# Procedural Impact of a Kissing-Balloon Predilation (Pre-Kissing) Technique in Patients With Complex Bifurcations Undergoing Drug-Eluting Stenting

Francesco Burzotta, MD, PhD[1*]; Osama Shoeib, MD, PhD[2*]; Cristina Aurigemma, MD, PhD[1]; Italo Porto, MD, PhD[1]; Antonio Maria Leone, MD, PhD[1]; Giampaolo Niccoli, MD, PhD[1]; Lorenzo Genuardi, MD[1]; Carlo Trani, MD[1]; Filippo Crea, MD[1]

**ABSTRACT: Aim.** To assess the impact of lesion predilation with kissing inflation using under-sized balloons (pre-kissing [PK]) on the procedural outcome of percutaneous intervention (PCI) on coronary bifurcation lesions (CBLs). **Methods.** Patients who underwent PCI with second-generation drug-eluting stenting on a complex CBL (Medina 1,1,1 or 1,0,1 or 0,1,1) were selected. The study population was divided according to the lesion preparation into the PK group and the control group. To adjust for higher anatomic complexity of PK patients, a 2:1 propensity-matched (PM)-control group was selected. The PCI procedural details were assessed to evaluate occurrence of "side-branch trouble" (primary procedural endpoint) after main-vessel (MV) stenting. Angiographic characteristics, including side-branch TIMI flow during PCI, were also systematically evaluated. **Results.** A total of 538 patients were identified, with 66 patients in the PK group, 472 patients in the control group, and 126 patients in the PM-control group. Side-branch trouble was less common in side-branch PK patients vs the PM-control patients (7.5% vs 18.0%, respectively; *P*=.03). In multivariable analysis, the absence of PK independently predicted side-branch trouble. Among selected patients with a long side-branch lesion (122 patients), the PK technique improved post-MV stenting side-branch TIMI flow. **Conclusions.** Use of PK with under-sized balloons may facilitate side-branch management after MV stenting in patients with complex CBL undergoing provisional stenting.

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**KEY WORDS:** bifurcated lesions, drug-eluting stent, kissing-balloon technique, percutaneous coronary interventions



The search for the best treatment of coronary bifurcated lesions (CBLs) is an evolving field of interventional cardiology.[1] Among many options, a simple, crossover main-vessel (MV) stenting with provisional stenting of the side-branch (SB) represents a valuable approach for a broad spectrum of CBLs.[2] According to the provisional technique, a second stent may be implanted in the SB only if considered necessary after MV stenting using different modalities.[1] The main drawbacks of the provisional technique are the risk of SB occlusion causing acute ischemia and the risk of technical troubles (failure to rewire, dilate, and stent), hindering optimal SB treatment after MV stent implantation.[3] Such issues are more relevant as the CBL becomes more anatomically complex.[4] Indeed, a series of anatomic features have been shown to predict the occurrence of SB impairment after stent implantation in the MV.[2,3,5] Lesion preparation before stent implantation is usually adopted in the treatment of patients with high CBL complexity. Yet, data defining the optimal CBL preparation technique in this context are lacking.

The kissing-balloon inflation technique represents a well-established option to optimize the result of CBL-PCI after stent implantation[6] with a controversial clinical impact.[7] In the present study, we report promising procedural results achieved using kissing-balloon dilation with under-sized balloons before MV stenting (the pre-kissing [PK] technique).

## Methods

**The PK balloon technique rationale and description.** In CBLs of higher angiographic complexity, the amount of atherosclerotic plaque located in the bifurcation area (the "polygon of confluence" [POC]) is higher (Figure 1). To facilitate stent placement and proper expansion, balloon dilation is usually practiced in both the MV and SB. Yet, dilation in one branch is known to have the potential of compromising the daughter branch due to the occurrence of plaque and carina shift.[4] A possible alternative may be using kissing-balloon dilation before MV stenting. As shown in Figure 1, this technique aims to maintain the bifurcation carina in its central location while displacing the plaque away. To achieve simultaneous inflation and deflation, we used to connect the two balloons to a single indeflator using a triple-way stopcock and a double-male connector. At that point, the procedure continues to follow the provisional technique by implanting the stent across the SB (sized according to distal MV diameter and performing a proximal optimization technique [POT] with a balloon sized according to the proximal MV diameter) (Figure 1).[2]

