The International Journal of Cardiovascular Imaging (2019) 35:981–990
https://doi.org/10.1007/s10554-019-01581-1

ORIGINAL PAPER

Efficacy of the proximal optimization technique on crossover stenting in coronary bifurcation lesions in the 3D-OCT bifurcation registry

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Received: 26 September 2018 / Accepted: 7 March 2019 / Published online: 18 March 2019

Abstract

Aim We sought to investigate the efficacy of the proximal optimization technique (POT) on crossover stenting followed by side branch (SB) dilation under optical coherence tomography guidance in a multicenter registry study.

Methods and results A total of 135 bifurcation lesions in 134 patients were divided into POT (n = 52) and non-POT groups (n = 83). The POT was performed before SB dilatation (pre-POT; n = 26), finally (final-POT; n = 12), at both timing (re-POT; n = 13), and uncertain (n = 1). There were no significant intergroup differences in the success rate of guide wire re-crossing (GWR) into the optimal cell (72% vs. 65%), incidence of the link-free type in the configuration of the SB jailed struts (51% vs. 49%), or incomplete strut apposition at the bifurcation (13 ± 11% vs. 10 ± 9%). However, insufficient stent expansion close to the carina in the proximal main vessel (MV) due to inappropriate POT was likely to induce greater incomplete strut apposition (ISA) around the bifurcation. Only re-POT provided more symmetric proximal MV expansion, while pre- and final-POT did not.

Conclusion The POT did not provide the expected beneficial effects, such as reduction of ISA or more optimal GWR, under the OCT guidance. Wide stent expansion in the proximal MV induced by the POT increased the likelihood of achieving optimal GWR, whereas symmetric stent expansion was provided by re-POT.

Keywords Coronary bifurcation · Proximal optimization technique · Optical coherence tomography

Electronic supplementary material The online version of this article (https://doi.org/10.1007/s10554-019-01581-1) contains supplementary material, which is available to authorized users.

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Introduction

Kissing balloon inflation (KBI) has failed to demonstrate significant efficacy in provisional coronary bifurcation stenting [1–5] except for reducing side branch (SB) restenosis [3, 6], and clinical adverse effects have been reported in some previous studies [4, 5]. Those were mainly attributed to increase in revascularization of the main vessel (MV) caused by unpredictable dilation of juxta-positioned balloons with various overlapping styles, overdilation of the proximal stent edge, non-uniform dilation, and stent deformation in the proximal MV (PMV) [2, 7]. The proximal optimization technique (POT), which has been recommended as the optimal treatment, consists of dilation with a short balloon adjusted to the size of the PMV with its distal end positioned at the carina. It is expected to provide the certain advantages over conventional KBI based on the results of several bench tests [7–9]: (a) Symmetric and optimal size dilation in the PMV; (b) Avoiding proximal edge dissection due to

decreased arterial overstretching; (c) Decreased malapposition; (d) Facilitating optimal guide wire re-crossing (GWR) into the distal cell in the side branch (SB) ostium and reducing the jailed struts. Recently, the first study on POT for stent expansion guided by intravascular ultrasound (IVUS) was reported, which demonstrated symmetrical PMV expansion and remaining significant physiological SB stenosis in a third of cases [10]. However, the clinical efficacy of the POT over conventional KBI has not yet been fully investigated; imaging studies, in particular, are lacking.

Three-dimensional optical coherence tomography (3D-OCT) is useful for clarifying the certain matters in provisional bifurcation stenting [11, 12]: (a) stent expansion, apposition, and deformation; (b) jailing strut pattern and GWR point in the SB ostium before SB dilation; (c) patterns of the remaining jailing struts after SB dilation. The use of 3D-OCT guidance elevates the success rate of distal cell GWR in the SB ostium, thus reducing incomplete strut apposition (ISA) and effective removal of jailed struts with less stent deformation after KBI [12–14]. We investigated the efficacy of the POT on crossover stenting followed by SB dilation in this multicenter registry study regarding successful GWR to the distal cell, SB jailed strut pattern, and stent expansion/apposition. In the study, the entire procedure was performed under OCT guidance and the analysis was performed using a dedicated high-resolution 3D imaging software.

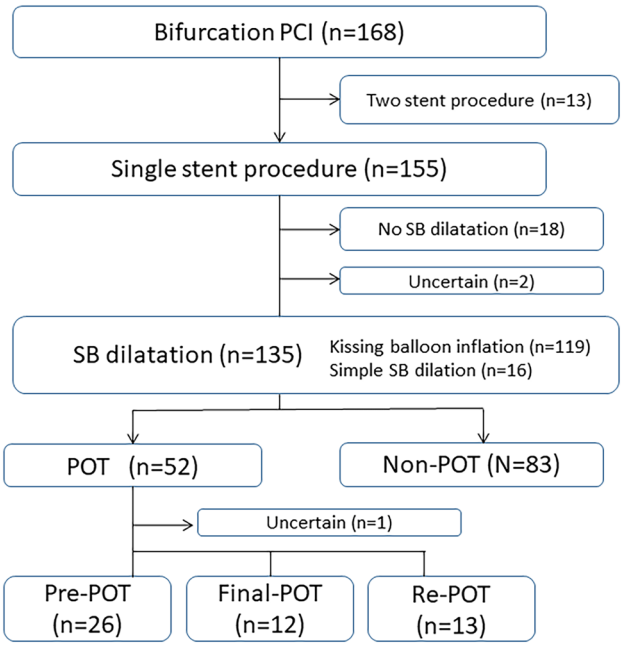

Fig. 1 Flow of the study groups from entry into the 3D-OCT Bifurcation Registry to the analysis of the present study. *SB* side branch, *POT* proximal optimization technique

