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The approach to coronary bifurcation treatment and its outcomes in Poland: The single center experience

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Abstract

Background: *Coronary bifurcation lesions pose therapeutic problems during percutaneous coronary interventions. The aim of this study was to analyze the strategy of coronary bifurcation treatment and associated angiographic as well as clinical outcomes in a large hospital in Northern Poland.*

Methods: *Between January 2012 and January 2014 patients with stable coronary artery disease or non-ST-elevation acute coronary syndrome (NSTE-ACS) were treated with regular drug-eluting stents (rDES) or dedicated bifurcation stents (BiOSS Expert® or BiOSS LIM®). Clinical and angiographic controls were planned at 12 months. The primary endpoint was major adverse cardiovascular events (MACE) rate composed of cardiac death, myocardial infarction, and target lesion revascularization (TLR) at 12 months.*

Results: *In total, 152 patients were enrolled in whom 158 stents were deployed (99 BiOSS stents and 59 rDES). Left anterior descending artery (50%) was the dominant target vessel followed by left circumflex (25%). There was no stent implantation failure. In 10 (6.3%) patients rDES was required within the side branch. At 12 months MACE rate was 11.2%, whereas TLR rate was 7.9%. In the logistic regression analysis final kissing balloon technique was the prognostic factor for better clinical outcome, whereas NSTE-ACS and true bifurcations were risk factors of a poor outcome.*

Conclusions: *Percutaneous coronary bifurcation treatment is a safe and effective procedure, and provisional T-stenting is the preferred technique. Both rDES as well as dedicated bifurcation stents enabled a simple and fast bifurcation treatment option with comparable MACE and TLR rates.* (Cardiol J 2017; 24, 6: 589–596)

Key words: BiOSS, culotte technique, dedicated bifurcation stent, provisional T-stenting

Introduction

Coronary bifurcation lesions pose a therapeutic challenge and are linked with higher rates of periprocedural complications as well as higher rates of in-stent restenosis and stent thrombosis [1]. Presently, provisional T-stenting (PTS) is the best approach [2, 3]. However, the optimal strategy for coronary bifurcations treatment remains a subject of debate, mainly when the side branch (SB) is large, not easily accessible or narrowed by a long lesion [4–7].

The aim of this study was to analyze the strategy for coronary bifurcation lesion treatment

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and associated clinical as well as angiographic outcomes in a large hospital in Northern Poland.

Methods

Study population and study plan

It was a prospective registry conducted between January 2012 to January 2014 in a high-volume center (> 1500 percutaneous coronary intervention [PCI] per year) in Poland (Olsztyn). Patients with stable coronary artery disease (CAD) or non-ST-segment elevation acute coronary syndrome (NSTE-ACS) were considered eligible for enrollment. The inclusion criteria were: age ≥ 18 years old, *de novo* coronary bifurcation lesion (including unprotected left main), main vessel (MV) diameter ≥ 2.5 mm and SB diameter ≥ 2.0 mm assessed by visual estimation. Main exclusion criteria were: ST-elevation myocardial infarction (STEMI), inability to take dual antiplatelet therapy for 12 months, left ventricular ejection fraction ≤ 30% as well as lack of written informed consent. Institutional Review Board approved the study protocol.

Interventional procedure and concomitant medications

Procedures were performed by six independent operators. Single stent implantation in the proximal MV-distal MV across SB was the default strategy in all patients (PTS). Bifurcation lesions were assessed according to Medina classification using an index of 1 for stenosis greater than 50% and 0 for no stenosis (visual estimation). There was no restriction regarding lesion length in patient selection. The main indication for using dedicated bifurcation stents was the ratio of proximal MV diameter to distal MV diameter > 1.2. If required, additional regular drug-eluting stents (rDES) were implanted. A stent in SB was implanted only if proximal residual stenosis was greater than 70% after balloon dilatation and/or significant flow impairment after proximal MV-distal MV stenting and/or a flow limiting dissection were noted. The implantation protocol was as follows:

1. Wiring of both branches;
2. MV predilatation and/or SB predilatation according to the operator's decision;
3. Stent implantation (inflation for at least 20 s);
4. Proximal optimization technique (POT) at operator's discretion;
5. SB postdilatation/stent implantation if necessary;
6. Final kissing balloons (FKB) inflation at operator's discretion.