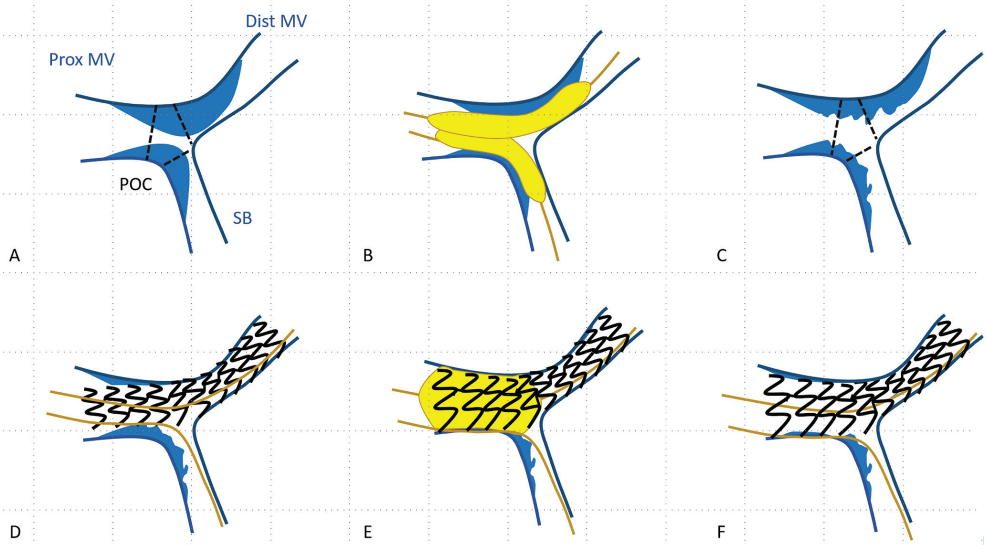



**FIGURE 1.** (A) Schematic drawing of a complex bifurcation lesion showing the polygon of confluence (POC). (B) Under-sized balloon inflation inside the lesion. (C) Schematic drawing showing the effect of pre-kissing technique for lesion preparation. (D) Stent implantation according to the size of the distal main vessel. (E) Proximal-optimization technique (POT) for the proximal main vessel. (F) Final result. MV = main vessel; SB = side branch.

The main drawback of simultaneous balloon inflation is the risk of causing overstretch in the proximal MB, causing an "oval" vessel expansion.[8] To reduce proximal dissection risk and oval shape deformation, we use under-sized balloon diameters (usually the two balloon diameters are at least 0.5 mm smaller as compared with the estimated distal MV reference diameter, Figure 1). Moreover, the routine POT is expected to correct asymmetricity in the proximal MV.

Figure 2 shows an example of PK technique in a patient with a complex Medina 1,1,1 lesion. Angiography and intravascular imaging obtained by optical coherence tomography show how PK was able to increase the space at the level of the POC, while the carina was not displaced and preserved its central position.

**Study population selection.** The study was conducted in a single, tertiary, high-volume center (1100 PCIs per year). Patient data were prospectively recorded on a dedicated catheterization laboratory database (Estensa Esaote Radiology Image Management System) that has previously helped assess the role of Euroscore I and II in PCI[9,10] and the safety of the transradial approach.[11] This database is equipped with a bifurcation PCI lesion section that was customized according to our specific requests and allowed us to prospectively collect key anatomic and procedural variables at the time of PCI, including angiographic Medina bifurcation classification, bifurcation angle, and sequence and type of technical steps performed during the bifurcation intervention. The procedural devices/materials and the sequence of their usage were also prospectively recorded. All patients gave written informed consent to the procedure. The study conformed to the Declaration of Helsinki on human research.

We retrospectively selected patients who underwent PCI between January 2010 and December 2016 on a complex CBL, defined as Medina 1,1,1 or Medina 1,0,1 or Medina 0,1,1 lesions. Patients treated with bare-metal stenting and those with in-stent restenosis were excluded (Figure 3).

All patients were on dual-antiplatelet therapy (DAPT) before intervention. Procedural anticoagulation was achieved with unfractionated heparin (70-100 U/kg intravenous bolus with further dose adjustment to maintain an activated clotting time of ~300 seconds). After the procedure, all patients received DAPT for 12 months, with the indication to continue aspirin indefinitely.

All PCIs were systematically conducted according to the previously reported provisional TAP-stenting strategy.[12] After guide-catheter intubation, both branches were wired and MV predilation was routinely performed, while the decision regarding the type of SB intervention was variable according to the operator's discretion. Thus, the study population was divided into those who received kissing-balloon predilation with under-sized balloons (the PK group) and those who were treated with the conventional technique of MV with or without SB dilation (the control group). After lesion preparation, all patients were treated by MV stenting (stent size selected according to the distal MV diameter) under SB protection with jailed guidewire followed by systematic POT. Then, SB intervention was attempted if considered necessary by the operator. Generally, SB intervention was performed by SB rewiring followed by kissing-balloon inflation. The occurrence of SB flow impairment after MV stenting was prospectively recorded and then rechecked by reviewing all cases. When attempted, SB rewiring was performed with a BMW Universal guidewire (Abbott Vascular) as the workhorse wire; in cases of failure, other guidewires were chosen according to the operator's discretion. Failure to rewire or to dilate the SB after MV stenting was prospectively recorded. If judged necessary by the operator, a second stent was implanted in the SB according to the TAP-stenting technique.[12]

After PCI, in-hospital clinical course was monitored, and patients were followed after discharge by hospital visit or by phone interview.

