



Original Article

Added Value of Optical Coherence Tomography for Complex Coronary Lesion Revascularization: Insights From a Clinical Study

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Abstract

Introduction: During complex coronary lesions revascularization, procedural outcome optimization is critical due to the significant hazard of stent underexpansion, incomplete stent apposition and edge dissection. Optical coherence tomography (OCT) is an established imaging modality for the precise identification of such adverse features. The study aimed to assess the effect of OCT on intraprocedural planning modification during complex coronary lesions revascularization.

Methods: Consecutive patients who had OCT-guided Xience stent implantation from January 2014 to December 2020 were included. The study comprised 177 lesions from 138 patients with the following lesion complexities: 24 true bifurcation lesions requiring stenting (13.5%), 31 moderate/heavily calcified lesion (17.5%), 10 coronary total occlusions (CTOs) (5.6%), 63 ostial left anterior descending (LAD)/Left circumflex (LCX) (35.6%), and 45 in-stent restenosis (25.4%).

Results: Despite optimal angiographic results, 45.8% of the examined stents required additional intervention based on OCT assessment. The OCT-based modifications were more prevalent in specific lesion complexity; ostial LAD/LCX lesions (62.7%), overlapped stents (55%), moderate and heavy calcifications (48.4%), CTOs (50%), bifurcation stenting (54%), and left main stenting (54.5%).

Conclusion: Intraprocedural OCT guidance significantly changed interventional procedural planning in complex coronary interventions particularly in cases of ostial LAD/LCX lesions and overlapped stents.

Keywords: OCT, Complex coronary lesions, PCI, Edge dissection, Ostial LAD/LCX, Underexpansion, Stent malapposition

Introduction

Percutaneous coronary intervention (PCI) is an established therapeutic modality in coronary artery disease treatment.¹ During complex coronary lesions revascularization, final result optimization is critical due to the significant adverse effects of stent underexpansion, incomplete stent apposition (ISA), and edge dissection, as they increase the risk of stent failure via thrombosis or restenosis.²⁻⁶ Recently, several studies have emphasized the importance of intravascular imaging in procedural treatment planning of complex coronary lesions as it provides additional information to the sole angiographic guidance, thereby, playing a crucial role in optimizing revascularization outcomes.^{2,7,8} Optical coherence tomography (OCT) with an ultra-high-resolution, around 10 to 20um, has a unique value in the precise identification of subtle morphological features including stent underexpansion, ISA, residual thrombus, plaque prolapse, and edge dissections.⁹ Despite

severely underestimated on angiography, these indices are deemed clinically significant and linked to post-procedural worse outcomes.¹⁰⁻¹²

The ILUMIEN IV trial showed lower incidence of stent thrombosis in the OCT-guided group during complex coronary lesion stenting, but failed to show advantage of OCT in reduction of the primary clinical endpoint (target vessel failure).¹³ The recently published OCCUPI trial showed that OCT guidance during complex lesion revascularization resulted in a lower major adverse cardiac events (MACE) rate compared to angiography guidance.¹⁴ Two observational studies demonstrated that OCT imaging influences operator's decision during non-complex coronary interventions.^{1,15} This effect is expected to be augmented in the complex subset of lesions.¹³ The aim of the study is to assess the impact of OCT on intraprocedural-plan changing during complex coronary lesions revascularization.



Materials and Methods

Study Design

Consecutive patients who had OCT-guided coronary intervention at Al Qassimi Hospital, Sharjah, from January 2014 to December 2020 were screened. Patients treated with one or more Xience stents were included in the study (N = 138). The demographic, clinical, and angiographic characteristics were documented, and the data of the index PCI procedure were directly obtained from the original procedural records. Cases were reviewed for any additional unplanned intervention following OCT imaging on top of what was considered to be optimal angiographic outcome defined as diameter stenosis < 30% with Thrombolysis In Myocardial Infarction (TIMI) 3 flow by visual assessment.¹⁶ The retrospective design was selected to avoid operators bias on the effect of OCT imaging on the procedural planning. The protocol adhered to the Helsinki declaration and was approved by the United Arab Emirates Ministry of Health and Prevention Research Ethics Committee, MOHAP/DXB-REC/ D21-FM23 /No.128 / 2021. Informed consent was waived during ethical approval in view of the retrospective observational study design providing patient's confidentiality. Nevertheless, all patients provided written informed consent prior to the index procedure.

