

Role of optical coherence tomography for distal left main stem angioplasty

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Abstract

Objective: The objective is to analyze the acute and midterm angiographic outcome of percutaneous treatment of left main coronary stem (LM-PCI) guided by optical coherence tomography (OCT).

Background: LM-PCI is a complex procedure, and several anatomical factors may impair its outcome. Intravascular imaging is emerging as a useful tool to guide the procedure.

Methods: We conducted a retrospective analysis of patients undergoing LM-PCI at three European centers between 2014 and 2017 with a control angiography at 6–12 months. Patients were divided into two groups: OCT-guidance (pre- and post-PCI) and control group (standard angiographic guidance with/out intravascular ultrasound [IVUS]). A blinded core lab analyzed all angiographic images. Primary endpoint was late lumen loss (LLL) after 6 months.

Results: A total of 112 patients entered the study, 55 in the OCT group and 57 in the control group (10 IVUS). Baseline and procedural characteristics were similar between groups. Overall, reference vessel diameter of the LM was 3.98 ± 0.65 mm. OCT guidance detected four cases of stent underexpansion (7.2%) and six cases of acute malapposition (10.9%). After a median of 207 ± 23 days, LLL of LM tended to be lower in the OCT group (0.12 ± 0.41 vs. 0.26 ± 0.52 mm, $p = .10$), and was significantly reduced in the distal portion of the main vessel (0.03 ± 0.45 vs. 0.24 ± 0.53 mm, $p = .025$). Percent diameter stenosis was also lower (14 ± 9 vs. $19 \pm 16\%$, $p = .05$). Adverse event rates were similar in the two groups.

Conclusions: In this study, systematic OCT guidance during LM-PCI allowed a timely detection and correction of acute stent underexpansion and malapposition, and was associated with signs of improved angiographic outcome at midterm, compared to standard practice.

KEYWORDS

drug eluting stent, left main coronary disease, optical coherence tomography, percutaneous coronary intervention

1 | INTRODUCTION

For decades, significant lesions of the left main stem (LM) have represented a straight indication to coronary artery bypass graft. However, recent studies have shown similar short- and long-term clinical outcomes for percutaneous coronary intervention (PCI), in patients with low to medium SYNTAX scores.^{1–3}

Nevertheless, LM still represents a complex target for PCI. Critical issues and anatomical variables need to be addressed, like plaque composition and distribution, significant vessel tapering and frequent involvement of the bifurcation with the left anterior descending (LAD) and circumflex (LCX) arteries. Intravascular imaging was introduced to improve the outcomes of PCI, and the most recent ESC/EACTS revascularization guidelines⁴ emphasize