In patients with NSTE-ACS, a loading dose of clopidogrel (600 mg), ticagrelor (180 mg) or prasugrel (60 mg) was given, and, if needed, also a loading dose of acetylsalicylic acid (ASA) was applied (300 mg). In planned procedures, 72 h before PCI each patient received ASA (75 mg/24 h) and clopidogrel (75 mg/24 h). All procedures were performed in a standard way via radial or femoral access using 6 Fr or 7 Fr guiding catheters. After insertion of the arterial sheath each patient received unfractionated heparin (70–100 IU/kg). Additional bolus was given to maintain an activated clotting time > 250 s. Dual antiplatelet therapy (ASA 75 mg q.d. and clopidogrel 75 mg q.d., prasugrel 10 mg q.d. or ticagrelor 90 mg b.i.d.) was prescribed for 12 months.

All patients had troponin I (TnI), creatinine kinase (CK) and CK-MB levels examined before the procedure, 6 h and 24 h thereafter. Periprocedural myocardial infarction (MI) (type 4a) was assessed according to the third universal definition [8].

Device description

All drug-eluting stents available in the cathlab could have been used. In this study there were regular paclitaxel-eluting stents LucChopin2 with strut thickness of 120 μm, sirolimus-eluting stents Alex with strut thickness of 70 μm or Cre8 with strut thickness of 80 μm and everolimus-eluting stents Xience with strut thickness of 81 μm and two dedicated bifurcation stents: paclitaxel-eluting BiOSS Expert® with strut thickness of 120 μm and sirolimus-eluting BiOSS LIM® with strut thickness of 120 μm [9, 10].

Follow-up

Clinical follow-up was performed with office visits or telephone contact at 12 months after intervention. Adverse events were monitored throughout the study period. Follow-up coronary angiography was performed at 12 months unless clinically indicated earlier.

Endpoints

The primary endpoint was the cumulative rate of major adverse cardiovascular events (MACE) including cardiac death, MI and repeated revascularization of the target lesion (TLR). The secondary endpoints included cardiac death, all-cause death, MI, TLR and late lumen loss (LLL). All deaths were deemed cardiac unless proven otherwise.

Angiographic analysis

All angiograms were recorded after intracoronary administration of nitroglycerin (200 μg). Two orthogonal views were chosen to visualize the

target lesion. A quantitative coronary angiography (QCA) was performed using dedicated bifurcation software CAAS version 5.9 (2D analysis). Catheter calibration was performed in all cases. The proximal main vessel (the artery before SB take-off), the distal main vessel (artery beyond the ostium of SB), and the SB (the smaller vessel at the point of vessel divergence) were analyzed separately — subsegmental QCA analysis was performed according to European Bifurcation Club (EBC) Consensus [11]. The following parameters were calculated: lesion length, reference vessel diameter (RVD), minimal lumen diameter (MLD), % diameter stenosis (%DS), acute lumen gain and LLL before and after stent implantation and/or on follow-up. All reference diameters were measured 5 mm from the end of angiographically visible plaque in all 3 segments of bifurcation without use of interpolations (user defined reference diameters). Percent diameter stenosis (using parameters from each segment) was measured for each vessel segment separately using the following formula: %DS = [1 – (MLD/ /RVD)] × 100% [12].

Statistical analysis

Continuous variables were presented as mean ± standard deviation. Categorical data were presented as numbers (%). Continuous variables were compared using an unpaired Student t test, and categorical data using the χ^2 test or Fisher exact test, as appropriate. If distribution was not normal, Wilcoxon signed-rank tests and Mann-Whitney U-tests were used. P values of < 0.05 were considered statistically significant. Also, univariate and multivariate logistic regression analyses were performed. Statistical analysis was performed using R 3.0.2 for OS (R Foundation, Vienna, Austria).

Results

Baseline clinical characteristics

Between January 2012 and January 2014, a total of 152 patients were enrolled of whom 158 coronary bifurcation lesions were treated. The mean age was 62.6 ± 9.11 years and women had a share of 26.3% in the population. Most patients had stable CAD (67.1%), arterial hypertension (82.2%) and dyslipidemia (88.2%). The detailed data are presented in Table 1.

Angiographic and procedural characteristics

The bifurcation lesions were most frequently located in left anterior descending artery; 50%; Fig. 1A), and true bifurcations (Medina type 1,1,1;

Table 1. Demographics (n = 152).

