Cardiology Journal
2022, Vol. 29, No. 6, 899–905
DOI: 10.5603/CJ.a2022.0078
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ISSN 1897–5593
eISSN 1898–018X

VIA MEDICA

ORIGINAL ARTICLE

A novel technique of proximal optimization with kissing balloon inflation in bifurcation lesions

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Abstract

Background: *Percutaneous coronary interventions (PCI) of bifurcation lesions poses a technical challenge with a high complication rate. Kissing balloon inflation (KBI) and proximal optimization technique (POT) are used to correct bifurcation carina after stenting. However, both may still lead to uncomplete strut apposition to the side branch (SB) lateral wall. Proposed herein, is a new stent-optimization technique following bifurcation stenting consisting of a combination of POT and KBI called proximal optimization with kissing balloon inflation (POKI).*

Methods: *Bench and in-vivo evaluations were performed. For the bench visualization bifurcated silicone mock vessel was used. The POKI technique was simulated using a 3.5 mm POT balloon. For the in-vivo evaluation patients with angiographic bifurcation lesions in a native coronary artery with diameter ≥ 2.5 mm and ≤ 4.5 mm, SB diameter ≥ 2.0 mm, and percentage diameter stenosis (%DS) more than 50% in the main vessel (MV) were included. Provisional stenting was the default strategy.*

Results: *In total 41 vessels were evaluated. The target vessel was left main in 9 (22.0%) patients, left anterior descending artery — in 26 (63.4%), left circumflex artery — in 4 (9.8%) and right coronary artery — in 2 (4.9%). The predominant type of bifurcation was Medina 1-1-1 (61.8%). Baseline proximal MV DS% was 60.0 ± 23.7%, distal MV DS% — 58.8 ± 28.9% and SB DS% 53.0 ± 32.0%. The application of POKI was feasible in 41 (100%) of the vessels. Post-PCI residual DS at proximal MV was 11.5 ± 15.4%, distal MV — 6.6 ± 9.3%, and SB — 22.9 ± 28.5%. Both procedural and angiographic success was 100%.*

Conclusions: *POKI is a novel stent-optimization technique for bifurcation lesions. It showed excellent feasibility and success rate both in bench and in-vivo evaluation.* (Cardiol J 2022; 29, 6: 899–905)

Key words: coronary bifurcations, stent optimization, procedural outcome

The article is accompanied by the editorial on page 894

Introduction

Coronary bifurcation lesions correspond to nearly 20–25% of all percutaneous coronary interventions (PCI) [1, 2]. Interventions in this subset of lesions pose a technical challenge with high early and late complication rates [3]. PCI of bifurcation lesions can be performed using a variety of techniques, depending on the plaque distribution across the main and daughter branches, and the bifurcation geometry [4]. The fractal geometry of coronary

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Received: 24.05.2022 Accepted: 14.06.2022 Early publication date: 16.08.2022

bifurcations defines a discrepancy in diameters between the proximal main vessel (MV) and the daughter branches — the distal MV (main branch, MB) and side branch (SB) [5]. Kissing balloon inflation (KBI) has been one of the first proposed stent-optimization techniques specific for bifurcation lesions and continues to play an essential role in bifurcation PCI by optimizing stent apposition and improving SB access. However, the application of KBI requires SB recrossing after main vessel stenting, which adds additional procedure and fluoroscopy time, as well as contrast. It also requires certain operator experience, especially in cases with SB occlusion after stenting. Additional disadvantages of KBI are the elliptical deformation of the proximal MV, which can further compromise long-term results [6]. Proximal optimization technique (POT) has been proposed as a stent-optimization technique able to adjust the tubular design of the coronary stent to the natural bifurcation anatomy [7]. It was expected that POT could correct stent apposition, respecting fractal vessel anatomy, without compromising and even improving SB patency. However, studies demonstrated that for the preservation of SB patency, without any functional vessel flow compromise, an additional SB balloon dilation is required [8]. The optimal result of POT is highly dependent on the precise balloon positioning, and inaccurate placing of the balloon may lead to uncomplete strut apposition to the SB lateral wall [9, 10]. Moreover, it is currently demonstrated that even an appropriately positioned POT balloon (according to the current criteria [4]) could cause further elliptical deformation at SB ostium thus additionally stenosing it [11]. Therefore, proposed herein is a new stent-optimization technique following bifurcation stenting consisting of a combination of POT and kissing-balloon inflation.

