

# Incorporation of a Balloon-Cushion Stenting Technique into the Culotte Stenting Technique in Left Main Coronary Artery Bifurcation Interventions

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## Abstract

**Background:** Percutaneous coronary intervention (PCI) for a left main coronary artery (LMCA) with its distal bifurcation lesions remains a challenge. Acute sidebranch occlusion after main branch stenting can potentially lead to catastrophic events. Here we describe a novel balloon-cushion stenting technique to be incorporated into the culotte stenting technique for true LMCA bifurcation lesions to prevent acute sidebranch occlusion.

**Methods and Results:** 1) Predilatation with 2 balloons with kissing for better sidebranch preparation. 2) Balloon-stent simultaneous kissing inflation, with a stent in the dominant artery and a 1.5/20 mm balloon from LMCA to the sidebranch. 3) After the stent deployment, a Crusade microcatheter was introduced via wire in the dominant vessel for wire re-crossing of the stent strut. The standard culotte technique and final kissing balloon inflation were then performed. Twelve patients were treated with this balloon-cushion stenting technique (Group A) and 18 patients with the conventional double-stent techniques (Group B). One case of acute sidebranch occlusion occurred in Group B. The amount of contrast medium and procedural time did not differ statistically between the 2 groups.

**Conclusions:** The present study suggests that incorporation of the balloon-cushion stenting technique into the culotte stenting technique for LMCA bifurcation intervention is feasible and effective in avoiding acute sidebranch occlusion.

**Keywords:** Left main coronary artery; Bifurcation lesions; Percutaneous coronary interventions; Intravascular ultrasound; Drug-eluting stents

## Introduction

Coronary artery bypass surgery is the recommended treatment for patients with left main coronary artery (LMCA) disease. However, recent data from randomized and registry cohort studies suggest that percutaneous coronary intervention (PCI) for unprotected LMCA stenosis is a feasible alternative to bypass surgery [1–4]. Main branch stenting associated with provisional sidebranch (SB) stenting is the current strategic technique of choice in PCI for bifurcation lesions [5,6]. Using this procedure in the complex setting of an LMCA true bifurcation, however, poses the challenge of acute sidebranch (SB) occlusion, which occurs in about 6–15% of cases and can potentially lead to catastrophic events, such as massive myocardial infarction or death [7,8]. While the crush stenting technique is useful for avoiding acute SB occlusion [9], it has a higher side-branch restenosis rate than the culotte stenting technique [10].

We report here a novel balloon-cushion stenting technique, devised to be incorporated into the culotte stenting technique for use in complex PCIs for LMCA bifurcation lesions to prevent acute SB occlusion and reduce the SB restenosis rate.

## Methods

### Patients

Between October 2008 and October 2010, among 4,623 elective PCI cases, 86 patients underwent PCIs for unprotected LMCA lesions. Of the 86 cases, 30 consecutive patients with true bifurcation lesions (as defined below) requiring a double-stent strategy were enrolled in this study and divided into two groups.

Group A consisted of 12 consecutive patients who were treated with the novel balloon-cushion stenting technique. Group B consisted of the other 18 patients who were treated with the conventional double-stenting technique before April 2010, when the novel balloon-cushion technique became a practical substitute. The baseline clinical characteristics of the patients are shown in Table 1. The study was approved by the institutional review board of Chi-Mei Medical Center.

### Procedure

Written informed consent was obtained from each patient after a discussion with the heart team. Upon cannulation of the left coronary artery with a 7 Fr guiding catheter using either the femoral or radial arterial approach, two 0.14 inch guide wires were inserted into the left anterior descending artery (LAD) and the left circumflex artery (LCX), respectively. Rota-ablation was applied, when indicated, to prepare the lesions (Figure 4). Subsequent interventions for the bifurcation lesions were performed using the 3-step kissing techniques as follows. *Step 1–Predilatation:* 2-balloon kissing inflation was performed using the

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**Received** November 10, 2012; **Accepted** December 04, 2012; **Published** December 06, 2012

**Citation:** Ku PM, Huang TY, Chen ZC, Woo M, Hung JS (2013) Incorporation of a Balloon-Cushion Stenting Technique into the Culotte Stenting Technique in Left Main Coronary Artery Bifurcation Interventions. J Clin Exp Cardiol 4:230. doi:10.4172/2155-9880.1000230

