

Feasibility and efficacy of an ultra-short side branch-dedicated balloon in coronary bifurcation stenting

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KEYWORDS

- bifurcation
- drug-eluting stent
- other technique

Abstract

Background: Side branch (SB) dilation with an ultra-short balloon after main vessel (MV) stenting may minimise stent failure in coronary bifurcation lesions.

Aims: We sought to investigate the feasibility and efficacy of the Glider balloon (GB), a side branch (SB)-dedicated balloon 4 mm in length, in coronary bifurcation stenting.

Methods: In bench testing, stent configuration was examined with micro-focus computed tomography after crossover stenting followed by GB dilation or kissing balloon inflation (KBI). In the clinical study we performed GB dilatation after MV stenting for 207 lesions in 194 patients. Failure of the GB dilation and additional procedures due to inducible stent failure were investigated as well as adverse cardiac events at 1-year follow-up.

Results: In bench testing GB dilation maintained cross-sectional stent area without significant deformation and presented effective jailed strut removal in a high-angled bifurcation model. In the clinical study the cohort included left main, true bifurcation lesion, and two-stent treatment in 42.0%, 45.9%, and 14.0%, respectively. The proximal optimisation technique (POT) or POT-like inflation was performed in 82.1%. GB crossing failure, SB stenting due to dissection, and stent deformation requiring correction by KBI or MV dilation occurred in 8.7%, 1.4%, and 5.8%, respectively. Finally, simple GB dilation without KBI was completed in 91.8% for SB dilation. At one-year follow-up, target lesion revascularisation, cardiac death, myocardial infarction, and stent thrombosis were found in 7.2%, 2.1%, 2.1%, and 1.0%, respectively.

Conclusions: Simple GB dilation after adequate expansion of the proximal MV stent provided acceptable acute and long-term results as an alternative to KBI.

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Abbreviations

CT	computed tomography
GB	Glider balloon
IVUS	intravascular ultrasound
KBI	kissing balloon inflation
LAD	left anterior descending artery
LCX	left circumflex artery
LM	left main
MACE	major adverse cardiac events
MV	main vessel
OCT	optical coherence tomography
OFDI	optical frequency domain imaging
POT	proximal optimisation technique
RCA	right coronary artery
SB	side branch

Introduction

Provisional stenting in coronary bifurcation lesions is universally recommended to reduce elective two-stent techniques which increase adverse events due to larger metal overlap or stent deformation induced by this complex procedure¹. The proximal optimisation technique (POT) with a short balloon dilation only in the proximal main vessel (MV) stent is also strongly recommended, because it provides a more symmetric stent expansion

with less malapposition¹⁻³. Kissing balloon inflation (KBI) with simultaneous inflation of the MV and SB balloons is a conventional method for SB dilation; however, routine performance of KBI in clinical studies has not been shown to be beneficial⁴ and is associated with adverse results^{5,6}. KBI with two balloons that minimally overlap in the proximal MV and re-POT after KBI are recommended to reduce oval dilation, overdilation in the proximal stent, and stent malapposition induced by the KBI^{1,3,7,8}. The re-POT sequence, which is the subsequent performance of POT, simple SB dilation, and re-POT, is also recommended as a treatment which may be considered¹. This is a superior procedure in terms of global strut malapposition, stent obstruction at the SB ostium, and symmetric stent expansion compared to conventional KBI^{9,10}.

The Glider™ PTCA balloon catheter (Teleflex Medical, Wayne, PA, USA) is a unique SB-dedicated balloon with an ultra-short length (4 mm), obliquely skived tip, and torqueable shaft^{11,12} (**Figure 1**). Combining POT and SB dilation with the Glider balloon (GB) possibly provides SB ostial expansion without damaging the distal SB and minimises MV stent deformation. We sought to examine the feasibility of the GB for SB dilation as an alternative to KBI in a coronary bifurcation model and to investigate the efficacy of the GB in a single-centre observational study.

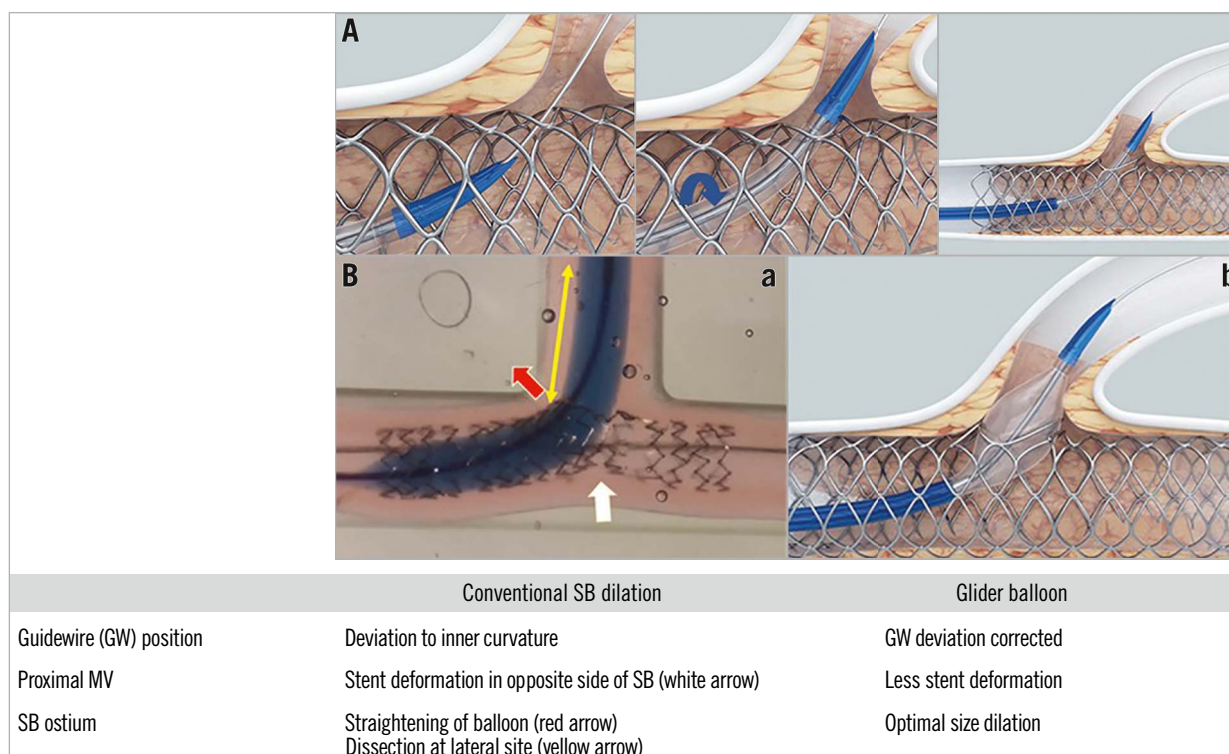


Figure 1. Scheme of SB dilation. A) Scheme showing how to deal with the initial stack of the Glider balloon (GB). When the GB tip is stacked at the SB jailed strut (left), the catheter is pulled back proximally and rotated to change the direction of the obliquely skived tip (middle). Finally, the catheter is advanced into the SB without any significant resistance (right). Courtesy of Teleflex Medical Incorporated. B) Comparison between conventional SB dilation and GB dilation. GB dilation can provide more optimal SB dilation with less guidewire (GW) deviation and stent deformation.

