Original Research Article

Optical Coherence Tomography Guidance in Management of Complex Lesions Intervention

Abstract

Background: Optical Coherence Tomography(OCT) can identify tissue charactersdepending on the polarisation properties of light, allowing detailed investigation of plaque form, content, and distribution. Calcification strongly correlates with advanced atherosclerosis, increased age, and comorbidities. The presence of calcified and hard lesions makes percutaneous coronary intervention (PCI) difficult and frequently needs adjunctive procedures to get excellent stent outcomes.The purpose of this research was to assess the role of OCT, and how it affects the operator decision in management and optimizing of PCI for complex coronary lesions, including left main and non-left main bifurcation lesions, calcific lesions and in stent restenosis.

Methods: This prospective observational single center research was carried out on 60 patients underwent elective PCI for complex coronary lesions. Cases were classified into two groups based on the change in the operator opinion after performing OCT, either before or after stenting. Group I (n=19) patients with no change in operator decision based on OCT. Group II (n=41) patients with change in operator decision based on OCT.All patients were subjected toClinical examination, Twelve leads surface electrocardiogram (ECG), Echocardiography, diagnostic coronary angiography.

Results: Among the 60casesinvolved in the research, the decision of the operator was changes in 41 patients (68%). The change based on the pre-PCI assessment was found in 21patients

(51% of all changes). The changes were either change in the number of stents, the technique of the bifurcation intervention, or the need of atherectomy devices in calcific lesion for good lesion preparation. The change in the decision based on pots-PCI OCT only was found in 10 patients (41% of all changes). The main change of the procedure based on post-PCI OCT was mainly further post dilatation due to malapposition or significant tissue protrusion, or implantation of another stent for distal edge dissection.

Conclusion:OCTis a very helpful intravascular imaging for optimization of PCI for complex coronary lesion. It significantly changed the decision of the operator for the aim of optimal stent apposition and to reduce complications in complex lesions.

Keywords:OCT,Complex Lesions Intervention, Coronary Angiography, PCI

Introduction:

Coronary angiography is regularly utilised to direct invasive coronary artery disease (CAD) treatments. Nonetheless, just as the most expert interventionalist may reconsider conclusions depending only on the angiographic lumen profile when confronted with lesion and case complexity. (1)Several limitations of coronary angiography (e.g., limited reliability in evaluating true diameter and length, low sensitivity in detecting calcium and limited planar resolution to provide information on complex 3-dimensional anatomy) might influence choices made through percutaneous coronary interventions (PCI). In addition to advancing age and comorbidities, casesperforming PCI frequently exhibit many, diffuse, calcified lesions that involve bifurcations. (2)

Even though drug eluting stents (DES) have significantly decreased rates of restenosis and target vessel revascularization (TVR), DES outcomes are not as anticipated, particularly in complex lesions. Stent expansion is a significant indicator of restenosis (3, 4) - and stent thrombosis,(5, 6)even with new generations of DES. (7)

Consequently, the decision-making process regarding lesion preparation and the evaluation of the current stent outcomes are the pillars of result. Intravascular imaging has developed as a crucial method for improving stent implantation success in complex case, with better clinical results than coronary angiography alone. (8, 9)

Optical coherence tomography (OCT) is a high-resolution, light-based intravascular imaging method that enables automatic recognition parameters of the coronary lumen and stents over the whole investigated vessel immediately after image acquisition. OCT automatically offers longitudinal lumen contour that which is simpler to assessdue to the high frame rate during acquisition and fast pullback. (10)OCT can distinguish tissue features depending on the polarisation properties of light, allowing for a precise investigation of plaque form, content,

and distribution.(11)Strong correlations exist between calcification and advanced atherosclerosis, increased age, and comorbidities. (12)

The occurrence of calcified and lesions makes PCI difficult and frequently necessitates the use of adjunctive methods to achieve excellent stent outcomes. (13)Angiography has a low sensitivity (48%) for calcium recognition, with the exception of severe calcification, which is described as radio-opacities noted prior to contrast injection.(14)In contrast, calcium is discovered by OCT as a signal-poor or heterogeneous zone with distinct sharpborders.OCT predicts the extent of calcification more precisely than intravascular ultrasonography based on pathology (IVUS), (15)because light permeates calcium without casting shadows. (16)The purpose of this work was to assess the role of OCT, and how it affects the operator decision in management and optimizing PCI for complex coronary lesions, including left main and non-left main bifurcation lesions, calcific lesions and in stent restenosis.