Methods

Study design

The 3D-OCT Bifurcation Registry is a multicenter prospective registry that enrolled a total of 168 lesions in 167 patients who underwent drug-eluting stent implantation for de novo coronary bifurcation lesions in 10 participating centers between June 2014 and December 2015 [13, 14]. The inclusion criteria were described previously [13, 14], 1) ≥ 75% MV stenosis with or without ≥ 75% SB stenosis; 2) ≥ 2.5-mm MV and ≥ 2.0-mm SB reference diameters by visual estimates; 3) mandatory intra- and post-procedural OCT examination results. The intervention strategy and stent type were selected at the operator's discretion. The main exclusion criteria were (1) in-stent restenosis; (2) cardiogenic shock; (3) chronic total occlusion; (4) chronic kidney disease (creatinine ≥ 1.5 mg/dL); (5) emergency procedures. A total of 135 lesions in 134 patients who were treated with single crossover stenting with SB treatment were extracted for analysis after excluding two-stent procedure (13 lesions) and crossover stenting without any certain SB treatment (20 lesions) (Fig. 1). All cases preserved SB flow with more than TIMI II after PCI.

Percutaneous coronary intervention

The bifurcation lesions were treated with crossover stenting from proximal to distal MV followed by KBI (119 lesions) or simple SB dilation (16 lesions) according to the reference diameter in the OCT observation. In the KBI, it was recommended that juxtaposition of two balloons were simultaneously inflated at the same pressure. Routine POT after MV stenting was not recommended and it was performed at the operator's discretion. The POT was likely to be performed in cases with malaaposition detected in the proximal MV at any timing before or after SB treatment (Fig. 2). The POT was defined as the only PMV dilation with a short balloon that was larger than the stent size. The lesions were divided into two groups: POT (n = 52) and non-POT (n = 83). POT before SB dilation only (pre-POT), after SB dilation only (final POT), or both before and after SB dilation (re-POT) were performed in 26, 12, and 13 lesions, respectively. The data of POT timing was uncertain in one case (Fig. 1). All patients received dual antiplatelet therapy with 81–200-mg aspirin daily and 75-mg clopidogrel or 3.75-mg prasugrel daily, which was continued for ≥ 6 months.

