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# Impact of Side-Branch Management in Non-Left Main Bifurcation Lesions Provisionally Stented

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ORIGINAL ARTICLE

# Impact of Side-branch Management in Nonleft Main Bifurcation Lesions Provisionally Stented

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**Abstract**

*Background*: **It is estimated that 15–20 % of all percutaneous coronary interventions are bifurcation percutaneous coronary intervention. Bifurcation intervention is regarded as one of the most challenging procedures in the field of interventional cardiology, both in terms of the success rate of the procedure itself as well as the incidence of long-term cardiac events.**

*Aim and objectives*: **To assess the impact of side-branch ostium management with either kissing balloon inflation (KBI) or repeated proximal optimization technique (RE-POT) in nonleft main bifurcations provisionally stented.**

*Patients and methods*: **Retrospective and prospective study of 100 patients, 73 male and 27 female with nonleft main bifurcation lesions treated with single drug-eluting stent strategy, in Damanhour Medical National Institute and the Islamic Cardiac Center from March 2021 to March 2023. After provisional stenting and proximal optimization, cases were separated into three groups according on the method utilized for side-branch postdilatation. In one group KBI was used, in another group RE-POT was used and in the third group no further management after proximal optimization.**

*Results*: **TIMI flow in the main branch and side-branch postintervention, procedural complications, and recurring chest discomfort in a minimum of 3-month follow up presented no statistically significant difference among the trial groups.**

*Conclusion*: **Side-branch ostium dilatation after provisional stenting in nonleft main bifurcations provisionally stented is not a routine step, only performed if there is no satisfactory flow in a sizable side-branch. There is no significant difference between kissing balloon inflation and RE-POT as complementary steps for side-branch ostium dilatation after provisional stenting of the main vessel and proximal optimization.**

*Keywords:* Nonleft main bifurcation lesions, Provisionally stented, Side-branch management

## 1. Introduction

Interventional cardiologists still confront significant difficulties in coronary bifurcation revascularization. Fractal geometry between vessel diameters, which controls bifurcation anatomy, encourages local atherogenesis and makes revascularization more difficult.[1]

Atherosclerosis in coronary bifurcations result from endothelial shear stress disturbance.[2]

The endothelial shear stress (ESS) is lower on the lateral bifurcation walls and higher on the carina. Both the development and progression of atherosclerotic plaque can be directly attributed to the low ESS.[3]

Bifurcations are difficult to categorize because of their rich diversity, however, the straightforward Medina classification has become the standard for their classification based on angiographic involvement (>50 vs. <50 % stenosis) in the proximal main vessel, distal main vessel also side-branch. This classification, however, does not cover the following factors: lesion length, SB calcification grade, and SB bifurcation angle.

The European Bifurcation Club (EBC) currently recommends the use of drug-eluting stents (DES) of

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the new generations for bifurcation angioplasties. These DES are sized along with the standard MB diameter.[4]

Sizing according to the mother vessel diameter may result in distal dissection of the MB and/or loss of the SB due to carina shifting. Complex revascularization procedures ($\geq$ two stents) have been described but have never shown any advantage over provisional stenting in the studies while having greater complication rates, hence a provisional stenting strategy is advised instead.[5]

However, if the SB lesion is particularly lengthy, the carina angle is particularly sharp, or there is significant calcification, provisional stenting may not be an appropriate treatment option. If the outcomes of the provisional stenting are unfavorable (>70 % stenosis, TIMI flow less than III, or dissection > B), a 'bailout' SB stenting procedure can be performed.

Since the 1980s, interventionists have been using a method called 'kissing balloon inflation' to compensate for proximal mal-apposition and to limit strut displacement during SB ostium opening. The idea of balloon juxtaposition first looked attractive.[6] Kissing balloon inflation (KBI) became the standard method since it had no true alternatives. Despite the lack of any evidence about its clinical value in provisional stenting, routine KBI is highly recommended in complex revascularization interventions with two stents.