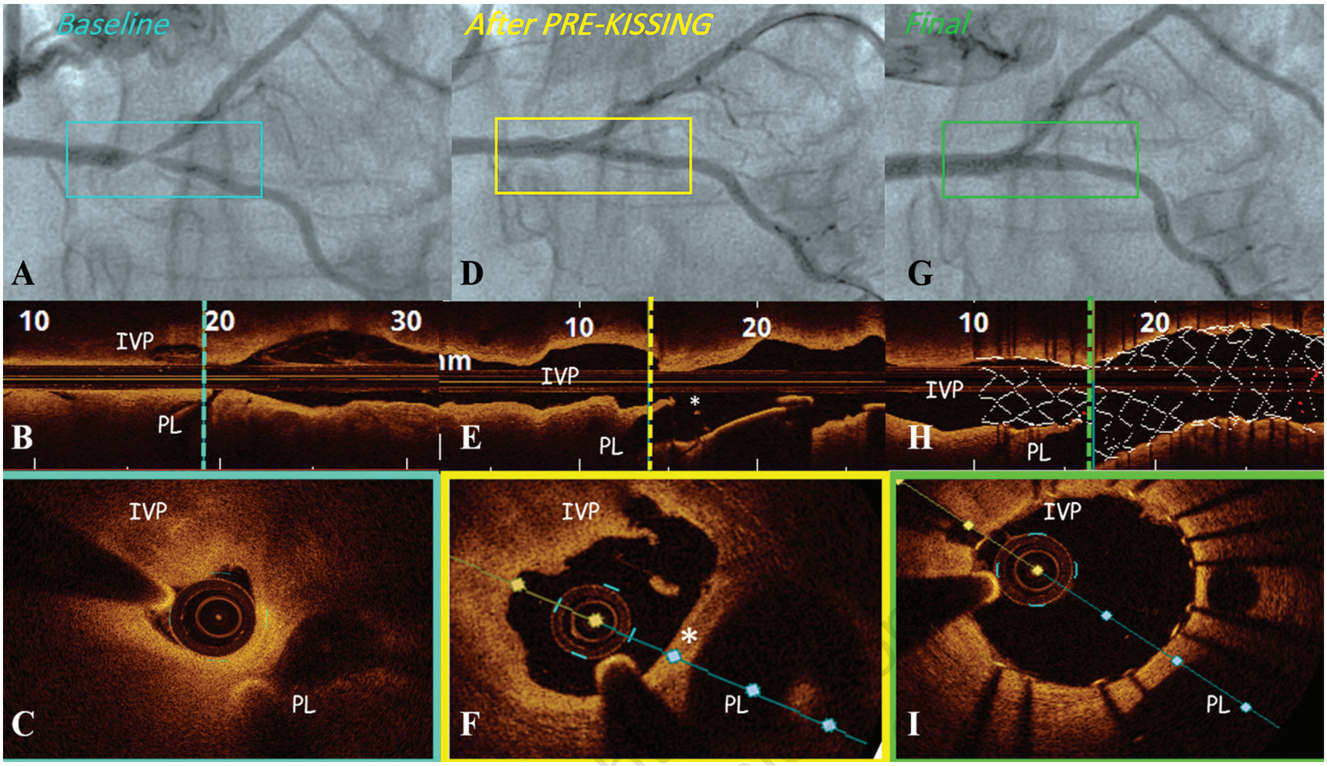



FIGURE 2. Patient with a complex Medina 1,1,1 distal right coronary artery (RCA) lesion treated by optical coherence tomography (OCT)-guided provisional stenting using the pre-kissing technique. (A) Angiography, (B) longitudinal OCT, and (C) cross-sectional OCT of the lesion showing high plaque burden causing subocclusion of the intraventricular posterior descending (IVP) and posterolateral (PL) branches at baseline. (D) Angiography, (E) longitudinal OCT, and (F) cross-sectional OCT images after pre-kissing technique performed with two 2.5 mm balloons. Note the maintained central location of the bifurcation carina while space all around in the polygon of confluence is present (boxes). (G) Final angiographic (H) and longitudinal OCT (obtained with metallic stent optimization software) and (I) cross-sectional images. Pre-kissing procedure was conducted by implanting a last-generation 2.75 mm zotarolimus-eluting stent in the RCA-IVP, followed by proximal-optimization technique (POT) with 3.5 mm balloon, kissing-balloon technique with 2.75 mm balloon in the IVP and 2.5 mm balloon in the PL, and re-POT with a 3.75 mm balloon.

**Definitions.** *Clinical events* were defined as follows: death; *myocardial infarction (MI)*, as defined according to the universal definition of MI;[13] *stent thrombosis*, as defined by the Academic Research Consortium criteria;[14] *target-vessel revascularization (TVR)*, defined as repeat PCI or coronary surgery on the target vessel due to recurrent ischemia; *major adverse coronary events (MACE)*, defined as death, MI, or TVR; and *target-vessel failure (TVF)*, defined as TVR, death, or MI not clearly related with another vessel.

**Study aim and endpoints.** The study aim was to assess the impact of PK technique on the procedural outcomes of PCI on complex CBLs conducted according to the provisional technique. The *primary procedural and angiographic endpoint* compared between PK group and control group was termed *SB trouble*, and was defined as the occurrence of at least one of the following procedural events: (1) TIMI flow <3 in the SB after MV stenting; (2) need for guidewire(s) different from the workhorse wire to rewire the SB after MV stenting; (3) failure to rewire the SB after MV stenting; and (4) failure to dilate the SB after MV stenting and SB