Methods

BENCH TESTING

Two different coronary bifurcation models consisting of 3.5 mm and 3.0 mm silicone tubes with bifurcation angles of 45° and 80° were prepared (**Figure 2A**). A couple of three different kinds of 3.5/18 mm stent (**Supplementary Appendix 1**) were implanted at 12 atm in each model. The SBs were dilated with a 3.0/4 mm GB in the SB ostium at 10 atm in one stent and with KBI using 3.5 mm and 3.0 mm non-compliant balloons at 10 atm, the proximal sites of which were minimally overlapped, in the other stent (**Figure 2A**). The stent was examined with micro-focus computed tomography (CT) (TDM1300-IS; Yamato Scientific, Tokyo, Japan) (**Figure 2B**). The cross-sectional areas at the second struts neighbouring both edges and at the most dilated site in the proximal MV were measured (**Supplementary Figure 1A(1)**). The jailed area was defined as the area of remaining overhanging struts at the SB ostium after the SB dilation procedure (**Supplementary Figure 1A(2)**).

CLINICAL STUDY

STUDY DESIGN

This clinical study is a single-centre observational study that enrolled a total of 194 patients with 207 consecutive coronary bifurcation lesions who underwent drug-eluting stent implantation and GB treatment in the National Hospital Organization Kyushu Medical Center between February 2014 and April 2018. The inclusion criteria are listed in **Supplementary Appendix 2**. The intervention

strategy and stent type were selected at the operator's discretion. The local Ethics Committee of our institution approved the study protocol and all patients provided written informed consent.

PERCUTANEOUS CORONARY INTERVENTION

All coronary interventions were performed with a 6 to 8 Fr guiding catheter under intravascular ultrasound (IVUS) guidance (OptiCross™ Polaris; Boston Scientific, Marlborough, MA, USA), optical coherence tomography (OCT) (Dragonfly™, ILUMIEN™, OPTIST™; Abbott Vascular, Santa Clara, CA, USA), or optical frequency domain imaging (OFDI) (FastView®, Lunawave®; Terumo, Tokyo, Japan). In the crossover stenting, MV stent size was selected according to the distal MV reference in the imaging observation, and POT with a short non-compliant balloon larger than the stent size was encouraged before SB dilation in cases where the difference between the proximal and distal MV references was >0.20 mm. In cases which did not satisfy this criterion and coinciding with inadequate proximal stent expansion, a stent delivery balloon after semi-retrieval, or a predilation balloon which was the same as or downsized by one quarter from the size of the stent was inflated with high pressure (16-26 atm) at the appropriate position of the POT balloon (POT-like inflation). After confirmation by imaging observation of the SB guidewire recrossing in the optimal distal cell of the overhanging struts at the SB ostium, a GB was advanced to the SB and dilated 2 to 4 times with its marker at the SB ostium not touching the GB proximal edge to the MV stent at the opposite side of the SB. In case of stack of

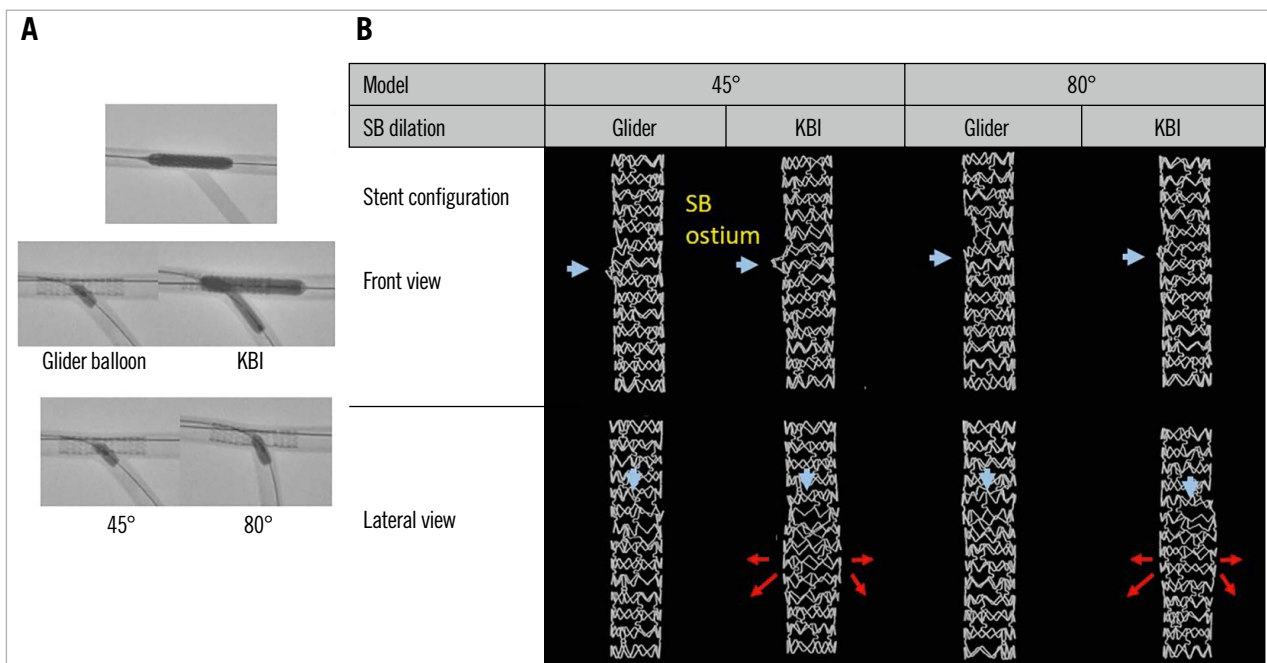


Figure 2. Bench testing comparison of side branch dilation with the GB and KBI. *A) Procedure: after crossover stenting in the MV (upper panel), SB dilation with the GB or KBI was performed (middle panel) in the silicone models with bifurcation angles of 45° and 80° (lower panel). B) Representative stent configuration of each bench test (XIENCE PRIME®; Abbott Vascular, Santa Clara, CA, USA). Upper and lower panels show front and lateral views, respectively. Blue arrows indicate the SB ostium. The KBI induced oval-shaped dilation at the balloon overlapping site (red arrows) in both the 45° and 80° models.*

the GB at the SB ostium initially, it was pulled back into a larger proximal site and rotated to change the direction of the obliquely skived tip before passing through the obstacle struts. In case of failure of GB advancement to the SB, another attempt was made after dilation with a 1.25 to 2.0 mm semi-compliant balloon. In the elective two-stenting procedures, GB dilation was performed in the stent-jailed branch ostium after the POT, similar to crossover stenting. Finally, imaging observation was performed. Re-POT or MV stent dilation with a balloon of the same size as the stent was encouraged in case of detection of significant stent malapposition or underexpansion, and final KBI was encouraged in case of significant carina shift. All patients received dual antiplatelet therapy with 81 to 200 mg aspirin daily and 75 mg clopidogrel or 3.75 mg prasugrel daily, which was continued for ≥ 6 months.