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	Group A, n = 12	Group B, n = 18	P
Age (mean ± SD), yr	72.6 ± 8.3	73.1 ± 7.0	0.89
Men, n (%)	9 (75.0)	14 (77.8)	0.33
BMI (mean ± SD), Kg/m <sup>2</sup>	26.8 ± 4.6	27.2 ± 5.4	0.48
Risk factors, n (%)			
Diabetes mellitus, n (%)	6 (50.0)	10 (55.6)	0.76
Hypertension, n (%)	7 (58.3)	12 (66.7)	0.27
Dyslipidemia, n (%)	7 (58.3)	11 (61.1)	0.29
Smoking, n (%)	6 (50.0)	12 (66.7)	0.20
Family history, n (%)	5 (41.6)	7 (38.9)	0.29
LVEF (mean ± SD)	52.6 ± 8.0	50.8 ± 4.6	0.52
Additive EuroSCORE, (mean ± SD)	4.6 ± 1.2	5.2 ± 1.3	0.18
SYNTAX score, (mean ± SD)	34.6 ± 9.5	36.6 ± 7.4	0.54

SD: standard deviation; BMI: body mass index; LVEF: left ventricular ejection fraction

**Table 1:** Baseline clinical characteristics.

appropriate-sized balloons, followed by an intravascular ultrasound (IVUS) assessment. *Step 2-Balloon-stent kissing dilatation:* As can be seen in Figures 1B and 1C, this step was performed using a 1.5

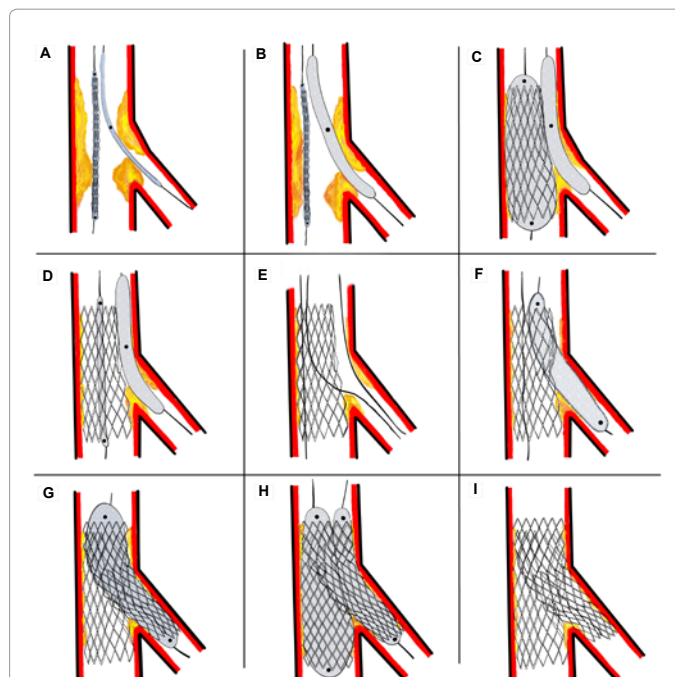
×20 mm balloon in the less dominant artery (usually the left circumflex artery [LCX]) to be used as a cushion. An appropriate-sized (IVUS-derived) drug-eluting stent (DES) was inserted into the dominant artery (usually the left anterior descending artery [LAD]). The proximal end of the balloon should exceed the proximal end of the stent closer to the aorta in order to avoid entrapment of the balloon between the stent and the vessel wall after the stent is inflated. The balloon was first inflated to 14 atm for use as a cushion for the stent, and the stent was subsequently inflated to 12 atm. The deflations of both devices were performed in reverse sequence. *Step 3-Standard culotte technique and final kissing balloon technique:* After the stent deployment in Step 2, a second guide wire was placed in the LCX, crossing the stent struts with the aid of a Crusadetwin-lumen microcatheter (Kaneka Medix Corp., Tokyo, Japan) (Figure 2). Subsequently, the stent strut was dilated (Figure 1F) and a second drug-eluting stent (DES) was added in the LCX (Figure 1G). Following the final kissing balloon dilatation (Figure 1H), the IVUS was repeated to confirm adequate apposition of the stents.