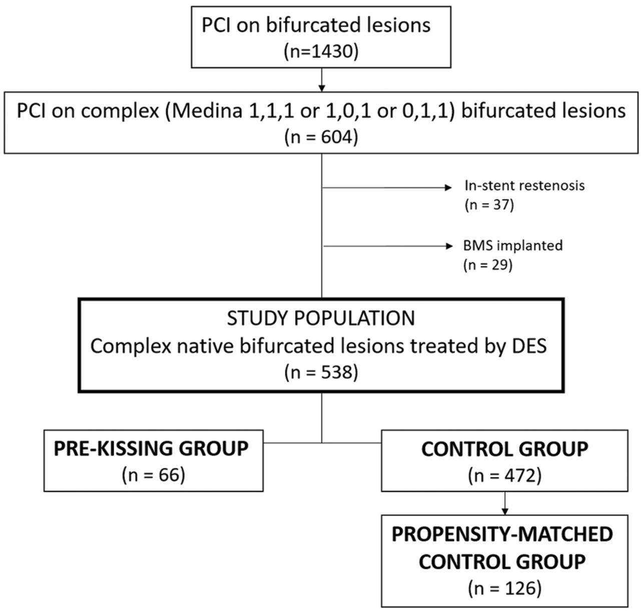



FIGURE 3. Study flow chart.

| | PK Group (n = 66) | Control Group (n = 472) | *P*-Value (PK vs Control) | PM-Control Group (n = 126) | *P*-Value (PK vs PM-Control) |
|---|---|---|---|---|---|
| **Demographics** | | | | | |
| Age (years) | 69 ± 11 | 68 ± 10 | .30 | 68 ± 9 | .10 |
| Female | 10 (15%) | 112 (28%) | .07 | 22 (17%) | .40 |
| Risk factors | | | | | |
| Diabetes mellitus | 13 (20%) | 130 (27%) | .10 | 45 (35%) | .01 |
| Hypertension | 48 (73%) | 358 (75%) | .30 | 102 (80%) | .10 |
| Dyslipidemia | 37 (56%) | 260 (55%) | .40 | 64 (50%) | .20 |
| Smoking | 12 (18%) | 80 (17%) | .40 | 20 (16%) | .40 |
| Renal impairment | 4 (6%) | 33 (7%) | .50 | 14 (11%) | .10 |
| **Clinical Presentation** | | | | | |
| Stable | 50 (76%) | 338 (72%) | .20 | 95 (75%) | .50 |
| NSTE-ACS | 4 (6%) | 40 (8%) | .30 | 8 (6%) | .60 |
| STEMI | 6 (9%) | 40 (8%) | .50 | 7 (5%) | .20 |
| Previous history | | | | | |
| MI | 2 (3%) | 32 (6%) | .10 | 8 (6%) | .20 |
| PCI | 17 (25%) | 104 (22%) | .20 | 24 (19%) | .20 |
| CABG | 6 (9%) | 30 (6%) | .20 | 11 (9%) | .50 |

Table 1. Baseline angiographic characteristics.

Data presented as mean ± standard deviation or number (%).
CABG = coronary artery bypass graft; MI = myocardial infarction; NSTE-ACS = non-ST segment elevation acute coronary syndromes; PCI = percutaneous coronary intervention; PK = pre-kissing group; PM-control = propensity-matched control; STEMI = ST-segment elevation myocardial infarction.



rewiring.[3] *Angiographic success* was defined as successful MV stenting with TIMI 3 flow in both the MV and SB. *Secondary endpoints* were the individual components of SB trouble and post-PCI TIMI flow in the MV and in the SB.

**Statistical analysis.** Continuous variables were reported as mean ± standard deviation and compared with analysis of variance (paired Student's t-test). Categorical variables were expressed as frequencies and compared with Chi-square test. Normality of data was determined using the D'Agostino-Pearson test and verified using histogram plots. A two-sided *P*-value of .05 was considered significant for Student's t-tests, while a one-sided *P*-value of .05 was considered significant for Chi-square tests. A propensity-score matched analysis was performed to adjust for possible confounders; a propensity score was calculated by giving each patient a score according to the clinical or angiographic characteristics found to be differently distributed between the PK and control groups (see Tables 1 and 2 for baseline characteristics). For each PK patient, two patients with the same propensity score were selected from the control group using the nearest-neighbor matching algorithm from the propensity-score matching plug-in for SPSS.[15] Multivariable analysis to assess independent predictors of the primary procedural endpoint (SB trouble) was performed using a backward elimination model that included the baseline clinical and angiographic characteristics, as well as the lesion preparation techniques adopted before MV stenting. Statistical analyses were conducted using SPSS version 18 (SPSS, Inc).

## Results

Out of 1420 consecutive patients who underwent PCI on a bifurcated lesion, a total of 538 patients (38%) who underwent PCI with drug-eluting stent implantation on a complex CBL constituted the study population (Figure 3). Zotarolimus-eluting stents (Resolute, Resolute Integrity, or Resolute Onyx; Medtronic) were used in 350 patients, everolimus-eluting stents (Xience V or Xience Pro; Abbott Vascular) were used in 122 patients, sirolimus-eluting stents (Orsiro; Biotronik AG) were used in 36 patients, and other drug-eluting stent types were used in the remaining 28 patients. The PK technique was performed in 66 patients (12%), while the remaining 472 patients represented the control group. Baseline clinical characteristics are reported in Table 1, and show the prevalence of stable ischemic heart disease and the absence of significant differences between the PK and control groups. Preintervention angiographic characteristics are shown in Table 2. Briefly, most treated lesions were in the left anterior descending/diagonal or left main bifurcations and were Medina lesion class 1,1,1. Relevant differences were disclosed when comparing the PK and control groups; adverse features (higher target left main bifurcation; Medina lesion class 1,1,1; long SB disease) were significantly more prevalent in the PK group as compared with the control group (Table 2). These differences were not maintained in the comparison between the PK group and the propensity-matched control group (Table 1).

