecture, followed by LAD balloon inflation. Then, both the balloons were simultaneously deflated; (8) after the first kiss, the LCx wire was removed, and the LAD stent was deployed cross-over from LAD to LM at nominal pressure; (9) the second POT of the stent in LM was performed; (10) the wire was recrossed into LCx through the most distal strut of the LAD stent, and it was confirmed with OCT. If required, the struts were opened with a smaller balloon; (11) next, the second sequential kissing balloon inflation was performed, using balloons fitted to the distal branch diameters. The LAD balloon was inflated first to maintain its architecture, followed by the LCx balloon, with simultaneous deflation; (12) the third POT in LM was performed; (13) finally, a postprocedure OCT run was taken to assess apposition, expansion, and minimal stent area (MSA), and exclude distal edge dissection.

If the OCT run showed suboptimal MSA or significant malapposition, additional sequential kissing balloon dilation with a larger noncompliant balloon was performed to achieve the desired MSA.

Demographic data including age, gender, cardiovascular risk factors, medical history, and clinical presentation were noted. Details of the affected lesions and implanted stents were recorded. Adverse events were monitored during the hospital stay. Subsequently, patients were clinically examined after 1, 6, and 12 months. A mandatory coronary artery angiogram is performed if a patient develops ischemic symptoms or after 12 months. Quantitative coronary artery analysis was conducted before and after the procedure, and at 1-year follow-up.

The primary end point was a procedural success as defined by successfully delivering and deploying coronary artery stents at the intended coronary artery bifurcation lesions as per the DK mini-culotte technique. It also involved withdrawing the stent delivery systems with  $< 20\%$  residual stenosis observed angiographically and achieving Thrombolysis In MI grade 3 flow in both the MV and SB vessels. This success was determined without the incidence of death, MI, or repeat revascularization of the treated lesions during the index hospitalization. The secondary end point was an incidence of major adverse cardiac events (MACEs) at 1-year follow-up. MACE was defined as a combination of cardiac death, MI, and any repeat revascularization in the target vessel. Unless stated otherwise, all deaths were considered cardiac in origin. MI was identified by the development of new ischemic ST-T changes or pathological Q-waves in  $\geq 2$  contiguous electrocardiogram leads or by an elevation of cardiac troponin levels  $> 5$  times the normal value.<sup>14</sup> Target vessel revascularization encompassed any repeat revascularization procedure, whether percutaneous or surgical, in the target vessel. Moreover, events classified as stent thrombosis by the Academic Research