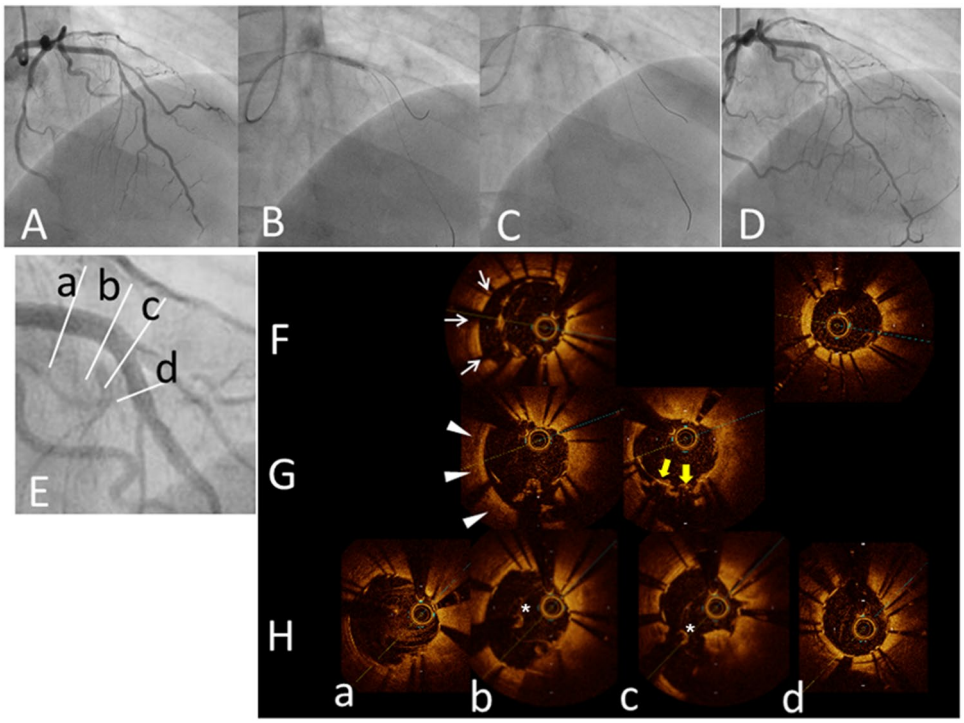

Fig. 2 A representative case with the lesion located between the left anterior descending artery and the diagonal branch. **A** Baseline coronary angiography. **B** POT after crossover stenting. **C** Kissing balloon inflation. **D** Final angiography. **E** Magnified view of the treated lesion. Lines *a–d* correspond to OCT cross-sectional images in panels (**F, G**, and **H**). Line *b* is located 1 mm proximal to the SB origin (PMV_1 mm). **F** After crossover stenting. Arrows indicate stent malapposition at the PMV_1 mm. **G** After the POT. Corrections of stent malapposition with a stent area of 5.7 mm^2 and GWR between the distal struts are indicated by triangles (*b*). The SB ostium was still jailed by the struts (*c*, yellow arrows). **H** After kissing balloon inflation. Adequate stent expansion and apposition were obtained with no jailed struts at the SB ostium. (*b* and *c*, SB guide wire is indicated by asterisks)

OCT image acquisition

OCT images were obtained using an ILUMIEN™ FD-OCT imaging system (St. Jude Medical, Minneapolis, MN, USA) and a Dragonfly™ imaging catheter after GWR into the SB at the post-MV stenting and after the final intervention procedure. OCT pullback was performed from an MV ≥ 10 mm distal to the stent with a high-resolution mode pullback speed using 100% contrast medium.

Quantitative coronary angiography analysis

Angiographic data were sent to the core laboratories, which were set in Yamaguchi University and Osaka Saiseikai Nakatsu Hospital. Quantitative coronary angiography before the PCI procedure was analyzed by independent analysts (T.O. and R.N.) using QAngioXA version 7.3 with a bifurcation-dedicated tool (Medis Specials, Leiden, The Netherlands).

Three-dimensional OCT image reconstruction

OCT raw data were also sent to the core laboratories and three-dimensional reconstruction of stent struts after automatic detection and enhancement was performed with volume-rendering software (INTAGE Realia, Cybernet, Tokyo, Japan) by the independent analysts (T.O. and R.N) [13, 14] and double checked (by T.O., R.N. and Y.M.). The jailing configurations at the SB orifice and the GWR position were classified into the link-connecting type with a link connecting to the carina, and the link-free type with no link connecting to the carina according to a previous report [12]. The area enclosed by the carina and the stent strut, with at least one distal top of the stent hoop located on the SB ostium, was defined as the distal cell.

Quantitative OCT analysis

Quantitative OCT analysis was performed using proprietary software (St. Jude Medical) in the core laboratories (by T.O. and R.N). Frame-by-frame cross-sectional images

were analyzed by counting each strut on each frame at the bifurcation segment, which extended from the origin of the bifurcated branches to the carina, and similar analysis was performed at 1-mm intervals 5 mm proximal and distal to the bifurcation segment. The lumen and stent area were also measured. The ISA was a separation of even one stent strut from the vessel wall and defined as a distance between the strut marker and the lumen contour greater than the specific strut thickness plus the axial resolution of the OCT (14 μm) [13, 14]. Strut apposition was assessed at four segments: the PMV segment (extending 5 mm proximal to the SB origin); two sides of the bifurcation (divided into two 180° halves toward or opposite the SB); the distal MV segment (extending 5 mm from the carina) [13, 14]. The eccentricity index was defined as the ratio of maximal to minimal diameter of the cross-section. The stent expansion ratio was defined as the ratio of stent area to that in the distal MV where was 5 mm distal to the carina.

Endpoints

Primary endpoints are success rate of distal cell GWR, frequency of free carina type, frequency of ISA and eccentricity index. Secondary endpoints are determinant factors of successful distal GWR.

Statistical analysis

The distribution of the data was assessed using Shapiro–Wilk normality test and the data are expressed as mean ± SD in normal distribution, median (interquartile range 25–75%, IQR) in non-normal distribution or number and percentage. Mean individual values were compared using Student's paired t-test, while between-group comparisons were examined using Student's unpaired t test. Between-group differences in counts and percentages were examined using the Chi square test, corrected by Fisher's exact test when appropriate. All p-values were two-sided and considered statistically significant at levels < 0.05. All statistical analyses were performed with EZR software (Saitama Medical Center, Jichi Medical University, Saitama, Japan), a modified version of R commander (The R Foundation for Statistical Computing, Vienna, Austria) [15].

Results

Baseline clinical and lesion characteristics

Baseline clinical and lesion characteristics are shown in Table 1. Similar clinical characteristics were observed between the two groups except for a lower frequency of diabetes mellitus in the POT group than in the non-POT group (26.4% vs. 48.8%, p = 0.02). Because the left main coronary artery in the POT group and left anterior descending artery in the non-POT group were more numerically involved, a significantly larger PMV reference was seen in the POT group (3.3 ± 0.6 mm vs. 3.0 ± 0.7 mm, p = 0.02).