Methods

Proximal optimization with kissing balloon inflation (POKI) technique

After stent deployment in MV (sized according to the distal vessel diameter) the POKI technique includes the following steps: (1) Proximal optimization technique with a non-compliant (NC) balloon sized according to the proximal MV diameter; (2) SB recrossing with a wire and removal of jailed wire; (3) Kissing balloon inflation using a NC balloon in the SB, with proximal marker of the balloon into the stent borders and an NC POT balloon in the MV, with distal balloon marker positioned parallel to carina tip.

Bench visualization

For the bench visualization custom bifurcated silicone model, with proximal MB internal diameter (ID) 3.5 mm, distal MB ID 3.0 mm, SB ID 2.5 mm, and 3.0 mm. Three types of models were used according to distal branching angle — 30°, 45° and 60° models. The POKI technique has been simulated using a dedicated 3.5 mm diameter to 6 mm length non-compliant POT balloon (Brosmed, China). The balloon is specifically designed for the POT technique with shortened balloon shoulders and specific cylindrical shape. This prevents inappropriate stent deformations at the place of inflation. Following deployment, the models were visualized using fluoroscopy and fluorography (Innova, GE Healthcare).

In-vivo procedure

Stable patients with angiographic bifurcation lesions in a native coronary artery with diameter ≥ 2.5 mm and ≤ 4.5 mm and SB diameter ≥ 2.0 mm and percentage diameter stenosis (%DS) more than 50% in MV were included. PCI was performed according to the current guidelines [12]. Provisional stenting was the default PCI procedure in all patients. All lesions were stented with second-generation drug-eluting stents. Angiographic success was defined as end procedural MV %DS < 20% and SB stenosis < 50% without significant dissection and flow impairment. Procedure success included angiographic success in the absence of in-hospital major adverse cardiac events (MACE; death, stroke, and myocardial infarction). All patients received double antiplatelet therapy with acetylsalicylic acid 75–100 mg and a P2Y2 inhibitor (clopidogrel, prasugrel, or ticagrelor).

Angiographic analysis

Dedicated bifurcation quantitative coronary angiography (QCA) analysis was performed according to the recommendation of the consensus on QCA methods for bifurcation lesions using General Electric QCA software and MicroDicom QCA software [13]. True bifurcation lesions were defined as visual percent diameter stenosis (%DS) > 50% at the SB. The minimal luminal diameter (MLD), reference vessel diameter (RVD), and %DS were measured for every segment of the bifurcation (i.e., proximal, and distal MV and SB) pre-and post-intervention. Lesion length was measured from the proximal main vessel to the distal main branch (i.e., we considered beginning and ending points where hypothetically the stent will be implanted). SB lesion length was measured from the ostium to the first normal-appearing part of the vessel. All analyzes were