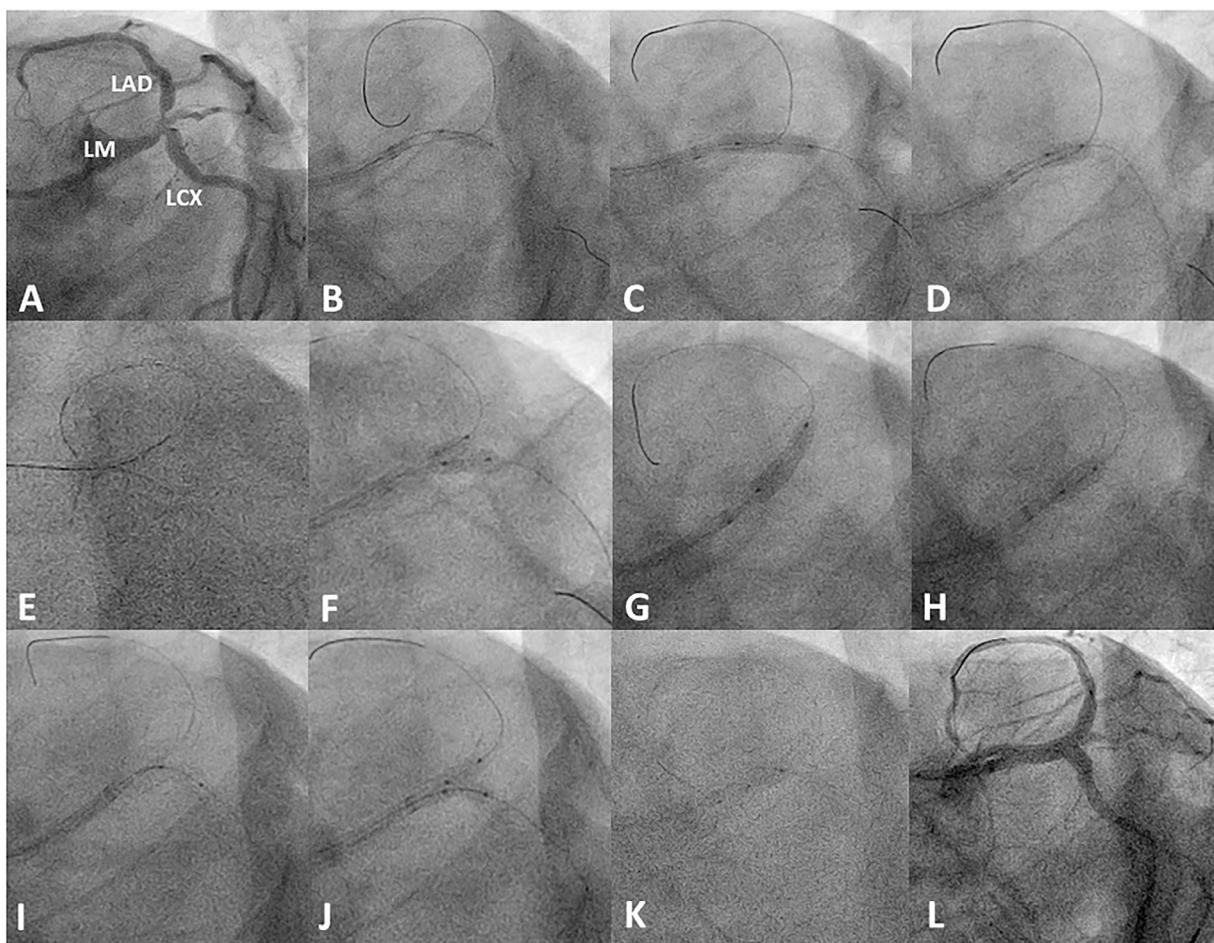


Figure 1. Schematic description of DK-culotte stenting technique through a transfemoral approach. Coronary artery angiogram (A) showed Medina 1,1,1 distal LM bifurcation lesions; both branches were wired, and the LCx was predilated (B); a 3.5 × 18-mm Xience Prime (Abbott Vascular) stent (C) was inflated in the LCx with 2-to-3-mm protrusion into LM; first POT was performed in LM with 4 × 6 Sprinter noncompliant balloon (D); LAD artery was rewired (E) through the distal strut of the stent; first kissing (F) was performed sequentially; LCx balloon was inflated first to maintain the stent architecture, followed by LAD balloon inflation, and the deflation was simultaneous; next, the LCx wire was removed, and a 3.5 × 18-mm Xience Prime™ (Abbott Vascular) stent (G) was deployed from LM to LAD; second POT (H) was conducted in LM with 4 × 6 Sprinter noncompliant balloon; LCx was rewired (I) through the distal strut of the LAD stent and struts opened with smaller balloon; second kissing (J) was performed sequentially; the LAD balloon was inflated first to maintain the stent architecture, followed by LCx balloon inflation, and the deflation was simultaneous; as a last step, the third POT was performed (K); the final result was acceptable (L).

Consortium were considered an additional safety end point.<sup>15</sup> It was classified as “definite” if angiographically detected, “probable” in cases when the patient experienced an MI related to the target vessel or died owing to a coronary artery event within the initial 30 days, and “possible” if any unexplained death occurred between 30 days after the index procedure and the final follow-up.<sup>15</sup>

On OCT, the expansion was considered successful if the MSA/reference MLA was  $\geq 80\%$  in both proximal and distal stent sections as per the LEMON study (LEft Main Oct-guided iNterventions) criteria<sup>16</sup> without significant stent malapposition. Malapposition was defined as stent struts clearly separated from the vessel wall without any tissue behind the struts, with a distance from the adjacent intima of  $\geq 0.2$  mm and not associated with any SB.<sup>17</sup> Malappositions were further classified as major if associated with unacceptable stent expansion and minor if associated with acceptable stent expansion.<sup>17</sup> The significant edge dissection on OCT was defined as  $\geq 60^\circ$  of the circumference of

the vessel at the site of the dissection and  $\geq 3$  mm in length when additional stent implantation was recommended unless anatomically prohibitive.<sup>17</sup>

All the statistical analyses were performed with SPSS software (version 24.0, SPSS, IBM Corporation, Armonk, New York). All categorical variables were expressed as counts (percentage, %) with the number of patients as denominators; continuous variables were expressed as mean  $\pm$  SD or as median with interquartile range (IQR) (twenty-fifth and seventy-fifth percentiles).