	No. of patients (%)
Age	62.6 ± 9.11
Women	40 (26.3%)
Stable CAD	102 (67.1%)
NSTE-ACS	50 (32.9%)
Hypertension	125 (82.2%)
Dyslipidemia	134 (88.2%)
Diabetes type 2	43 (28.3%)
Prior MI	65 (42.8%)
Prior PCI	68 (44.7%)
Coronary artery bypass graft	16 (10.5%)
Lower extremity artery disease	12 (7.9%)
Carotid artery disease	6 (3.9%)
Chronic kidney disease	12 (7.9%)
Smoking	54 (35.5%)

CAD — coronary artery disease; NSTE-ACS — non-ST-elevation acute coronary syndrome; MI — myocardial infarction; PCI — percutaneous coronary intervention

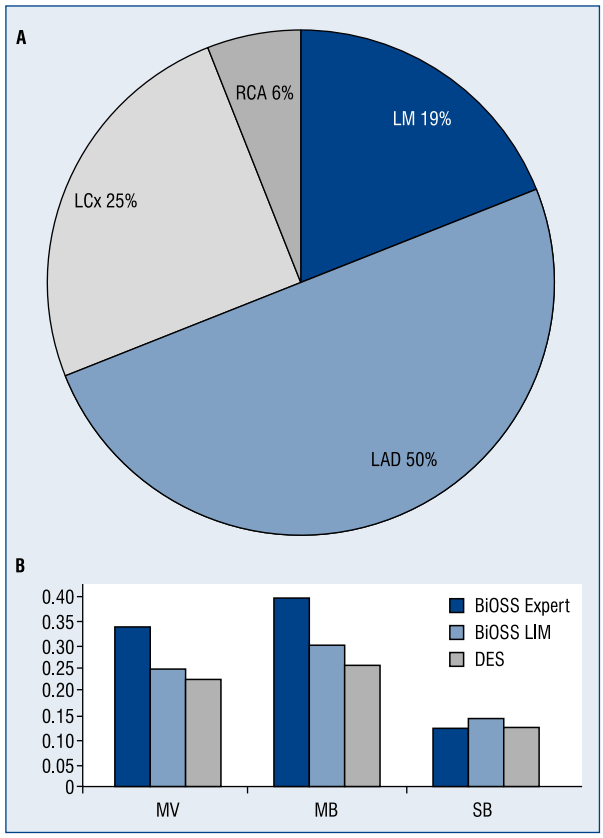

Figure 1. A. Lesion location; **B.** Late lumen loss in mm; LAD — left anterior descending artery; LCx — left circumflex artery; LM — left main coronary artery; RCA — right coronary artery; MB — main branch; MV — main vessel; SB — side branch.

Table 2. Lesion and stent characteristics (n = 158).

Lesion characteristics	No. of lesions (%)
Medina type	
1.1.1.	34 (21.5%)
1.1.0.	22 (13.9%)
1.0.1.	32 (20.2%)
0.1.1.	36 (22.8%)
1.0.0.	21 (13.3%)
0.1.0	13 (8.2%)
Lesion type	
A	0 (0%)
B1	76 (48.1%)
B2	50 (31.6%)
C	32 (20.3%)
Stent type	
Regular DES:	**59 (37.3%)**
Paclitaxel eluting DES	18 (11.4%)
Sirolimus eluting DES	19 (12.0%)
Everolimus eluting DES	22 (13.9%)
Dedicated bifurcation stent:	**99 (62.7%)**
BiOSS Expert (paclitaxel eluting)	20 (12.7%)
BiOSS LIM (sirolimus eluting)	79 (50%)

DES — drug eluting stent

Table 3. Procedural characteristics (n = 158).

Parameter	No of lesions (%)
Successful implantation	158 (100%)
Main vessel predilatation	130 (82.3%)
Side branch predilatation	115 (72.8%)
Both branches predilatation	6 (3.8%)
Regular DES nominal parameters [mm]	3.15 ± 0.60 × 20.69 ± 8.81
Dedicated bifurcation stent nominal parameters (proximal diameter x distal diameter x length) [mm]	3.63 ± 0.36 × 2.95 ± 0.35 × 18.42 ± 3.34
Side branch postdilatation	38 (24.1%)
Proximal optimization technique	7 (4.4%)
Final kissing balloon	38 (24.1%)
Additional stent in side branch	10 (6.3%)
Fluoroscopy time [min]	12.5 ± 8
Contrast volume [mL]	161 ± 93
Vascular access femoral/radial	7%/93%
Guiding catheter 6 F/7 F	100%/0%
Double-stent technique:	n = 10 (%)
T-stenting	1 (10%)
TAP	4 (40%)
Mini-crush	1 (10%)
Culotte	4 (40%)

DES — drug-eluting stent; TAP — T-and-protrusion technique

1,0,1 or 0,1,1) stand for 102 (64.6%) treated lesions. Only DES were deployed among which most frequently dedicated bifurcation stents were used (n = 99, 62.7%), followed by rDES (n = 59, 37.3%) (Table 2).