Procedure

Prior to PCI, patients received 300 mg aspirin and either clopidogrel 600 mg or ticagrelor 180 mg. The procedures were performed using standard practice via radial or femoral access. Lesion preparation, balloon type and pressure pre-dilatation, were based upon operators' decision. The Xience Everolimus-eluting cobalt–chromium stent (Abbott Vascular, Santa Clara, USA) was used to treat all cases. Stents were implanted with standard technique. Post-dilatation was performed with non-compliant (NC) balloons to achieve optimal angiographic outcome. OCT imaging was subsequently performed to evaluate stent expansion and struts apposition, and to exclude the presence of edge dissection and residual lesion at the stent edges. Based on OCT analysis, decisions about the necessity for procedural modifications were taken; additional post-dilatation in case of stent underexpansion or ISA and bailout stenting in case of significant edge dissection or considerable residual lesion.

Optical Coherence Tomography Performance and Interpretation

The ILUMIEN OPTIS PCI Optimisation System (St. Jude Medical, St. Paul, Minnesota, USA, and Abbott Vascular, USA) was used for OCT acquisition. Automatic pullbacks were performed at 20 mm/s and analysis included the 4 mm proximal and distal to the stent edges. Iso osmolar iodixanol (Visipaque; GE Healthcare, Little Chalfont, Buckinghamshire, UK) was used during pullbacks to limit blood artefacts. Underexpansion was defined as minimum stent area < 90% of the mean reference largest lumen areas within 4 mm proximal and distal to the stent edge.⁸ Edge dissection was defined as a medial tear at the stent edge

creating a flap.⁷ ISA was considered significant when the axial distance between the strut's abluminal surface and the vessel wall exceeds 300µm excluding side branches take offs.⁸

Follow-up

Clinical follow-up for all subjects was performed as per local practice at 6 months and 1 year to assess the rate of cardiac death, myocardial infarction (MI), stent thrombosis, and target lesion revascularization (TLR) defined as revascularization within the stent or within the 5-mm borders adjacent to the stent. Deaths that could not be attributed to any other cause were regarded as cardiac deaths. The Academic Research Consortium criteria (ARC) classified stent thrombosis as acute (0 to 24 hours after stent implantation), subacute (after 24 hours but within 1 month after implantation), late thrombosis (from 1 month to 1 year), very late stent thrombosis (VLST) (after 1 year).¹⁷

Statistical Analysis

Study endpoints were: 1. the rate of procedural modification based on OCT findings, decisions about the necessity for procedural modifications were taken; additional post-dilatation in case of stent underexpansion or ISA and bailout stenting in case of significant edge dissection or considerable residual lesion. 2. the independent predictors of OCT findings leading to procedural modification.

Statistical Package for Social Science (SPSS) version 22 was used to analyze data. Continuous variables were compared with a student's t-test and presented as mean ($\pm$ standard deviation). Categorical variables were compared with the chi-squared test and presented as n (%). Univariate logistic regression was used to recognize the independent predictors of the OCT features prompting additional intervention. The test was performed separately for each of the following variables: age, diabetes mellitus, clinical presentation, target vessel, lesion complexity, and stent diameter. Covariates with $P < 0.20$ by univariate analysis were included into the final model of multivariate logistic regression to identify independent predictors of OCT-triggered modifications and to estimate adjusted odds ratios and 95% confidence intervals (CIs). P value < 0.05. was considered statistically significant.