ANGIOGRAPHIC AND CLINICAL FOLLOW-UP

Acute procedural failure was defined as follows: 1) GB crossing failure, 2) SB dissection induced by the GB dilation which required SB stenting, and 3) stent deformation induced by the GB dilation which required correction with the final KBI or MV dilation. Follow-up angiography was performed at 8 to 12 months. Cardiac death, myocardial infarction, stent thrombosis, target lesion revascularisation, and the composite of these endpoints defined as major adverse cardiac events (MACE) were surveyed at one-year follow-up. The definitions of these endpoints are described in **Supplementary Appendix 3**.

ANGIOGRAPHY AND IMAGING ANALYSIS

Serial angiographies at the PCI and follow-up period were assessed quantitatively. In the imaging analysis, stent malapposition, deformation, and underexpansion were detected in each component of the bifurcation - proximal MV, bifurcation site, distal MV, and SB. Details of these analyses are shown in **Supplementary Appendix 4**.

STUDY ENDPOINTS

The primary endpoint is failure of the GB dilation including crossing failure, SB stenting due to dissection, and additional procedure due to inducible stent failure. Secondary endpoints are target lesion revascularisation and MACE at one-year follow-up of the GB treatment.

STATISTICAL ANALYSIS

Data are presented as numbers and percentages for categorical variables and mean \pm SD for continuous variables. Continuous variables were compared between the groups using an unpaired Student's t-test, whereas categorical variables were compared using a chi-square test. 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 (R Foundation for Statistical Computing, Vienna, Austria).

Results

BENCH TESTING

GB dilation in the SB ostium did not show any increase of MV stent area, while KBI induced large stent expansion at the balloon

overlapping site, the so-called bottleneck phenomenon (**Figure 2, Supplementary Figure 1B(1), Supplementary Figure 1B(2), Moving image 1, Moving image 2**). GB dilation showed a comparable remaining jailed area in the 45° model and less in the 80° model compared to KBI (**Supplementary Figure 1B(3)**). Stent deformation at the opposite side of the SB after GB dilation was not present in any of the three stent platforms.

CLINICAL STUDY

PATIENT AND LESION BACKGROUND (Table 1, Supplementary Table 1)

The majority of the patients were male; hypertension and dyslipidaemia were noted in approximately 80% of the treated patients. Of the enrolled patients, 22.3% had acute coronary syndrome. The treated lesions were in 87 left main arteries (LM; 42.0%), 83 left anterior descending arteries (LAD; 40.0%), 18 left circumflex arteries (LCX; 8.7%), and 19 right coronary arteries (RCA; 9.2%).

PROCEDURE AND PROCEDURAL FAILURE OF THE GLIDER BALLOON

A total of 178 and 29 lesions were treated with crossover stenting (**Figure 3**) and two-stenting, respectively. Two-stenting cases included more true bifurcation lesions with severe SB stenosis, more final KBI (**Supplementary Table 1**), and less SB stenosis at post-PCI angiography (**Supplementary Table 2**). The lesions were treated with the relatively large size GB (2.72 \pm 0.34 mm). POT/POT-like inflation was performed before GB dilation in 82.1%, in which the balloon size was also large enough (3.61 \pm 0.62 mm) compared to the stent size (3.13 \pm 0.43 mm) (**Table 1**).

Primary crossing failure of the GB was found in 13 lesions (6.3%) including five two-stenting cases, and secondary failure after dilation with a small balloon was noted in only five lesions (2.4%). GB crossing failure occurred more in the LM and in two-stenting (**Table 2, Supplementary Table 3**). SB stenting due to dissection was performed in only three lesions (1.4%) (**Table 2**). One case of spiral dissection due to slippage of the GB into the distal SB occurred because the GB was not positioned precisely in the SB ostium (**Supplementary Figure 2**). Imaging immediately after GB dilation showed a similar incidence of stent malapposition around the bifurcation as in the proximal MV (14.0% vs 12.6%) (**Supplementary Table 2**), and stent deformation around the bifurcation was found in only 4.8% (**Supplementary Table 2**). Serious carina shift with luminal narrowing in the distal MV was induced in 7 lesions (3.4%), which occurred most often in the LAD (6/83 cases, 7.2% vs non-LAD lesion 1/124 cases, 0.8%, $p=0.02$) (**Table 2, Supplementary Figure 3**). All of these failure lesions were corrected by MV dilation or re-POT without final KBI. Stent deformation induced by GB dilation was detected in 5 cases (2.4%), which required final KBI in only one case. Thus, 192 lesions (92.8%) were free from additional procedure for correction of the failure induced by the GB dilation. Since re-POT and MV dilation were subsequently performed for correction of the stent failure in a non-bifurcation site detected by the imaging in 32 (15.5%) and 15 (7.2%) lesions, respectively, the procedure

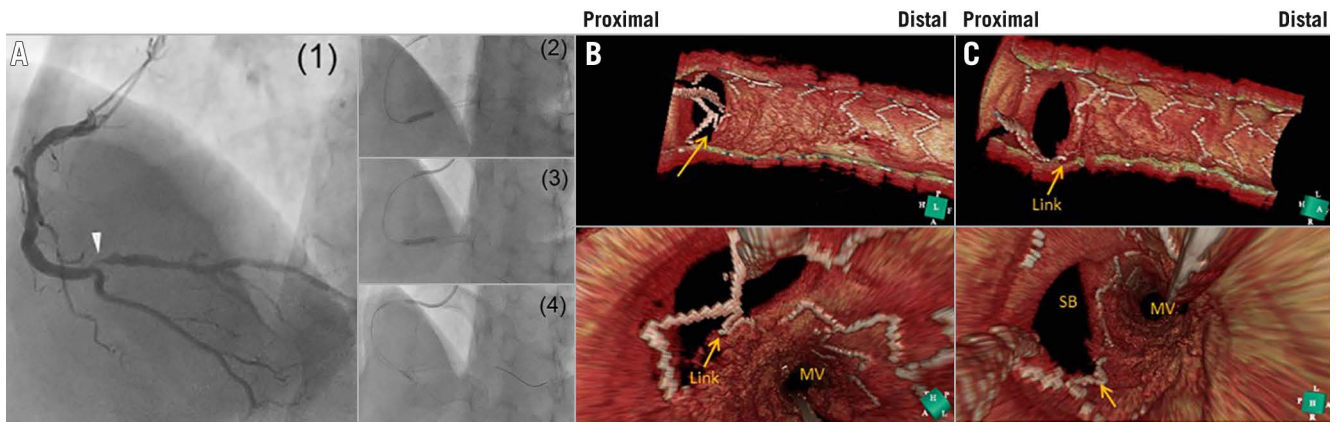


Figure 3. A representative effective case of GB dilation after crossover stenting. *A*) Coronary intervention. (1) Baseline coronary angiography showed a 0,1,0 bifurcation lesion with right bifurcation angle in the distal RCA. (2) A 3.25/15 mm XIENCE Xpedition® stent (Abbott Vascular) was deployed at 12 atm. (3) The stent delivery balloon was inflated at 16 atm again after some retrieval of the balloon proximally to appose the stent completely. (4) A 2.5/4 mm GB was inflated at the SB ostium. *B*) Three-dimensional OCT images after guidewire recrossing the SB (upper, cut-plane view; lower, fly-through view). The guidewire was recrossed in the distal cell; however, a link connection was located at the centre of the carinal site (arrows). *C*) Three-dimensional OCT images after the GB dilation. The jailed strut and link connection were clearly removed from the SB ostium (arrows).

was completed by GB dilation without any additional procedures in 141 lesions (68.1%) (**Table 2**).