The main procedural aspects are presented in Table 3. All stents were successfully implanted. In 10 cases the additional stent was implanted into the SB, mainly using T-and-protrusion (TAP) or culotte techniques. In the dedicated bifurcation stent subgroup SB was stented in 4 (4.04%) cases due to significant stenosis and large diameter, whereas in regular DES 6 (10.2%) cases were registered due to significant stenosis in a large SB (n = 4) or due to flow limiting dissection (n = 2). Final kissing balloon was applied in 24.1% of procedures.

Clinical outcomes

There were 5 (3.2%) cases of periprocedural MI due to transient SB occlusion. Additionally, there were 9 (5.7%) cases of in-hospital increase of TnI level (max 1.8 ng/mL) — however, they were asymptomatic/without electrocardiogram changes which did not require repeated angiography (MI type 4a criteria not met).

Clinical follow-up data at 12 months were available in all patients (Table 4). The MACE incidence was 11.2% (n = 17) and it was similar between the dedicated bifurcation stent subgroup and the regular DES subgroup, 11.5% and 10.5%, respectively. There were 5 cardiac deaths, in which 4 were sudden cardiac deaths and one death was caused by complications of MI. The TLR rate was 7.9% (n = 12). No definite in-stent thrombosis was registered, but one cannot exclude in-stent thrombosis since there were 4 sudden cardiac deaths. Further analyses are presented as **Supplementary Table 1 and 2 (see journal website)** — they describe clinical outcomes in diabetic and left main subgroups, respectively.

Quantitative coronary angiography analysis

Angiographic follow-up at 12 months was available in 78 (51.3%) patients, of whom 34 had BiOSS Expert® stent implanted, 28 — BiOSS LIM® and 16 — regular DES. The late lumen loss values in separate segments of coronary bifurcation are presented in the Figure 1B. Similar LLL values were obtained in rDES and BiOSS LIM® groups,

Table 4. Clinical results.

	Whole population (n = 152)	DBS (n = 95)	Regular DES (n = 57)
MACE	17 (11.2%)	11 (11.5%)	6 (10.5%)
All-cause death	9 (5.9%)	5 (5.3%)	4 (7.0%)
Cardiac death	5 (3.3%)	2 (2.1%)	3 (5.3%)
Myocardial infarction	5 (3.3%)	3 (3.2%)	2 (3.5%)
Stent thrombosis	0 (0%)	0 (0%)	0 (0%)
Target lesion revascularization	12 (7.9%)	7 (7.4%)	5 (8.8%)

MACE — major adverse cardiovascular events; DBS — dedicated bifurcation stents; DES — drug eluting stent

Table 5. Logistic regression for major adverse cardiovascular events.

Variate	Univariate analysis		Multivariate analysis	
	OR (95% CI)	P	OR (95% CI)	P
BiOSS vs. DES	0.918 (0.547–1.247)	0.547		
BiOSS Expert vs. DES	1.111 (0.650–1.831)	0.568		
BiOSS LIM vs. DES	0.714 (0.665–1.120)	0.341		
Sex: female vs. male	0.747 (0.670–1.123)	0.789		
Age [increase per 1 year]	0.814 (0.684–1.336)	0.238		
NSTE-ACS	2.180 (1.560–2.446)	0.008	1.801 (1.391–3.150)	0.044
Arterial hypertension	1.361 (0.775–2.562)	0.345		
Diabetes mellitus	1.254 (0.881–1.565)	0.258		
Dyslipidemia	1.127 (0.454–1.665)	0.456		
Prior MI	1.742 (0.910–2.774)	0.412		
Prior PCI	1.113 (0.712–1.975)	0.651		
Coronary artery bypass graft	1.343 (0.763–3.129)	0.345		
Chronic kidney disease	1.232 (0.447–2.002)	0.782		
Smoking	1.468 (0.751–1.802)	0.753		
True bifurcation	2.279 (1.114–4.751)	0.021	1.758 (1.114–2.452)	0.035
LM bifurcation	1.238 (1.110–3.272)	0.019	1.831 (0.893–2.318)	0.441
MV predilatation	1.701 (1.443–3.678)	0.009		
SB predilatation	1.315 (0.822–2.215)	0.245		
SB stenting	1.360 (0.985–2.642)	0.348		
Final kissing balloon	0.501 (0.396–0.950)	0.038	0.401 (0.246–0.820)	0.021
Proximal optimization technique	1.101 (0.656–1.352)	0.392		