## Results

The baseline clinical characteristics of the patients are listed in Table 1. Of the total 45 patients, 35 were male (77.77%), and the mean age was  $63.96 \pm 4.79$  years. Chronic coronary artery syndrome was the clinical presentation in 26 subjects (57.8%) and unstable angina in the remainder. Hypertension was present in 26 patients

Table 1  
Baseline characteristics of the patients (n = 45)

Population characteristics	
Age	63.96±4.79 years
Male	35(77.77%)
Female	10(22.33%)
<b>Comorbidities</b>	
Hypertension	26 (57.8%)
Diabetes mellitus	22 (48.89%)
Smoking	20 (44.44%)
Dyslipidemia	4 (8.9%)
Serum creatinine (mg/dL)	1.07± 0.19
Peripheral vascular disease	2(4.44%)
Previous PCI	4(8.89%)
Ejection fraction, (%)	54.56±6.73%
<b>Clinical presentation</b>	
CCS	26(57.8%)
UA	19(42.2%)

Values are mean ± SD or n (%).

CCS = chronic coronary syndrome; UA = unstable angina.

(57.8%), and type 2 diabetes mellitus was present in 22 patients (48.89%). The ejection fraction at baseline was 54.56% ± 6.73%.

Angiographic data and procedural details are listed in Tables 2 and 3. The quantitative coronary analysis findings before and after the procedure and at 1-year follow-up are summarized in Supplementary Table 1.

All patients underwent distal LM bifurcation stenting, with 30 patients (66.67%) having Medina 1,1,1 bifurcation disease and a median Synergy between Percutaneous Coronary Intervention with Taxus and Cardiac Surgery score of 28 (IQR 23 to 29). All procedures were performed through femoral access using a 7-F arterial sheath in 35 patients (77.78%)s and a 6-F sheath in the rest. Lesions were predilated using conventional balloons in 88.89% and cutting balloons in 11.11% of cases. All procedures were performed as per the prespecified protocol without deviation, with the first sequential kiss and final sequential kiss being

Table 2  
Lesion characteristics and procedural risk scores (n = 45)

Variable	
<b>Number of vessels involved</b>	
Single vessel	0
Double vessel	39(86.67%)
Triple vessel	6(13.33%)
<b>Lesion type</b>	
Medina 1,1,1	30(66.67%)
Medina 0,1,1	13(28.89)
Medina 1,0,1	2(4.44%)
Angle between LAD and LCx	63.78±6.43
<b>Plaque features</b>	
B2/C type lesion	100(100%)
Total occlusion	0
Calcification	10(22.22%)
SYNTAX score, median (IQR)	28(IQR=23-29)

Values are mean ± SD or n (%).

LAD = left anterior descending; LCx = left circumflex; SYNTAX = Synergy between Percutaneous Coronary Intervention with Taxus and Cardiac Surgery.

Table 3  
Procedural detail (n = 45)

Variable	
<b>Artery sheath</b>	
6F	10(22.22%)
7F	35(77.78%)
<b>Femoral Access</b>	
Prelesion modification in LAD	45(100%)
Cutting balloon in LAD	5(11.11%)
Prelesion modification in LCx	45(100%)
Cutting balloon in LCx	2(4.44%)
OCT	45(100%)
siKBI	45(100%)
fKBI	45(100%)
Final POT	45(100%)
Number of stents used	3.11±0.6
LAD	1.96±0.42
LCx	1.11±0.31
<b>Total stent length (mm)</b>	
LAD	45.4±13.25
LCx	24.2± 8.64
<b>Stent diameter (mm)</b>	
LAD	3.44± 0.24
LCx	3.21± 0.25
<b>Stent type</b>	
EES (Xience)	12(26.67%)
SES (Ultimaster)	33(73.33%)
Procedural time (min)	54.69±15.61
Total fluoroscopy time (min)	22.07±4.52
Contrast volume (ml)	144.22±8.82
<b>Angiographic success</b>	
LAD	45(100%)
LCx	45(100%)
CIN	0

Values are mean ± SD or n (%).