Patients and Methods:

This prospective observational single centerresearchwas performed in Cardiovascular Department, Policlinico Largo Agostino Gemelli, Catholic University of Sacred Heart, Rome, Italy. It was carried out on 60 patients underwent elective PCI for complex coronary lesions, starting from December 2019 to December 2020. The research was conducted with consent from the Catholic University of the Sacred Heart's Ethical Committee.Informed written consent was taken from the cases guardians or relatives.

The inclusion criteria werecaseshad stable angina, unstable angina, or NSTEMI, diagnosed according to European Society of Cardiology (ESC) guidelines. Patients underwent elective or ‘ad hoc’ PCI for de novo complex coronary lesions. Complex coronary lesions included in the study were bifurcation coronary lesions, including both left main and non-left main bifurcation and heavily calcific lesions, and in-stent restenosis.

The exclusion criteria werecases presented with STEMI, cardiogenic shock, vessel(s) and lesion(s) not amenable for PCI, extreme angulation (> 90°) or excessive tortuosity (> two 45° angles) proximal to or within the target lesion, planned for using bare metal stents, known renal insufficiency (eGFR < 60 ml/kg/m2, serum creatinine ≥ 2.5 mg/dL, or on dialysis), Aorto-ostial lesion location within 3 mm of the aorta junction (both right and left), haematological disorders, recent major surgical procedure or trauma, life expectancy less than 1 year and lack sufficient data.

Caseswere categorized into two groups according to the change in the operator opinion after performing OCT, either before or after stenting. Group I (n=19) patients with no change in operator decision based on OCT. Group II (n=41) patients with change in operator decision based on OCT, either depend on pre-PCI OCT (n=21), or post PCI OCT (n=10), or both pre-PCI OCT and post-PCI OCT (n=10).

The caseswere subjected to the following:Personal history, risk factors, family history of premature CAD, history of previous coronary angiography or PCI, types ofdiameters and length of any previously deployed stents.

Clinical examination included vital signs. Signs of atherosclerosis: stroke, peripheral vascular disease.Signs of heart failure or hemodynamic instability.Signs of co-morbidities: renal or hepatic insufficiency, diabetes.local cardiac examination.**Twelve leads surface electrocardiogram (ECG):**Routine baseline 12-lead ECG was done for all patients before intervention.**Echocardiography:**Patient were examined using Philips iE33 ultrasound machine, and performed measurements, including ejection fraction (Simpson's method)[i], dimensions, segmental wall motion abnormalities and thorough assessment of heart valves and any detectable complications of myocardial ischemia.

Patients subjected to diagnostic coronary angiography and intervention and procedure planning: Coronary angiography was done with local anesthesia. The routine access adopted

in the center was radial approach, using hydrophilic introducers, with routine administration of 5,000 IU of unfractionated heparin after placement of introducer. Under fluoroscopic guidance, diagnostic coronary angiography was performed using diagnostic catheters. Lesions were identified and assessed angiographically, and complex lesions were categorized as planned into left main or non-left main coronary bifurcation lesions, heavily calcific lesions or in stent restenosis. The plan for intervention was noted and recorded based upon angiographic data from the diagnostic angiography for each individual case, putting in mind all technical aspects, types and sizes of balloons and stents. Then pre-PCI first OCT run was performed to offer intra-vascular assessment of lesion. The decision based on OCT data was noted and recorded, to see if there were any changes in the operator plan according to OCT data.After giving unfractionated heparin to complete the dose to (70-100 IU/Kg), the operator proceeded to PCI for each case with the technique based upon pre-PCI OCT data. Finishing procedure, post-PCI second OCT run was performed, to assess the results or presence of any complications not seen angiographically, and to assess the need of further intervention. Any change of the decision after post-PCI Oct run was recorded and noted. Final OCT run was performed to all patients. Caseswere classified into two groups as regard the changes of operator's decision according to OCT data into: group I, with no changes in operator decision and group II, with noted changes in operator decision based on OCT data, either pre-PCI OCT, post-PCI OCT, or both.