In provisional stenting it seems that KBI was either clinically neutral or caused more target lesion revascularization (TLR) along the main axis than simple stent placement, which negated the predicted advantage from SB opening.[7] In a meta-analysis[8] of five randomized trials examining the therapeutic value of KBI in provisional stenting, KBI considerably lowered restenosis rates in the SB, but it quadrupled them in the mother vessel). This discrepancy could explain the final neutrality. It is significant to note that these trials compared KBI to simple stenting without any other technique to optimize struts opposition and side-branch ostium.

Therefore, several methods were suggested to enhance KBI, including inflating the balloons to different pressure limits experimentally decreasing the elliptic deformation of the mother vessel.[9]

A 'mini-kissing' or 'snuggle' technique[10] was suggested to shorten the length of juxtapositions and in turn, limit the risk of overstretch. In these 'KBI-like' variations, two balloons are still juxtaposed. Finet et al.[11] came up with a brand-new sequential method called repeated proximal optimization technique (RE-POT). This three steps procedure was developed to meet the requirements of bifurcation stenting: initial POT, SB opening, and final POT.

(1) Correction of mal-opposition.
(2) Optimization of SB opening.
(3) Maintenance of the structural integrity of the vessel, without excessive stretching or elliptic deformation.

## 2. Patients and methods

Retrospective and prospective study of 100 patients, 73 male and 27 female with bifurcation lesions treated with single DES strategy, in Damanhour Medical National Institute and Islamic Cardiac Center from March 2021 to March 2023, 66 patients were retrospective and 34 patients were prospective.

Inclusion criteria: nonleft main bifurcation lesions, diameter of side branches more than 2.5 mm, and lesions more than 50 % of a major bifurcation.

Exclusion criteria: using a BMS for main branch stenting, cardiogenic shock, severe renal impairment (creatinine clearance under 30 ml/min) or requiring dialysis, and contraindication to dual antiplatelets and using two DES for the main vessel and side-branch.

We have started the study with 102 patients but two patients were excluded as we were obligated to stent the side-branch, in one case due to side-branch dissection and in the other case due to severe osteal affection and TIMI I flow in a sizable side-branch.

After thoroughly outlining the benefits and risks, all participants gave their informed consent.

### 2.1. Methods

All patients will be subjected to revision of all demographic data: age, risk factors (family history, hypertension, diabetes mellitus, dyslipidemia, and smoking), history of previous MI, previous percutaneous coronary intervention (PCI), cerebrovascular disease, previous bypass operation, peripheral arterial disease, clinical indication (chronic stable angina, silent ischemia, STEMI, NSTEMI, unstable angina), medications at discharge, laboratory investigation: renal functions, echocardiography to assess the left ventricular systolic function, 12 leads ECG, PCI procedural details, TIMI flow in the main branch and side-branch at the end of the procedure, procedural complications and the major adverse cardiac events (MACE) throughout the follow up period that ranged from three months for prospective cases to one year for retrospective cases.

### 2.2. Statistical analysis of the data

The IBM SPSS software package (version 20.0, (IBM Corporation, Armonk, New York, USA) was used to perform the analysis once the data were entered into the computer. The qualitative data were characterized with the use of numbers and percentages. The Kolmogorov−Smirnov test was used to verify the normality of distribution. The range, mean, SD, median as well as interquartile range were used to describe the quantitative data. Significance of the obtained results was judged at the 5 % level.

## 3. Results

Table 1.

The studied group ages ranged from 45 to 84 years old with a mean of 60.73 ± 9.67, 76 % of the studied group were older than 50 years. The 100 patients were 73 male and 27 female (Table 2).

The percentages of true bifurcation lesions in the three studied groups were nearly similar (Table 3).

Among 100 cases, balloon predilatation of the main vessel was done in 50 patients, 57 % of the KBI group, 69.6 % of the POT-side-POT group, and 33.3 % of the only POT group.