### Term definitions for this study

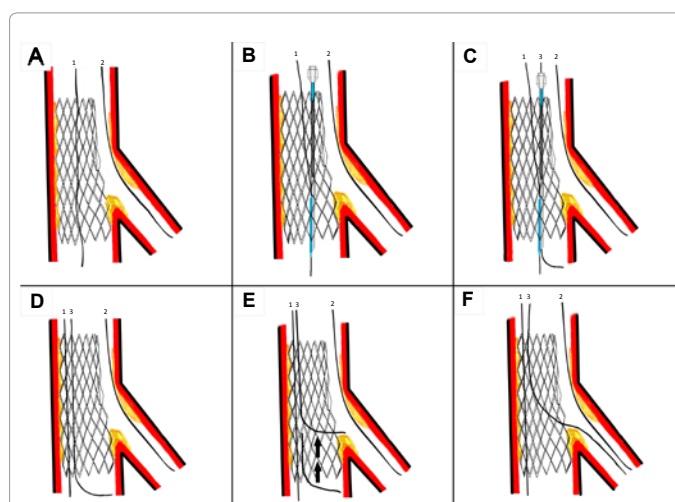
An LMCA true bifurcation lesion was defined as type 1-1-1 or type 0-1-1 based on Medina's angiographic classification [11]. Critical stenosis was defined as ≥75% stenosis as assessed by quantitative coronary angiography. Stent thrombosis was defined by the ARC definition [12]. Periprocedural acute myocardial infarction (AMI) was defined as CK-MB >3× the upper normal limit within 24 hours after the PCI. Acute side-branch occlusion was defined as a TIMI flow <1 in the sidebranch following the PCI with stenting for the main branch. Procedure time was defined as the total time spent from guiding catheter engagement in the left main artery to the completion of the PCI. Contrast volume was quantified as the total amount of contrast medium consumed during the PCI.

### Statistical methods

The continuous variables, expressed as the mean value standard deviation, were analyzed using the Student unpaired *t*-test, Fisher's exact test, or  $\chi^2$  test as appropriate. Comparisons among the different measurements within each patient were done using the Student paired *t*-test and a comparison of the repeated measurements between the two groups of patients by analysis of variance. *P*<0.05 was considered



**Figure 1:** A: Placement of stent and 1.5/20 mm balloon catheter in the LMCA, with the distal segment in the LAD and LCX. The proximal end of the balloon is positioned closer to the ostium of LMCA; B: Dilatation of the LCX ostium, with the balloon inflated to 14 atm; C: Dilatation of the LMCA and LAD by kissing inflation of the stent and cushion balloon; D: With the cushion balloon still inflated, the stent balloon is deflated; E: Removal of the deflated cushion balloon and stent catheters. Placement of the second guide wire in the LCX through the stent struts, with the aid of a Crusade microcatheter; F: After removing the first guide wire in the LCX, there is stent cell expansion with the inflation of the proper size balloon catheters; G.: Side-branch stent being inflated fully; H: Kissing-balloon inflation; I: Final result. LAD, left anterior descending artery; LCX, left circumflex artery; LMCA, left main coronary artery. Refer to the text for technical detail.



**Figure 2:** A: After step 2: balloon-stent kissing, the guide wire 1 in the LAD, the guide wire 2 in the LCX; B: The advance of a Crusade microcatheter through guide wire 1; C: The advance of guide wire 3 through the over-the-wire lumen of a Crusade microcatheter; D: Pull out the Crusade microcatheter, a large curvature of the tip of the guide wire 3; E: Gradual withdrawal of guide wire 3, allowing this guide wire to jump into the distal stent strut; F: Successful rewiring with guide wire 3.

statistically significant. The calculations were performed on a personal computer using SPSS Statistics, v17.

## Results

The baseline clinical characteristics of the 30 patients who underwent the double-stent strategy are summarized in Table 1. The additive EuroSCORE ( $4.6 \pm 1.2$  in Group A vs.  $5.2 \pm 1.3$  in Group B;  $P=0.18$ ) and the SYNTAX score ( $34.6 \pm 9.5$  in Group A vs.  $36.6 \pm 7.4$  in Group B;  $P=0.54$ ) were similar in both groups. The procedural and angiographic characteristics are summarized in Table 2. Of the 18 Group B patients, 12 were treated with crush stenting and 5 with culotte stenting. The remaining patient with a short left main coronary artery was treated with the V-stenting technique. We performed balloon predilatation for both branches and final kissing balloon inflation after double-stenting on all the Group A and B patients. The Crusade twin-lumen microcatheter was used with success in all but one Group B patient, who was managed with the V-stenting technique.

There were no in-hospital adverse cardiovascular events (myocardial infarction, acute stent thrombosis, or stroke) in any of the patients, with the exception of one Group B patient. In this patient, acute side-branch occlusion of the LCX occurred after stenting from the LMCA to the LAD, preceding the planned culotte stenting. Despite rescue measures including rewiring through the stent struts, subsequent balloon dilatation of the LCX and the culotte stenting, the patient developed an uncomplicated AMI with a CK-MB elevation 3×the normal limit. No patient event was later found. During the short-term follow-up periods of up to 12 and 30 months, respectively, for the Group A and B patients, there was no target-vessel revascularization, stent thrombosis, non-fatal AMI, or death.