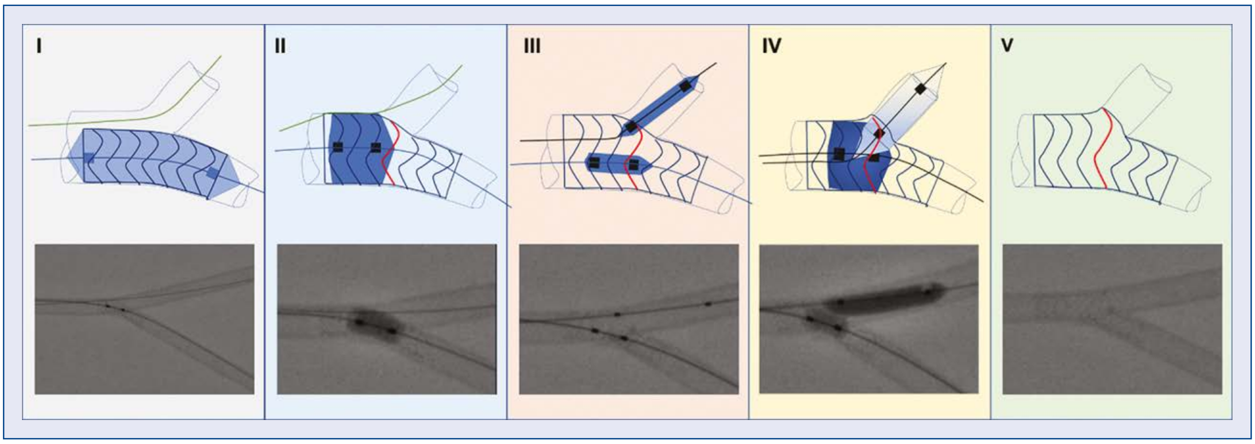

Figure 1. Schematic representation (above) and bench visualization (below) of each step of the proximal optimization with kissing balloon inflation (POKI) technique. I) The stent is implanted in main vessel (MV). Stent sizing is performed according to the distal reference diameter. II) Proximal optimization balloon is inflated in the proximal MV. The exact positioning is made by placing the distal balloon marker proximal from the carina tip. The proximal optimization technique (POT) balloon is inflated several times to ensure complete stent strut apposition in proximal region. III) The balloon positioning for POKI — in MV the distal balloon marker touches the carina tip, the side branch balloon is positioned with proximal marker exactly at the stent struts borders. The proximal SB balloon marker and MV balloon distal marker could be in parallel or MV balloon marker could be a little bit distally in the direction to the carina tip (depending on anatomy in practice). IV) During balloon inflation the stent is optimally deformed to achieve maximum apposition to the side branch ostium. V) Final result.

performed by two investigators (N.M. and P.P.) and in case of disagreement, a consensus was formed with additional analysis from the first author (D.V.).

Statistical analysis

Normality distribution of continuous variables was assessed visually with histograms and with the Shapiro–Wilk test. Continuous variables were summarized using the median and interquartile range. Categorical variables are presented as frequency counts and percentages. An independent sample T-test was performed to assess the difference between the study group and previously reported data. A p value < 0.05 was considered statistically significant. The study was investigator-initiated, funded by the local institution. The local ethics committee approved the study. All statistical calculations were performed via SPSS version 23 (SPSS, PC version, Chicago, IL, USA).

Results

Bench simulation

The POKI procedure was performed adhering to the following steps:

— **Step I: The stent is implanted in MV.** Stent sizing is performed according to the distal reference diameter.
— **Step II: POT in proximal MV.** Proximal optimization balloon is inflated in proximal MV. The exact positioning is made by placing the distal balloon marker proximal from the carina tip. The POT balloon is inflated several times to ensure complete stent strut apposition in the proximal region.
— **Step III: Balloon's positioning for POKI.** In MV the distal balloon marker is exactly at the carina tip. SB balloon is positioned with proximal marker exactly at the stent struts borders. The proximal SB balloon marker and MV balloon distal marker could be in parallel or MV balloon marker could be a little bit distally in the direction to the carina tip (depending on the specific anatomy).
— **Step IV: Simultaneous balloon inflation.** During balloon inflation the stent is optimally deformed to achieve maximum apposition to the SB. A schematic representation of the POKI procedure is illustrated in Figure 1.

In-vivo evaluation

In total 41 patients (41 vessels) were evaluated. Two case examples are illustrated in Figure 2. The mean age was 72.5 ± 8.4, and 70.6% were males. Patient clinical characteristics are shown in Table 1. The target vessel was left main in