*Table 1. Demographic data distribution (N = 100) of the cases under study.*

| Demographic data | *n* (%) |
|---|---|
| Sex | |
| Male | 73 (73.0) |
| Female | 27 (27.0) |
| Age (years) | |
| ≤50 | 24 (24.0) |
| >50 | 76 (76.0) |
| Minimum−maximum | 45.0−84.0 |
| Mean ± SD | 60.73 ± 9.67 |
| Median (IQR) | 61.0 (53.0−66.0) |

IQR, Inter quartile range.

*Table 2. Distribution of the studied cases according to bifurcation (N = 100).*

| Bifurcation | *n* (%) |
|---|---|
| LAD/D | 82 (82.0) |
| LCX/OM | 14 (14.0) |
| RCA/RV | 1 (1.0) |
| RCA/PLA | 1 (1.0) |
| RCA/PDA | 1 (1.0) |
| LCX-OM2/OM1 | 1 (1.0) |

Balloon predilatation of the side-branch was performed in 28 cases, 20 % of the KBI group, 30.4 % of POT-side-POT group, and 33.3 % of the group in which neither KBI nor POT-side-POT were performed (Table 4).

Among 100 patient, by the end of the procedure TIMI III flow in the main vessel was achieved in all patients but three patients required intracoronary GPIIB IIIA regarding the side-branch only 96 % of patients had final TIMI III flow, four cases had TIMI II flow in the side-branch, two (4.8 %) cases in the group in which no further management after POT, one (2.9 %) patient in KBI group and one (4.3 %) patient in RE-POT group (Table 5).

In one patient planned to undergo RE-POT for LAD bifurcation with sizable diagonal, side-branch was dissected on SB balloon inflation so side-branch stenting with transitional culotte was performed.

The procedure was terminated with TIMI III flow in both the main vessel and the side-branch without complications.

In another patient with LCX-OM bifurcation, after LCX provisional stenting and side-branch osteal dilatation, there was significant side-branch osteal stenosis, so side-branch stenting with TAP was performed with final TIMI III flow in both the MV and SB (Table 6).

Seven patients developed postprocedure chest pain three in the only POT group, two in KBI group and two in POT-side-POT group, four out of those seven cases had TIMI II flow in the side-branch, in all these cases chest pain was transient and controlled with nitrates (Figure 1, Table 7).

During follow up only two cases developed unstable angina, the two patients were in the group that did not have KBI or POT-side-POT after provisional stenting, coronary angiography revealed nonsignificant lesions for medical treatment in both of them.

## 4. Discussion

In the present study, 100 patients were involved 73 (73 %) male patients and 27 (27 %) female patients, the mean age was 60.73 years with SD 9.67 years.

*Table 3. Balloon predilatation of the main vessel and the side-branch.*

| | Total (*N* = 100) [*n* (%)] | Only POT (*N* = 42) [*n* (%)] | KBI (*N* = 35) [*n* (%)] | RE-POT (*N* = 23) [*n* (%)] | $\chi^2$ | *P* |
|---|---|---|---|---|---|---|
| Predilatation MV | 50 (50.0) | 14 (33.3) | 20 (57.1) | 16 (69.6) | 8.903[a] | 0.012[a] |
| Predilatation SB | 28 (28.0) | 14 (33.3) | 7 (20.0) | 7 (30.4) | 1.771 | 0.412 |

$\chi^2$, $\chi^2$ test; KBI, kissing balloon inflation; RE-POT, repeated proximal optimization technique.
*P*: *P* value for comparing among the three studied groups.
[a] Statistically significant at *P* value less than or equal to 0.05.

