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Dedicated bifurcation stents or regular drug eluting stents in distal left main stenosis: A retrospective study

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Abstract

Background: *In the distal left main (LM) atherosclerosis mainly develops within bifurcation or trifurcation. The aim of this study was to analyze the strategy of distal LM stenosis treatment and associated clinical outcomes in a large hospital in Northern Poland.*

Methods: *The study population consisted of consecutive patients with stable coronary artery disease or acute coronary syndrome (ACS) and distal LM stenosis who were hospitalized between June 2012 and June 2013. Patients were treated with regular drug-eluting stents (rDES), including bioresorbable vascular scaffolds, or dedicated bifurcation stents (BiOSS LIM®). Clinical outcomes were analyzed at 12, 24 and 36 months. Primary endpoint was cumulative major adverse cardiovascular events (MACE) inducing rate of cardiac death, myocardial infarction, and target lesion revascularization (TLR) after 36 months.*

Results: *One hundred and two patients were identified, 90 of whom were treated with percutaneous coronary intervention (56 rDES, including 9 Absorb, and 34 BiOSS) with no stent implantation failure. In 15 (16.7%) patients rDES was required within side branch (SB). After 36 months MACE rate was 19.0% (BiOSS: 18.8% vs. rDES 19.2%), whereas TLR rate was 10.7% (BiOSS 12.5% vs. rDES 9.6%). In logistic regression for 36-month TLR rate proximal optimization technique (OR 0.311, 95% CI 0.211–0.644) was a prognostic factor of better clinical outcome, whereas non-ST-elevation ACS (OR 2.211, 95% CI 1.642–5.110), ST-elevation myocardial infarction (OR 2.771, 95% CI 1.325–7.209) and SB stenting (OR 1.141, 95% CI 1.002–1.881) were risk factors of poor outcome.*

Conclusions: *Regular drug-eluting stents as well as dedicated bifurcation BiOSS LIM® stents enabled a simple and fast distal LM treatment option with a single stent. Both resulted in comparable MACE and TLR rates.* (Cardiol J 2018; 25, 2: 188–195)

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

Introduction

Results of randomized trials and observational studies showed that percutaneous coronary intervention (PCI) is a potential alternative to bypass surgery for patients with unprotected left main (LM) coronary artery stenosis [1, 2]. Moreover, 2 recent meta-analyses showed that primary endpoint of 1-year major adverse cardiac and cerebral events was non-significantly different in PCI group compared with the coronary artery bypass grafting (CABG) one, 14.5% and 11.8%, p = 0.11, respectively [3–5].

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In most cases atherosclerosis develops in the distal part of LM within bifurcation or trifurcation [6]. In general, based on non-randomized studies and extrapolations from the results of non-LM bifurcation trials, the provisional 1-stent approach has been considered a preferred strategy over the elective 2-stent technique for patients with LM bifurcation disease. In practice, however, 2-stent techniques are chosen more frequently for LM bifurcation than for non-LM lesions due to concerns regarding the ischemic myocardial volume, which would be jeopardized by adverse events [7].

The aim of this study was to analyze the strategy of distal LM stenosis treatment and associated clinical outcomes in a large hospital in Northern Poland.

Methods

Study population and study design

It was a retrospective registry conducted between June 2012 to June 2013 in a high-volume center (> 1500 PCI per year) in Poland (Olsztyn). The local database was searched for patients with LM stenosis treatment on 12.09.2016. The inclusion criteria were: age ≥ 18 years old and distal LM stenosis qualified for PCI. Present CABG treatment was the exclusion criterion. All patients with symptomatic stable coronary artery disease (CAD), non ST-elevation acute coronary syndrome (NSTE-ACS) as well as ST-elevation myocardial infarction (STEMI) were taken into account. Patients were contacted by telephone to obtain follow-up data. The Institutional Review Board approved the study protocol.