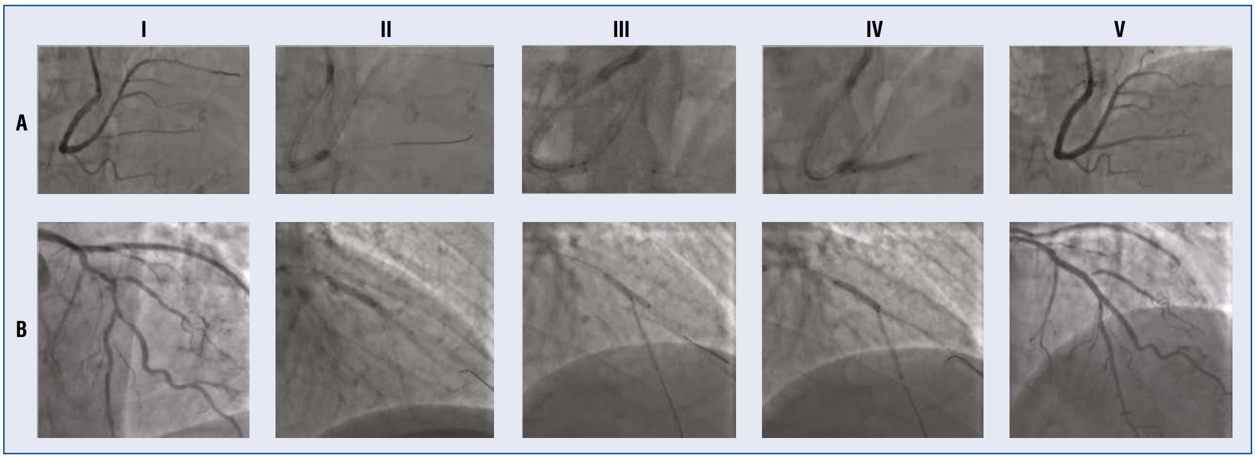

Figure 2. Clinical examples of proximal optimization with kissing balloon inflation (POKI) procedures. **A.** Percutaneous coronary intervention (PCI) of right coronary artery; **B.** PCI of left anterior descending artery. Procedural steps are the same as described in Figure 1.

Table 1. Patient demographic and clinical characteristics.

Variables	Overall (n = 41)
Age [years]	72.5 ± 8.40
Sex, male	24 (70.6%)
Body mass index [kg/m^2]	29.7 ± 5.86
Dyslipidemia	38 (92.7%)
Hypertension	41 (100.0%)
Diabetes mellitus	13 (31.7%)
Current smoker	10 (24.4%)
Previous MI	11 (26.8%)
Previous PCI in non-target vessel	22 (53.7%)
Cerebro-vascular disease	4 (9.8%)
Peripheral-artery disease	2 (4.9%)
Clinical presentation:	
Stable angina CCS II	2 (6%)
Stable angina CCS III	16 (47%)
Stable angina CCS IV	15 (44%)
Acute coronary syndrome	1 (3%)
Non-anginal symptoms	10 (50.0%)
Creatinine clearance	74.8 ± 10.1
LVEF	51.7 ± 11.0
Hospitalization days	2.62 ± 0.88

Data are shown as mean ± standard deviation or number (percentage); MI — myocardial infarction; PCI — percutaneous coronary intervention; CCS — Canadian Cardiovascular Society; LVEF — left ventricular ejection fraction

Table 2. Patient's procedural characteristics.

Variables	Value
Target vessel:	41
LM	9 (22.0%)
LAD	26 (63.4%)
LCX	4 (9.8%)
RCA	2 (4.9%)
Multivessel disease	34 (82.9%)
Radial access	38 (92.7%)
SYNTAX	17.1 ± 6.66
Contrast	252.5 ± 82.6
Procedural time	91.6 ± 24.5
Scopic time	22.6 ± 11.0
Number of stents	1.5 ± 0.78
Stent length	11.25 ± 3.21
Stent diameter	6.65 ± 1.35

Data are shown as mean ± standard deviation or number (percentage); LM — left main; LAD — left anterior descending artery; LCX — left circumflex artery; RCA — right coronary artery

9 (22.0%) patients, left anterior descending artery — in 26 (63.4%), left circumflex artery — in 4 (9.8%) and right coronary artery — in 2 (4.9%). The predominant type of bifurcation lesion was Medina 1-1-1 (62.6%). Eight (19.5%) patients presented with chronic total occlusions of the target vessels. Patient procedural characteristics are shown in Table 2.