CIN = contrast-induced nephropathy; EES = everolimus-eluting stent; fKBI = final kissing balloon inflation; LAD = left anterior descending; LCx = left circumflex; OCT = optical coherence tomography; POT = proximal optimization technique; SES = sirolimus-eluting stent; siKBI = sequential initial kissing balloon inflation.

successfully performed in all the subjects; 33 patients (73.33%) received Ultimaster™ (sirolimus-eluting, Terumo) whereas others received Xience Prime (everolimus-eluting, Abbott Vascular) stents. A mean of 3.11 ± 0.6 stents was used per patient, with 1.96 ± 0.42 stents in LAD and 1.11 ± 0.31 in LCx. The mean stent length was 45.4 ± 13.25 mm and 24.2 ± 8.64 mm in LAD and LCx, respectively, whereas the mean stent diameter was 3.44 ± 0.24 mm and 3.21 ± 0.25 mm in LAD and LCx, respectively. The mean procedure time was 54.69 ± 15.61 minutes whereas the fluoroscopy time was 22.07 ± 4.52 minutes. The procedural success rate was 100%, with no cases of periprocedural complication. No incidence of contrast-induced nephropathy was reported. A stent fracture developed in 1 patient (2.2%) while the first sequential kissing balloon inflation was being performed after deployment of the SB stent, and that was successfully managed by excluding the fracture segment with MV stent (Supplementary Video 1).

All procedures were performed under OCT as per the protocol, and the OCT data are listed in Table 4. Most of the patients, 29 (64.44%), had mixed morphology plaque.

Table 4

OCT characteristics	
Lesion characteristics	
Lipid plaque	3(6.67%)
Calcified plaque	5(11.11%)
Fibrous plaque	8(17.78%)
Mixed plaque	29(64.44%)
Thrombus	4(8.89%)
<b>Pre-PCI analysis</b>	
<b>Minimal lumen area</b>	
LAD	2.24± 0.29
LCx	1.83± 0.26
<b>Lesion length</b>	
LAD	39.8± 12.72
LCx	19.4± 6.64
<b>Area stenosis</b>	
LAD	88%(72-94)
LCx	84%(74-90)
<b>Reference EEL-EEL diameter</b>	
LM	4.25± 0.48
LAD	3.28± 0.27
LCx	3.08± 0.2
<b>Final post-PCI analysis</b>	
<b>Minimal stent area, mm<sup>2</sup></b>	
LM	13.28 ± 0.77
POC	13.52 ± 0.78
LAD ostium	8.25 ± 0.29
LCx ostium	7.54 ± 0.45
<b>Expansion, %</b>	
LM	91(83-101)
LAD ostium	104(91-114)
LCx ostium	94(88-104)

EEL = external elastic lumina; LAD = left anterior descending; LCx = left circumflex; LM = left main; PCI = percutaneous coronary intervention; POC = polygon of confluence.

The mean lesion length and MLA were  $39.8 \pm 12.72$  mm and  $2.24 \pm 0.29$  mm<sup>2</sup> in LAD and  $19.4 \pm 6.64$  mm and  $1.83 \pm 0.26$  mm<sup>2</sup> in LCx, respectively. The OCT run had confirmed successful distal strut crossing of LCx stent in 38 patients (84.44%) at the first attempt whereas in the remaining 7, we had to recross the LCx stent through the distal strut. In all patients, optimal stent coverage was seen in LAD and LCx, with diameter stenosis <30% of the reference diameter. The proximal stent edge was visualized in all patients. Proximal edge dissection was not seen in any case whereas distal edge dissection was noted in 7 patients (15.56%); however, significant distal edge dissections were noted in only 2 patients (4.44%), which were successfully managed with the deployment of an additional stent in each case. Minor malapposition with acceptable stent expansion was seen in 4 patients (8.88%) in the post-PCI run, successfully managed with poststenting noncompliant balloon dilation. Final analysis after PCI reveals MSA of  $13.28 \pm 0.77$  mm<sup>2</sup> in LM,  $8.25 \pm 0.29$  mm<sup>2</sup> in LAD, and  $7.54 \pm 0.45$  mm<sup>2</sup> in LCx. All patients achieved >80% expansion at both proximal and distal stents (Supplementary Videos 2 and 3).