The amount of contrast medium ( $286 \pm 68.3$  mL in Group A vs.  $298 \pm 62.4$  mL in Group B;  $P=0.58$ ) and the procedure times ( $84 \pm 15.9$  minutes in Group A vs.  $92 \pm 17.2$  in Group B;  $P=0.24$ ) were not statistically different between the two groups.

## Discussion

Main-branch stenting associated with provisional side-branch stenting is the current strategic technique of choice in PCI for LMCA bifurcation lesions in selected patients [5,6,13]. Using this procedure poses the challenge of acute SB occlusion, which occurs in about 6–15% of cases [7,8,14]. While the crush stenting technique is useful to avoid such acute SB occlusion [9], it has a higher side-branch restenosis rate than the culotte stenting technique [10]. Consequently, the balloon-cushion technique has been devised to incorporate the culotte stenting technique into an LMCA bifurcation intervention, using a 3-step procedure with the following rationales.

In Step 1, we performed 2-balloon kissing inflation using the appropriate-sized balloons and pre-dilated for better sidebranch preparation. In Step 2, simultaneous dilatation of the LMCA stent with a cushion balloon decreased the snowplow effect during the main-branch stenting. Thus, the flow of the sidebranch was kept patent, allowing the subsequent threading of the second wire into the non-dominant vessel with the aid of a Crusade micro catheter (Figure 2). The Crusade was useful in preventing improper rewiring through a relatively under-expanded stent in the LMCA (Figure 3) [15]. The larger curvature at the tip of the second wire, inserted through the opening of the Crusade side-port using the pull-back rewiring maneuver, was aimed for rewiring through the distal stent strut into the sidebranch [16,17].

	Group A, n = 12	Group B, n = 18	P
7F guiding catheter, n (%)	12 (100)	18 (100)	1.0
Radial approach	3 (25.0)	4 (22.2)	0.33
Bifurcation type, n (%)			
Medina 1,1,1	6 (50.0)	8 (44.4)	0.28
Medina 0,1,1	6 (50.0)	10 (55.6)	0.28
Bifurcation angle > 70 degree	6 (50.0)	9 (50.0)	0.29
Bifurcation stenting technique, n (%)			
Crush	-	12 (66.7)	-
Culotte	-	5 (27.8)	-
V-stenting	-	1 (5.5)	-
Predilatation, n (%)	12 (100)	18 (100)	1.0
IVUS used, n (%)	12 (100)	18 (100)	1.0
Crusade used, n (%)	12 (100)	17 (94.4)	0.6
IABP used, n (%)	3 (25.0)	4 (22.2)	0.33
Rota-ablation, n (%)	3 (25.0)	5 (27.8)	0.32
Cutting balloon used, n (%)	4 (33.3)	4 (22.2)	0.26
Final kissing balloons, n (%)	12 (100)	18 (100)	1.0
Contrast volume, mL (mean ± SD)	$286 \pm 63.8$	$298 \pm 62.4$	0.58
Procedure time, min (mean ± SD)	$84 \pm 15.9$	$92 \pm 17.2$	0.24
Periprocedural AMI, n (%)	1 (8.0)	2 (11.1)	0.45
Stent thrombosis, n (%)	0	0	1.0
Side-branch occlusion, n (%)	0	1 (5.5)	0.6

IVUS: intravascular ultrasound; IABP: intra-aortic balloon pump; SD: standard deviation; AMI: acute myocardial infarction

Table 2: Procedure characteristics.