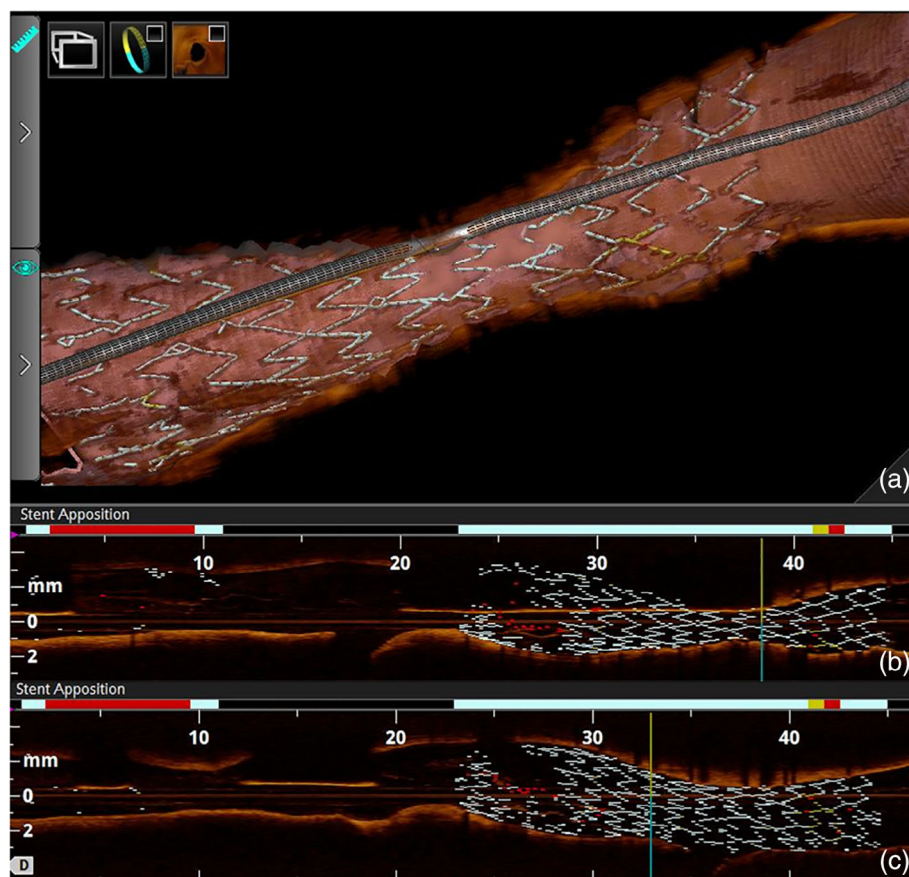


FIGURE 1 OCT reconstruction in 3D (a) and 2D (b) showing severe stent underexpansion at the distal portion of the LM. After balloon postdilatation, the OCT control shows adequate final stent expansion (c) [Color figure can be viewed at wileyonlinelibrary.com]

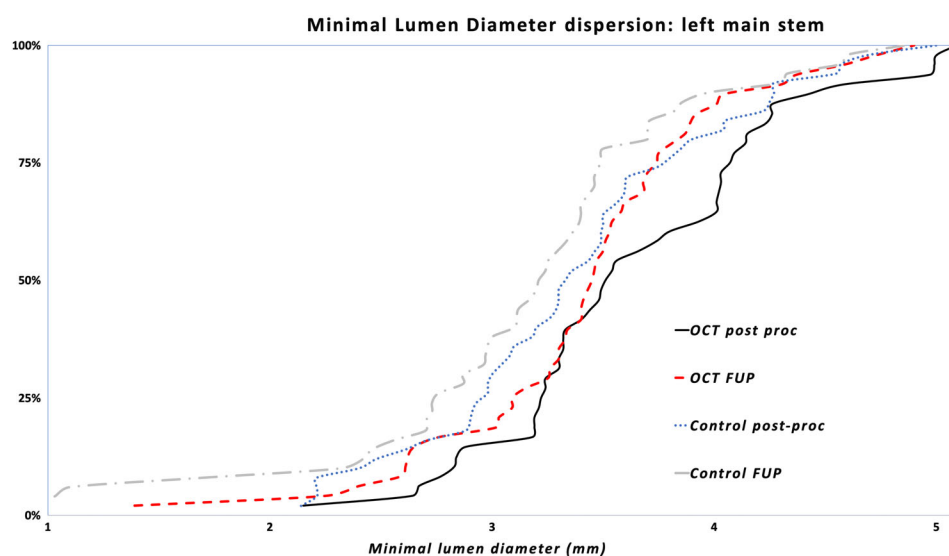


FIGURE 2 Schematic representation of the classification of the bifurcation in proximal and distal segment, for quantitative coronary angiography. LAD, left anterior descending; LCX, circumflex artery; QCA, quantitative coronary angiography [Color figure can be viewed at wileyonlinelibrary.com]

the role of intravascular ultrasound (IVUS) as a support to diagnosis and treatment of LM disease. Optical coherence tomography (OCT) has a higher resolution than IVUS (despite a reduced penetration power), and proved to be a valid guidance to PCI. However, no studies have tested the OCT performance in the setting of LM disease so far.

The aim of the ROCK I study is to provide systematic data on acute and the midterm angiographic outcomes of OCT-guided LM-PCI.