All patients were followed up for 1 year and underwent follow-up angiography at the initial ischemic symptom or 1 year. The median follow-up period was 18 months (IQR 12 to 24 months). MACE at the end of 1-year follow-up was seen in only 1 patient (2.2%), who had nonfatal MI, but

there was no incidence of cardiac death or target vessel revascularization (TVR). This patient had inferior wall MI approximately 8 months after the procedure, which was managed successfully by PCI to the right coronary artery. In 1 patient (2.2%), 50% ISR was seen at the SB ostium (Figure 2), but because he was asymptomatic and his exercise treadmill test result was negative, he was left on medical management. Angiographic follow-up in the remaining patients revealed normal stent patency at 1 year. There was no stent thrombosis event reported during follow-up. The detailed study outcomes are listed in Table 5.

## Discussion

Stenting of bifurcation lesions poses a significant challenge to the interventional cardiologist. Each bifurcation differs not just in its structural aspects such as plaque distribution, branch angles, and size but also in ways its anatomy may change during treatment, such as plaque shift or potential dissections.<sup>1-3</sup> This individuality means there is no universal approach that fits all bifurcations.<sup>1-3</sup>

Multiple randomized control trials and meta-analyses have shown that the provisional single-stent approach is superior and should be the preferred strategy in patients with simple bifurcation lesions.<sup>2-5</sup> However, it is not universally applicable in complex bifurcation lesions as defined by the DEFINITION study (Definitions and impact of complex bifurcation lesions on clinical outcomes after percutaneous coronary Intervention using drug-eluting stents) criteria.<sup>6</sup> In these patients, the DK-crush strategy is the preferred modality, which can be briefly described as follows: stenting SB, balloon crush, first kissing balloon inflation, stenting MV, and final kissing balloon inflation.<sup>3,7,8</sup> The specificity of this technique, as compared with the conventional crush technique, is the performance of additional kissing balloon dilation of the SB before the MV stenting, which prevents the deformation of the SB stent.<sup>7</sup> The DK-crush technique thus ensures optimal coverage of SB ostium, minimal distortion of SB stent, and the least possible overlap between MV and SB stent.<sup>7,8</sup> However, sometimes, difficulty in crossing the SB and longer procedure time come as a hindrance to the ideal line of management for bifurcation strategy.<sup>18</sup> Moreover, in cases with an acute SB angle, a wider protrusion of the SB stent into MV leads to an extended neocarina formation.<sup>19</sup> If the bifurcation angle is >70°, it acts as an independent predictor of future MACE because of insufficient expansion of the SB stent even after kissing balloon dilation.<sup>20</sup> However, clinical follow-up of DK crush of 3 years is available to support its superiority to other techniques. In the DKCRUSH (DK Crush Versus Culotte Stenting for the Treatment of Unprotected Distal Left Main Bifurcation Lesions)-III study,<sup>7</sup> the 3-year follow-up in patients with complex distal LM bifurcation lesions revealed higher rates of MACE with culotte than in patients with DK crush (51.5% vs 15.1%,  $p < 0.001$ ), mostly driven by increased TLR (36.4% vs 7.5%,  $p < 0.001$ ) or TVR (40.9% vs 11.3%,  $p < 0.001$ ). Collectively, these results suggest that DK crush might offer better procedural safety than does culotte stenting.