The mean MV lesion length was 38.6 ± 20.5 and the mean SB lesion length was 9.18 ± 2.24. Baseline proximal MV DS% was 60.0 ± 23.7%, distal MV DS% — 58.8 ± 28.9% and SB DS% 53.0 ± 32.0%. The application of the POKI technique was feasible in 41 (100%) of the vessels.

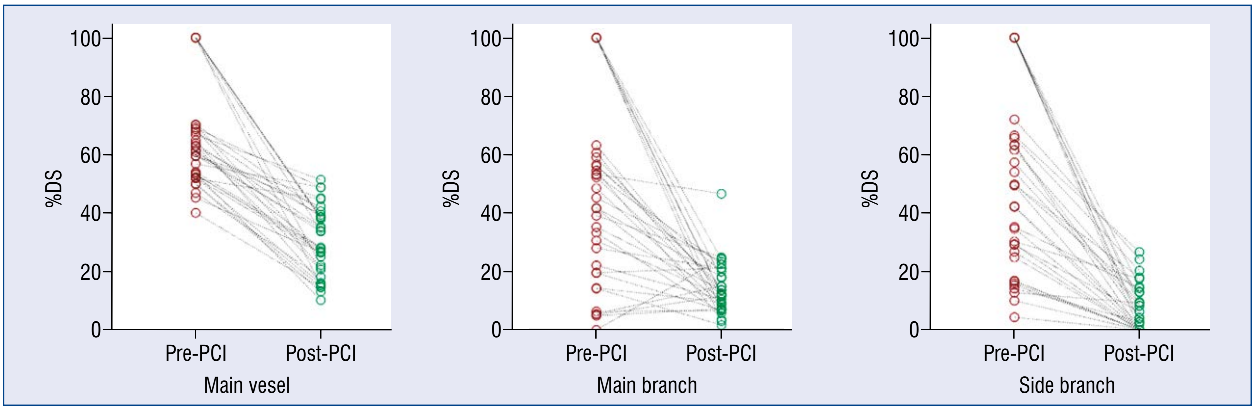

Figure 3. Changes in percentage diameter stenosis before and after percutaneous coronary intervention (PCI) in the main vessel (**A**), main branch (**B**), and side branch (**C**) of the bifurcation lesion; %DS — percentage diameter stenosis.

Table 3. Patient's procedural characteristics.

Variables	Value
MV lesion length	38.6 ± 20.5
SB lesion length	9.18 ± 2.24
MV MLD [mm]	1.31 ± 0.23
MV RVD [mm]	3.20 ± 0.46
MV DS [%]	60.0 ± 23.7
MB MLD [mm]	1.36 ± 0.45
MB RVD [mm]	2.23 ± 0.35
MB DS [%]	58.8 ± 28.9
SB MLD [mm]	1.44 ± 0.51
SB RVD [mm]	2.33 ± 0.44
SB DS [%]	53.0 ± 32.0
POKI MB balloon diameter	3.65 ± 0.5
POKI MB balloon length	10.3 ± 5.2
POKI SB balloon diameter	2.60 ± 0.42
POKI SB balloon length	18.3 ± 4.97
Maximum pressure	16 ± 1.7
Post-PCI	
MV MLD [mm]	2.20 ± 0.32
MV RVD [mm]	3.40 ± 0.40
MV DS [%]	11.5 ± 15.4
MB MLD [mm]	1.99 ± 0.35
MB RVD [mm]	2.31 ± 0.30
MB DS [%]	6.6 ± 9.3
SB MLD [mm]	2.34 ± 0.37
SB RVD [mm]	2.47 ± 0.52
SB DS [%]	22.9 ± 28.5

Data are shown as mean ± standard deviation; MV — main vessel; SB — side branch; MLD — minimal luminal diameter; RVD — reference vessel diameter; DS — diameter stenosis; MB — main branch; POKI — proximal optimization with kissing balloon inflation; PCI — percutaneous coronary intervention

Post-PCI residual DS at proximal MV was 11.5 ± ± 15.4%, distal MV — 6.6 ± 9.3%, and SB — 22.9 ± 28.5% (Fig. 3). Patient QCA characteristics are shown in Table 3. Both procedural and angiographic success were 100%.