OR — odds ratio; CI — confidence interval; DES — drug eluting stents; NSTE-ACS — non-ST-elevation acute coronary syndrome; MI — myocardial infarction; PCI — percutaneous coronary intervention; LM — left main; MV — main vessel; SB — side branch

whereas BiOSS Expert® group characterized a slightly larger neointima growth. Also, when comparing LLL value significant differences in proximal MV and in distal MV, but not in SB, were observed.

Logistic regression analysis

Results of logistic regression analyses are presented in Table 5 and Table 6 for MACE and TLR, respectively. Regarding MACE rate, NSTE-ACS and true bifurcation were associated with worse clinical outcome, whereas FKB was associated with better clinical outcome. Similar results were obtained when the TLR rate was analyzed.

Discussion

The main findings of this study are: 1) coronary bifurcations were mainly treated with 1 stent (PTS

Table 6. Logistic regression for target lesion revascularization.

Variate	Univariate analysis		Multivariate analysis	
	OR (95% CI)	P	OR (95% CI)	P
BiOSS vs. DES	1.018 (0.537–1.237)	0.623		
BiOSS Expert vs. DES	1.211 (0.609–2.001)	0.755		
BiOSS LIM vs. DES	0.814 (0.615–1.760)	0.188		
Sex: female vs. male	0.647 (0.450–0.993)	0.046		
Age [increase per 1 year]	0.694 (0.523–1.416)	0.623		
NSTEMI/UA	2.080 (1.640–3.566)	0.007	1.921 (1.231–3.120)	0.004
Arterial hypertension	1.411 (0.675–3.102)	0.212		
Diabetes mellitus	1.244 (0.651–1.675)	0.498		
Dyslipidemia	1.317 (0.732–1.455)	0.578		
Prior MI	1.412 (0.830–2.414)	0.243		
Prior PCI	1.223 (0.872–2.275)	0.878		
Coronary artery bypass graft	1.523 (0.863–2,729)	0.465		
Chronic kidney disease	1.412 (0.767 - 2.122)	0.619		
Smoking	1.218 (0.751–1.802)	0.773		
True bifurcation	2.339 (1.324–3.671)	0.019	1.988 (1.442–4.172)	0.031
LM bifurcation	1.328 (1.115–3.672)	0.042	1.421 (0.893–2.218)	0.655
MV predilatation	1.211 (1.013–3.128)	0.032		
SB predilatation	1.215 (0.782–1.785)	0.166		
SB stenting	1.210 (0.765–3.542)	0.174		
Final kissing balloon	0.721 (0.496–0.980)	0.037	0.798 (0.226–0.960)	0.041
Proximal optimization technique	0.941 (0.508–1.122)	0.534		

OR — odds ratio; CI — confidence interval; DES — drug eluting stents; NSTEMI/UA — non-ST-elevation myocardial infarction/unstable angina; MI — myocardial infarction; PCI — percutaneous coronary intervention; LM — left main; MV — main vessel; SB — side branch

strategy), 2) 1-year MACE and TLR rates were 11.2% and 7.9%, respectively, 3) clinical outcomes for dedicated bifurcation stents BiOSS and regular DES were similar, 4) optimization techniques (FKB, POT) were rarely used.

In this study the population was severely diseased, with rates of diabetes (28.3%), prior MI (42.8%) and prior PCI (44.7%) which is higher than in other studies assessing bifurcation treatment, 11–25.7%, 19.5–46% and 11.3–37.1% [13–17] respectively.