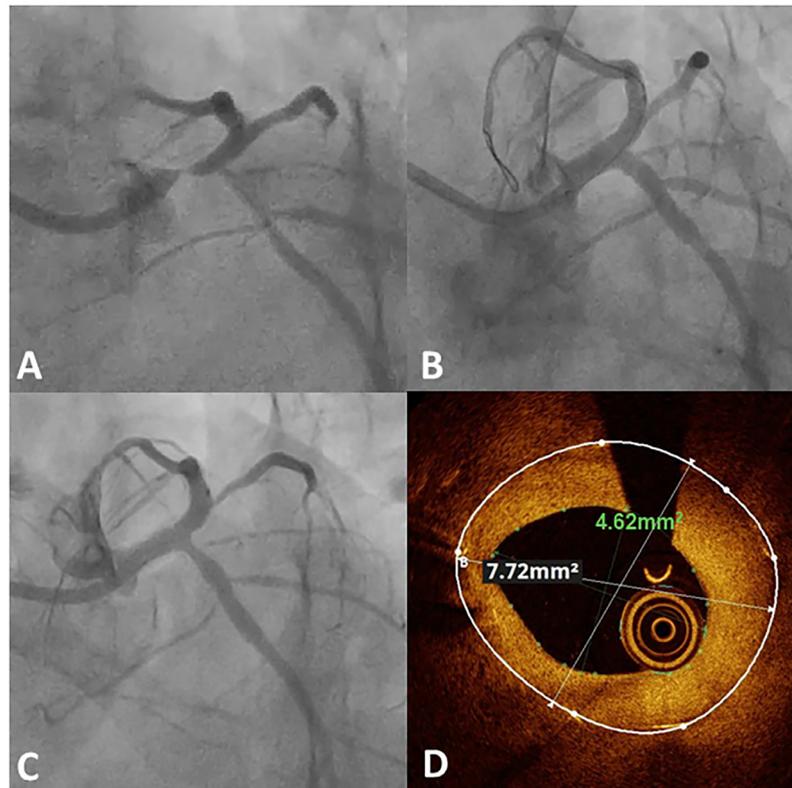


Figure 2. Coronary artery angiogram (A) showed a Medina 1,1,1 distal LM bifurcation lesion; final result (B) after DK-culotte stenting; coronary artery angiogram at 1-year follow-up (C) showing 50% restenosis of the LCx ostium; OCT image at the LCx ostium showing MSA of  $7.72 \text{ mm}^2$  and MLA of  $4.62 \text{ mm}^2$ .

The culotte technique ensures full coverage in all 3 segments (as compared with T-stenting); there is minimal or no neocarina (as compared with T-and-protrusion); there is no triple layer (as compared with DK crush); and the tubular architecture of the stents is maintained.<sup>3</sup> The culotte stenting after its first description by Chevalier et al<sup>21</sup> had undergone modifications in the form of reverse Culotte, mini-culotte, nano culotte, and so on for its betterment. Still, the risk of short-term closure of MV and distortion of the carina comes as a hindrance to ideal bifurcation treatment. Moreover, if the diameter difference between 2 branches is too great ( $>0.75 \text{ mm}$ ), a circular underexpansion band of the stent around the bifurcation will be encountered given the SB stent implanted earlier will limit the

expansion of MV stent implanted subsequently through the struts of SB stent.<sup>22</sup> Culotte stenting involves a closer interaction between the 2 stents, particularly in the overlapped segment. This tighter interaction in culotte may lead to stent-stent malapposition due to limited expansion of the MV stent constrained by the side-hole of the SB stent (napkin phenomenon).<sup>23</sup> Stent malapposition and napkin phenomenon act as an independent predictor of future MACE in the form of stent thrombosis, increased TLR, and increased restenosis rate. Three-year follow-up of the NOR-DIC study showed stent thrombosis of up to 4.7% due to stent malapposition.<sup>24</sup> Toth et al<sup>11</sup> in their bench study have shown that DK-culotte significantly reduced malapposed stents, especially in the proximal MV and the roof of the polygon of confluence.<sup>12</sup> It closely mimicked physiological flow patterns, exhibiting lower shear rates. Interestingly, DK-culotte minimally affected native bifurcation angles compared with DK crush, potentially affecting fluid dynamics positively. Overall, the anatomy of DK-culotte after the procedure closely resembled the native structure, indicating promising benefits for bifurcation interventions.

A retrospective study by Fan et al,<sup>25</sup> comparing DK-culotte stenting with provisional T-stenting by propensity score matching, showed a MACE rate of 4.55% for the DK-culotte versus 13.6% for provisional T-stenting ( $p = 0.127$ ). However, the rate of TVR/TLR was significantly lower with DK-culotte than with provisional T-stenting (1.52% vs 12.12%,  $p = 0.033$ ), and the SB restenosis rate was 5.6% versus 22.4% in the DK-culotte as compared with

Table 5

Clinical outcome at 1-year follow-up (n = 45)

Outcomes	At 1-year follow-up (n=45)
Major adverse cardiac events	1(2.2%)
Cardiac death	0
Myocardial infarction	1(2.2%)
Target vessel revascularisation	0
Overall stent thrombosis*	0
Definite stent thrombosis	0
Probable stent thrombosis	0
Possible stent thrombosis	0
Instant restenosis	1(2.2%)