Analysis of angiography and OTC pre-PCI:OCT analysiswas donein the target vessel for revascularization. OCT images were obtained through the accessible system (ILUMIEN OPTIS OCT Intravascular Imaging System, St. Jude Medical, St. Paul, MN, USA), using an over the wire OCT catheter (C7 Dragonfly™ OPTIS™, St. Jude Medical, St. Paul, MN, USA).Over a 0.018-inch conventional angioplasty guidewire, the OCT imaging catheter was advanced distal to the lesion. Following catheter insertion, contrast media at 37 °C

(Omnipaque 350 Injection; Daiichi Pharmaceutical, Tokyo, Japan) was injectedwith the catheter guide at 2 to 4 mL/s for ≈3 to 6 seconds utilizing an injector pump (Mark V; Medrad, Warrendale, PA). When a RBC'S were cleaned out, the OCT probe wasretracted at 20 or 40 mm/s. The OCT pictures were digitally archived for later study.Before beginning the pullback, the optimal positioning of the guiding catheter was ensured.

Typically, a 6 Fr catheter was adequate for good imaging, permitting the usual usage of 6 Fr guiding catheters.The OCT catheter was placed distal to the target lesion or stent, and the pullback was continued till the guiding catheterwas reached or the maximum pullback length was achieved.A longitudinal cross section of the whole length of the vessel was created automatically, providing information about locations of lesion and its MLA, thrombus accumulation and general anatomical information on vessel size, length, presence of side branches and longitudinal extent of the lesion. After that, the portions of interest were browsedthoroughly.In addition, the real-time co-registration of OCT pictures with angiography enabled combined angiographic and intracoronary high-resolution imaging of coronary arteries directly in the catheter laboratory, where the exact localisation of the collected OCT frame was shown alongside the angiogram.

Bifurcations lesions were categorized angiographically according to Medina classification,[90] with identification of proximal, distal main vessel, and side branch. Operator identified the technique suited for treatment according to angiographic data, either one stent or two stent technique, with planned types and sizes of balloons and stents, with the need of pre-kissing or side branch dilatation or not. All the operator’s plans were recorded before the beginning of intervention. Then, OCT was performed in main vessel, in selected cases another OCT run was performed inside branch for proper assessment.

Regarding calcific lesions, they were identified and graded angiographically into:Mild: faint radiopacities observedin the cardiac cycles.Moderate: dense radiopacities observed only inthe

cardiac cycle.Severe: dense radiopacities observed without cardiac motion prior to contrast injection generally compromising both sides of the arterial lumen.After documenting the operator decision using angiographic information, pre-PCI OCT run was performed, and OCT-based calcium scoring system was utilized. If it showed maximum calcium angle > 180°, continuous length > 5 mm, and calcium thickness > 0.5 mm, these lesions were indicated foran upfront lesion preparation strategy to enable plaque modification and calcium fracture prior to stent implantation. This was accomplished by preparing the lesion with either orbital or rotational atherectomy.

For the cases of in stent restenosis, after angiographic assessment of the lesions, correlating it with the time of deployment, type, and diameter of the stent, and the postulated mechanism of restenosis, operator's plan for intervention was recorded.

Analysis of angiography and OTC post-stenting: Co-registered images from coronary angiography and OCT were examinedfor pre-specified variables. In order to report on physician decision-making, on-site classification of malapposition, under-expansion, thrombus/tissue protrusion, and edge dissection should be based on the approved definitions listed below. Significant malapposition described as > 200 micron in axial diameter and present in at least five consecutive frames on OCT.Edge dissection $>180^{o}$ in more than five frames on OCT.

Measurement and detecting all procedural variables. All Procedural variables including total dose area product (DAP), fluoroscopy time, procedure duration and contrast media used in the procedure were thoroughly calculated and noted.