CLINICAL OUTCOME AT ONE-YEAR FOLLOW-UP

One-year clinical follow-up was completed in 174 patients (89.7%), and follow-up angiography was performed in 165 patients (85.1%). MV and SB angiographic restenosis was found in 10 (5.2%) and 24 lesions (12.4%), respectively. Revascularisation of the target lesion and vessel occurred in 14 (7.2%) and 20 patients (10.3%), respectively. Four cardiac and three non-cardiac deaths were documented at the follow-up (**Supplementary Appendix 5**). Myocardial infarction and stent thrombosis occurred with acceptably low frequency (2.1% and 1.0%, respectively) (**Table 3, Supplementary Table 4**).

Discussion

BENCH TESTING

Since SB dilation with a regular-length balloon involves the risk of carina shift and stent malapposition in the opposite side of the SB, final KBI is generally regarded as a first-line standard technique for SB dilation¹, and re-POT is recommended for their correction in the re-POT sequence^{1,2,9,10}. In the present bench testing, SB dilation with a 4 mm GB precisely positioned at the SB ostium did not present either of these findings, because its ultra-short length provided the following benefits: GB location with no contact of the stent struts at the opposite side of the SB, less stent stretch due to straightening during the balloon inflation and dilation in the limited area of the SB (**Figure 1B**). More effective reduction of the jailed area was also present in the GB dilation in high-angled bifurcations, while the regular-length balloon inflation induced restriction of the SB ostial dilation¹³. Balloon overlapping in the KBI induced oval-shaped dilation in the proximal MV, which was likely to

result in stent overdilation, while SB dilation with the GB did not induce significant stent deformation (**Figure 2B, Supplementary Figure 1B, Moving image 1, Moving image 2**), indicating no need for routine performance of re-POT after GB dilation.

CLINICAL STUDY

TECHNICAL SUCCESS OF GB CROSSING

Crossing failure in the present study (primary 6.3%, secondary 2.4%) was acceptably low, which is comparable to a previous multicentre study that showed a rate of 8% for 96 patients¹². The GB is a dedicated SB balloon that has special characteristics: ultra-short length, obliquely skived tip and torqueable strong shaft to escape from the obstacle, and long wire port to provide strong pushability^{11,12}. A high success rate of GB crossing into the SB (80–83%) was reported even after failure of a conventional balloon^{11,12} at higher-angled bifurcations¹¹. In the present study, more GB crossing failure was observed in high-angled LM and two-stenting cases. Once the GB could be advanced in the high-angled bifurcation, more effective removal of the jailed struts was achieved compared to conventional KBI in the bench testing (**Supplementary Figure 1B(3)**).

CARINA SHIFT

Significant carina shift with luminal narrowing in the distal MV was observed more frequently in the LAD-diagonal bifurcation, which was likely to have rich plaque burden at the opposite side of the SB in the lower-angled bifurcation. All cases were corrected by MV dilation or re-POT, not by final KBI. In such cases, adequate lesion preparation before MV stenting is effective to prevent luminal narrowing. Final KBI using the GB is another option to avoid carina shift, which is available in ≥ 7 Fr systems. Most of the POT+GB sequence requires only two balloons, which leads to cost savings.

Table 1. Patient background, lesion background, and procedural characteristics of the clinical study.

		Total
Patient, n		194
Lesion, n		207
Patient background		
Age, years		69.6±11.1
Male gender, n (%)		155 (79.9)
Hypertension, n (%)		154 (79.4)
Dyslipidaemia, n (%)		159 (81.9)
LDL, mg/dL		97.8±27.8
Diabetes mellitus, n (%)		79 (40.7)
Insulin user, n (%)		13 (6.7)
HbA1c, %		6.2±1.0
Current smoker, n (%)		55 (28.4)
Haemodialysis, n (%)		12 (6.2)
Acute coronary syndrome, n (%)		44 (22.3)
Lesion background		
Location, n (%)	Left main	87 (42.0)
	Left anterior descending artery	83 (40.0)
	Left circumflex artery	18 (8.7)
	Right coronary artery	19 (9.2)
Medina classification, n (%)	1,1,1	50 (24.2)
	1,1,0	49 (23.7)
	1,0,1	16 (7.8)
	0,1,1	29 (14.0)
	1,0,0	15 (7.2)
	0,1,0	41 (19.8)
	0,0,1	7 (3.4)
	True bifurcation lesion	95 (45.9)
De novo lesion, n (%)		201 (97.1)
Procedure		
Stent size, mm		3.13±0.43
Stent length, mm		24.7±7.5
Stent type, n (%)	XIENCE	74 (35.7)
	Resolute	70 (33.8)
	Ultimaster	27 (13.0)
	Nobori	15 (7.2)
	PROMUS/SYNERGY	17 (8.2)
Glider balloon size, mm		2.72±0.34
Proximal optimisation technique (POT), n (%)		145 (70.0)
Size, mm		3.68±0.63
Length, mm		10.0±3.3
POT and POT-like inflation, n (%)		176 (85.0)
Size, mm		3.61±0.62
Length, mm		11.5±5.4
Sequence after MV stenting, n (%)	POT/POT-like inflation followed by SB dilation	170 (82.1)
	POT/POT-like inflation after SB dilation	6 (2.9)
Final SB dilation, n (%)	Glider balloon	190 (91.8)
	KBI using a Glider and another balloon	8 (3.9)
	Conventional KBI	8 (3.9)
Imaging, n (%)	IVUS	97 (46.9)
	OCT	69 (33.3)
	OFDI	41 (19.8)

Table 2. Procedural failure of the treatment with a Glider balloon and additional procedure.

	Total, n (%)	Lesion location, n			
		LM	LAD	LCX	RCA
Procedural failure					
GB crossing failure	18 (8.7)	11	5	1	1
Primary	13 (6.3)	8	4	1	
Secondary	5 (2.4)	3	1		1
SB stenting due to dissection induced by GB	3 (1.4)	2	1		
Stent deformation due to GB dilation	12 (5.8)		10*	1	1
Carina shift	7 (3.4)		6*	1	
Corrected by re-POT	3 (1.4)				
Corrected by MV dilation with stent size or smaller balloon	4 (1.9)				
Other stent deformation	5 (2.4)		4		1
Corrected by re-POT	2 (1.0)				
Corrected by MV dilation with stent size or smaller balloon	2 (1.0)				
Corrected by final KBI	1 (0.5)				
Free from additional procedure due to the failure induced by GB	192 (92.8)				
Additional procedure					
Additional procedure due to stent failure in non-bifurcation site	51* (24.6)	28	17	4	3
Re-POT	32 (15.5)				
MV dilation with stent size or smaller balloon	15 (7.2)				
Final KBI	4 (1.9)				
Free from any additional procedure	141 (68.1)				

*p<0.05 versus non-LAD lesion. #Both LM and LAD were treated simultaneously in one case.