\* According to the Academic Research Consortium (ARC) criteria.

provisional T-stenting ( $p = 0.014$ ). This study showed that in true bifurcation lesions, DK-culotte significantly reduces TLR/TVR compared with provisional T-stenting at 1 year. However, there were certain limitations of this study. Firstly, the most distal strut crossing was not mandatory; secondly, sequential kissing as suggested in a bench model by Toth et al,<sup>11</sup> which might have produced a better outcome, was not performed. Our study addressed these limitations, and the addition of intracoronary artery imaging further improved this technique and results.

To the best of our knowledge, this is the first prospective study to report the immediate and short-term results of distal LM stenting performed by the DK mini-culotte technique under OCT guidance. Our results have confirmed the clinical benefit of the first sequential kissing balloon inflation during culotte stenting in preventing ostial LCx (SB) restenosis. Restenosis of the LAD (main branch) was also not seen in any patient given its deformity was prevented by the second sequential kissing balloon inflation. A restenosis rate of 2.2% in SB (LCx) in the present study again reaffirms the significance of sequential kissing balloon dilation. It is possible that both DK-crush and DK-culotte techniques, which optimize the expansion of SB stent by additional kissing, can lead to a lesser risk of TLR/TVR, in true bifurcation lesions. Moreover, in our study, a mandatory coronary artery angiogram was performed if ischemic symptoms developed in a patient, or after 12 months. This systematic angiographic surveillance is of major value because it gives a true picture of stent performance, disease progression, and ISR. Such ISR detected early during angiographic surveillance can be timeously treated with drug-coated balloons.

There is increasing evidence supporting the use of intravascular imaging in complex PCI, especially IVUS in reducing TLR and mortality during unprotected LM PCI. Revascularization guidelines now give a class IIA recommendation for IVUS guidance in such cases, and the use of OCT is a reasonable alternative to IVUS except in ostial LM disease intervention and a diameter of  $>5$  mm.<sup>12</sup> In the ROCK 1 cohort study, OCT use was associated with better midterm angiographic outcomes than those with angiography or IVUS.<sup>26</sup> The ROCK 2 cohort study has proved the noninferiority of OCT to IVUS in distal LM intervention, and further OCT was able to detect more edge dissection, stent malapposition, and stent underexpansion.<sup>27</sup> Subgroup analysis of the OCTIVUS trial, which included 72% of bifurcation lesions and 17% LM, has also shown that OCT-guided PCI had a similar rate of ischemic events to that of IVUS-guided PCI. In addition, the incidence of major procedure complications was less in the OCT group than in the IVUS group.<sup>28</sup> Given all the cases were performed under OCT guidance, we could achieve the desired MSA for LM, LAD, and LCx, leading to a negligible restenosis rate in the LCx ostium at 1 year. In general, IVUS overestimates MSA by 10% in comparison with OCT. In the EXCEL trial, the IVUS criterion for optimal stent expansion was a 6-7-10 rule for LCx, LAD, and LM, respectively.<sup>29</sup> Kim et al<sup>30</sup> have also shown that achievement of MSA with IVUS of 11.8, 8.3, and 5.7 mm<sup>2</sup> in distal LM, LAD, and LCx, respectively, is associated with fewer MACE at 5-year follow-up. In our study, we could achieve the MSA of  $13.28 \pm 0.77$