Clinical Follow up: Follow up for all cases during the hospital stay and in the first 30 days after discharge for any detectable complications,MACE or death.

Statistical analysis

SPSS v26 was used to perform statistical analysis (IBM Inc., Chicago, IL, USA). Comparing the two groups using an unpaired Student's t- test, quantitative datawere provided as mean and standard deviation (SD). When applicable, qualitative variables were given as frequency and percentage (percent) and examinedutilizing the Chi-square test. A two-tailed P values below or equal to 0.05 were considered statistically significant.

Results:

Demographic data and risk factors in the studied groups. Table 1

Table 1: Demographic data and risk factors in the studied groups.

		Group I (n=19)	Group II (n=41)	P value
Age (years)	**Mean ± SD**	66.11 ± 6.27	60.76 ± 11.96	0.072
	Range	56-75	41-80	
Sex	**Male**	13 (68.4%)	27 (65.9%)	0.844
	Female	6 (31.6%)	14 (34.1%)	
BMI (kg/m^2)	**Mean ± SD**	29.89 ± 6.01	29.90 ± 6.99	0.596
	Range	22-38	19-41	
HTN		10 (53%)	29 (71%)	0.245
DM		5 (26%)	18 (44%)	0.628
Hypercholesterolemia		12 (63%)	20 (49%)	0.406
Smoking		11 (58%)	21 (51%)	0.630
Family history		8 (42%)	9 (22%)	0.131

(BMI: Body mass index, HTN: hypertension, DM: diabetes milletus)

Regarding clinical presentation and procedural variables in the studied groups, there were insignificantly different in two groups. Table 2

Table 2: Clinical presentation and procedural variables in the studied groups.

		Group I (n=19)	Group II (n=41)	P value
Previous PCI		10 (53%)	16 (39%)	0.404
Previous MI		2 (11%)	4 (10%)	1.000
Pre-procedure indication	**NSTEMI**	2 (11%)	5 (12%)	0.180
	Chronic Stable angina	11 (58%)	23 (56%)	
	Unstable angina	6 (31%)	13 (32%)	
Target vessel	**LMC**	3 (16%)	11 (27%)	0.221
	LAD	11 (58%)	20 (49%)	
	LCX	1 (5%)	6 (14%)	
	RCA	4 (21%)	4 (10%)	
Complex Lesions	**BIF**	7 (37%)	27 (66%)	**0.035***

	Calcific	6 (32%)	10 (24%)	0.558
	ISR	6 (32%)	4 (10%)	0.059

(NSTEMI: non-ST segment elevation myocardial infarction, LMC: left main coronary artery, LAD: Left ascending Anterior, LCX: left circumflex, RCA: right coronary artery, BIF: bifurcation lesions, ISR: in-stent restenosis)

Regarding procedural details in the studied groups, fluoroscopy was found that it was significantly longer in the group II. Also, total procedure duration was insignificantly longer in group II. Total DAP in group II showed insignificant increase when compared to group I. Regarding contrast agent used in two groups, there was insignificantly different when comparing group I. Table 3

Table 3: Procedural details in the studied groups.

		Group I (n=19)	**Group II (n=41)**	**P value**
Fluoroscopy duration (min)	**Mean ± SD**	22.97 ± 8.58	28.36 ± 9.73	**0.043***
	Range	10.15-47.4	13.7-53.75	
Procedure duration (min)	**Mean ± SD**	86.65 ± 13.09	97.45 ± 12.73	0.729
	Range	63.22-105.4	74.7-124.38	
Total DAP (Gy /cm^2)	**Mean ± SD**	30722.15 ± 26627.09	32534.79 ± 21902.55	0.797
	Range	10222-162721	13588-106186	
Contrast agent used (mL)	**Mean ± SD**	321.58 ± 104.31	311.22 ± 88.92	0.693
	Range	160-460	170-460	

(DAP: dose area product)