Interventional procedure and concomitant medications

Single stent implantation was the default strategy [8]. 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) [9]. There was no restriction regarding lesion length in patient selection. The main indication for using dedicated bifurcation stents was the ratio of proximal main vessel (MV) diameter to distal MV diameter > 1.2. If required, additional regular DES (rDES) was implanted. A stent in the side branch (SB) was implanted only if there was a proximal residual stenosis greater than 70% after balloon dilatation and/or a significant flow impairment after proximal MV — distal MV stenting and/or a flow limiting dissection.

In patients with STEMI or NSTE-ACS loading dose of clopidogrel (600 mg), ticagrelor (180 mg) or prasugrel (60 mg) was given, and, if also needed, 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 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, creatine kinase (CK) and CK-MB levels examined before the procedure, 6 h and 24 h afterwards. Periprocedural myocardial infarction (MI; type 4a) was assessed according to the third universal definition [10].

Device description

Second generation drug-eluting stents (DES) available in the cath lab, Absorb bioresorbable vascular scaffold (BVS) (Abbott, USA) and dedicated bifurcation stent BiOSS LIM® (Balton, Poland) could have been used [11].

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) at 3 years. The secondary endpoints included cardiac death, all-cause death, MI, and TLR at 1-, 2- and 3-year follow-up. All deaths were deemed cardiac unless proven otherwise.

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 analysis were performed. Statistical analyses were performed using R 3.0.2 for OS (R Foundation, Vienna, Austria).

Results

Baseline clinical characteristics

Between June 2012 and June 2013 102 patients with distal LM stenosis were identified.

Table 1. Demographics.

Parameter	No. of patients n = 90 (%)
Age [years]	65.6 ± 8.0
Women	24 (26.7%)
Stable CAD	59 (65.5%)
NSTE-ACS	27 (30%)
STEMI	4 (2.5%)
Hypertension	78 (86.7%)
Dyslipidemia	81 (90%)
Diabetes type 2	33 (36.7%)
Prior MI	60 (66.7%)
Prior PCI	54 (60%)
Prior CABG	33 (36.7%)
Lower extremity artery disease	9 (10%)
Carotid artery disease	9 (10%)
Chronic kidney disease	12 (13.3%)
Smoking	27 (30%)

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

Table 2. Lesion and stent characteristics.

Lesion characteristics	No. of lesions n = 90 (%)
Medina type:	
1.1.1.	15 (16.7%)
1.1.0.	24 (26.7%)
1.0.1.	13 (14.4%)
0.1.1.	18 (20.0%)
1.0.0.	14 (15.6%)
0.1.0	6 (6.7%)
SYNTAX score	22.39 ± 7.48
Lesion type:	
A	0 (0%)
B1	5 (5.6%)
B2	57 (63.3%)
C	28 (31.1%)
Stent type:	
Regular DES:	56 (62.2%)
Sirolimus eluting stent	29 (32.2%)
Everolimus eluting stent	18 (20.0%)
Bioresorbable vascular scaffold	9 (10.0%)
Dedicated bifurcation stent BiOSS LIM	34 (37.8%)

DES — drug eluting stent

Table 3. Procedural characteristics.

Parameter	No. of lesions n = 90 (%)
Successful implantation	90 (100%)
Main vessel predilatation	69 (76.7%)
Side branch predilatation	45 (50.0%)
Both branches predilatation	9 (10.0%)
Regular DES nominal parameters [mm]	3.79 ± 0.45 × 17.0 ± 6.60
Dedicated bifurcation stent nominal parameters (proximal diameter × distal diameter × length) [mm]	3.98 ± 0.32 × 3.23 ± 0.33 × 16.92 ± 2.99
Side branch postdilatation	33 (36.7%)
Proximal optimization technique	51 (56.7%)
Final kissing balloon	39 (43.3%)
Additional stent in side branch	15 (16.7%)
Fluoroscopy time [min]	18.8 ± 10.6
Contrast volume [mL]	244 ± 150
Vascular access femoral/radial	6.7%/93.3%
Guiding catheter 6 F/7 F	100%/0%
Double-stent technique:	N = 15 (%)
T-stenting	2 (13.3%)
T-and-protrusion technique	7 (46.7%)
Mini-crush	2 (13.3%)
Culotte	4 (26.7%)

DES — drug-eluting stent

Nevertheless, 90 patients were qualified for PCI and only those patients were further analyzed (12 patients were referred to CABG). The mean age was 65.6 ± 8 years and women stand for 26.7% (n = 24) of the population. Most patients had stable CAD (n = 59, 65.5%), hypertension (n = 78, 86.7%) and dyslipidemia (n = 81, 90%). The detailed data are presented in Table 1.