Procedural observations

Stent size, length, type, and balloon sizes in the MV and SB were similar between the groups. POT balloon size was approximately 3.5 mm. The POT led to a longer operation time (112.2 min vs. 90.4 min, p = 0.001) with a trend of greater consumption of contrast medium (174.3 mL vs. 156.4 mL, p = 0.06) (Table 2).

Guide wire re-crossing

As shown in Table 2, the success rate of distal cell GWR did not differ significantly, 65% in the POT group vs. 72% in the non-POT group (p = 0.44). Likewise, the frequency of the link-free type did not differ between groups (POT, 60% vs. non-POT, 49%, p = 0.29).

Stent expansion and ISA

Numerically greater stent eccentricity index was observed in the PMV in the POT group; however, the difference did not reach statistical significance (Fig. 3A). Stent expansion ratio (Fig. 3B) and ISA frequency (Fig. 4A) were similar regardless of additional POT procedure.

Effect of POT timing

Neither pre- nor final POT improved stent eccentricity index in the PMV, whereas re-POT involved more uniform stent expansion than non-POT in the area 3–5 mm apart from the SB origin in the PMV (Fig. 3C). In terms of stent expansion ratio, the three POT types provided similar values of 30–40% enlargement to the distal reference (Fig. 3D). Re-POT had no significant impact on reducing ISA compared to the other POT types (Fig. 4B).

Comparison of POT method among participating institutes

To investigate the variety of POT methods among participating institutes, the cases performed in the four leading institutes (Hospitals A–D) in which > 20 cases were enrolled in the 3D-OCT Bifurcation Registry were compared. The cases treated in Hospital D had greater stent eccentricity index, which meant more symmetric expansion (Fig. 5A). Regarding the stent expansion ratio, the higher value in Hospital B and the smaller value in Hospital C at 1 mm from the SB origin

Table 1 Patient background and lesion characteristics by group

	POT (n = 52)	Non-POT (n = 83)	p-value
Age (years old)	70.5 ± 9.5	70.7 ± 9.9	0.89
Male, n (%)	36 (67.9)	62 (75.6)	0.55
Primary disease			
Stable angina, n (%)	32 (61.5)	53 (63.9)	0.86
Unstable angina, n (%)	3 (5.8)	4 (4.8)	1.00
Previous myocardial infarction, n (%)	6 (11.5)	9 (10.8)	1.00
Silent myocardial ischemia, n (%)	11 (21.2)	16 (19.3)	0.83
Risk factor			
Hypertension, n (%)	47 (88.7)	71 (86.6)	0.60
Dyslipidemia, n (%)	35 (66.0)	60 (73.2)	0.56
Diabetes mellitus, n (%)	14 (26.4)	40 (48.8)	0.02
Smoking, n (%)	25 (47.2)	42 (51.2)	0.86
Creatinine (mg/dL)	0.86 ± 0.41	0.90 ± 0.48	0.60
Left ventricular ejection fraction (%)	60.0 ± 9.6	61.1 ± 12.3	0.60
Lesion location			
Left main, n (%)	22 (42.3)	22 (26.5)	0.22
Left anterior descending artery, n (%)	20 (38.5)	42 (50.6)	
Left circumflex artery, n (%)	5 (19.2)	13 (15.7)	
Right coronary artery, n (%)	5 (19.2)	6 (7.2)	
Medina classification			
1-1-1	5 (9.6)	21 (25.3)	0.09
1-1-0	9 (17.3)	11 (13.3)	
1-0-1	6 (11.5)	2 (2.4)	
1-0-0	4 (7.7)	7 (8.4)	
0-1-1	4 (7.7)	12 (14.5)	
0-1-0	19 (36.5)	25 (30.1)	
0-0-1	1 (1.9)	3 (3.6)	
True bifurcation lesion, n (%)	15 (28.9)	35 (42.2)	0.14
Quantitative coronary angiogram			
Proximal MV reference (mm)	3.3 ± 0.6	3.0 ± 0.7	0.02
% diameter stenosis (%)	18.4 (3.4–48.4)	24.7 (5.8–49.8)	0.64
Distal MV reference (mm)	2.6 ± 0.5	2.4 ± 0.6	0.14
% diameter stenosis (%)	52.3 (32.7–61.2)	44.1 (26.3–59.3)	0.24
SB reference (mm)	2.3 ± 0.6	2.2 ± 0.7	0.33
% diameter stenosis (%)	18.5 (8.3–30.7)	21.5 (10.2–43.1)	0.14

POT proximal optimization technique, *MV* main vessel, *SB* side branch

in the PMV (PMV_1 mm) were notable (Fig. 5B, arrow). In Hospital C, the frequency of ISA at the bifurcation site in the POT group was significantly higher than that in the non-POT group (24.3 ± 7.9% vs. 11.8 ± 6.4%, p = 0.004, Fig. 5C). A significant difference in this frequency of the ISA in the POT group was also found between Hospitals B and C (6.1 ± 7.3% vs. 24.3 ± 7.9%, p = 0.001, Fig. 5C).