Table 3. Clinical outcome at one-year follow-up after the treatment with a Glider balloon.

	Total, n (%)
Complete clinical follow-up	174 (89.7)
Follow-up coronary angiography	165 (85.1)
Angiographic restenosis	
Main vessel	10 (5.2)
Side branch	24 (12.4)
Target lesion revascularisation	14 (7.2)
Target vessel revascularisation	20 (10.3)
All-cause death	7 (3.6)
Cardiac death	4 (2.1)
Myocardial infarction	4 (2.1)
Periprocedural/spontaneous, n	0/4
Stent thrombosis	2 (1.0)
Definite/probable, n	2/0
Major adverse cardiac events	20 (10.3)
Major adverse cardiac events: composite endpoint of target lesion revascularisation, cardiac death, myocardial infarction, stent thrombosis	

SB DISSECTION

SB dissection is a concern in SB dilation with the ultra-short GB, which is likely to slip distally. One case of spiral dissection from the LCX ostium to its distal part occurred, because the GB was not positioned precisely at the LCX ostium (**Supplementary Figure 2**). From this case on, we confirmed the position of the GB marker at the SB ostium carefully and did not experience any spiral dissection. Since the ultra-short GB minimised vascular injury, SB stenting was performed in only two cases except for the case with spiral dissection.

ADDITIONAL PROCEDURES

Less requirement of additional procedures after GB dilation is another merit. Simple SB dilation with a regular-length balloon was likely to cause more stent malapposition at the opposite side of the SB and significant carina shift^{8,13}, which required correction by re-POT¹⁰ or final KBI; however, these were unlikely to occur in the GB dilation in the present study (5.8%) (**Table 2**). Stent deformation was likely to occur due to deep engagement of the guiding catheter, retrieval of the jailed wire, insertion of the rewrapped balloons, and the additional procedure itself⁴. In the present study, the sequence of POT/POT-like inflation followed by GB dilation was a simple procedure with fewer or no complications involving problems with the rewrapped balloon, balloon twisting, and guide-wire wrapping, which may occur during final KBI or re-POT. It also provides uniform and predictable lesion dilation regardless of the operator's experience of complex bifurcation stenting.

CLINICAL OUTCOME AT ONE-YEAR FOLLOW-UP

Clinical follow-up and angiography were completed adequately in a large percentage of cases (>85%). Target lesion revascularisation occurrence was acceptably low at 7.2% even after frequent performance of follow-up angiography, which is comparable to the KBI-treated group in other studies (1.3-17.9%)^{4,6,15-18}. The frequency of MACE was 10.3%, which was also comparable to previous reports (2.1-23.2%)^{4,6,15-18}. These findings indicate the efficacy of the GB treatment with a simple procedure.

Study limitations

There was a lack of experiments for comparisons in the bench testing. The difference between a silicone tube and a human coronary vessel may exaggerate some experimental results. The clinical study was a single-arm observational study of GB dilation in a single centre. A comparison between other SB dilation procedures, such as KBI or re-POT sequence, was not available. Since the study was not a randomised trial, selection of the lesion and the interventional treatment included some bias.

Conclusions

Simple GB dilation after MV stenting provided effective removal of jailed struts at the SB ostium without any significant MV stent deformation in the bench testing. A single-centre observational clinical study also showed that simple GB dilation after adequate expansion of the proximal MV stent provided acceptable acute and long-term results without routine performance of KBI or re-POT.

Impact on daily practice

In coronary bifurcation stenting, POT followed by 4 mm GB dilation in the SB ostium is a simple procedure without routine performance of re-POT or KBI. It can provide uniform and predictable stent expansion and effective removal of the jailed struts at the SB ostium without an increase in SB stenting. One-year clinical outcome after GB treatment is also comparable to KBI treatment in previous studies.

Conflict of interest statement

The authors have no conflicts of interest to declare.

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Supplementary data

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Supplementary Table 1. Patient background, lesion background, and procedural characteristics of the clinical study: crossover stenting versus two-stenting.

Supplementary Table 2. Quantitative angiography and imaging analysis.

Supplementary Table 3. Procedural failure of the treatment with a Glider balloon and additional procedure: crossover stenting versus two-stenting.

Supplementary Table 4. Clinical outcome at one-year follow-up after treatment with a Glider balloon: crossover stenting versus two-stenting.

Moving image 1. Three-dimensional micro-focus CT image of the stent (3.5/18 mm XIENCE PRIME) followed by KBI using 3.0 mm and 3.5 mm non-compliant balloons.

Moving image 2. Three-dimensional micro-focus CT image of the stent (3.5/18 mm XIENCE PRIME) with a 3.0 mm GB dilation in the SB.

The supplementary data are published online at:
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Supplementary data

Supplementary Appendix 1. Stent type in bench testing

XIENCE PRIME[®] (Abbott Vascular, Santa Clara, CA, USA), Resolute Integrity[®] (Medtronic, Santa Rosa, CA, USA), and Nobori[®] (Terumo, Tokyo, Japan).

Supplementary Appendix 2. Inclusion criteria

(1) $\geq 75\%$ MV stenosis with or without $\geq 75\%$ SB stenosis, (2) ≥ 2.5 mm MV and ≥ 2.0 mm SB reference diameters by visual estimation, (3) MV treated with crossover stenting or elective two-stent strategy, (4) GB dilation in the SB after crossover stenting or in the stent-jailed branch of the two-stenting, and (5) under imaging guidance.

Supplementary Appendix 3. Definition of endpoints

- ◆ Cardiac death: cardiovascular death includes sudden cardiac death, death due to acute MI, heart failure or cardiogenic shock.
- ◆ Myocardial infarction (MI): post-procedure MI is defined as occurring within 72 hours after PCI.
 - ✓ CK-MB $> 10x$ the upper reference limit (URL), OR
 - ✓ CK-MB $> 5x$ URL, PLUS: new pathological Q-waves in at least two contiguous leads or new persistent non-rate-related left bundle branch block, or new regional wall motion abnormality.

Spontaneous MI is defined as occurring > 72 hours after any PCI.

- ✓ The rise and/or fall of cardiac biomarkers (CK-MB or troponin) $> 1x$ URL* PLUS: ECG changes indicative of new ischaemia, or development of pathological Q-waves in > 2 leads of the ECG, or angiographically documented coronary artery occlusion or imaging evidence of new loss of viable myocardium or new regional wall motion abnormality.