Angiographic and procedural characteristics

The bifurcation lesions were most frequently assessed as type B2 (n = 57, 63.3%), and true bifurcations stand for 46 (51.1%) treated lesions. Only DES were deployed among which most frequently rDES were used (n = 56, 62.2%), including bioresorbable vascular scaffold systems (n = 9), and were followed by dedicated bifurcation BiOSS LIM stents (n = 34, 37.8%) (Table 2).

The main procedural aspects are presented in Table 3. All stents were successfully implanted. In 15 (16.7%) cases the additional stent was implanted into the SB, mainly using T-and-protrusion

Table 4. Clinical results.

	1-year FU (n = 84)	2-year FU (n = 84)	3-year FU (n = 84)
MACE	8 (9.5%)	12 (14.3%)	16 (19.0%)
All-cause death	2 (2.4%)	3 (3.6%)	5 (5.9%)
Cardiac death	1 (1.2%)	2 (2.4%)	2 (2.4%)
Myocardial infarction	2 (2.4%)	3 (3.6%)	5 (5.9%)
Stent thrombosis	0 (0%)	0 (0%)	0 (0%)
Target lesion revascularization	5 (5.9%)	7 (8.3%)	9 (10.7%)

FU — follow-up; MACE — major adverse cardiovascular events

or culotte techniques. Final kissing balloon ended 43.3% of procedures.

Clinical outcomes

During the in-hospital period 6 deaths occurred. They were caused by: multi-organ failure as a result of persisting cardiogenic shock (n = 5) or cardiac tamponade as a result of free wall rupture (n = 1). Therefore, in further analysis only 84 patients were taken into consideration. No acute stent thrombosis was observed.

Clinical follow-up data were available in all patients at 12, 24 and 36 months (Table 4). At 3 years (median: 35 months, interquartile range [IQR] 32–39 months) the MACE incidence was 19% (n = 16). There were 2 cardiac deaths (heart failure deterioration), 3 deaths caused by cancer (lung cancer — 2, pancreas cancer — 1), 5 cases of MI (MI caused by lesions within deployed stents — 2 cases and lesions in other vessels — 3 cases) and 9 (10.7%) TLR cases. Seven TLR cases were treated with PCI, and 2 patients were referred for CABG. There were no statistical differences between BiOSS LIM stents, sirolimus-eluting stents, everolimus-eluting metallic stents and Absorb BVS stents in terms of MACE or TLR rates (Table 5).

Logistic regression analysis

Table 6 and Table 7 presents logistic regression analyses for MACE and TLR, respectively. In multivariate analysis regarding MACE rate NSTE-ACS and STEMI were associated with worse clinical outcome. And in the case of TLR rate in regression analysis, NSTE-ACS, STEMI and SB stenting were associated with worse clinical outcome, but proximal optimization technique (POT) was associated with better clinical outcome.

Discussion

The main findings of this paper are: 1) distal LM stenosis was mainly treated with 1 stent (provisional T-stenting [PTS]), 2) 3-year MACE and TLR rates were 19% and 10.7%, respectively, 3) the clinical outcomes between dedicated bifurcation stents BiOSS and rDES were similar, 4) optimization techniques, especially POT, improved clinical outcomes.