Results

A total of 177 stents from 138 patients were assessed. The mean age was 55.25 ($\pm$ 11.38), with 81% male; 58% hypertension, 68% dyslipidemia, 62% diabetes mellitus and 27.5% were current smokers. The lesions included had the following complex characteristics; 24 bifurcation lesions (13.5%), 31 moderate/heavy calcified lesions (17.5%), 10 coronary total occlusions (CTOs) (5.6%), 63 ostial left anterior descending (LAD)/Left circumflex (LCX) lesions (35.6%), and 45 in-stent restenosis (25.4%). The male predominance (4/5 of the study population) might be due to either demographic reasons as smoking is more predominant in males in gulf region,¹⁸ or variances in health seeking behavior as females were found to be less likely to

undergo cardiac catheterization and revascularization in a study conducted by Rao et al.¹⁹

Despite angiographic success, 81 of the 177 examined stents (45.8%) required unplanned intervention following OCT assessment. There was no difference in clinical, demographic variables, or the procedural indication between the two groups (Table 1).

The OCT modified stents showed a significantly larger post-dilatation balloon diameter (3.7 ± 0.9 vs 3.4 ± 0.8 , $P=0.049$) and greater difference in post-dilatation balloon and the stents diameters (0.47 ± 0.44 vs. 0.29 ± 0.35 , $P=0.004$) compared to the non-modified ones. There was no difference in the post-dilatation rate (96.3% vs. 96.6%, $P=0.832$), and post-dilatation pressures (16.54 ± 5.6 vs. 16.56 ± 4.9 , $P=0.981$) between the two groups. Lesion and procedural characteristics are summarized in Table 2.

OCT revealed intracoronary adverse features leading to unplanned interventions in 45.8% of the stents. Additional post-dilatation was required in 40.5% of stents for underexpansion and/or ISA, while bailout stenting was performed in 7.3% of cases for stent edge dissection (Figure 1) and residual lesion at stent edge.

The OCT- based modifications were found to be more prevalent in specific lesions: ostial LAD/LCX lesions (62.7%), overlapped stents (55%), moderate and heavy calcifications (48.4%), CTOs (50%), bifurcation stenting (54%), and left main (LM) stenting (54.5%). Univariate predictors for OCT guided additional interventions were primary PCI indication, intracoronary thrombus, overlapping stents, and ostial LAD/LCX lesions. The overlapping stents, and ostial LAD/LCX lesions were independent predictors in multivariate analysis (Table 3).

At 1 year follow-up, cardiac death and non-fatal MI was 0.7%. There was no difference in clinical outcomes between the two groups in terms of clinical outcomes. Total TLR rate was 4.5%, and subacute stent thrombosis 0.6%. There

were no cases of acute, late or very late stent thrombosis.

Discussion

To our knowledge this is the first study to assess the impact of OCT guidance on intraoperative planning during complex coronary interventions reflecting routine practice including ostial lesions, in-stent implantation, overlap stents, left main artery, bifurcation stenting, and CTO.

OCT-based strategy modification was necessary in 45.8% of the stents implanted in anatomically complex lesions. Our findings are consistent with the recent upgrade of the OCT guidance for complex lesions' PCI to class I recommendation in the 2024 ESC Guidelines for the management of chronic coronary syndromes.²⁰ Plan modification was primarily due to underexpansion and significant ISA (88.8%), and to a lesser extent due to major edge dissection (8.6%), or residual lesions at stent edges (6.2%).

Post optimal angiographic result, OCT revealed adverse characteristics in 45.8% of cases, which is higher than

Table 1. Patients' baseline characteristics

	Modifications 70 (50.7%)	No modifications 68 (49.3%)	P-value
Male	54 (77.1)	58 (85.3)	0.221
Age (mean)	54.9 (12.2)	55.6 (10.5)	0.713
Hypertension	37 (53)	43 (63.2)	0.217
Diabetes Mellitus	41 (58.6)	45 (66.2)	0.357
Receiving insulin	8 (11.4)	12 (17.6)	0.3
Dyslipidemia	46 (65.7)	48 (70.6)	0.539
Current smoking	20 (29)	18 (26.5)	0.742
Previous MI ^a	11 (15.7)	15 (22.1)	0.633
Post CABG ^b	3 (4.3)	0 (0)	0.135
Indications			
Primary PCI ^c	4 (5.7)	2 (2.9)	0.425
Late or lysed MI	2 (2.9)	1 (1.5)	0.577
UA/NSTEMI ^d	35 (50)	38 (55.9)	0.489
Stable CAD ^e	29 (41.4)	27 (39.7)	0.837

a: Myocardial infarction, b: coronary artery bypass grafting, c: percutaneous coronary intervention, d: unstable angina/non-ST elevation myocardial infarction, e: coronary artery disease.