2 | METHODS

2.1 | Study design

The ROCK I study is a multicenter, observational, and retrospective study, performed at three European centers with significant experience in LM-PCI and OCT. From an OCT-dedicated database active in these centers, the investigators reviewed all the data regarding successful PCI with stent implantation in the distal LM portion between July 2014 and June 2017, also with available 6 months angiographic follow-up. Patients in the three centers usually undergo control angiography within the year in case of distal LM stenting. Exclusion criteria were STEMI presentation and previous PCI of LM. Out of the selected patients, those who had an OCT evaluation before and after intervention composed the final treatment group. Patients treated with standard strategy (visual assessment with or without IVUS, according to operator judgment and preference) composed the control group. All OCTs were performed and analyzed with the Optis system, using DragonFly catheters, from St. Jude Medicals-Abbott Vascular (USA) (Figure 1).

2.2 | Study procedure

All basal and final angiograms were taken after a bolus of intracoronary nitroglycerin. PCI was performed via femoral or radial access, using unfractionated heparin anticoagulation following operator preference. Operators administered dual antiplatelet therapy and other medications as per local standard of care. OCT and IVUS acquisitions were performed following a validated technique, and images were interpreted based on standard practice with the goal of optimizing lumen dimensions in stented and nonstented segments, with mandatory pre-PCI and post-PCI imaging. In patients undergoing OCT, special care was taken to ensure complete blood clearance. When required, OCT was repeated ensuring deeper sitting of the guiding catheter or higher injection velocity of contrast volume to optimize the image. The choice of OCT criteria for stent sizing was left to the single operators, based on local standards and international recommendations, with preference for distal reference lumen diameter or external elastic lamina to external elastic lamina (EEL-to-EEL), followed by proximal optimization technique.

All angiograms, IVUS and OCT recordings, were analyzed in a centralized, independent core lab, blinded respect to PCI details and clinical course (Eurolmaging Core Lab, Roma, Italy). Being the LM a complex bifurcation milieu, for the purposes of this study, we decided to split the

TABLE 1 Clinical and procedural characteristics of index hospitalization

	OCT guidance (n = 55)	Standard PCI (N = 57)	p value
Clinical characteristics			
Age, years	69.4 ± 11.8	67.0 ± 11.7	.23
Male sex, n (%)	35 (63)	40 (70)	.11
Diabetes, n (%)	26 (48)	15 (26)	.02
Creatinine >1.5 mg/dL, n (%)	1.19	1.06	.21
Dyslipidemia, n (%)	42 (77)	38 (66)	.13
Left ventricular ejection fraction, mean ± SD	54.8 ± 12.0	51.8 ± 14.3	.27
Stable angina, n (%)	30 (55)	20 (35)	.06
Unstable angina, n (%)	8 (14)	10 (17)	.75
STEMI, n (%)	10 (19)	7 (13)	.54
NSTEMI, n (%)	7 (12)	20 (35)	.0001
Syntax score, mean ± SD	22.9 ± 14	19.7 ± 13.3	.43
Severe calcification at lesion site, n (%)	10 (18)	20 (35)	.07
LM RVD, mm ± SD	3.9 ± 1.0	4.0 ± 0.9	.81
LAD RVD, mm ± SD	3.1 ± 0.9	3.2 ± 0.8	.66
CX RVD, mm ± SD	2.8 ± 0.9	2.8 ± 1.0	.83
Culprit lesion length, n (%)	20.5 ± 8.0	19.2 ± 7.2	.73
Percent diameter stenosis at lesion site ± SD	76.7 ± 8.2	69.4 ± 12.2	.45
LM MLD, mm ± SD	1.86 ± 1.8	1.92 ± 1.6	.38
Predilatation, n (%)	39 (71.4)	40 (71.1)	.87
Stent length, mm ± SD	24.9 ± 8.4	23.9 ± 7.9	.71
Postdilatation, n (%)	50 (90.4)	47 (82.3)	.55
LM-LAD stenting, n (%)	42 (76.0)	39 (69.2)	.42
2-stent use, n (%)	10 (18.4)	9 (16.4)	.78
Final MLD LM, mm ± SD	3.48 ± 0.4	3.61 ± 0.7	.48
Acute gain, mm ± SD	1.62 ± 0.61	1.69 ± 0.57	.76
Technical success, n (%)	55 (100)	57 (100)	1
Procedural success, n (%)	55 (100)	55 (95.6)	.28
Duration of procedure, minutes ± SD	83.3 ± 38.3	86.2 ± 36.0	.38
Amount of contrast used, ml ± SD	237 ± 121	261 ± 93	.29
Total fluoroscopic time, min ± SD	26.3 ± 19.1	25.5 ± 17.2	.57