*Table 4. Comparing the TIMI flow between the three groups.*

| | Total ($N = 100$) [$n$ (%)] | Only POT ($N = 42$) [$n$ (%)] | KBI ($N = 35$) [$n$ (%)] | RE-POT ($N = 23$) [$n$ (%)] | $\chi^2$ | $^{MC}P$ |
|---|---|---|---|---|---|---|
| TIMI flow in MV | | | | | | |
| II | 0 | 0 | 0 | 0 | – | – |
| III | 100 (100.0) | 42 (100.0) | 35 (100.0) | 23 (100.0) | | |
| TIMI flow in SB | | | | | | |
| II | 4 (4.0) | 2 (4.8) | 1 (2.9) | 1 (4.3) | 0.486 | 1.000 |
| III | 96 (9.0) | 40 (95.2) | 34 (97.1) | 22 (95.7) | | |

KBI, kissing balloon inflation; RE-POT, repeated proximal optimization technique.

*Table 5. Procedural complications in the three groups.*

| Procedural complications | Total ($N = 100$) [$n$ (%)] | Only POT ($N = 42$) [$n$ (%)] | KBI ($N = 35$) [$n$ (%)] | POT-side-POT ($N = 23$) [$n$ (%)] | $\chi^2$ | $^{MC}P$ |
|---|---|---|---|---|---|---|
| Free | 93 (93.0) | 40 (95.2) | 32 (91.4) | 21 (91.3) | s | 0.691 |
| Positive | 7 (7.0) | 2 (4.8) | 3 (8.6) | 2 (8.7) | | |
| VT self-terminated | 1 (1.0) | 0 | 0 | 1 (4.3) | 2.671 | 0.226 |
| VT cardioverted with xylocaine | 2 (2.0) | 1 (2.4) | 1 (2.9) | 0 | 0.794 | 1.000 |
| Sinus bradycardia relieved with atropine | 2 (2.0) | 1 (2.4) | 1 (2.9) | 0 | 6.203 | 0.706 |
| Femoral hematoma | 2 (2.0) | 0 | 1 (2.9) | 1 (4.3) | 1.998 | 0.341 |

KBI, kissing balloon inflation.

*Table 6. Comparative analysis of the three groups evaluated regarding the occurrence of chest discomfort or changes in ECG postprocedural.*

| | Total ($N = 100$) [$n$ (%)] | Only POT ($N = 42$) [$n$ (%)] | KBI ($N = 35$) [$n$ (%)] | POT-side-POT ($N = 23$) [$n$ (%)] | $\chi^2$ | $^{MC}P$ |
|---|---|---|---|---|---|---|
| Postprocedure chest pain or ECG change | | | | | | |
| No | 93 (93.0) | 39 (92.9) | 33 (94.3) | 21 (91.3) | 0.417 | 1.000 |
| Chest pain | 7 (7.0) | 3 (7.1) | 2 (5.7) | 2 (8.7) | | |

KBI, kissing balloon inflation.