Table 2. Lesion and procedural features

	Modifications 81 No (%)	No modifications 96 No (%)	P-value
Target vessel			
Left main artery	12 (14.8%)	10 (10.4%)	0.377
Left anterior descending	56 (69.1%)	62 (64.6%)	0.522
Left circumflex	10 (12.3%)	14 (14.6%)	0.665
Ramus intermedius	1 (1.2%)	0 (0%)	0.275
Right coronary artery	14 (17.3%)	18 (18.8%)	0.801
Saphenous vein graft	0 (0%)	2 (2.1%)	0.191
Bifurcation	28 (34.6%)	28 (29.2%)	0.441
Bifurcation stenting	13 (16.0%)	11 (11.5%)	0.374
Overlapped stents	60 (74.1%)	49 (51%)	0.002*
Moderate/heavy calcification	15 (18.5%)	16 (16.7%)	0.747
Thrombus	7 (8.6%)	4 (4.2%)	0.219
Chronic total occlusion	5 (6.2%)	5 (5.2%)	0.782
Ostial lesion	37 (45.7%)	26 (27.1%)	0.01*
In-stent restenosis	20 (24.7%)	25 (26%)	0.837
Total predilatation	62 (76.5%)	82 (85.4%)	0.131
Predilatation with non-compliant balloon	48 (59.3%)	53 (55.2%)	0.588
Predilatation with cutting balloon	14 (17.3%)	21 (21.9%)	0.445
Predilatation pressure (mean $\pm$ SD)	11.53 ($\pm$ 5.72)	10.25 ($\pm$ 6.81)	0.175
Postdilatation with non-compliant balloon	78 (96.3%)	93 (96.9%)	0.832
Postdilatation pressure (mean $\pm$ SD)	16.54 ($\pm$ 5.6)	16.56 ($\pm$ 4.9)	0.981
Stent inflation pressure (mean $\pm$ SD)	13.82 ($\pm$ 2.51)	13.18 ($\pm$ 2.84)	0.128
Post-dilatation balloon diameter	3.7 (0.9)	3.4 (0.8)	0.049*
Post-dilatation balloon/stent ratio	1.12 ($\pm$ 0.18)	1.09 ($\pm$ 0.11)	0.157
Post-dilatation balloon-device diameter/mm	0.47 ($\pm$ 0.44)	0.29 ($\pm$ 0.35)	0.004*

Table 3. Multivariate logistic regression analysis of OCT based modification in studied population

	Univariate		Multivariate	
	Odds ratio (95% CI)	P-value	Odds ratio (95% CI)	P-value
Age	0.99 (0.97-1.02)	0.711	-	-
Diabetes mellitus	1.17 (0.5-2.73)	0.702	-	-
Clinical presentation:				
Stable CAD ^a	0.97 (0.53-1.76)	0.922	-	-
UA/NSTEMI ^b	0.81 (0.45-1.47)	0.493	-	-
Late/Lysed MI ^c	1.19 (0.16-8.6)	0.864	-	-
Primary PCI ^d	2.9 (0.73-11.73)	0.128*	3.57 (0.8-15.82)	0.093
Target vessel:				
Left main artery	1.5 (0.61-3.66)	0.379	-	-
Left anterior descending	1.2 (0.65-2.3)	0.522	-	-
Left circumflex	0.82 (0.34-1.97)	0.665	-	-
Right coronary artery	0.9 (0.41-1.95)	0.801	-	-
Thrombus	2.17 (0.61-7.71)	0.229*	1.92 (0.51-7.16)	0.328
Bifurcations	1.28 (0.68-2.42)	0.442	-	-
Bifurcation stenting	1.47 (0.62-3.5)	0.376	-	-
Moderate/heavy calcification	1.13 (0.52-2.46)	0.747	-	-
Overlap	2.74 (1.44-5.18)	0.002*	2.6 (1.34-5.05)	0.005*
In-stent restenosis	0.93 (0.47-1.83)	0.837	-	-
Chronic total occlusion	1.19 (0.33-4.29)	0.782	-	-
Ostial LAD/LCX ^e	2.26 (1.2-4.2)	0.011*	2.04 (1.06-3.92)	0.033*
Stent diameter	1.8 (0.97-3.3)	0.062*	1.17 (0.57-2.39)	0.664