quantitative coronary angiography (QCA) analysis of minimum lumen diameter and, therefore, late lumen loss (LLL) into (a) proximal segment (from the ostium to the distal portion of the LM), and (b) distal segment (the main stented vessel, being either the LAD artery, or the left

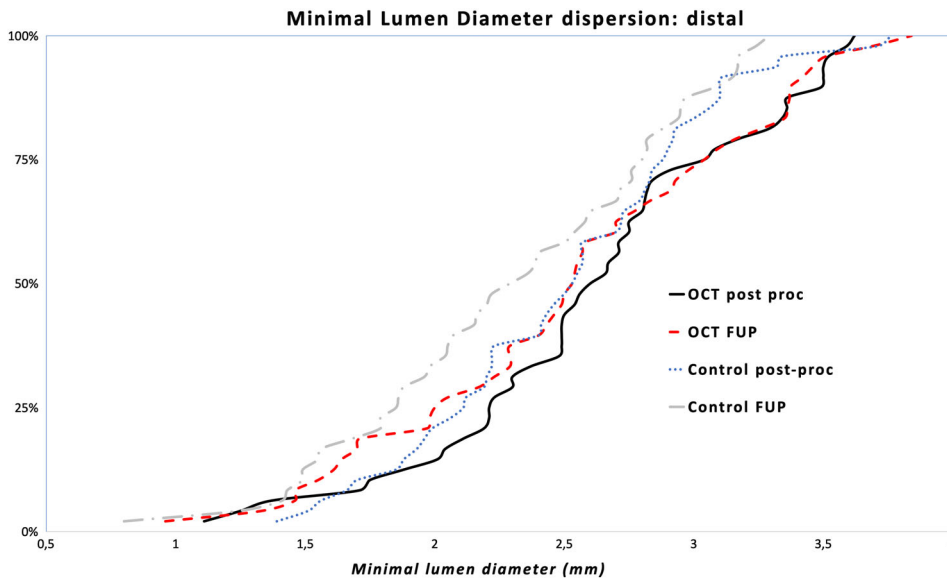


FIGURE 3 Distribution of the MLD in the two groups, at the end of PCI and during the angiographic follow-up. LM segment [Color figure can be viewed at wileyonlinelibrary.com]

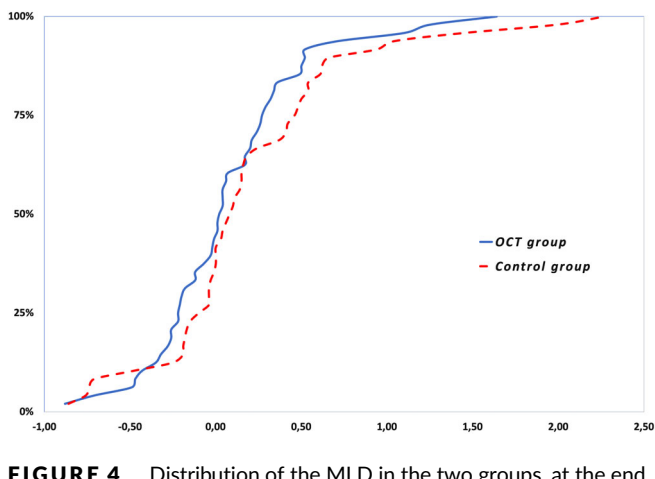


FIGURE 4 Distribution of the MLD in the two groups, at the end of PCI and during the angiographic follow-up. Distal segment [Color figure can be viewed at wileyonlinelibrary.com]

circumflex artery) (Figure 2). Malapposition was considered to be significant in case of an axial distance between the struts and the vessel wall >0.4 mm and for a length >1 mm. Underexpansion was defined using the cut-off of minimal stent area being $<80\%$ than the average reference lumen area.