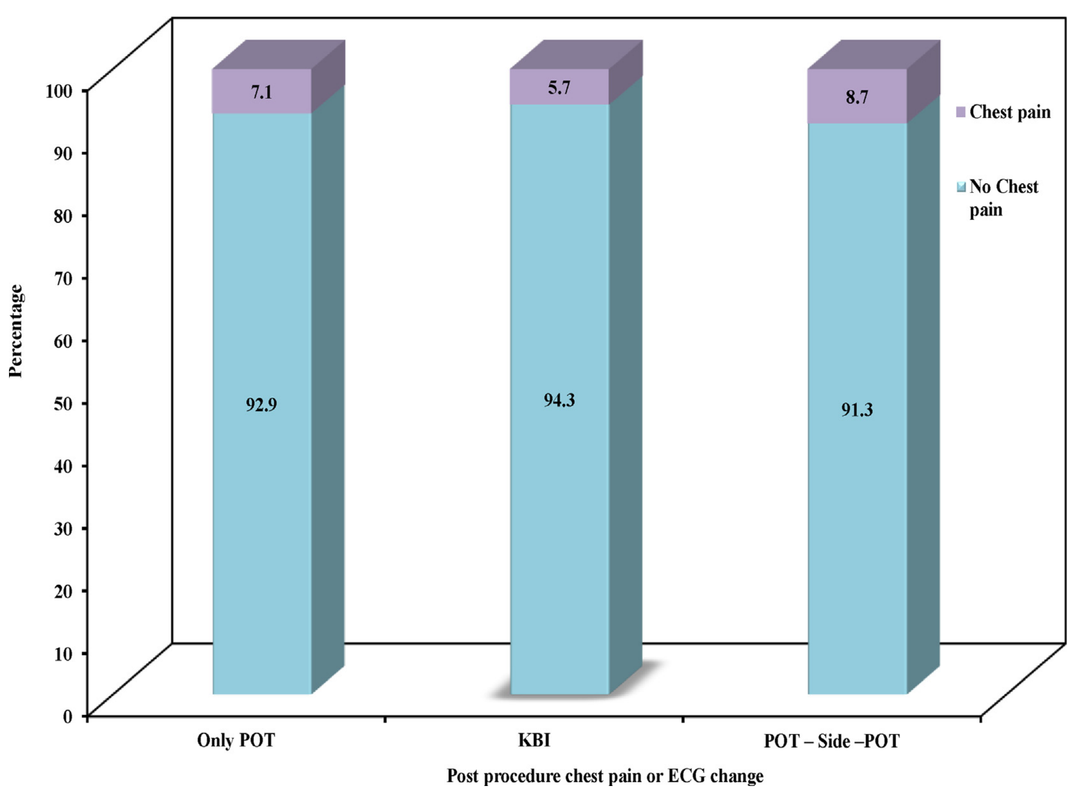


*Figure 1. Comparison among the three examined groups of cases based on postprocedure chest pain or ECG change.*

*Table 7. Comparison among the three studied groups based on recurrent chest pain in a minimum of 3 months follow up.*

| | Total ($N = 100$) [$n$ (%)] | Only POT ($N = 42$) [$n$ (%)] | KBI ($N = 35$) [$n$ (%)] | POT-side-POT ($N = 23$) [$n$ (%)] | $\chi^2$ | $^{MC}p$ |
|---|---|---|---|---|---|---|
| Recurrent chest pain in 3 months follow up | | | | | | |
| No | 98 (98.0) | 40 (95.2) | 35 (100.0) | 23 (100.0) | 1.863 | 0.514 |
| UA | 2 (2.0) | 2 (4.8) | 0 | 0 | | |

KBI, kissing balloon inflation.

Cases were separated into three groups according to the used technique for side-branch postdilatation after provisional stenting and proximal optimization. In one group KBI was used (35 patients), in another group RE-POT was used (23 patients), and in the third group no further management after proximal optimization (42 patients).

Balloon predilatation of the main branch was done in 50 (50 %) patients, in 16 (69.6 %) cases of the RE-POT group, 20 (57 %) patients of the KBI group, and in 14 (33.3 %) cases of the only POT group.

Balloon predilatation of the side-branch was performed in 28 (28 %) patients, seven (30.4 %) patients of the RE-POT group, seven (20 %) cases in the KBI group, and 14 (33 %) cases in the only POT group.

All stents used were new generation DES.

TIMI III flow in the main vessel was achieved in 100 (100 %) patients, but three patients required intracoronary GP IIB IIIA, two cases in the only POT group and one patient in the KBI group and in the side-branch, TIMI III flow was achieved in 96 (96 %) cases. In four patients the procedure was terminated with TIMI II flow two patients in the only POT group, one case in the KBI group, and one case in the RE-POT group.

In one patient planned to undergo RE-POT for LAD bifurcation with sizable diagonal, side-branch was dissected on SB balloon inflation so side-branch stenting with transitional culotte was performed, the procedure was terminated with TIMI III flow in both the main vessel and the side-branch. In another patient with LCX-OM bifurcation, after LCX provisional stenting and side-branch osteal dilatation, there was significant side-branch osteal stenosis, so side-branch stenting with TAP was performed with final TIMI III flow in both the main vessel and side-branch.