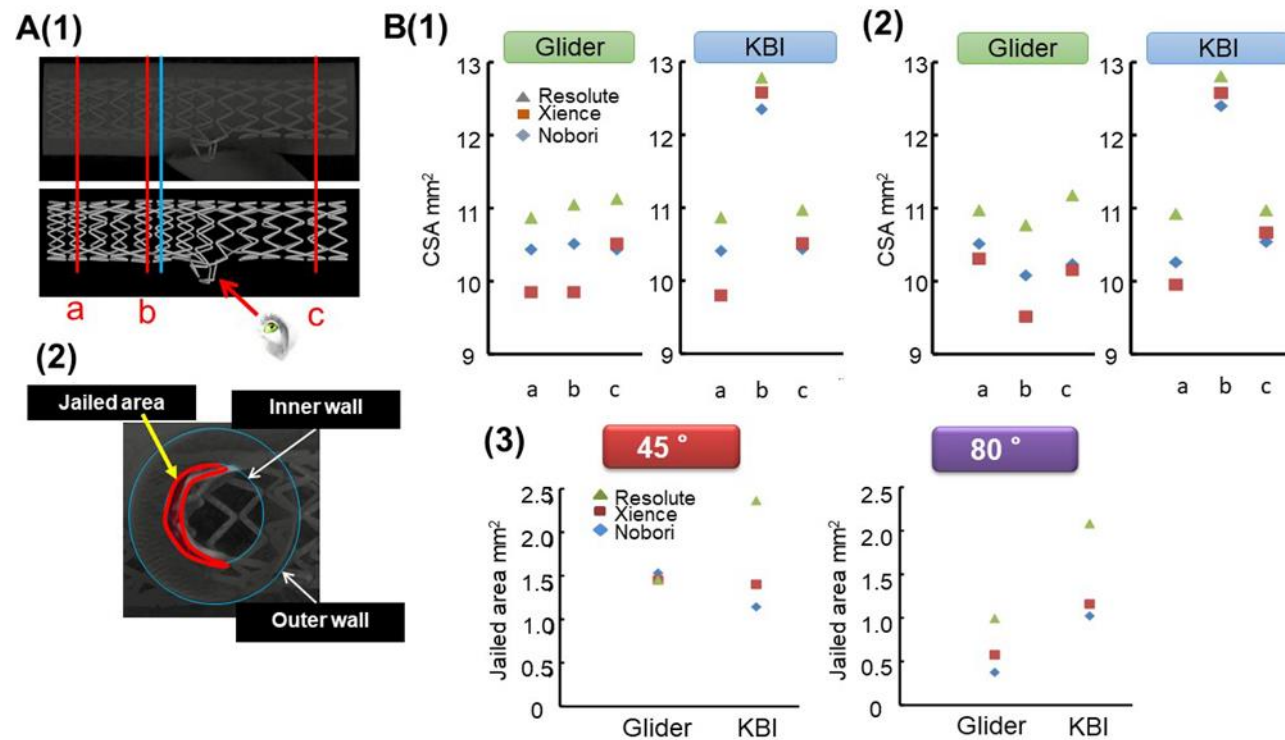
- ◆ Stent thrombosis: “definite” and “probable” according to Academic Research Consortium definitions.
- ◆ Target lesion revascularisation: a lesion revascularised in the ischaemia-driven procedure or during a planned or provisional staged procedure.

Supplementary Appendix 4. Angiography and imaging analysis

Serial angiographies at the PCI and during the follow-up period were assessed quantitatively in relation to reference diameter, minimal lumen diameter, diameter stenosis of proximal MV, distal MV and SB using CAAS ver. 7.1 software (Pie Medical, Maastricht, the Netherlands). In the imaging analysis, the treated site was divided into parts: proximal MV (>5 mm proximal to the carina), bifurcation SB side (half of the vessel at SB side around the carina within a distance of 5 mm), bifurcation opposite side (the other half of the bifurcation), distal MV (>5 mm distal to the carina), and SB. Imaging data immediately after the GB dilation were available in 169 cases (crossover stenting 151 cases, two-stenting 18 cases) to assess the effect of the GB dilation. Significant stent malapposition (IVUS: separation of a strut from the intimal surface, OCT/OFDI: strut-adjacent vessel lumen distance >350 µm) [3], deformation, and underexpansion (stent expansion index referring to the average of proximal and distal reference area <80%, OR minimal stent area <5.5 mm² on IVUS or <4.5 mm² on OCT/OFDI) were detected in each part.

Supplementary Appendix 5. Details of cardiac and non-cardiac death

Four cardiac deaths were documented in two patients with acute myocardial infarction in the LM complicating severely depressed cardiac function, one with severe heart failure and one with sudden death during the follow-up period. Two cases were treated with crossover stenting in the LM, one with two-stenting in the LM, and one with crossover stenting in the LAD. Three patients died of pneumonia, sepsis, and acute pancreatitis during the follow-up period.



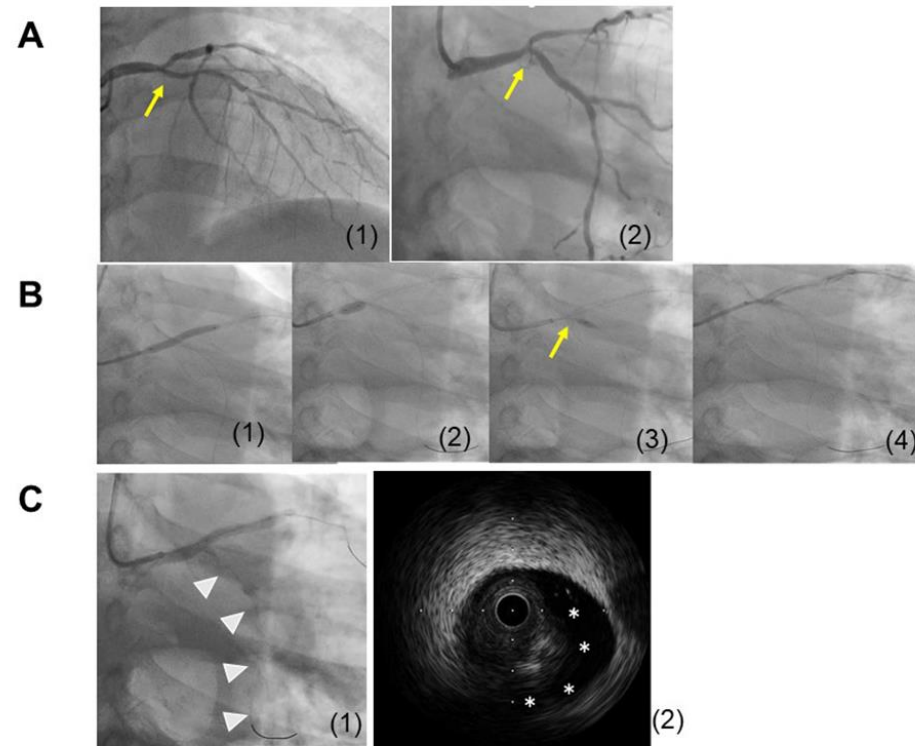
Supplementary Figure 1. Analysis of stent configuration in bench testing comparison between side branch dilation with the GB and KBI.