**PCI procedural and angiographic outcomes.** Table 2 details the angiographic and procedural characteristics. As expected in complex lesions, the lesion was usually prepared with balloon dilation, while a minority of patients received thrombus aspiration or rotational atherectomy. No significant differences were observed between the PK group and the control group in terms of lesion preparation (except PK) and MV stent length or size.

Flow impairment in the SB and the assessed adverse SB management procedural characteristics tended to be less common in the PK group (Figure 4). After propensity matching,

**Table 2. Angiographic and procedural characteristics.**

| | PK Group (n = 66) | Control Group (n = 472) | *P*-Value (PK vs Control) | PM-Control Group (n = 126) | *P*-Value (PK vs PM-Control) |
|---|---|---|---|---|---|
| **Angiographic Features** | | | | | |
| Target bifurcation | | | | | |
| LM bifurcation | 15 (22%) | 57 (12%) | .01 | 23 (18%) | .20 |
| LAD/D1 | 37 (56%) | 282 (60%) | .30 | 73 (58%) | .40 |
| CX/OM | 10 (15%) | 95 (20%) | .20 | 21 (17%) | .40 |
| Distal RCA | 4 (6%) | 24 (5%) | .40 | 6 (5%) | .40 |
| Bifurcation class | | | | | |
| Medina 1,1,1 | 56 (85%) | 300 (63%) | <.01 | 103 (82%) | .30 |
| Medina 1,0,1 | 4 (6%) | 67 (14%) | .04 | 12 (9.5%) | .20 |
| Medina 0,1,1 | 6 (9%) | 105 (22%) | <.01 | 11 (9%) | .50 |
| SB stenosis length | | | | | |
| ≤5 mm | 32 (48%) | 332 (70%) | <.001 | 60 (48%) | .50 |
| >5 mm | 34 (52%) | 139 (30%) | | 66 (52%) | |
| Bifurcation angle | | | | | |
| <45° | 7 (11%) | 83 (17%) | | 10 (8%) | |
| 46°-70° | 44 (67%) | 310 (66%) | .20 | 72 (57%) | .20 |
| >70° | 15 (22%) | 79 (17%) | | 44 (35%) | |
| Pre-PCI MV flow | | | | | |
| TIMI 0-1 | 8 (12%) | 39 (8%) | | 8 (6%) | |
| TIMI 2 | 8 (12%) | 35 (7%) | .10 | 14 (11%) | .50 |
| TIMI 3 | 50 (76%) | 398 (85%) | | 104 (83%) | |
| Pre-PCI SB flow | | | | | |
| TIMI 0-1 | 5 (8%) | 31 (7%) | | 8 (6%) | |
| TIMI 2 | 21 (32%) | 73 (15%) | .01 | 31 (27%) | .60 |
| TIMI 3 | 40 (60%) | 368 (78%) | | 87 (67%) | |
| Post-PCI MV flow | | | | | |
| TIMI 0-1 | 0 (0%) | 0 (0%) | | 0 (0%) | |
| TIMI 2 | 0 (0%) | 6 (1%) | .40 | 1 (1%) | .60 |
| TIMI 3 | 66 (100%) | 466 (99%) | | 125 (99%) | |
| Post-PCI SB flow | | | | | |
| TIMI 0-1 | 1 (1%) | 8 (2%) | | 5 (4%) | |
| TIMI 2 | 3 (4%) | 35 (7%) | .50 | 12 (9%) | |
| TIMI 3 | 62 (95%) | 429 (91%) | | 109 (87%) | .30 |
| Angiographic success | 45 (68%) | 366 (77%) | | 86 (68%) | |
| **Procedural Features** | | | | | |
| Vascular access | | | | | |
| Radial | 53 (80%) | 423 (90%) | .02 | 110 (87%) | .10 |
| Femoral | 13 (20%) | 49 (10%) | | 16 (13%) | |
| Invasive imaging | | | | | |
| OCT | 2 (3%) | 25 (5%) | .30 | 4 (3%) | .60 |
| IVUS | 2 (3%) | 6 (1%) | .20 | 0 (0%) | .10 |

*Continued*

SB trouble (the primary procedural endpoint) was significantly more frequent in the control group than in the PK group. This was the result of a numerically lower occurrence of all secondary procedural SB management endpoints (which achieved statistical significance for both failures in SB rewiring and dilation). However, this difference was not clear in our second primary endpoint (angiographic success), as there were no statistical differences between the two groups either before or after the propensity matching.

Multivariable analyses showed that the absence of PK technique ($P$=.01), together with SB TIMI flow <3 ($P$<.01), SB lesion >5 mm ($P$<.01), and Medina lesion class 1,1,1 ($P$=.03) independently predicted SB trouble.