Seven patients developed postprocedure chest pain during hospital stay, three (7.1 %) in the only POT group, two (5.7 %) in KBI group, and two (8.7 %) in POT-side-POT group, four out of those seven cases had TIMI II flow in the side-branch, in all these cases chest pain was transient and controlled with nitrates. There was no in-hospital death, TLR, or non-TLR.

In a minimum of 3 months follow up, UA recurred in two cases in the only POT group, coronary angiography revealed nonspecific lesions and no further intervention was done and there are no other MACEs in follow up.

Overall, there was no statistically significant difference among the three studied groups in TIMI flow in both the main branch and side-branch, procedural complications, in hospital complications and MACE in a minimum of 3 months follow up.

While in the J-REVERSE registry published in February 2016 to assess kissing balloon inflation's effectiveness in bifurcation lesion treatment after provisional stenting. There were a total of 299 persons with 300 nonleft main bifurcation lesions, 242 men and 57 women, who were split evenly between the KBT ($n = 163$) and non-KBT ($n = 137$) groups.[12]

The mean age for the KBI group was 67.6 ± 8.5 years while in the non-KBI group the mean age was 67.6 ± 10.0 years.

Balloon predilatation of the main vessel was performed in 116 (71.2 %) cases of the KBI group and in 94 (68.6 %) cases of the non-KBI group.

Balloon predilatation of the side-branch was performed in 29 (17.8 %) patients of the KBI group and in 22 (16 %) cases of the non-KBI group.

All stents used were everolimus-eluting stent or sirolimus-eluting stent.

Angiographic assessment was performed pre-PCI, post-PCI, and after 9 months for each group according to minimal lumen diameter (MLD) and diameter stenosis (%DS) for proximal main vessel, distal main vessel, and side-branch.

Pre-PCI MLD and %DS of the proximal and distal MV were similar between groups, while greater stenosis was observed in the SB of the KBT group.

Post-PCI, there was larger MLD and in the proximal MV and significantly larger minimal lumen diameter and lower % diameter stenosis in the SB in the KBT group. In 9-month follow-up, significantly larger minimal lumen diameters in the proximal MV and SB were maintained in the KBT group.

In the acute phase, KBI was associated with more SB dissection with flow limitation (10.5 vs. 1.5 %) and required more stenting (5.6 vs. 0.7 %) than non-KBI.

Clinically, there was not a significant difference among the KBI group and the non-KBI group in terms of MACE at the 9-month follow-up: 6.3 % in the KBI group versus 9.1 % in the non-KBI group ($P = 0.47$).

Finally, the major findings of the J-REVERSE registry were: (a) KBI induced more luminal enlargement with less symmetry in the proximal MV and larger luminal diameter was maintained up to 9-month follow-up. (b) KBT brought more SB dissection and required SB stenting in the acute phase. (c) The angiographic restenosis rate in the SB was greater in non-KBT-treated than KBT-treated lesions. (d) But MACE up to 9-month follow-up did not differ among the two groups. (e) The beneficial effect of KBT on SB restenosis was confirmed, but any effect on MACE was not shown.

Zhong et al.[8] conducted a meta-analysis published in June 27, 2018 comparing the clinical results of the routine KBI strategy versus non-KBI strategy for coronary bifurcations in the one-stent approach.

The meta-analysis included five appropriate studies with an overall of 1264 individuals. These studies were the Murasato and colleagues research, Nordic III, CROSS, SMART-STRATEGY, and THUEBIS. Of the 1264 participants, 631 were assigned to the KBI strategy group and 633 were assigned to the non-KBI strategy group. The participant population included 943 men, 321 women, 311 diabetics, and 796 hypertensives. New DESs were employed in all cases. All studies employed kissing balloon inflation following main vascular stenting in the non-KBI group when the TIMI flow in the side-branch is less than III except for the Nordic III and CROSS trials, which used the stent directly. Clinical follow-up for the five trials was 6–36 months. Angiographic follow-up was done 6 ± 9 months following the index intervention. Three studies assessed treated arteries using intravascular ultrasonography after stenting and during follow-up. Two studies reported 150 left main stem bifurcation lesions.

