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Application of Optical Coherence Tomography in Determining Stent Deployment Position in Coronary Artery Left Main Bifurcation Lesions

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Abstract

Objective: To investigate the clinical value of optical coherence tomography (OCT) in determining stent deployment position and post-procedural optimization during percutaneous coronary intervention (PCI) for coronary artery left main (LM) bifurcation lesions. **Methods:** A total of 90 patients with LM bifurcation lesions were prospectively enrolled and randomly assigned to an OCT-guided group (45 cases) and an IVUS-guided group (45 cases). Both groups received intravascular imaging guidance in addition to standard angiography. The intraoperative imaging findings, accuracy of stent deployment position, postoperative hemodynamic improvement, and 12-month major adverse cardiovascular events (MACE) were compared. **Results:** The post-procedural minimal stent area (MSA) in the OCT group was significantly larger than in the IVUS group (8.6 ± 1.2 mm^2 vs 7.8 ± 1.1 mm^2, $p < 0.01$). The incidence of malapposition was lower (6.7% vs 17.8%, $p = 0.04$). The rate of additional optimization due to edge dissection or malapposition during the procedure was higher (31.1% vs 15.6%, $p = 0.03$). At 12-month follow-up, the MACE rate in the OCT group was 8.9%, lower than the IVUS group's 20.0% ($p = 0.045$). **Conclusion:** OCT can more precisely identify lesion borders and ostial morphology in LM bifurcation lesions, and is superior to IVUS in determining stent deployment position and post-procedural optimization. This suggests its higher clinical application value in complex bifurcation lesions.

Keywords

Optical Coherence Tomography, Left Main Bifurcation Lesion, Stent Deployment Position, Intravascular Ultrasound, Percutaneous Coronary Intervention

1. Introduction

Coronary artery disease is one of the leading causes of death globally [1]. Among its types, left main (LM) disease is considered the most dangerous coronary lesion type because it supplies a large area of the myocardium and involves a core hemodynamic region [2]. According to previous studies, the one-year mortality risk for patients with untreated significant LM stenosis can be as high as 30% or more [3]. Therefore, how to precisely and safely manage left main lesions has always been a clinical focus [4]. Especially when the lesion involves a bifurcation, issues such as hemodynamic disturbances, uneven plaque distribution, and protection of the side branch significantly increase the complexity of the PCI procedure [5] [6].

Although coronary angiography is the conventional method for assessing coronary lesions, its 2D imaging often has limitations in judging the nature of the lesion, plaque burden, and involvement of the branch ostium [7]. The emergence of intravascular imaging technology has provided more evidence for precise PCI [8].