a: coronary artery disease, b: unstable angina/non-ST elevation myocardial infarction, c: Myocardial infarction, d: percutaneous coronary intervention, e: left anterior descending/left circumflex.

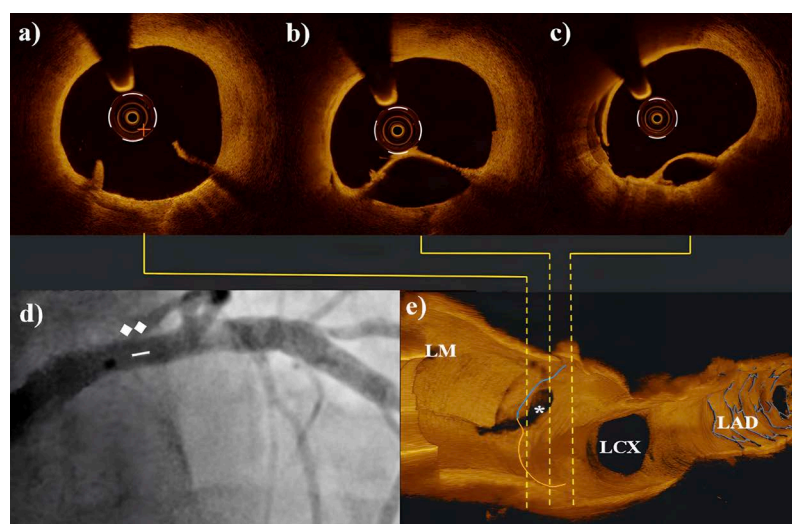


Figure 1. Left main artery dissection, demonstrated by optical coherence tomography with 3 cross-section images showing intimal flap (a) and double-lumen morphology (b, c). Left coronary angiography showing normal left main artery morphology at the area of the dissection (between 2 dots) (d), OCT 3-dimensional view showing dissecting flap in the left main artery (as denoted by the asterisk *) (e). LM: left main, LAD, left anterior descending, LCX: left circumflex

the 34.7% disclosed in the CLIO-PCI study. This can be explained by the more complex nature of coronary lesions in the current population, including overlapping stents (61.6 vs. 14.6%), which was an independent predictor for OCT-guided procedural modification.¹ For the same reason additional stent optimization was performed in 40.5% of cases in our cohort compared to 29.3% in the CLIO-PCI study, indicating that increasing the lesion complexity increases the benefit of OCT guidance. The

above-mentioned observation is also corroborated by the results of the ILUMIEN I study that included simple de-novo coronary lesions where suboptimal stent deployment was detected by OCT in 25% of patients.¹⁵ OCT identified significant edge dissection requiring stenting in 4% of the current population, which is similar to the ILUMIEN IV trial, owing primarily to comparable lesion complexities included in both studies.¹³

OCT had a greater impact on intraoperative decision-

making in patients with certain lesion complexities. We reported a 62.7% change in intraprocedural decisions following OCT imaging of ostial LAD/LCX stents. Despite the fact that LM-LAD crossover stenting is the recommended modality to treat ostial LAD lesion, it may lead to LM-stent underexpansion or malapposition due to size discrepancy.²¹ Moreover, ostial LAD stenting is still attempted in case of high risk of compromising LCX flow.²² For isolated LCX ostial lesions, current data are insufficient to support definitive treatment recommendations. Consequently, operators often avoid bifurcation stenting that could jeopardize LAD patency, given the LAD's typically larger myocardial territory.²³ Stenting of ostial LAD/LCX bears an inherent risk for excessive struts protrusion into LM artery, potentially resulting in an area of underexpansion and/or significant ISA (figure 2), which carry hazard of stent thrombosis.¹² OCT imaging allows accurate visualization of the ostial stent position and planning of subsequent management in case of significant protrusion.³ This is potentially reflected by the very low stent thrombosis rate observed in our cohort where stent apposition was optimized in this subset lesion group.