The primary end point was cardiac death. Stent thrombosis, MI, TVR, as well as main vessel and side-branch restenosis were secondary end points.

Zhong and colleagues found that compared with the non-KBI strategy, the KBI strategy was connected with a significant decrease in side-branch restenosis angiographically. A high risk of main vessel restenosis was noted in the KBI group. There were no significant alterations in rates of cardiac death, stent thrombosis, MI, TLR, or TVR.

So, The KBI technique lowered the probability of side-branch restenosis as well as raised the risk of main branch restenosis in the one-stent approach. This was in comparison to the non-KBI strategy. But clinical outcomes were similar.

RE-POT was frequently compared with the classical KBI for side-branch postdilatation in provisional stenting in experimental models, but clinical validation of RE-POT came in March 2018 after the RE-POT clinical study was published by François Derimay.

RE-POT clinical study was a prospective multicenter trial, 106 patients were included, from October 2014 to October 2016, patients indicated for valvular or coronary surgery, severe multivessel involvement, contraindications to OCT (clearance <60 ml/min, tortuous coronary, major calcification, massive thrombus, narrow artery), contraindications to 12-month dual antiplatelet therapy, and patients with revascularization strategy other than provisional stenting were excluded.[13]

The mean age of the studied group was 65.2 ± 11, 80 male and 26 female, 30 (28.3 %) cases had diabetes, 57 (53.8 %) patients were hypertensive, and 30 (28.3 %) patients were current smokers.

There were 43 (40.6 %) LM bifurcations, 50 (47.2 %) LAD/D bifurcation, 10 (9.4 %) LCX bifurcations, and three (2.8 %) RCA bifurcations.

All patients underwent provisional stenting and RE-POT, four (3.9 %) procedures were completed by SB stenting, without difficulty, namely one SB dissection and three residual SB stenosis more than 70 %.

All stents used were new generation DESs.

In 103 cases the procedure was terminated with TIMI III flow in the main vessel and the side-branch, three patients had TIMI II flow in the side-branch at the end of the procedure, side-branch dissection occurred in one patient so side-branch stenting was done.

OCT data for three runs, baseline, just after stent implantation and after complete RE-POT. Compared with simple stenting, RE-POT reduced global mal-apposition from 18.9 ± 13.4 to 3.2 ± 3.9 % ($P < 0.05$) and residual side-branch obstruction from 44.3 ± 12.9 to 17.0 ± 14.3 % ($P < 0.05$). This optimization induced no additional elliptic deformation; indeed, the proximal ellipticity ratio improved significantly, from 1.19 ± 0.11 at baseline to 1.13 ± 0.12 at the end of the sequence ($P < 0.05$).

Through-out 6 months follow up, there was only one adverse event, that is, TLR treated by complementary angioplasty for a focal restenosis at stent entry in the mother vessel.

Compared with J-REVERSE registry, the RE-POT clinical study and the meta-analysis conducted by Zhong and colleagues, our study compared simple provisional stenting followed by proximal optimization with the two techniques used for side-branch postdilatation, RE-POT and KBI in non-LM bifurcations.

During a minimum of 3 months of follow-up, our research showed that there was no any significant difference among the three groups statistically, both angiographically and clinically, in terms of the incidence of MACE, however we did not assess stent struts opposition and side-branch opening with OCT or IVUS.

### *4.1. Conclusion*

We found no statistically or clinically significant difference between KBI and RE-POT as a complementary step after provisional stenting of the main vessel in nonleft main bifurcations.

Results also showed that provisional stenting followed by proximal optimization showed no significant increase in MACE through-out the follow up period so, side-branch postdilatation with KBI or RE-POT is not a mandatory step in nonleft main bifurcation lesions in single stent approach as long as there is satisfactory flow in the side-branch.

## Conflicts of interest

There are no conflicts of interest.

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