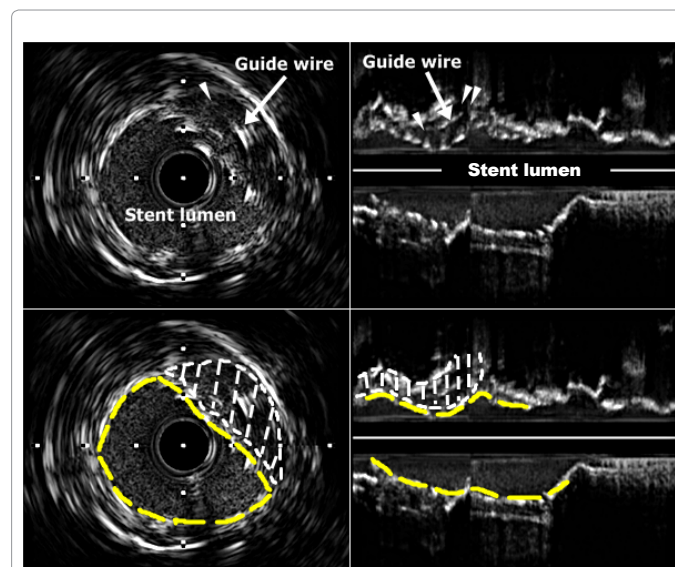
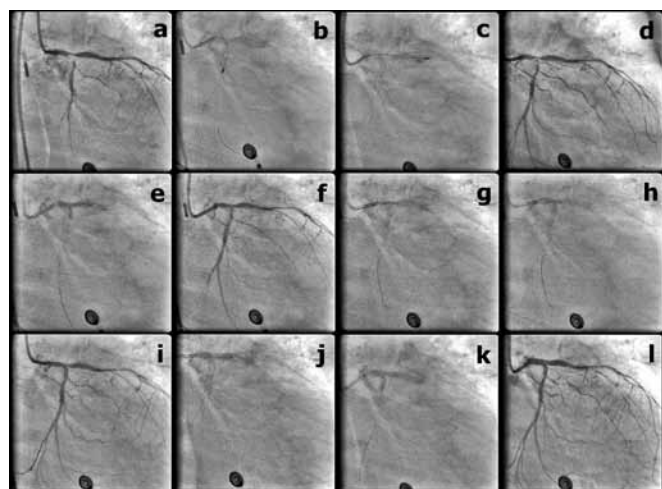


Figure 3: IVUS images (left panel, cross-section; right panel, longitudinal section) obtained after kissing predilatation of stent and cushion balloon (refer to Fig. 1C); note the under-expanded stent and guide wire (arrow) within the expanded lumen (single arrowhead and area surround by dot, both panels), resulting from cushion balloon inflation, and the patent LCX orifice (double arrowheads, right panel). IVUS, intravascular ultrasound; LCX, left circumflex artery; Yellow dash line, stent struts.

Finally, in Step 3, culotte kissing stenting was used instead of the crushing technique because the latter has a higher side-branch restenosis rate than the culotte stenting technique [9]. Following the final post-stenting balloon dilatations, the IVUS was repeated to assure adequate stent apposition and side-branch patency, lessening the chance for stent restenosis [18]. Another potential advantage of the



**Figure 4:** (a) Initial angiography, RAO 24°, caudal 30° with IABP support; (b) Rota-ablation with 1.5mm burr from LMCA to LCX; (c) Rota-ablation with 1.5mm burr from LMCA to LAD; (d) after Rota-ablation; (e) Pre-dilatation with 2-balloon kissing inflation, a 3.0/15 mm balloon from LMCA to LCX and a 3.0/20 mm balloon from LMCA to LAD; (f) After pre-dilatation with 2-balloon kissing inflation; (g) 1.5/20 mm balloon was inflated first to 14 atm; (h) Balloon-stent kissing dilatation, with a 1.5/20 mm balloon from LMCA to LAD and TaxusLiberte 3.0/16 mm stent from LMCA to LCX; (i) After balloon-stent kissing dilatation; (j) TaxusLiberte 3.5/20 mm stent from LMCA to LAD after rewiring the stent strut and adequate balloon dilatation; (k) Final kissing balloon dilatation with 3.5/15 mm and 3.0/15 mm NC balloons to 8 atm; (l) Final angiography, RAO 24°, caudal 30°.

culotte technique over the crush technique is the reduced likelihood of future stent thrombosis because of the presence of fewer stent strut layers in the vessel wall, specifically 2 layers instead of the 3 required in the crush technique.

There are two major limitations in this single-center preliminary study, namely, the small number of patients and the short follow-up period. While acute procedural success and freedom from adverse cardiovascular events during a short follow-up period of up to 12 months in the 12 patients are encouraging, further studies are warranted to document the safety and efficacy of this novel balloon-cushion stenting incorporated into culotte stenting for LMCA bifurcations. In addition, neither the amount of contrast medium used nor the procedure times for the PCI were increased using this novel technique, as compared to the use of the conventional double-stent technique previously used. However, these results will most likely improve with gains in procedure experience.

## Conclusion

The present study with its limited number of patients suggests that incorporation of the balloon-cushion stenting technique into the culotte stenting technique for LMCA bifurcation intervention is feasible, safe, and effective at avoiding acute side-branch occlusion. Further large-scale, long-term study is required to substantiate the safety and effectiveness of this novel technique, especially for prevention of stent restenosis and thrombosis.

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