The continuous advancement of angioplasty procedures broadens the range of lesions, which could be safely treated with PCI. Bifurcation stenosis in distal LM stem is one of such cases and its rate is systematically increasing in the population of patients subjected to PCI [12]. This study showed a high rate of device success (100%) with favorable acute and long-term clinical results expressed by MACE rate at 12 as well as 36 months, 9.5% and 19%, respectively. It is worth mentioning that in the original paper by Serruys et al. [13], 12-month cumulative rate of major adverse cardiac or cerebrovascular events in a population of patients with low SYNTAX score (0–22) was 14.7% and with intermediate SYNTAX score (23–32) — 16.7%. Also, the present results are in agreement with recently published 3-year results of the EXCEL trial, in which MACE and TLR rates were 18.2% and 9.5%, respectively [2]. Moreover, the present study population was severely diseased, with a rate of diabetes (36.7%), prior MI (66.7%) and prior PCI (60%) higher than in other studies assessing bifurcation treatment, respectively, 11–25.7%, 19.5–46% and 11.3–37.1% [13–18].

European Bifurcation Club recommends provisional SB stenting as standard strategy for treatment of coronary bifurcation. Although there are lesions for which PTS is not an optimal approach, the need for an alternative strategy is relatively rare in most lesions. Similar results were obtained in the presented registry, most bifurcations (83.3%) were treated with PTS strategy and of importance is that 51.1% of cases were true bifurcations. As it was proved earlier PTS strategy ensures the best angiographic and clinical outcomes in a majority of studies [14]. Moreover, Kim et al. [7] as well as

Table 5. Three-year clinical results — subgroup analysis.

Parameter	Three-year follow-up				
	Whole (n = 84)	BiOSS LIM (n = 32)	SES (n = 26)	EES (n = 17)	BVS (n = 9)
MACE	16 (19.0%)	6 (18.8%)	6 (23.1%)	3 (17.6%)	1 (11.1%)
All-cause death	5 (5.9%)	1 (3.1%)	3 (11.5%)	0 (0%)	1 (11.1%)
Cardiac death	2 (2.4%)	1 (3.1%)	0 (0%)	1 (5.9%)	0 (0%)
Myocardial infarction	5 (5.9%)	1 (3.1%)	2 (7.7%)	1 (5.9%)	1 (11.1%)
Target lesion revascularization	9 (10.7%)	4 (12.5%)	4 (15.4%)	1 (5.9%)	0 (0%)

BVS — bioresorbable vascular scaffold; EES — metallic everolimus-eluting stent; MACE — major adverse cardiovascular events; SES — metallic sirolimus eluting stent

Table 6. Logistic regression for major adverse cardiovascular events at 3-year follow-up.

Variate	Univariate analysis		Multivariate analysis	
	OR (95% CI)	P	OR (95% CI)	P
BiOSS vs. DES	0.958 (0.721–1.355)	0.634		
Sex: female vs. male	0.821 (0.490–1.331)	0.542		
Age [increase per 1 year]	1.213 (0.693–1.459)	0.365		
NSTE-ACS	1.770 (1.390–2.879)	0.005	1.922 (1.441–4.210)	0.038
STEMI	2.365 (1.772–4.222)	0.003	3.021 (2.321–6.409)	0.001
Diabetes mellitus	1.851 (1.281–2.169)	0.028		
Prior MI	1.543 (0.780–2.004)	0.652		
Prior PCI	1.329 (0.602–1.841)	0.411		
Coronary artery bypass graft	1.201 (0.883–2.261)	0.653		
Chronic kindey disease	1.781 (0.833–3.099)	0.201		
True bifurcation	1.899 (1.004–2.102)	0.044		
Side branch stenting	1.260 (0.778–1.901)	0.247		
Fnal kissing balloon	0.722 (0.567–1.114)	0.061		
Proximal optimization technique	0.882 (0.491–0.997)	0.042		

CI — confidence interval; DES — drug eluting stent; MI — myocardial infarction; NSTE-ACS — non-ST-elevation acute coronary syndrome; STEMI — ST-elevation myocardial infarction; OR — odds ratio; PCI — percutaneous coronary intervention

Table 7. Logistic regression for target lesion revascularization at 3-year follow-up.