After the SB management stage, the procedural course was characterized by a higher use of post-stenting kissing-balloon inflation in the PK group than in the control group. Such differences in the procedural course did not translate into major angiographic differences. Indeed, no angiographic primary and secondary endpoints were significantly different between the PK and control groups, and propensity matching analyses provided similar results (Table 2).

To assess the possible impact of PK technique on more complex bifurcated lesion subsets at higher risk of SB impairment, a subgroup analysis was performed in patients with bifurcated lesions with Medina class 1,1,1 and SB lesion length >5 mm. A total of 122 patients (22.6%) had these characteristics, with 33 patients of these patients in the PK group and 89 patients in the control

| Table 2. Angiographic and procedural characteristics. *continued* | | | | | |
|---|---|---|---|---|---|
| | PK Group (n = 66) | Control Group (n = 472) | *P*-Value (PK vs Control) | PM-Control Group (n = 126) | *P*-Value (PK vs PM-Control) |
| Lesion preparation | | | | | |
| MV predilation | 62 (94%) | 428 (91%) | .20 | 116 (92%) | .40 |
| SB predilation | 16 (24%) | 148 (31%) | .10 | 44 (35%) | .10 |
| Kissing-balloon predilation | 66 (100%) | – | – | – | – |
| Thombus aspiration | 6 (9%) | 33 (7%) | .30 | 9 (7%) | .10 |
| Rotablator | 2 (3%) | 6 (1%) | .20 | 3 (2%) | .50 |
| MV stent | | | | | |
| Total stent length (mm) | 25 ± 7 | 26 ± 8 | .30 | 27 ± 8 | .90 |
| Size (mm) | 3 ± 0.4 | 3 ± 0.4 | .30 | 3 ± 0.4 | .20 |
| Kissing-balloon post stent | 55 (83%) | 279 (59%) | .10 | 23 (18%) | .03 |
| SB stenting followed by kissing (TAP) | 10 (14%) | 35 (7%) | .20 | 11 (9%) | .40 |
| SB stent | | | | | |
| Total stent length (mm) | 21 ± 8 | 20 ± 8 | .90 | 2.8 ± 0.5 | .90 |
| Size (mm) | 3 ± 0.4 | 3 ± 0.5 | .60 | 2.8 ± 0.3 | .20 |
| Contrast media (mL) | 332 ± 100 | 326 ± 110 | .60 | 327 ± 126 | .70 |

Data presented as mean ± standard deviation or number (%).
LAD = left anterior descending coronary artery; D1 = first diagonal branch of the LAD; CX = circumflex coronary artery; OM = obtuse marginal of the CX; RCA = right coronary artery; SB = side branch; MV = main vessel; PK = pre-kissing group; PCI = percutaneous coronary intervention; PM-control = propensity-matched control; TIMI = Thrombolysis in Myocardial Infarction score; OCT = optical coherence tomography; IVUS = intravascular ultrasound; TAP = T-stenting and minimal protrusion.



group. Baseline characteristics were not significantly different between the two groups. The procedural endpoint of SB trouble was strongly reduced in the PK group vs the control group (9.1% vs 29.2%, respectively; *P*=.02). Interestingly, TIMI flow analysis showed similar behavior in the MV, but significant differences in the SB. In particular, the SB flow was significantly better in the PK group vs the control group after MV stenting, with a trend toward improved post-PCI results (Figure 5).

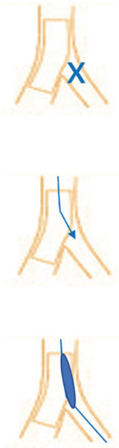
**Clinical outcomes.** The median follow-up duration was 578 days (IQR, 119-894 days). Table 3 shows the cumulative clinical outcomes, with no differences between groups.

## Discussion

Complexity of CBL is known to increase procedural complexity.[16] The best preparation for complex CBLs represents a daily clinical problem with limited scientific data. The present study retrospectively evaluated the impact of the PK technique on a large group of patients with complex CBLs collected from a real-world practice. The observed results suggest that the PK technique may help manage these patients by providing smoother SB management after stenting. Furthermore, the PK technique may reduce procedure-related ischemia (improved SB TIMI flow after stenting) in more complex patients.

PCI on bifurcated lesions is usually recommended using a provisional technique.[2,17] Nevertheless, SB flow maintenance represents a major problem.[18,19] In recent years, a remarkable series of data have supported the concept that plaque and carina shift occur to cause SB occlusion[20,21] in spite of standard protection with a "jailed wire" technique. In particular, carina shift is considered the main determinant of SB anatomical compromise after MV stenting, a phenomenon that usually has marginal functional significance.[22,23] In contrast, plaque shift superimposition over carina shift appears to be the mechanism leading to hemodynamically relevant SB impairment.[21,24] The abrupt, procedure-related, transient or irreversible SB occlusion is expected to determine various degrees of myocardial ischemia on the supplied territory size.[25,26] These notions led to an evolution in the provisional technique, which has been optimized with refinements aimed at reducing carina shift (ie, MV stent sizing according to distal MV).[2] Yet, the best management of plaque shift and its possible interaction with carina shifting is still an unresolved issue causing clinical events. Recently, advanced complex techniques to "protect" and rescue SBs have been developed.[27]