A) Assessment of final stent configuration.

(1) Cross-sectional area (CSA) at the second strut adjacent to the proximal edge (line a), at the most dilated site in the proximal MV (line b) and the second strut adjacent to the distal edge (line c). (2) Jailed area at the SB ostium (enclosed by red line) that is the visibly remaining strut inside the inner wall at the SB ostium from the indicated lateral view in the upper panel.

B) Results.

(1) CSA in the 45° model. (2) CSA in the 80° model. The KBI induced more stent expansion at line b in any kind of stent or bench model. (3) Jailed area (left 45° model, right 80° model). The GB removed the jailed struts more effectively in the 80° model.



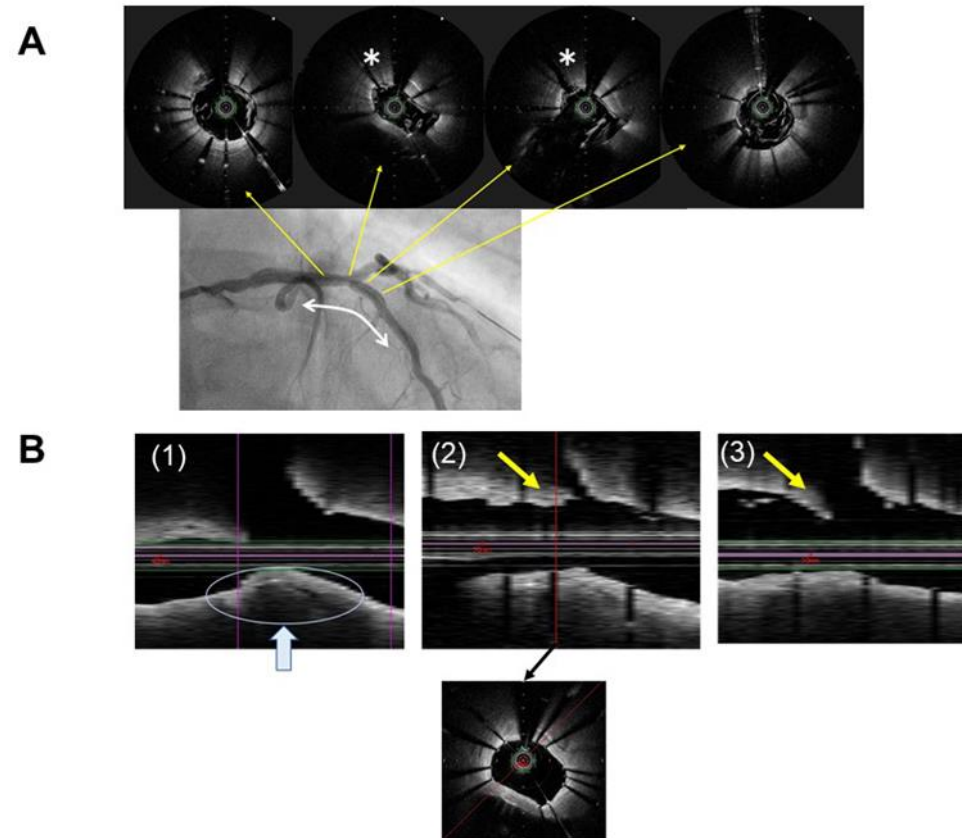
Supplementary Figure 2. A case of spiral dissection after GB dilation.

A) Baseline coronary angiography showing a 1,1,1 lesion in the LM bifurcation (arrows). (1) Right anterior oblique cranial view. (2) Anterior-posterior caudal view.

B) Coronary intervention. (1) A 3.5/24 mm Nobori stent was implanted from the LM to LAD crossing over the LCX. (2) POT was performed with a 4.5/6 mm non-compliant balloon. (3) A 3.0/4 mm GB was positioned more distally from the LCX ostium (arrow) and inflated, which led to balloon slippage to the distal. (4) The GB was dilated again at the precise position at the LCX ostium.

C) Spiral dissection. (1) Angiography showed no coronary flow at the dissected site (triangles).

(2) IVUS showed huge dissected lumen (asterisks).



Supplementary Figure 3. A representative case of significant carina shift to the distal MV after GB dilation.

A. OFDI images corresponding to the lines indicated on a 2.75/33 mm XIENCE Xpedition® stent deployed at the LAD indicated by a white arrow after a 2.5/4 mm GB dilation at the diagonal branch. Serious luminal narrowing in the LAD was present in the bifurcated site (asterisks).

B. Serial OFDI images in the LAD during the bifurcation intervention. (1) Pre-intervention image showed rich plaque burden at the opposite side of the diagonal branch (enclosed line). (2) After direct stenting in the MV. Significant carina shift to the SB ostium (arrow) occurred despite underexpansion of the MV stent (lower panel). (3) After GB dilation. The carina was relocated in the direction of the MV, which resulted in luminal narrowing of the MV.

Supplementary Table 1. Patient background, lesion background, and procedural characteristics of the clinical study: crossover stenting versus two-stenting.

	Crossover stenting	2-stent
Patient, n	167	28
Lesion, n	178	29
Patient background		
Age, years	69.1±11.1	72.8±10.3
Male gender, n (%)	136 (81.4)	19 (70.4)
Hypertension, n (%)	136 (81.4)	18 (66.7)
Dyslipidaemia, n (%)	139 (83.2)	20 (74.1)
LDL, mg/dL	98.4±27.6	93.7±29.7
Diabetes mellitus, n (%)	69 (41.4)	11 (40.7)
Insulin user, n (%)	10 (6.0)	3 (11.1)
HbA1c	6.2±1.0	6.0±0.7
Current smoker	48 (28.7)	7 (25.9)
Haemodialysis	10 (6.0)	2 (7.4)
Acute coronary syndrome, n (%)	37 (22.2)	8 (29.6)
Lesion background		
Location		
Left main, n (%)	74 (41.5)	13 (44.8)
Left anterior descending artery, n (%)	70 (39.3)	13 (44.8)
Left circumflex artery, n (%)	18 (10.1)	0
Right coronary artery, n (%)	16 (9.0)	3 (10.3)
Medina classification		
1,1,1, n (%)	32 (18.0)	18 (62.1)
1,1,0, n (%)	48 (27.0)	1 (3.4)
1,0,1, n (%)	15 (8.4)	1 (3.4)
0,1,1, n (%)	24 (13.5)	5 (17.2)
1,0,0, n (%)	15 (8.4)	0