Discussion

This study investigated the efficacy of POT on crossover stenting in coronary bifurcation lesions under OCT guidance in an actual clinical setting. Our major findings were that: (1) POT did not bring any significant benefits

Table 2 Procedural characteristics and results of three-dimensional optical computed tomography analysis

	POT (n = 52)	Non-POT (n = 83)	p-value
Stent size (mm)	2.98 ± 0.44	3.04 ± 0.47	0.44
Length (mm)	22.6 ± 7.0	23.1 ± 7.3	0.72
Stent type			
Xience, n (%)	7 (13.5)	28 (33.7)	0.09
Resolute, n (%)	18 (34.6)	22 (26.5)	
Nobori, n (%)	16 (30.8)	17 (20.5)	
Promus, n (%)	7 (13.5)	12 (14.5)	
Ultimaster, n (%)	4 (7.7)	4 (4.8)	
KBI/SB dilation, n (%)	46 (88.5)/6 (11.5)		
MV balloon size (mm)	3.10 ± 0.46	3.07 ± 0.49	0.72
SB balloon size (mm)	2.51 ± 0.47	2.40 ± 0.41	0.15
POT	52 (100.0)	–	–
Pre-POT, n (%)	26 (50.0)	–	–
Final POT, n (%)	12 (23.1)	–	–
Re-POT, n (%)	13 (25.0)	–	–
Uncertain, n (%)	1 (1.9)	–	–
POT balloon size (mm)	3.54 ± 0.65	–	–
Operation time (minute)	104.5 (82.5–132.3)	90.5 (64.3–111.5)	0.001
Radiation time (minute)	33.0 (25.2–45.8)	28.5 (21.0–38.4)	0.08
Amount of contrast medium (mL)	168 (130–215)	150.0 (64.3–111.5)	0.06
3-D OCT analysis			
Re-crossing cell			
Far distal cell, n (%)	2 (3.8)	3 (3.6)	0.77
Distal cell, n (%)	34 (65.4)	60 (72.3)	
Proximal cell, n (%)	11 (21.2)	12 (14.5)	
Unknown, n (%)	5 (9.6)	8 (9.6)	
Link connection in the SB			
Link-free type, n (%)	31 (58.5)	41 (49.4)	0.13
Link-connecting type, n (%)	20 (37.7)	33 (39.8)	
Unknown, n (%)	1 (1.9)	9 (10.8)	

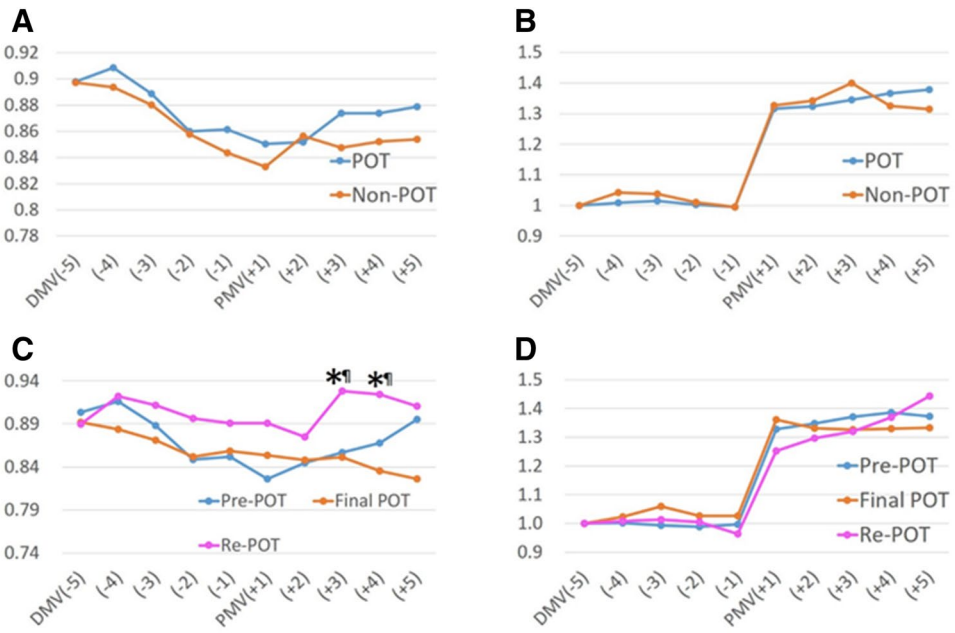

Fig. 3 Comparison of POT and non-POT groups in a 1-mm interval analysis of stent eccentricity index (**A**) and stent expansion ratio (**B**) in the bifurcation within the site 5 mm from the carina proximally and distally. Comparison of stent eccentricity index (**C**) and stent expansion ratio (**D**) among the pre-, final, and re-POT groups. *PMV* proximal main vessel, *DMV* distal main vessel. *$p < 0.05$ vs. pre-POT, ¶$p < 0.05$ vs. final POT