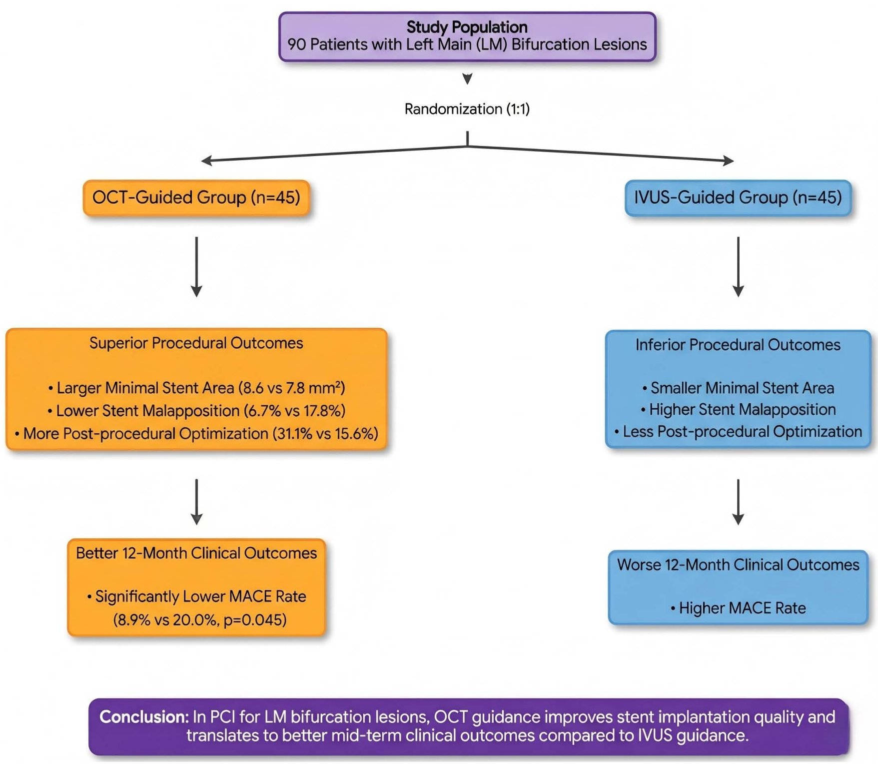

Figure 1. Study abstract graphic.

While IVUS has long served as the standard of care for guiding complex coronary interventions, it possesses inherent technical limitations, particularly regarding spatial resolution (approximately 100 μm). This relatively lower resolution can hinder the detailed visualization of calcified plaques, stent strut apposition, and subtle tissue characteristics [9] [10]. In contrast, Optical Coherence Tomography (OCT) offers a resolution of 10 - 20 μm—approximately ten times higher than that of IVUS. This superior imaging capability forms the core hypothesis of our study: that OCT's enhanced visualization may facilitate more precise stent sizing and optimization, potentially overcoming the diagnostic blind spots associated with conventional IVUS guidance [11]. Especially in left main bifurcation lesions, OCT can help the operator more precisely define the stent deployment position, thereby reducing complications such as edge dissection, stent underexpansion, and malapposition [12] [13], ultimately improving long-term prognosis.

Although some studies have suggested the value of OCT in complex coronary interventions, there is still a lack of prospective randomized controlled evidence regarding its clinical effect in guiding stent deployment position in LM bifurcation lesions. This study aims to systematically evaluate the clinical application value of OCT in guiding PCI for LM bifurcation lesions through a direct comparison with IVUS, providing evidence-based support for future guideline recommendations and clinical practice (**Figure 1**).

2. Methods

2.1. Study Design

This was a single-center, prospective, randomized controlled clinical trial. All patients were randomly assigned in a 1:1 ratio to either the OCT group or the IVUS group. The study protocol included pre-procedural assessment, intravascular imaging, PCI operation, post-procedural imaging review, and 12-month clinical follow-up.

2.2. Study Population

Inclusion criteria: (1) Age 40 - 75 years; (2) CAG indicating LM bifurcation stenosis ≥ 70%; (3) Suitable for PCI and willing to sign informed consent. Exclusion criteria: (1) Acute myocardial infarction or cardiogenic shock; (2) Severe cardiac dysfunction (LVEF < 30%); (3) Severe liver or kidney damage; (4) Malignancy or life expectancy < 1 year; (5) Allergy to contrast media or contraindication to antiplatelet therapy.

2.3. Procedure

Pre-procedural treatment: All patients received loading doses of aspirin and clopidogrel (or ticagrelor) before the procedure. Heparin was administered intravenously during the procedure to maintain ACT > 250 seconds.

Intravascular imaging examination:

- **OCT group:** A dedicated catheter was used for rapid pullback, and contrast agent was flushed to clear blood before image acquisition to analyze plaque components, ostial morphology, vessel diameter, and lesion length.
- **IVUS group:** An automated pullback system was used to acquire images, assessing plaque burden, external elastic membrane diameter, and stent matching.

Stent deployment strategy: Stent diameter and length were determined based on intravascular imaging results to ensure adequate lesion coverage. A single-stent or double-stent strategy was chosen based on imaging indications.

Post-procedural optimization: Both groups underwent post-procedural intravascular imaging review. If malapposition, underexpansion, or edge dissection were found, post-dilation or an additional stent was performed.