Variate	Univariate analysis		Multivariate analysis	
	OR (95% CI)	P	OR (95% CI)	P
BiOSS vs. DES	0.923 (0.701–1.295)	0.441		
Sex: female vs. male	0.781 (0.540–1.119)	0.622		
Age [increase per 1 year]	1.331 (0.713–1.521)	0.431		
NSTE-ACS	1.550 (1.430–2.121)	0.034	2.211 (1.642–5.110)	0.008
STEMI	2.198 (1.473–3.761)	0.015	2.771 (1.325–7.209)	0.001
Diabetes mellitus	1.651 (1.191–2.009)	0.018		
Prior MI	1.553 (0.612–1.834)	0.772		
Prior PCI	1.511 (0.709–1.927)	0.616		
Coronary artery bypass graft	1.321 (0.893–2.012)	0.499		
Chronic kidney disease	1.238 (0.653–2.387)	0.105		
True bifurcation	1.669 (1.214–2.342)	0.034		
Side branch stenting	1.345 (1.009–1.699)	0.047	1.141 (1.002–1.881)	0.042
Final kissing balloon	0.632 (0.437–0.991)	0.041		
Proximal optimization technique	0.512 (0.322–0.799)	0.012	0.311 (0.211–0.644)	0.002

CI — confidence interval; DES — drug eluting stent; MI — myocardial infarction; NSTE-ACS — non-ST-elevation acute coronary syndrome; STEMI — ST-elevation myocardial infarction; OR — odds ratio; PCI — percutaneous coronary intervention

others showed that one-stent technique is better than 2-stent technique [15].

There was a relatively low rate of stent implantation in SB (16.7% of cases). This value is lower than in other studies, where the value ranges between 30% and 50% [16–18]. Only 15 cases required double stent technique, mainly performed with T-and-protrusion and culotte. Worth stressing is the fact that all culotte procedures were performed in distal LM with 2 BiOSS LIM® stents as described previously (Fig. 1) [19].

Predilatation of MV prior to stenting is the common approach, when routine SB dilation is unnecessary. Nevertheless, in the presence of severe SB ostial stenosis it should be considered. In the presented registry MV predilatations were performed in 76.7% cases and SB predilatations in 50%. However, one has to keep in mind that the potential advantages of SB dilatation include increased ostial SB lumen, facilitated rewiring of the SB after stenting and avoidance of rewiring and post-dilatation of SB after implantation of MV stent [20].

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 bifurcation treatment. Also final kissing balloon technique (FKB) optimizes the procedure [14]. Unfortunately, in the present paper rates of POT and FKB were relatively low, 56.7% and 43.3%, respectively. This could be caused by the fact that only recently POT is strongly recommended by the European Bifurcation Club, and in cases of FKB — that only rarely 2-stent technique was used where FKB is obligatory. Also, in 37.8% of cases dedicated bifurcation BiOSS® stents were implanted. The stepped design of the BiOSS® stent delivery balloon theoretically was to ensure a FKB- and POT-like effect, thus allowing operators to frequently omit this part of the procedure. However, as was shown in POLBOS I trial not performing FKB and POT was associated with worse clinical outcomes and is a trend in larger late lumen loss, whereas in the NORDIC 3 study it was proved that FKB reduced angiographic side branch restenosis, especially in patients with true bifurcation lesions [21, 22]. These findings were confirmed in the MITO Registry [23]. Also, worth stressing is the fact that the negative impact of true bifurcation and positive impact of FKB on MACE