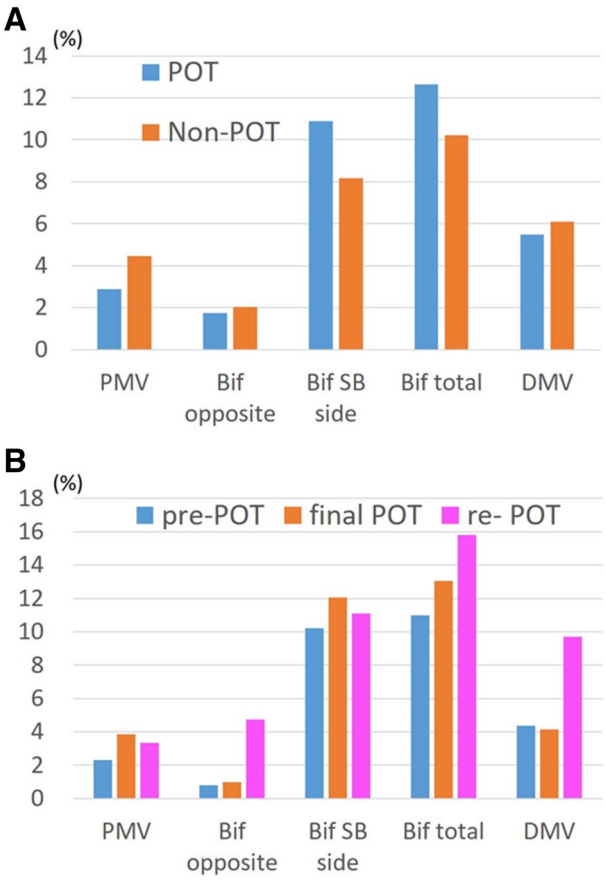

Fig. 4 **A** Comparison of frequency of incomplete strut apposition (ISA) at each site of the bifurcation in the POT and non-POT groups. PMV, located from the origin of the side branch (SB) to the site 5 mm proximal; Bif opposite, opposite side of the SB in the bifurcated area occupying the SB origin to the carina; Bif SB side, SB side of the bifurcated area; Bif total, entire count of the incidence of ISA in the bifurcated area; DMV, located from the carina to the site 5 mm distal. **B** Comparison among pre-, final- and re-POT groups in the incidence of ISA

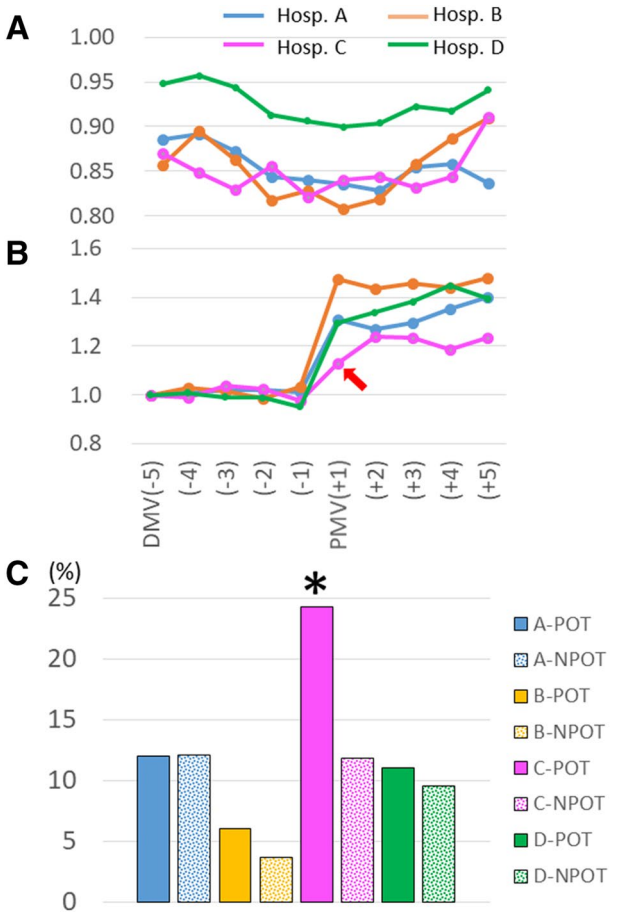

Fig. 5 Different POT methods among the four leading hospitals in the registry in stent eccentricity index (**A**), stent expansion ratio (**B**), and frequency of ISA (%) at the bifurcated area from the SB origin to the carina (**C**). Note that insufficient stent expansion in the PMV 1 mm from the SB origin in Hospital C (**B**, arrow) led to more frequent ISA after the POT, the value of which was significantly greater than that in the non-POT group (**C**, *$p < 0.05$)

on distal cell GWR or the frequency of free carina type regardless of requiring more operation time and contrast medium; (2) Re-POT improved PMV symmetry, but a single use of POT either before or after SB dilation did not influence it, and no POT type reduced ISA in the bifurcation; (3) Insufficient expansion at the carinal site induced by POT inversely increased ISA.