2.4. Endpoints

Primary imaging endpoint: Post-procedural minimal stent area (MSA), malapposition, underexpansion, and incidence of edge dissection.

Secondary imaging endpoint: Rate of additional optimization measures, post-procedural immediate TIMI flow.

Clinical endpoints: Major complications within 30 days (death, myocardial infarction, target vessel revascularization); 12-month MACE (cardiac death, non-fatal myocardial infarction, target vessel revascularization).

2.5. Follow-Up

All patients underwent clinical follow-up at 1 month, 6 months, and 12 months post-procedure, recording angina recurrence, rehospitalization, and adverse events. Follow-up angiography or imaging assessment was performed if necessary.

2.6. Statistical Analysis

Data were analyzed using SPSS 26.0 software. Measurement data are expressed as mean ± standard deviation, and t-tests were used for intergroup comparison; non-normally distributed data were analyzed using rank-sum tests. Count data were analyzed using the χ^2 test or Fisher's exact test. Kaplan-Meier curves were used to assess the 12-month MACE rate, and the log-rank test was used for intergroup differences. A $p < 0.05$ was considered statistically significant.

3. Results

3.1. Baseline Characteristics

A total of 90 patients were enrolled, with 45 in the OCT group and 45 in the IVUS group. There were no statistically significant differences between the two groups in terms of age, sex distribution, risk factors (hypertension, diabetes, smoking history), cardiac function (LVEF), and complexity of coronary lesions (SYNTAX score) (all $p > 0.05$), indicating good comparability (Table 1).

Table 1. Baseline clinical and angiographic characteristics of the two groups.

Variable	OCT Group (n = 45)	IVUS Group (n = 45)	p-value
Age (years)	63.1 ± 8.4	62.7 ± 8.1	0.78
Male (%)	71.1	68.9	0.82
Hypertension (%)	55.6	57.8	0.82
Diabetes (%)	37.8	35.6	0.81

Continued

Smoking history (%)	42.2	44.4	0.81
LVEF (%)	56.7 ± 7.2	57.1 ± 6.9	0.76
SYNTAX score	25.4 ± 6.7	24.9 ± 6.5	0.67

3.2. Procedural Imaging and Operational Results

The OCT group performed better than the IVUS group in terms of imaging outcomes. The Minimal Stent Area (MSA) in the OCT group was significantly larger than in the IVUS group (8.6 ± 1.2 mm^2 vs 7.8 ± 1.1 mm^2, p = 0.004). The incidence of stent malapposition was lower in the OCT group (6.7% vs 17.8%, p = 0.04). The incidence of underexpansion was 11.1% in the OCT group and 20.0% in the IVUS group, a difference approaching statistical significance (p = 0.09). The detection rate for edge dissection was slightly higher in the OCT group (13.3% vs 4.4%, p = 0.12), with most cases resolved after post-dilation. The rate of additional optimization measures was higher in the OCT group (31.1% vs 15.6%, p = 0.03), suggesting OCT's clear advantage in intraoperative correction (Table 2).

Table 2. Comparison of intraoperative imaging outcomes between the two groups.

Indicator	OCT Group (n = 45)	IVUS Group (n = 45)	p-value
Minimal Stent Area (mm^2)	8.6 ± 1.2	7.8 ± 1.1	0.004
Malapposition (%)	6.7	17.8	0.04
Underexpansion (%)	11.1	20.0	0.09
Edge Dissection (%)	13.3	4.4	0.12
Additional Optimization Measures (%)	31.1	15.6	0.03

3.3. Short-Term Clinical Outcomes (30 Days)

The 30-day major complication rates were low in both groups, with no statistically significant difference. Complications occurred in 4.4% of the OCT group and 6.7% of the IVUS group (p = 0.64). No cardiac deaths occurred in either group. The rates of non-fatal myocardial infarction and target vessel revascularization were low and not statistically different (Table 3).

Table 3. 30-day clinical outcomes for the two groups.