OCT-analysis guided procedural stent optimization for stent underexpansion and severe ISA occurred in 55% of overlapping stents. This finding is in accordance with the AUTHENTIC study outcome, where overlapping stents had higher rate of stent thrombosis and subsequent revascularization during long-term follow-up in more than 15.000 patients.²⁴ Same results were confirmed by Coughlan et al.²⁵

Post bifurcation stenting, OCT imaging led to procedural modification in 54% of cases. This is in line with the lower incidence of major adverse cardiac events in the OCT-guided arm in the randomized OCTOBER trial, compared to angiographic-guidance (10.1% vs 14.1%, $P=0.035$).³

In case of in-stent restenosis post-stenting OCT derived further modifications in 44% of stents, a smaller than expected percentage for such an indication. The clear explanation for this is the very high rate of pre-stenting OCT imaging (75% of the cases) that already provided the information needed for optimal lesion treatment (high pressure pre-dilatation in 95.5% and cutting balloon in 40% of cases). High pre-dilatation pressure helped to correct underexpansion of the old stent, while cutting balloons minimized the tissue recoil into the lumen in cases with neointimal hyperplasia, both enhanced proper expansion of the newly implanted stent.²⁶

In the ROCK cohort II study, OCT guidance during LM artery stenting allowed visualization and correction of stent underexpansion and ISA, and improved future outcome compared to standard practice.²⁷ A recent study involving OCT follow-up of DES implanted in LM lesions revealed a high prevalence of incomplete strut coverage, late stent malapposition, and elevated rates of subclinical DES failure.²⁸ These results align with our findings, where OCT analysis led to a modification in the planned strategy in 54% of cases following LM stenting. A lower incidence of unplanned intervention (26%) was spotted in the LEMON study during LM intervention, possibly due to their standardized protocol that involved three pre-specified OCT runs with pre-treatment OCT imaging.²⁹ All these findings underscore the necessity of OCT imaging strategies to enhance procedural outcomes in LM stenting.

Primary PCI indication, thrombus presence, overlapped stents, and ostial LAD/LCX lesions all demonstrated a significant positive association with OCT-triggered interventions by univariate logistic regression. Multivariable analysis identifies both ostial LAD/LCX lesions and overlapped stents as independent predictors of OCT-triggered modifications. However, the reduced