0,1,0, n (%)	40 (22.5)	1 (3.4)
0,0,1, n (%)	4 (2.2)	3 (10.3)
True bifurcation lesion, n (%)	71 (39.9)	24 (82.8)*
De novo lesion, n (%)	178 (100)	23 (79.3)
Procedure		
Stent size, mm	3.15 ± 0.43	3.04 ± 0.42
Stent length, mm	24.9 ± 7.6	23.4 ± 7.4
XIENCE, n (%)	68 (38.2)	6 (20.6)
Resolute, n (%)	56 (31.5)	14 (4.8)
Ultimaster, n (%)	23 (12.9)	4 (13.8)
Nobori, n (%)	14 (7.9)	1 (3.4)
PROMUS/SYNERGY, n (%)	15 (8.4)	2 (6.9)
Glider balloon size, mm	2.70 ± 0.33	2.83 ± 0.38
Proximal optimisation technique (POT)	123 (69.1)	22 (75.9)
size, mm	3.68 ± 0.64	3.68 ± 0.55
length, mm	9.9 ± 3.3	10.2 ± 3.4
POT and POT-like inflation	150 (84.3)	26 (89.6)
size, mm	3.61 ± 0.63	3.63 ± 0.54
length, mm	11.4 ± 5.1	12.3 ± 6.8
Sequence after MV stenting		
POT/POT-like inflation followed by SB dilation, n (%)	145 (81.5)	25 (86.2)
POT/POT-like inflation after SB dilation, n (%)	5 (2.8)	1 (3.4)

Final SB dilation		
Glider balloon, n (%)	170 (95.5)	21 (72.4)
KBI using a Glider and another balloon, n (%)	4 (2.2)	4 (13.8)*
Conventional KBI, n (%)	4 (2.2)	4 (13.8)*
2-stent		
Planned, n (%)		20 (71.4)
Provisional, n (%)		3 (10.7)
Additional SB stenting due to restenosis, n (%)		3 (10.7)
SB ostial restenosis after 2-stenting, n (%)		2 (7.1)
Technique (de novo lesion)		
Culotte, n (%)		12 (47.8)
Crush, n (%)		7 (30.4)
Modified T-stenting, n (%)		3 (13.0)
T-stenting and minimal protrusion, n (%)		1 (4.3)
Imaging		
IVUS, n (%)	80 (44.9)	17 (58.6)
OCT, n (%)	62 (34.8)	7 (24.1)
OFDI, n (%)	36 (20.2)	5 (17.2)

* p<0.05 versus crossover stenting.

Supplementary Table 2. Quantitative angiography and imaging analysis.

	Total	Crossover stenting	2-stent	
Quantitative angiography				
Proximal main vessel				
Reference vessel diameter, mm	3.5±0.6	3.5±0.6	3.6±0.6	
Minimal lumen diameter, mm	1.6±1.1	1.6±1.1	1.6±0.9	
Stenosis, %				
Baseline	56±28	56±28	55±24	
Post-PCI	9±9	9±9	10±11	
Follow-up	14±16	13±16	17±14	
Distal main vessel				
Reference vessel diameter, mm	2.9±0.3	2.9±0.3	2.9±0.3	
Minimal lumen diameter, mm	0.8±0.7	0.8±0.7	0.7±0.8	
Stenosis, %				
Baseline	73±23	72±23	75±23	
Post-PCI	12±11	12±10	10±10	
Follow-up	20±18	19±15	30±26*	
Side branch				
Reference vessel diameter, mm	2.7±0.4	2.7±0.4	2.7±0.3	
Minimal lumen diameter, mm	1.4±0.8	1.5±0.8	0.4±0.4*	
Stenosis, %				
Baseline	51±30	45±28	88±14*	
Post-PCI	29±17	31±16	12±10*	
Follow-up	34±19	35±18	34±21	
Imaging findings after GB dilation, n				
Malapposition				
Bifurcation	SB side, n (%)	22 (10.6)	21 (11.8)	1 (3.4)
	Opposite side, n (%)	7 (3.4)	7 (3.9)	0

Proximal MV, n (%)		26 (12.6)	25 (14.0)	1 (3.4)
Distal MV, n (%)		4 (1.9)	4 (2.2)	0
Stent deformation				
Bifurcation	SB side, n (%)	10 (4.8)	10 (5.6)	0
	Opposite side, n (%)	0	0	0
Proximal MV, n (%)		3 (1.4)	3 (1.7)	0
Distal MV, n (%)		1 (0.5)	1 (0.6)	0
Stent underexpansion				
Bifurcation, n (%)		9 (4.3)	9 (5.1)	0
Proximal MV, n (%)		28 (13.5)	27 (15.2)	1 (3.4)
Distal MV, n (%)		12 (5.8)	10 (5.6)	2 (6.9)

* p<0.05 versus crossover stenting.

Supplementary Table 3. Procedural failure of the treatment with a Glider balloon and additional procedure: crossover stenting versus two-stenting.

	Crossover stenting	2-stent
Procedural failure		
GB crossing failure	13 (7.3)	5 (17.2)
Primary, n (%)	8 (4.5)	5 (17.2) *
Secondary, n (%)	5 (2.8)	0
SB stenting due to dissection induced by GB, n (%)	3 (1.7)	0
Stent deformation due to GB dilation	12 (6.7)	0
Carina shift	7 (3.9)	0
Corrected by re-POT, n (%)	3 (1.7)	0
Corrected by MV dilation with stent size or smaller balloon, n (%)	4 (2.2)	0
Other stent deformation	5 (2.8)	0
Corrected by re-POT, n (%)	2 (1.2)	0
Corrected by MV dilation with stent size or smaller balloon, n (%)	2 (1.2)	0
Corrected by final KBI, n (%)	1 (0.6)	0
Free from additional procedure due to the failure induced by GB, n (%)	163 (91.6)	29 (100)
Additional procedure		
Additional procedure due to stent failure in non-bifurcation site	41 (23.0)	10 (34.5)
Re-POT, n (%)	26 (14.6)	6 (20.7)
MV dilation with stent size or smaller balloon, n (%)	12 (6.7)	3 (10.3)
Final KBI, n (%)	3 (1.7)	1 (3.4)
Free from any additional procedure, n (%)	122 (68.5)	19 (65.5)

* p<0.05 versus crossover stenting.

Supplementary Table 4. Clinical outcome at one-year follow-up after the treatment with a Glider balloon: crossover stenting versus two-stenting.

	Crossover stenting	2-stent
Complete clinical follow-up, n (%)	148 (88.6)	26 (92.9)
Follow-up coronary angiography, n (%)	142 (85.0)	23 (82.1)
Angiographical restenosis		
Main vessel, n (%)	8 (4.8)	2 (7.1)
Side branch, n (%)	17 (10.2)	7 (25.0)
Target lesion revascularisation, n (%)	12 (7.2)	2 (7.1)
Target vessel revascularisation, n (%)	17 (10.2)	3 (10.7)
All-cause death, n (%)	6 (3.6)	1 (3.6)
Cardiac death, n (%)	3 (1.8)	1 (3.6)
Myocardial infarction, n (%)	2 (1.2)	2 (7.1)
Periprocedural/spontaneous, n	0/2	0/2
Stent thrombosis, n (%)	1 (0.6)	1 (3.6)
Definite/probable, n	1/0	1/0
Major adverse cardiac events, n (%)	16 (9.6)	4 (14.3)

Major adverse cardiac events: composite endpoint of target lesion revascularisation, cardiac death, myocardial infarction, stent thrombosis.