Outcome	OCT Group (n = 45)	IVUS Group (n = 45)	p-value
Total Complications (%)	4.4	6.7	0.64
Cardiac Death (%)	0	0	-
Non-fatal Myocardial Infarction (%)	2.2	4.4	0.56
Target Vessel Revascularization (%)	2.2	4.4	0.56

3.4. Follow-Up Results (12 Months)

The follow-up rate was 95.6%. The OCT group had better long-term outcomes than the IVUS group. The incidence of MACE in the OCT group was 8.9%, lower than the IVUS group's 20.0% (HR 0.42, 95% CI: 0.18 - 0.97, p = 0.045). Target Vessel Revascularization (TVR) was 4.4% in the OCT group vs 11.1% in the IVUS group, with no statistically significant difference (p = 0.19). Non-fatal myocardial infarction was 2.2% in the OCT group vs 6.7% in the IVUS group (p = 0.29). No cardiac deaths occurred in either group (Table 4, Figure 2).

Table 4. 12-month follow-up outcomes for the two groups.

Outcome	OCT Group (n = 43)	IVUS Group (n = 43)	p-value
MACE (%)	8.9	20.0	0.045
Cardiac Death (%)	0	0	-
Non-fatal Myocardial Infarction (%)	2.2	6.7	0.29
Target Vessel Revascularization (%)	4.4	11.1	0.19

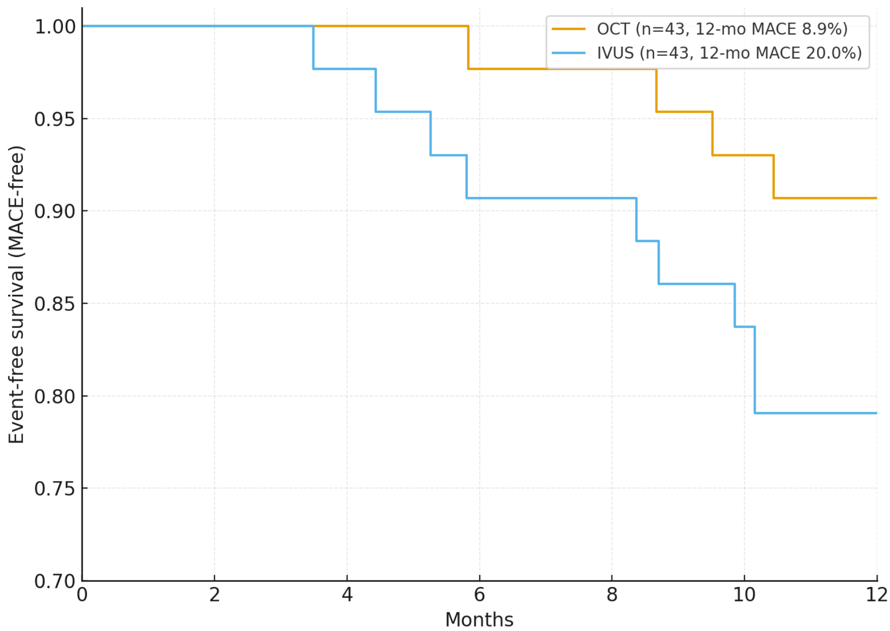

Figure 2. Kaplan-Meier survival curves.

3.5. Subgroup Analysis

In patients with complex bifurcation lesions (Medina 1, 1, 1 or 0, 1, 1), the improvement in MSA in the OCT group was more pronounced (8.4 ± 1.3 mm^2 vs 7.3 ± 1.2 mm^2, p = 0.002), and the 12-month MACE rate was lower (10.5% vs 27.3%, p = 0.03). This suggests that the benefit of OCT is more significant in complex bifurcation lesions.

4. Discussion

This study, through a prospective randomized controlled trial, compared the application effects of OCT and IVUS in LM bifurcation PCI. The results showed that OCT has significant advantages in both intraoperative imaging outcomes and long-term clinical prognosis. The post-procedural MSA in the OCT group was significantly larger than in the IVUS group, and the incidence of malapposition was lower. This indicates that OCT, with its high resolution, can more precisely guide stent expansion and apposition, thereby reducing potential complications.