2.3 | Study endpoints

Primary study endpoint was LLL at 6 months, defined as the difference in minimal lumen diameter between the immediate post-PCI result and the angiographic follow-up, either in the LM or in the distal segment (LAD or CX). The main reason for splitting this endpoint among the two segments is that LM is a typically tapered vessel toward the distal portion; therefore, an adequate angiographic analysis in our opinion should consider this “dual nature.”

Secondary endpoints were binary restenosis, target-lesion revascularization (TLR) rates and major adverse cardiovascular events

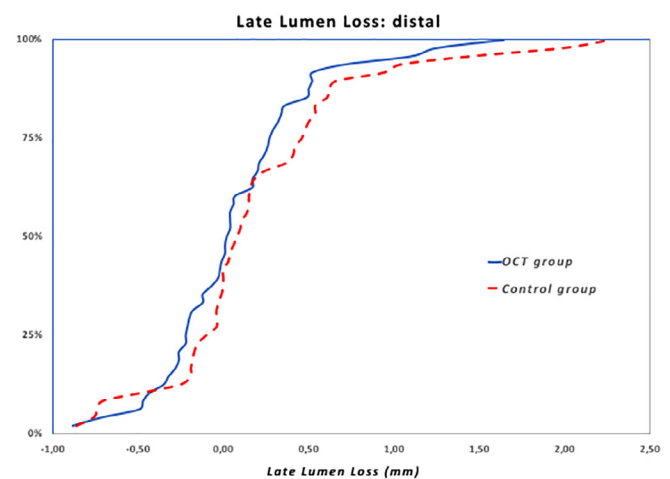


FIGURE 5 Distribution of the primary endpoint LLL in the two groups. Distal segment [Color figure can be viewed at wileyonlinelibrary.com]

(MACE) at 6 months. Binary restenosis was defined as diameter stenosis $\geq 50\%$ within a previously treated segment on follow-up QCA. TLR was defined as repeated PCI or coronary artery bypass grafting for the target segment or in the adjacent proximal or distal 5 mm segments. MACE was a composite endpoint of death due to cardiovascular causes, TLR, acute myocardial infarction (according to the third universal definition of myocardial infarction), major stroke, hospitalization due to acute heart failure. Technical success was defined as final diameter stenosis $<20\%$ with TIMI 3 flow. Procedural success was defined as technical success and the absence of in-hospital adverse events post-PCI.

2.4 | Statistical analysis

Continuous variables are presented as mean $\pm$ standard deviation. Categorical variables are presented as counts and frequencies (%).

TABLE 2 Angiographic follow-up

	OCT guidance (n = 55)	Standard PCI (N = 57)	p value
Available follow-up, n (%)	55 (100)	57 (100)	1
Follow-up length, days ± SD	201 ± 23	212 ± 18	.56
Percent diameter stenosis in LM, % ± SD	14 ± 9	19 ± 16	.05
LLL in LM, mm ± SD	0.12 ± 0.41	0.26 ± 0.52	.10
LLL in the distal portion of the stent, mm ± SD	0.03 ± 0.45	0.24 ± 0.53	.025
Binary restenosis, n (%)	2 (3.5)	9 (12.9)	.03

TABLE 3 Clinical follow-up

	OCT guidance (n = 55)	Standard PCI (N = 57)	p value
Available follow-up, n (%)	55 (100)	57 (100)	1
Follow-up length, days ± SD	345 ± 37	338 ± 22	.56
MACE, n (%)	4 (7.2)	5 (8.7)	.82
Cardiac death, n (%)	0 (0)	2 (3.5)	.49
Total death, n (%)	1 (1.8)	3 (5.1)	.63
TLR, n (%)	2 (3.6)	2 (3.5)	.78
Myocardial infarction, n (%)	1 (1.8)	1 (1.7)	.88
Stroke or transient ischemic attack, n (%)	0 (0)	0 (0)	NS

Abbreviations: MACE, major cardiovascular events; TLR, target lesion revascularization.