In recent years, a series of studies helped to characterize the coronary bifurcation anatomy, and geometric relations linking MV and SB were expressed as mathematical models such as Murray's, Finet's or Huo-Kassab's laws [13, 14, 18]. To some extent as a result, EBC recommends PTS as the standard strategy for treatment of coronary bifurcation. Although there are lesions for which PTS is not the optimal approach, the need for an alternative strategy is relatively rare in most cases [11]. Results obtained in this registry were concordant with these recommendations. Almost all bifurcations (93.7%) were treated with PTS strategy, and what is important is that 64.5% of cases were true bifurcations. As proven earlier, PTS strategy ensured the best angiographic and clinical outcomes in the majority of studies [11]. Moreover, Kim et al. [15] as well as others showed that a 1-stent technique was better than a 2-stent technique [15, 16].

Only 10 cases required a two-stent technique, mainly performed with TAP and culotte. Worth stressing is the fact that all culotte procedures were performed in distal left main with the deployment of two BiOSS LIM® stents as described previously [17].

Predilatation of MV prior to stenting is the common approach, whereas routine SB dilation is unnecessary. Nevertheless, in the presence of severe SB ostial stenosis it should be considered. We performed MV predilatations in 82.3% cases and SB predilatations in 72.8%. We had in mind that potential advantages of SB dilatation include

increased ostial SB lumen, facilitated rewiring of the SB after stenting and avoiding rewiring and post-dilatation of the SB after implantation of the MV stent [19].

Appropriate stent apposition in the proximal MV is achieved by POT, which is performed by dilating the proximal MV stent from the proximal stent edge to just proximal to the carina, using a short oversized balloon. POT facilitates SB access, reduces risk of accidental abluminal rewiring, lowers the risk of stent distortion by catheter collision, and enhances scaffolding at the SB ostium. Thus, POT should be considered a standard step in the bifurcation treatment. Also, FKB is the technique which optimizes the procedure [11]. Unfortunately, in our paper rates of POT and FKB were low, 4.4% and 24.1%, respectively. This could have been caused by the fact that only recently POT is strongly recommended by EBC, and in case of FKB — that only rarely a 2-stent technique was used where FKB is obligatory. Also, in 62.7% of cases dedicated bifurcation BiOSS stents were implanted. Theoretically, the stepped design of the BiOSS® delivery balloon was to ensure FKB- and POT--like effects, thus allowing operators to frequently omit this part of the procedure. However, operators firmly believed that the BiOSS® construction ensures those effects. As was shown in POLBOS I trial the lack of FKB/POT was associated with the worse clinical outcome and the trend in larger late lumen loss values, whereas in the NORDIC 3 study it was proved that FKB reduced angiographic side branch restenosis, especially in patients with true bifurcation lesions [20, 21]. These findings were confirmed in the MITO Registry [22]. Also worth stressing, is the fact that the negative impact of true bifurcation and positive impact of FKB on MACE and TLR rates were also confirmed in the present logistic regression analyses.

Nevertheless, the results obtained in the mentioned registry (MACE 11.2%, TLR 7.9%) were comparable or even better than in other clinical trials assessing coronary bifurcation treatment such as POLBOS I [21], POLBOS II [23] or EBC TWO [24].

As a kind of innovation in this study dedicated bifurcation stents were used. As was already mentioned dedicated bifurcation stents were used in 62.7% of cases. In recent years bifurcation dedicated stents were developed but majority of them did not enter routine clinical practice. In the Tryton trial, 704 patients with non-left main, true coronary bifurcation lesions were randomized to a Tryton-facilitated culotte technique or to a PTS with an everolimus-eluting stent [25]. At 9 months, the primary endpoint (target vessel failure) was 17.4% in the Tryton group compared with 12.8% in the PTS group. Obtained results showed that safety and efficacy reached by PTS with the latest-generation DES make the role of dedicated stents for non-left main lesions quite limited. Based on this, the EBC consensus was in favor of considering distal left main treatment due to its specific anatomic complexity, which at least in theory may benefit from technical improvements of dedicated stents [11]. This position is supported by published reports [9, 26–28].

Limitations of the study

This registry has several limitations that should be acknowledged. First of all the sample size was relatively small and no sample size calculation was performed. Other limitations of this study are its non-randomized manner as well as other drawbacks of registry studies. Also, the variety of rDES use, the lack of intravascular ultrasound, use and the relatively low diabetes type 2 rate could be treated as drawbacks.

Conclusions

Percutaneous coronary bifurcation treatment is safe and effective procedure, and provisional T-stenting is the preferred technique. Both regular DES as well as dedicated bifurcation stents BiOSS Expert® and BiOSS LIM® enabled a simple and fast bifurcation treatment option with a single stent and with comparable MACE and TLR rates.

Conflict of interest: None declared

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