Notably, our subgroup analysis revealed a pronounced benefit of OCT guidance in patients with complex lesions (Medina 1, 1, 1 or 0, 1, 1). In complex anatomical scenarios, such as calcified bifurcations, precise assessment of plaque burden and calcium thickness is critical for lesion preparation and stent expansion. The superior resolution of OCT allows for a more accurate delineation of the vessel lumen and calcium distribution compared to IVUS, which often suffers from acoustic shadowing in the presence of heavy calcification. Consequently, OCT enabled more targeted pre-dilation and post-dilation strategies in this subgroup, leading to the significantly improved acute gain observed in our results.

Regarding procedural safety, the detection rate of edge dissection was slightly higher in the OCT group. However, it is important to contextualize this finding. Rather than indicating a higher incidence of procedure-induced vessel injury, this likely reflects the superior diagnostic sensitivity of OCT [14]. Due to its near-microscopic resolution, OCT detects minor, sub-clinical intrastimal tears that often fall below the resolution threshold of IVUS [15]. The majority of these detected dissections were non-flow-limiting and did not require additional intervention, suggesting that OCT provides a more granular—albeit clinically distinct—assessment of vessel integrity post-stenting compared to IVUS [16].

Numerous previous studies have already demonstrated the important value of IVUS in left main PCI [17], while the evidence for OCT is relatively limited. Our findings are largely consistent with the ILUMIEN III: OPTIMIZE PCI trial [18], which demonstrated that OCT-guided PCI results in comparable minimum stent areas to IVUS guidance. However, our study extends these conclusions specifically to the context of LM bifurcation lesions, a subset often underrepresented in broader randomized trials. While ILUMIEN III established non-inferiority in general practice, our data reinforces that in anatomically challenging bifurcations, OCT's ability to visualize the ostium and carina provides specific additive value, ensuring optimal strut apposition in areas prone to thrombosis and restenosis.

The application of OCT helps to improve the safety and effectiveness of complex bifurcation PCI, especially when the branch angle is sharp, plaque burden is high, or a two-stent strategy is required. The results of this study support the wider application of OCT in LM bifurcation PCI, as an important supplement or even an alternative to IVUS, providing a more precise basis for clinical decision-making.

However, this study also has certain limitations. It is a single-center, small-sample study, limiting the generalizability of the results. The follow-up period was only 12 months, and long-term data are still needed to verify the sustained impact of OCT on long-term prognosis. Additionally, OCT has limited penetration in lipid-rich plaques and requires contrast agent for blood clearing, which may increase procedure time and contrast dose. Finally, potential operator bias and variability in experience must be acknowledged. As with any imaging modality, the interpretation of OCT images and the subsequent decision-making process are subject to the operator's learning curve. If operators were historically more experienced with one modality over the other, this could influence procedural times and optimization decisions. Future large-scale, multi-center randomized controlled trials should be conducted, combined with new imaging technologies (such as OCT-FFR fusion), to further evaluate the application value of OCT in complex left main bifurcation lesions.

5. Conclusion

OCT can provide more precise imaging guidance in LM bifurcation PCI, improving stent expansion and apposition quality, and reducing mid-term adverse event rates. Its application value is particularly prominent in complex bifurcation lesions, and it is expected to become the preferred imaging guidance tool for this type of high-risk lesion in the future.

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Authors' Contributions

Ruan Ruyi designed the study, collected and analyzed the data, and wrote the initial draft. Xiang Fu and Xu Xiaofeng participated in the procedures and data collection. Liu Quan and Luo Lan assisted with statistical analysis and follow-up. Shi Lijie supervised the project and revised the manuscript. All authors have read and approved the final version of the manuscript.

Conflicts of Interest

The authors declare that they have no conflicts of interest.

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