Efficacy of POT

The POT is proposed to ensure uniform PMV dilation to an optimal size and facilitate optimal GWR for the SB because of expansion of the jailed struts in the SB ostium [7–9]. Finet et al. demonstrated in bench testing that POT and subsequent SB dilation resulted in more uniform dilation (ellipticity index, 1.03 ± 0.02 vs. 1.36 ± 0.02) and fewer malapposed struts ($1.6 \pm 1.2\%$ vs. $42.8 \pm 5.6\%$) than conventional KBI without POT. Re-POT gave much better results regarding malapposed struts ($0.1 \pm 0.2\%$) [9]. POT was performed in 36–73% of bifurcation stenting in the clinical settings [16, 17], and Takagi et al. reported that POT combined with full stent coverage in the left main shaft resulted in fewer major adverse cardiac events (HR, 0.73; 95% CI, 0.53–1.01, $p = 0.05$) and target lesion revascularization of the MV (HR, 0.34; 95% CI, 0.15–0.76, $p = 0.008$) [16]. However, in the present clinical study, no advantage of the POT on optimal GWR, frequency of the free carina type, and degree of ISA was observed. Factors that may explain its ineffectiveness include (1) Less use of the re-POT sequence: only 25% of cases were treated with the re-POT sequence and final correction with POT was performed in 48% of cases, adding a final POT sequence. 50% of the cases were treated with pre-POT and

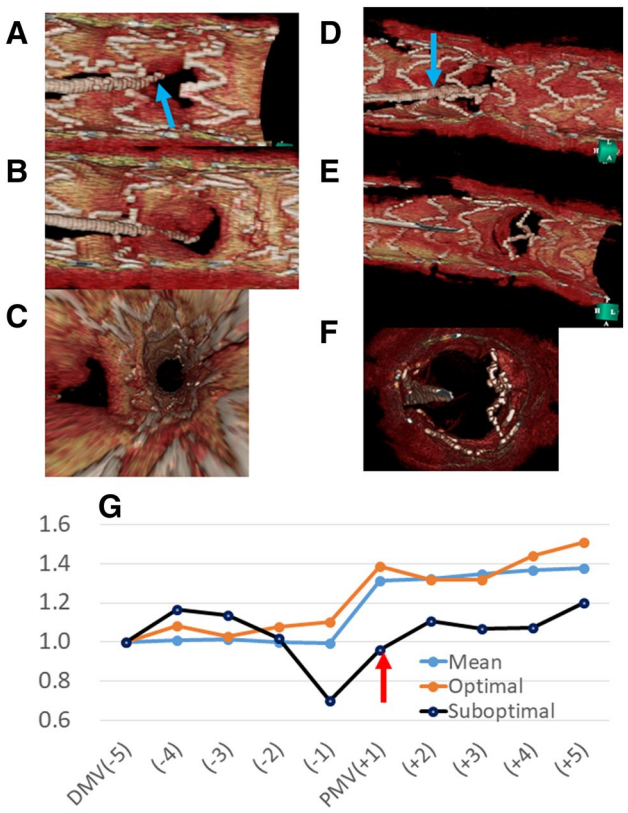

Fig. 6 3D OCT images in optimal POT. Guide wires were recrossed in the optimal distal cell (**A**, arrow) due to adequate stent expansion. Complete removal of jailed struts was achieved after SB dilation (**B**) and no metallic carina remained in the fly-trough view (**C**). 3D OCT images in suboptimal POT. Guide wires were recrossed in the proximal cell (**D**, arrow) due to inadequate stent expansion. After SB dilation, jailed struts at the carinal side remained with some protrusion in the MV (**E**). Fly-through view (**F**). Stent expansion ratio of the optimal POT (orange line) and the suboptimal POT (black line) cases with its mean value (blue line). The suboptimal POT did not lead sufficient stent expansion at PMV_1 mm (arrow)

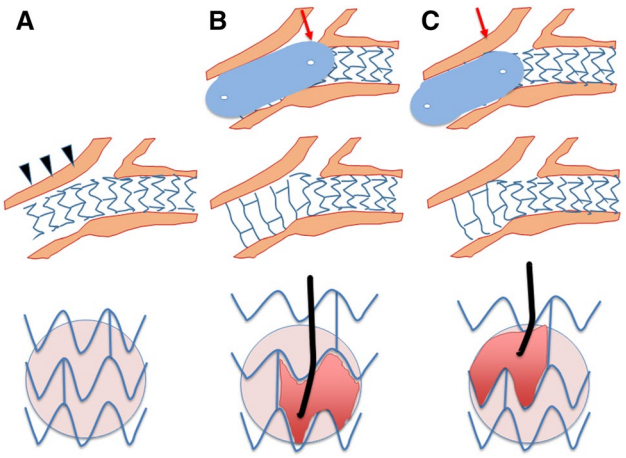

Fig. 7 Scheme of stent configuration before and after the POT. **A** Before the POT, immediately after MV stenting according to distal MV reference. The malapposition remained in the proximal MV (middle panel, triangles). Jailed struts covered on the SB ostium (lower panel). **B** Optimal POT. The POT balloon is located with the distal marker in the carina (upper panel, arrow). The malapposition in the proximal MV is reduced (middle panel). The jailed struts are enlarged uniformly, which facilitates the optimal GWR to the distal cell (lower panel, red cell). **C** Suboptimal POT. The POT balloon is located more proximally (upper panel, arrow). The stent apposition is improved in the POT-treated site (middle panel). However, the enlargement of jailed struts is obtained only in the proximal cell, which induces suboptimal GWR to the proximal cell and increase of ISA at the bifurcation (lower panel)