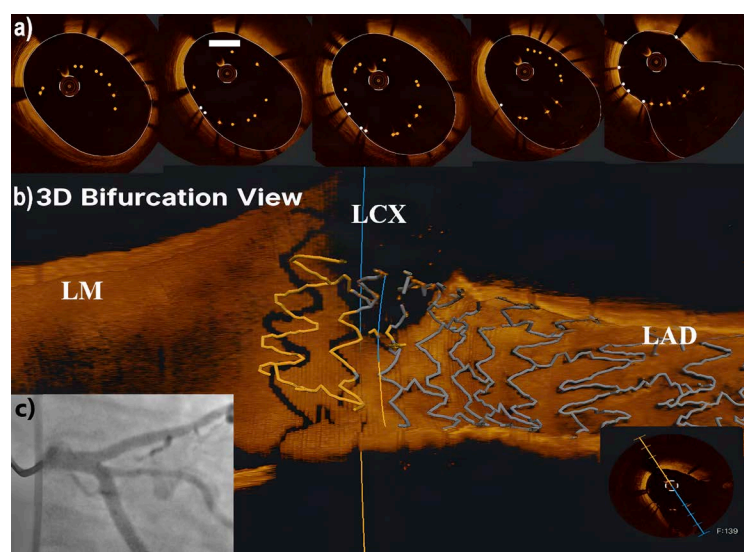


Figure 2. Optical coherence tomography (OCT) three-dimensional view at the level of left main artery (LM) bifurcation (b), showing a well-apposed stent in the left anterior descending artery (LAD) as denoted by the gray color of the stent struts, two levels of struts are protruding proximally in the LM, with incomplete struts apposition as denoted by the yellow color of the struts, and the struts shadow in the LM. OCT cross section images in the LM showing significant struts malapposition with an axial distance between the strut's abluminal surface and the vessel wall >300µm (a). Left coronary angiography in which incomplete struts apposition couldn't be identified (c).

prevalence of other lesion complexity in the study sample, such as primary PCI, bifurcation stenting, and CTO, may have contributed to the numerical, but not statistical, significance of OCT influence.

The one-year clinical outcome of the studied population was consistent with the OCT-guided arm in the CLIO-PCI study in terms of cardiac death (0.6% vs 1.2%), stent thrombosis (0.6% vs 0.3%), and TLR (4.5% vs 3.3%) respectively, and better than the angiographic guidance arm of the same study.¹ The ILUMIEN IV trial showed no significant difference in the target-vessel failure rate at 2 years between OCT and angiography guided PCI, which was mostly due to the low incidence of ischemia-driven target-vessel revascularization in both groups. However, there was a significant difference in the stent thrombosis rate at 2 years in favor of OCT guidance (0.5% vs. 1.4%, $p=0.02$). In the present study, stent thrombosis occurred in a single patient (0.6%) within 2 years, consistent with the 0.5% reported in the OCT group of the ILUMIEN IV trial. This finding may be due to the OCT exceptional ability to detect significant edge dissection, ISA and underexpansion, all known to be predictors of stent thrombosis, therefore improving treatment strategies and prognosis.¹³

The OCCUPI trial revealed a significantly lower 1-year MACE rate with OCT guidance compared to angiography guidance in patients with complex coronary lesions (5% vs. 7%, $p=0.02$). The current study showed 1-year clinical outcome comparable to the OCT-guidance arm of the OCCUPI study in terms of cardiac death (0.7% vs <1%), myocardial infarction (0.7% vs 1%), and definite stent thrombosis (0.6% vs <1%). OCCUPI reported a TLR of 1% in the OCT guidance arm, which is the lowest rate reported in the literature.^{1,13,14}

Our study has several limitations. It is a retrospective study, but such a design in the current protocol has the benefit of prohibiting bias while studying the influence of OCT on changes on the operators' decision post-stenting, moreover, the multivariable analysis was performed to control confounders and make statistical adjustments. The study due to its retrospective nature and the small number of patients was not intended for clinical outcome comparisons, we report on them for the completeness of the presentation of the data without making any conclusions regarding the impact of OCT on clinical outcomes in this cohort. Another limitation is the reduced prevalence of other anatomic complexities such as bifurcation stenting, CTO, and primary PCI with large thrombotic burden, that may have contributed to the numerical, but not statistical, significance of OCT impact. Therefore, further studies focusing on the OCT impact on each complexity are warranted.

Conclusion

Post-stenting OCT guidance significantly modified interventional procedural planning in complex coronary interventions particularly in cases of ostial LAD/LCX lesions and overlapping stents. The study provides a new perspective on the influence of OCT imaging on the

operators' decision-making during revascularization of specific coronary lesions complexities and contributes to the expanding literature aimed at successful treatment of complex coronary lesions.

Authors' Contribution

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Competing Interests

No conflicts of interest to declare.

Ethical Approval

The protocol was approved by the Ethics Committee of the United Arab Emirates Ministry of Health and Prevention Research, MOHAP/DXB-REC/ D21-FM23 /No.128 / 2021. Informed consent was waived during ethical approval in view of the retrospective observational study design providing patient's confidentiality. Nevertheless, all patients provided written informed consent prior to the index procedure.

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