mm<sup>2</sup> in LM,  $8.25 \pm 0.29$  mm<sup>2</sup> in LAD, and  $7.54 \pm 0.45$  mm<sup>2</sup> in LCx with OCT, which is optimal and even greater than that suggested by Kim et al<sup>30</sup> to prevent future MACE. Optimal stent expansion index of  $>80\%$  (as per the LEMON criteria)<sup>16</sup> was achieved in all the cases, which produced better short-term outcomes. Stent malapposition was significantly reduced, leading to a reduction in MACE. Fan et al<sup>25</sup> in their retrospective study used IVUS imaging in only 13% of the patients. In the EBC MAIN trial, intravascular imaging was used in only 40% of cases, of which only 7% were OCT-guided.<sup>5</sup> Better resolution of OCT than that of IVUS offers greater sensitivity for thrombus detection, stent under expansion, edge dissection, strut malapposition, and stent deformation, thus suggesting that it is a viable option for distal LM bifurcation PCI. OCT had helped identify the significant distal edge dissection in 2 cases, which were managed successfully, and thus helped prevent future MACE. In the OCTOBER trial, OCT-guided PCI in bifurcation lesion was associated with a lower MACE rate than that of angiographic-guided PCI at 2-year follow-up.<sup>31</sup> OCT assessment in our study was performed systematically before stenting (although predilation was not mandatory, contrary to the OCTOBER trial), during each rewiring, and after stenting, similarly to the OCTOBER protocol. The present study also differs from the OCTOBER trial in terms of bifurcation technique because the former had only DK mini-culotte stenting, and the latter study allowed various stent strategies: DK crush, culotte, T-stenting, and T-and-protrusion stenting.

From our preliminary short-term follow-up, we believe that the addition of first sequential kissing before MV stenting will not only improve the clinical outcome of patients who undergo culotte stenting but may also help to produce a comparable clinical outcome to that of the DK-crush technique in patients with unprotected distal LM bifurcation stenting. Thus, we suggest that DK-culotte stenting can be a promising alternative to culotte stenting. We believe that a head-to-head comparison of DK crush and DK-culotte should be undertaken in both LM and non-LM bifurcation stenting, requiring an upfront 2-stent strategy.

Our study has notable limitations, the most important of which is a relatively small patient cohort and the lack of a comparator group of other bifurcation stenting strategies. Moreover, owing to the limited sample size, the study is underpowered for clinical end points. Although angiographic follow-up was performed in all patients at 1 year, OCT imaging was not conducted at follow-up, which might have given further valuable information. In addition, the exclusion of patients with acute MI, lesions with large thrombus burden, vessels with differences in diameters of  $>0.5$  mm, and lesions with bifurcation angles of  $>70^\circ$  limit the universality of this approach.

In conclusion, the addition of the first sequential kiss before MV stenting in culotte effectively reduces the risk of deformity of the SB at its ostium and its clinical risk of developing ostial ISR. Furthermore, OCT guidance in distal LM intervention with desired MSA can help prevent future MACE.

#### Declaration of competing interest

The authors have no competing interest to declare.

## CRedit authorship contribution statement

**Saibal Mukhopadhyay:** Conceptualization. **Jamal Yusuf:** Writing – original draft, Methodology, Investigation. **Ankit Bansal:** Writing – review & editing, Writing – original draft, Investigation, Formal analysis. **Rupesh Agrawal:** Writing – review & editing, Writing – original draft, Formal analysis. **Vimal Mehta:** Methodology, Investigation. **Mohit D. Gupta:** Methodology, Investigation. **Girish M.P.:** Methodology, Investigation. **Arima Nigam:** Project administration, Investigation. **Safal Safal:** Project administration, Investigation. **Vishal Batra:** Project administration, Investigation. **Sanjeev Kathuria:** Project administration, Investigation. **Ankur Gautam:** Project administration, Investigation. **Subrat Kumar Muduli:** Project administration, Investigation. **Sumod Kurian:** Project administration, Investigation.

## Authors' Contributions

Dr. Mukhopadhyay undertook conceptualization (lead). Dr. Yusuf was responsible for methods (lead); investigation (lead); writing—original draft (equal). Dr. Bansal was responsible for investigation (supporting); original draft (equal); formal analysis (equal); writing—review and editing (equal). Dr. Agrawal was responsible for the original draft (equal); formal analysis (equal); writing—review and editing (equal). Dr. Mehta was responsible for the methods (supporting) and investigation (supporting). Dr. Gupta was responsible for methods (supporting) and investigation (supporting). Dr. Girish undertook methods (supporting) and investigation (supporting). Dr. Nigam undertook investigation (supporting) and project administration (equal). Dr. Safal was responsible for investigation (supporting) and project administration (equal). Dr. Batra undertook investigation (supporting) and project administration (equal). Dr. Kathuria undertook investigation (supporting) and project administration (equal). Dr. Gautam undertook investigation (supporting) and project administration (equal). Dr. Muduli was responsible for investigation (supporting); project administration (equal). Dr. Kurian undertook investigation (supporting) and project administration (equal).

## Supplementary materials

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