When dealing with high plaque burden, bifurcated lesion predilation is usually necessary before implanting the MV. In doing this, MV dilation is recommended, while SB dilation performance and technique are left to operator discretion. Pan et al[28] investigated the safety of SB dilation before MV stenting in a randomized trial conducted in 372 patients with true bifurcation lesions, and showed that predilation of the SB resulted in improved TIMI flow after MV stenting and did not hinder SB rewiring. SB predilation eventually alternated with MV predilation is not the only technique to predilate the SB. As early as 2002, Brueck et al compared sequential MV and SB predilation with kissing-balloon predilation in complex CBLs requiring lesion preparation.[29] A cohort of 59 patients was treated, and SB compromise



| | PK Group (n = 66) | Control Group (n = 472) | *P*-Value (PK vs Control) | PM-Control Group (n = 126) | *P*-Value (PK vs PM-Control) |
|---|---|---|---|---|---|
| SB flow <3 after MV stent | 4 (6.0%) | 43 (9.0%) | .06 | 17 (13.0%) | .09 |
| SB rewiring attempted | 52 (79.0%) | 319 (67.0%) | .10 | 88 (70.0%) | .10 |
| Need for non-workhorse guidewires for SB rewiring | 2 (3.0%) | 28 (6.0%) | .20 | 12 (9.5%) | .05 |
| Failure of SB rewiring | 0 (0.0%) | 13 (3.0%) | .10 | 7 (5.5%) | .049 |
| Failure of SB dilation after rewiring | 0 (0.0%) | 14 (3.0%) | .10 | 7 (5.5%) | .049 |
| **SB trouble** | **5 (7.5%)** | **60 (13.0%)** | **.10** | **23 (18.0%)** | **.03** |

Data provided as number (%).
MV = main vessel; PK = pre-kissing group; PM-control = propensity-matched control; SB = side branch.

**FIGURE 4.** Schematic representation of procedural course after main vessel (MV) stenting in pre-kissing, control, and propensity-matched control groups. SB = side branch.

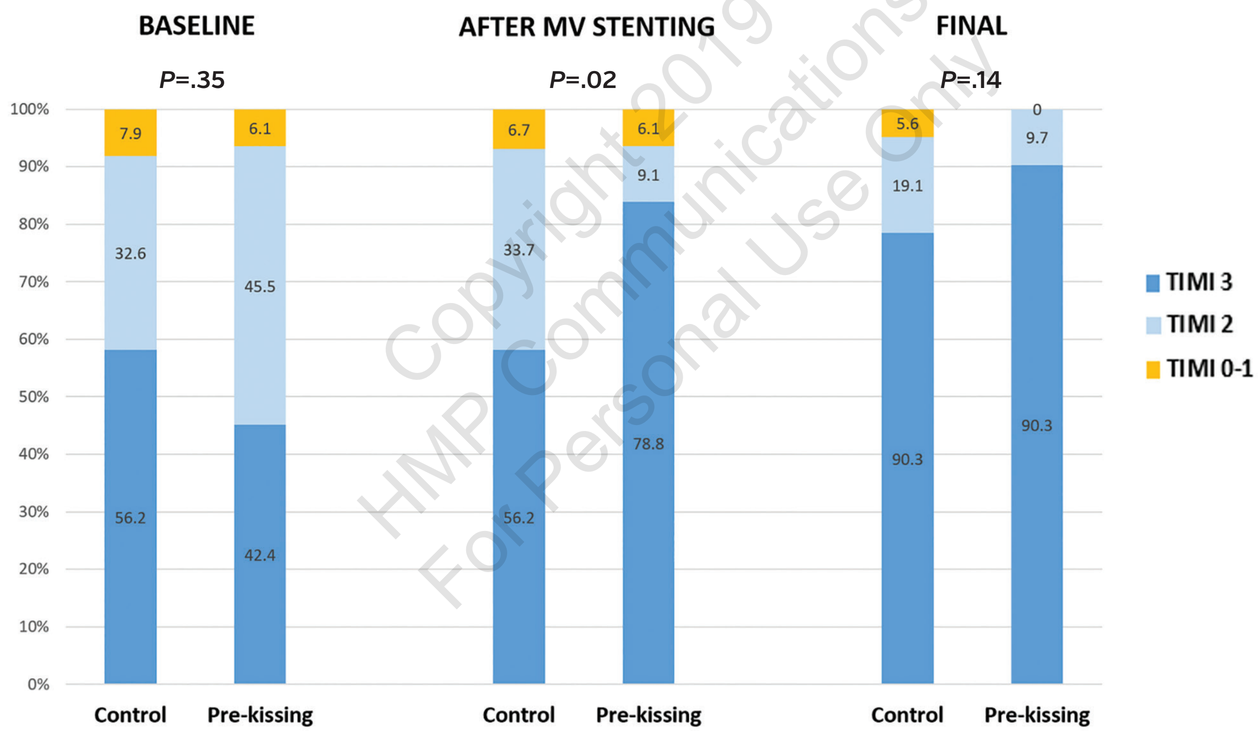





**FIGURE 5.** Side-branch (SB) TIMI flow in patients with Medina 1,1,1 lesion and SB lesion length >5 mm according to pre-kissing technique use. MV = main vessel.