Unpaired *t*-test (or Mann–Whitney *U* test in case of nonnormal distribution) for continuous variables was applied in order to evaluate significant between-group differences at baseline. Categorical data were compared with a χ^2 or Fisher's exact test.

After completion of follow-up, unpaired *t*-test for repeated measurements was used in case of normal distribution, and Friedman and Wilcoxon rank sum tests in case of nonnormal distribution. Models were unadjusted for baseline covariates. *P* values were two-tailed, with statistical significance set at .05 for superiority. SPSS for Macintosh (version 23; IBM, Armonk, NY) was used for statistical calculations.

3 | RESULTS

During the study period, 267 LM were treated at the three study centers. A total of 112 consecutive patients had available angiographic follow-up at 6 months, and were enrolled in the ROCK I study. A total of 55 patients had OCT guidance, and the remaining 57 patients had

angioguided procedures. In the control group, 10 patients (17.5%) underwent LM PCI with IVUS guidance.

Baseline clinical and procedural characteristics are depicted in Table 1. The two groups were similar, differing only for a higher percentage of diabetic patients in the OCT group, and more non-ST elevation myocardial infarctions in the control group. The operative characteristics, including procedural duration, contrast use, and procedural success, were not dissimilar. Mean lesion length was 20 mm in both groups, and the 2-stent strategy was low (<20%). Interesting, OCT guidance revealed four cases of stent underexpansion (7.2%) and six cases of acute malapposition (10.9%), which were fixed with balloon postdilatation. Acute gain was 1.62 ± 0.61 mm in the OCT group and 1.69 ± 0.57 mm in the control group ($p = .76$).

LLL, primary study endpoint, showed a trend toward reduction in the OCT group in the proximal stented segment (0.12 ± 0.41 vs. 0.26 ± 0.52 mm, $p = .10$) (Figure 1), and it resulted significantly lower in the distal analyzed segment (0.03 ± 0.45 vs. 0.24 ± 0.53 mm, $p = .025$) (Figures 3–5). Percent diameter stenosis and binary restenosis, study secondary endpoints, were significantly reduced in the OCT group as well (Table 2). In particular, the rate of significant restenosis was only 3.5% in the OCT group, compared to 12.9% in standard care ($p = .03$). Clinical endpoints were similar (Table 3).

4 | DISCUSSION

The ROCK I study shows the angiographic superiority of OCT guidance during distal LM stenting, when compared to a standard treatment strategy including IVUS in a minority of patients.

The anatomical characteristics of the LM make this lesion subset quite different from other settings, mainly due to a higher elastic component, that may hinder stent expansion; a higher propensity to calcification; a higher probability of tapering.^{5,6} The use of intravascular imaging may therefore be particularly appealing in order to better assess the lumen/plaque characteristics, help the decision process of stent sizing and to assess the final result, specifically DES expansion and apposition.^{7,8}

IVUS, despite the lack of randomized clinical trials, is often performed for this task and has been correlated with improved outcome. Current ESC/EACTS guidelines suggest the guidance of IVUS to optimize treatment of unprotected LM lesions, with Class IIa, level B.⁴ This assumption derives from the retrospective post hoc data of the MAIN-COMPARE study, which showed a reduction in mortality after elective DES implantation in the LM in the IVUS group vs. angiography alone.⁹ In a patient-level pooled analysis of four registries, IVUS-guided LM PCI was associated with higher freedom from cardiac death, MI and TLR at 3 years, and also showed a significant reduction in stent thrombosis.¹⁰ In another more recent analysis from the SCAAR study group, intracoronary guidance during LM PCI was associated with significantly lower occurrence of the composite endpoint of total mortality, need for revascularization and stent thrombosis (HR 0.65, CI 0.50–0.84) and all-cause mortality.¹¹ Unfortunately, however,

no prospective data have been available on this important subject so far.