subsequent KBI or SB dilation, which might increase the risk of stent deformation, and malapposition remained in the bifurcation. (2) Underexpansion of the carinal site due to inappropriate location of the POT balloon (Fig. 6): in the comparison of the four leading institutes, less expansion at the PMV_1 mm in patients treated at Hospital C led to greater ISA and less optimal GWR. The distal marker of POT balloon should be positioned in the carina to obtain adequate expansion [9], and a relatively proximally located POT balloon resulted in suboptimal GWR into the dilated proximal cell and the increased ISA (Fig. 7). (3) Correction of malapposition in the non-POT group: appropriate correction of stent malapposition could be achieved in the non-POT group under the OCT guidance, which might have minimized the differences between the POT and non-POT groups.

Significance of re-POT

In the POT group, 88% of cases were treated with KBI and the rest were with simple SB dilation. KBI induces oval stent deformation in the PMV because of balloon juxtapositioning [7–9], sometimes causes non-uniform dilation because of multi-directional balloon overlapping [7], and bottleneck-like dilation because of the non-aligned proximal edges of the balloons [2]. In the present study, the re-POT sequence maintained a greater stent eccentricity index value in the PMV, while pre- or final POT did not correct oval stent deformation. This suggests that pre-POT prevents excessive stent deformation and additional final POT corrects stent deformation induced by KBI, whereas the performance of only either is insufficient to correct the oval shape deformation. Dérimay et al. also reported the efficacy of additional final POT on the symmetric expansion in the bench study, which was more prominent in the groups treated with KBI than that with POT and SB dilation [18]. Since 88% of cases were treated with KBI in the present clinical study, the results were similar as those of KBI group in their bench test. Three POT types presented similar stent expansion ratio (1.30–1.45), which was consistent with the KBI values in the previous reports [6]. Round uniform dilation of the bifurcated branches in accordance with the vascular branching

law promotes an optimal flow circumstance with less low wall shear stress [7].

POT consensus

At the initiation of this study, the optimal POT procedure had not yet been established regarding the balloon location and need for re-POT. The comparison of the four leading institutes revealed that POT methods were quite different. Since operators in Hospital C were likely to perform the POT in more proximal site to the appropriate position for the fear of carina shift to the SB, less stent expansion at the PMV 1 mm and more ISA after the POT were presented (Figs. 5, 6). Adequate expansion of the SB ostial area is obtained after precise localization of the POT balloon, which facilitates optimal GWR in the distal cell (Fig. 7). Use of the re-POT sequence after KBI is necessary to maintain symmetric expansion. Since procedural consensus was not achieved among the participating institutes, a definite benefit of the POT might not be observed in the present study. "How POT was performed" is more important compared with just "whether POT was performed or not". Therefore, no availability of clear consensus of POT was major limitation of this study. Further studies are warranted to clarify the efficacy of the POT, after consensus among participating institutes is achieved, as well as the role of OCT to perform optimal POT.

Study limitation

Because the present study was not a randomized control study, there might be some bias for patient, lesion selection for the POT procedure or stent type other than the listed factors, which might lead to the insignificant results or decrease clinical impact of the POT. The greater prevalence of left main bifurcation lesions and the significantly larger PMV reference in the POT group might have influenced the results. Relatively lower prevalence of true bifurcation lesion might also have some influences. Insufficient number of POT cases might lead to lack of statistical power. Since sample sizes of pre-, final- and re-POTs were also small (26, 12, and 13, respectively), the results comparing these groups were limited and might not reach statistically significance. The use of 3D-OCT guidance on site was possible in only three institutes, which might improve the rate of successful distal GWR there. Clear consensus on the POT procedure, such as balloon location, size selection, and re-POT sequence, was not achieved among the participating institutes, thus resulting in a variety of stent expansions at the SB ostium and stent symmetric PMV expansion. As the post-PCI OCT images were obtained after final procedure, the effect of the POT on stent expansion at PMV_1 mm or difference in diameter between PMV and DMV was not directly assessed.

Conclusion

In the 3D-OCT analysis of the present multicenter study, the POT did not increase link-free type in the SB ostium or elevate the success rate of optimal SB GWR. However, the study revealed that adequate stent expansion at the carina introduced by the POT led to optimal GWR, while inadequate stent expansion due to inappropriate proximal positioning of the POT balloon inversely increased ISA. Use of the re-POT sequence was necessary to maintain symmetric PMV stent expansion.

Clinical implication

In the cross-over stenting followed by SB dilation, adequate proximal stent expansion introduced by the POT with appropriate positioning promotes optimal GWR to the SB. Re-POT sequence is required for symmetric proximal stent expansion.

Compliance with ethical standards

Conflict of interest Drs. Okamura and Shite received honoraria for technical consulting from St. Jude Medical. The other authors have no conflict of interest to disclose related to this investigation.

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