rate (TIMI flow <3) after MV bare-metal stent implantation was significantly lower with the PK technique.[29] More recently, Ohya et al reported the results of a retrospective study on 204 non-left main true CBLs in 182 patients in whom provisional crossover stenting was performed with PK technique (n = 144) or sequential predilation (n = 60).[30] The procedures were systematically conducted using the transfemoral approach with 8 Fr guiding catheters as well as intravascular ultrasound guidance. Kissing-balloon predilation was performed with two standard balloon sizes in the majority of patients (2.5 mm for the MV and 2.0 mm for the SB) regardless of the specific vessel size. The stents implanted in the MV were mainly first-generation drug-eluting stents. SB compromise immediately after stenting occurred in 3.5% of lesions in the PK group vs 11.7% of lesions in the sequential group (*P*=.04). Major

Table 3. Clinical outcomes (non-hierarchical) during the follow-up (mean duration, 19 months).

| | PK Group (n = 66) | Control Group (n = 472) | *P*-Value (PK vs Control) | PM-Control Group (n = 126) | *P*-Value (PK vs PM-Control) |
|---|---|---|---|---|---|
| Death | 3 (4.5%) | 12 (2.5%) | .30 | 3 (2.0%) | .30 |
| Myocardial infarction | 2 (3.0%) | 7 (1.0%) | .30 | 0 (0.0%) | .10 |
| Stent thrombosis (ARC definite or probable) | 0 (0.0%) | 1 (0.2%) | .80 | 0 (0.0%) | – |
| Coronary artery bypass graft | 0 (0.0%) | 2 (0.4%) | .70 | 0 (0.0%) | – |
| Target-lesion revascularization | 2 (3.0%) | 12 (2.5%) | .50 | 2 (1.5%) | .40 |
| Target-vessel failure | 5 (7.5%) | 24 (5.0%) | .30 | 6 (5.0%) | .30 |
| PCI to another vessel | 3 (4.5%) | 31 (6.5%) | .30 | 11 (9.0%) | .20 |

Data provided as number (%).
ARC = Academic Research Consortium; PCI = percutaneous coronary intervention; PK = pre-kissing group; PM-control = propensity-matched control.

adverse cardiac event rate at 6-8 months of follow-up was significantly lower in the PK group.[30] Compared with this study, we enrolled a larger study population that included a broader spectrum of bifurcations, including the high-risk subgroups of patients with left main and impaired pre-PCI flow. Regarding the kissing-balloon technique, instead of a "fixed" balloon sizing, we systematically under-sized by 0.5 mm to minimize the risk of dissections. In keeping with this, the need for SB stenting was not increased by PK utilization. Furthermore, the use of a single inflation device allows the achievement of simultaneous inflation/deflation (which facilitates the maintenance of a central carina location). Finally, since first-generation drug-eluting stents are known to have structural features (cell size, strut dimension) that may affect bifurcation intervention, we restricted the enrollment period to a period in which these stents were not used in our laboratory. Regarding the procedural assessment, we carefully investigated the ease of bifurcation management by assessing a series of potential pitfalls that may occur after MV stenting (including SB flow impairment, and rewiring and dilation failures) and used a previously reported SB management procedural endpoint (SB trouble).[3] The results suggest that PK has the potential to facilitate the procedural course, especially in very complex lesions such as those with higher plaque burden combined with SB disease. In such higher-risk patients, PK not only improved the procedural endpoints, but was also associated with strongly improved SB flow pattern after MV stenting.

Clinical outcome assessments did not show significant advantages for the PK technique. This might be explained by the marginal impact of some (SB-related) intraprocedural troubles and ischemia on long-term clinical outcomes of such a heterogeneous population. Moreover, our results suggested a more pronounced impact in higher-risk patients, which represent only a minority of those encountered in clinical practice.

**Study limitations.** This study is affected by the inherent limitations of a retrospective analysis of a single center. Thus, the reported findings should be regarded as hypothesis generating. Of note, the possibility that the procedural value of PK has been over-estimated is unlikely, because adverse features tended to be more common in treated patients. Moreover, analysis restricted to higher-complexity lesions tended to show an enhanced benefit. These findings suggest reserving this technique for highly selected patients eventually identified by novel scoring systems.[31,32]

## Conclusion

In patients with complex CBL undergoing bifurcation PCI according to provisional stenting, kissing-balloon predilation is feasible and may facilitate SB management.

**Impact on daily practice.** While conducting provisional stenting in complex CBLs, the PK technique can be considered a valuable lesion preparation option. Indeed, it may help facilitate SB management after MV stenting, especially in patients with higher plaque burden in the bifurcation lesion.



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*Joint first authors.

From the [1]Institute of Cardiology, Fondazione Policlinico Universitario A. Gemelli IRCCS, Università Cattolica del Sacro Cuore, Rome, Italy; [2]on behalf of absence from the Cardiology Department, Tanta University, Tanta, Egypt.


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Address for correspondence: Francesco Burzotta, MD, Universita Cattolica del Sacro Cuore, L. Augosto Gemelli, Roma 00168, Italy. Email: francescoburzotta@gmail.com