The OCT technology investigated in this study has some theoretical advantages over IVUS, including: (a) an improved detail and resolution of superficial intravascular structures prior to intervention (10–20 μm vs. 100–200 μm), (b) a complete analysis of stent apposition and expansion and final minimal lumen area assessment,^{12,13} and (c) the ability to discover tissue protrusion, thrombus, or edge dissections after stenting.¹⁴

In the ILUMIEN I study, this technology showed to be able to lead to modification of the treatment strategy in 57% of the cases,¹⁵ and subsequently also came out a growing evidence on its impact on clinical endpoints: the CLI-OPCI study showed how OCT guidance outperformed angiography in a cohort of 670 patients in terms of cardiac death and MI at 1 year (6.6% vs. 13%, $p = .006$).¹⁶ More recently, in the OPINION trial, OCT-guided PCI reached the noninferiority vs. IVUS-guided PCI in terms of target lesion failure at 1 year.¹⁷

Despite these promises, to this day, there have been few reports on the role of OCT for LM stenting.^{14,18} The technique has indeed some limitations, especially when analyzing deeper plaque components, large vessels, or ostial portion of the vessels. Even in these settings, however, performance may still be increased with some tips and tricks.¹⁹ Dato et al analyzed 122 patients with intermediate LM lesions, showing the feasibility of OCT in this setting, and also showing a good correlation with clinical outcome as regards the initial decision-making process.²⁰

Our study firstly confirmed the feasibility of OCT use for distal LM stenting, as stated by the procedural success obtained in all the 55 patients. Moreover, our study hypothesis was confirmed because the assistance of OCT helped in obtaining optimal stent deployment and improved angiographic outcomes in terms of LLL, binary restenosis, and percent diameter stenosis after 6 months. On the other hand, we have to admit that the comparison group does not reflect current guidelines recommendation in terms of IVUS use. Such a situation, however, reflects the common practice in catheterization laboratories, where this technology is used in a minority of patients yet. We strongly believe that intravascular imaging should be adopted in roughly all LM patients and, lacking clear advantages of one imaging technique or the other, the choice between the two should be based on local expertise.

Interestingly, in our study, the beneficial impact of OCT guidance on LLL was more relevant in the distal segment of the LM. First, it should be considered that there is a difference in LLL (even though not significant) even in the proximal segment of the bifurcation. This may be related to insufficient statistical power, due to the reduced sample size. Nevertheless, no definitive mechanistic explanation of such a stronger benefit on distal segment can be derived from this study, and additional randomized trials are needed to confirm this finding. Our hypothesis is that improved expansion and apposition of the stent may improve the long-term results especially in the distal part due to two main mechanisms. First, angiography-guided PCI may lead to less aggressive postdilatation of the distal portion of the vessel compared to the proximal, due to fear of “over-dilatation” of the

vessel, while in the middistal LM this risk would be perceived as lower. Second, treatment of bifurcations always introduces alterations in flow and shear stress. These factors may then have a synergic effect with stent-related issues, thus increasing the risk of worse outcomes compared to LM.

Interestingly, our results also show that OCT use was not associated with increases in contrast use or procedural time, probably reflecting the fact that this “fear” is not realistic when this technology is used expert hands.

There are several limitations regarding this study that we would like to share. The nonrandomized structure limits its scientific relevance, mainly due to possible biases in the choice to use OCT guidance, which was dependent on the judgment of individual operators. Thus, we eagerly expect more data on the matter from other studies. Another limitation is the limited use of IVUS in the control group (<20%). We would like to emphasize that the scope of this study is not to investigate the difference between OCT and IVUS, but either to stress on the role of intravascular imaging for LM stenting, and to clear the field for the role of OCT. Finally, the ROCK I study is hypothesis-generating: the ongoing ROCK II study, which is a comparison between angiography alone, IVUS or OCT guidance for LM stenting with long-term clinical endpoints assessment, will hopefully shed light on the questions raised here.

5 | CONCLUSION

In conclusion, this study shows that OCT guidance for LM stenting is feasible and safe, and suggests that this strategy could be associated with preliminary signals of improved angiographic outcome if compared to standard angiography-based treatment.

CONFLICT OF INTEREST

The authors declare no potential conflict of interest.

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