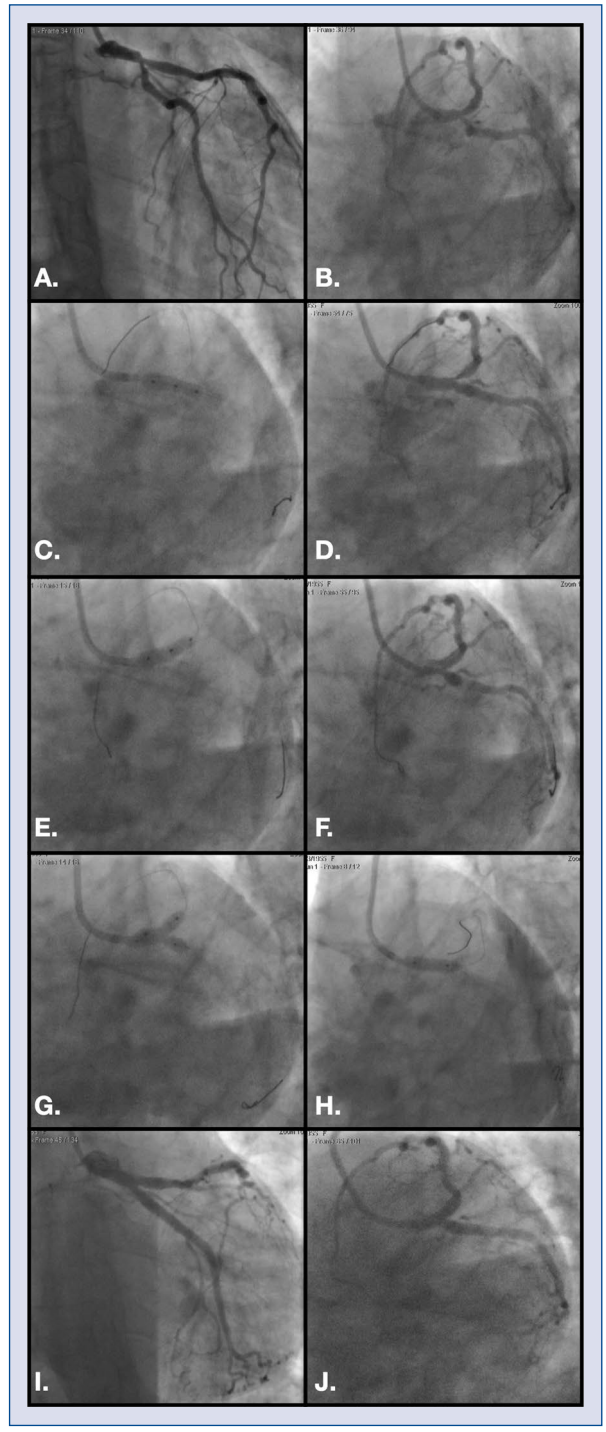

Figure 1. Two BiOSS stent implantation within distal left main; **A, B.** Initial views; **C, D.** First BiOSS LIM implantation in left main-left circumflex artery (LM-LCx); **E, F.** Second BiOSS LIM implantation in the left main-left ascending dimension artery (LM-LAD); **G.** Final kissing balloon; **H.** Proximal optimization technique; **I, J.** Final views.

and TLR rates were also confirmed in our logistic regression analysis.

Although the procedure was performed on LM stenosis, most cases were performed via the radial access (93.3%) and 6 F when guiding catheter was used (93.3%). This approach was associated with less risk of complications, such as severe bleeding or the need for blood transfusion.

Also, in 10% of cases where BVS were used, all cases were uneventful. The use of bioresorbable stents might present potential advantages compared with metallic DES for bifurcation treatment. Some limitations of currently available BVS, such as strut thickness and limited expansion capacity as well as the reports of increased late thrombosis influence the adoption of BVS as a standard strategy [24, 25]. Nevertheless, in the literature Absorb BVS was successfully deployed in the distal LM [26–28]. This registry has several limitations that should be acknowledged. First of all, the sample size was relatively small and heterogenous, additionally no sample size calculation was performed. Other limitations of this study are its non-randomized manner and all known drawbacks of retrospective studies. Moreover, intravascular ultrasound imaging was used only in 27.8% of cases (n = 25), and mainly manual pullback was performed.

Conclusions

Percutaneous distal LM stenosis treatment is a safe and effective procedure, and PTS is the preferred technique. Both rDES as well as dedicated bifurcation stents 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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