Discussion

The main findings of the present study are the following: i) A novel stent optimization technique combining proximal optimization balloon inflation and kissing balloon technique was introduced and was found to be feasible both in bench-test and in-vivo evaluation; ii) Procedural and angiographic success after POKI in the current patient series, was excellent; iii) The immediate angiographic result after the procedure was significantly better compared with previously reported data assessing stent optimization techniques in bifurcation lesions.

Stent underexpansion and malapposition are responsible for unsatisfactory post-PCI results and are associated with target lesion failure and stent thrombosis, therefore contemporary interventional practice uses stent optimization techniques to prevent these events [14, 15]. Current expert recommendations accept POT as mandatory step in bifurcation PCI as it enhances stent apposition in the proximal MV, and reduces stent deformation [4, 16]. However, inappropriate distal positioning of the POT balloon bears the risk of distal MV overstretch and carina shift to the SB. On the other hand, incorrect proximal positioning may lead to stent malapposition and underexpansion near the carina [17]. The present analysis demonstrated that POT could be a source of additional ostial SB stenosis, due to ostial stretch in elliptical fashion [11]. Concerning carina shift, KBI has shown to have an advantage over POT followed by SB balloon dilation [18]. However, KBI bears a risk of ellipsoid stent distortion of proximal MV and its overexpansion [19], which has been associated with higher rates of MV reintervention [20]. Furthermore, randomized clinical trials comparing provisional stent strategies with or without KBI failed to report any advantage on clinical outcomes for KBI [21, 22]. Finally, when comparing KBI and POT with a consequent SB dilation, randomized multicenter trial failed to show significant advantage for any of the two techniques over the other [23]. In the present view, these results could be justified by the improper choice of balloon diameters or inadequate balloon positioning which lead to insufficient correction of the stent deformation. The POT — SB dilatation — POT technique sounds logical, but in practice, as already mentioned, it did not correct SB ostial compromise. As mentioned above, POT at the level of SB ostium stretches SB perimeter in ellipse, which eliminates the positive effect of POT on carina shifting. Thus, in the end, regarding SB compromise, the final effect could be neutral.

Therefore, the current findings have important clinical implications. This novel stent optimization technique combines the benefits from POT and KBI and may provide improved post-PCI results in bifurcation lesions. POKI technique shortens the procedure time by combining POT and KBI in a one-step approach. The operator should not be concerned about further carina shifting as SB ostium is dilated simultaneously. Furthermore, the visualization of the SB balloon at the stent border provides a firm marker of the carina position and facilitates the positioning of the MV POT balloon. If during inflation the POT balloon slips proximally, it should be positioned one marker distally after deflation, without doubting excessive carina shifting.

What would be the clinical consequences and if a better angiographic result translates into better clinical result is currently under investigation by the present group.

Limitations of the study

The study has the following limitations to be considered: first, bench models fail to truly replicate the geometry and elasticity of diseased coronary vessels. Balloon inflation in diseased coronary vessels with differential distribution of fibrosis and calcification may behave differently to silicon. However, the results from this in-vivo evaluation were confirmatory of the on-bench findings. Second, the findings include a relatively low sample size of 41 vessels. Third, for the present study intravascular imaging was not performed. Lastly, presented herein are the immediate angiographic and QCA results after the index procedure. Further follow-up study with intravascular ultrasound assessment is currently performed to evaluate the long-term procedural result.

Conclusions

Proximal optimization with KBI is a novel stent-optimization technique for bifurcation lesions. It showed excellent feasibility and success-rate both in bench and in-vivo evaluation.

Funding

The study was investigator-initiated, and funded by the local institution (Medica Cor Hospital, Russe, Bulgaria).

Conflict of interest: Carlos Collet reports receiving research grants from Biosensor, Coroventis Research, Medis Medical Imaging, Pie Medical Imaging, Cathworks, Boston Scientific, Siemens, HeartFlow Inc., and Abbott Vascular; and consultancy fees from Heart Flow Inc., Opsens, Abbott Vascular, and Philips Volcano. The other authors have nothing to disclose.

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