RegardingAngiographic planning and OTC analysis in the studied groups, angiographic planning and OCT analysis in the studied groups, the actual number of implanted stents was considerably higher in group II. the angiographic assessment of the operator to the percentage of stenosis and the length of the lesion showedinsignificantly different in between both groups, the post-PCI OCT was significantly different in between both groups,the diameter of stenosis showed a significant difference.Post-PCI OCT run after optimization of OCI using CT showed insignificantly different among both groups. Table 4

Table 4: Angiographic planning and OTC analysis in the studied groups

		Group I (n=19)	**Group II (n=41)**	**P value**
Planned number of stents prior to OCT	**Mean ± SD**	1.11 ± 0.32	1.15 ± 0.36	0.670
	Range	1-2	1-2	
Actual number of	**Mean ± SD**	1.16 ± 0.37	1.49 ± 0.60	**0.031***

implanted stents after OCT	**Range**	1-2	1-3	
Diameter stenosis (%) by angiography	**Mean ± SD**	69.21 ± 15.48	68.41 ± 13.11	0.837
	Range	45-95	50-95	
Pre-PCI percentage of stenosis by OCT	**Mean ± SD**	68.68 ± 15.35	70.12 ± 13.44	0.714
	Range	50-95	50-95	
Post-PCI percentage of stenosis by OCT	**Mean ± SD**	15.26 ± 7.90	22.80 ± 13.60	**0.029***
	Range	5-35	5-50	
Pre-PCI MLA (mm^2)	**Mean ± SD**	1.79 ± 0.45	1.57 ± 0.42	0.067
	Range	0.9-2.3	0.9-2.3	
Post-PCI MLA (mm^2)	**Mean ± SD**	5.95 ± 1.18	5.65 ± 1.12	0.294
	Range	4-7.5	4-7.5	

(OCT: optical coherence tomography, MLA: minimal luminal area, PCI: percutaneous coronary intervention)

As regard mortality in both groups showed no statistical significance when compared to group II. Also, there was insignificantly different between both groups regarding MACE and stent thrombosis. Table 5

Table 5: Adverse events in hospital and at 30 days in the studied groups.

		Group I (n=19)	**Group II (n=41)**	**P value**
Mortality	**In hospital**	0 (0%)	0 (0%)	---
	30 days	1 (5%)	0 (0%)	0.317
MACE	**In hospital**	1 (5%)	0 (0%)	0.317
	30 days	1 (5%)	1 (2%)	0.537
Stent thrombosis	**In hospital**	0 (0%)	0 (0%)	---
	30 days	1 (5%)	0 (0%)	0.317

(MACE= major adverse cardiovascular events)

Discussion:

OTC is a high-resolution, light-based intravascular imaging method that enables automatic detection parameters of the coronary lumen and stents across the whole investigated channel immediately after image acquisition. OCT automatically presents a flawless longitudinal lumen contour that is simpler to quantify andexplain due to the high frame rate during acquisition and the high-speed pullback.

Mohr et al, (17) defined complex lesions in clinical SYNTAX trial, Waldo SW et al, (18) and Landes U et al,(19) same definition was used in the present study by anatomical features of coronary tree.

Our result was different from what was found with Fernando De la Garza-Salazar et al, (20)in their study, which concluded that the use of OCT didn't increase fluoroscopy time.Although there are lots of studies comparing IVUS guided PCI with angiographic guidance in complex intervention, limited studies comparing the results of angiographic guidance only and OCT guidance. Past studies comparing IVUS-guided PCI to angiography-guided PCI have yielded contradictory outcomes; nevertheless, multiple meta-analyses have demonstrated that IVUS-guided PCI is linked with considerably decreaseoccurrence of unfavourable clinical events than angiographic guidance.

In iOPEN Complex study, which enrolled 6,855 patients treated for complex lesions, 67% of those patients with guided by intravascular imaging (IVUS or OCT), Evan Shlofmitz et al, (21) concluded that the usage of intravascular imaging was linked to decrease occurrence of MACE at 1-year follow up in complex lesions handledby PCI, also it was related to small increased procedural duration and contrast volume. That study recommended routine use of intravascular imaging in most of complex lesions, as its feasible and safe.Another case-level pooled assessmentrecommends that IVUS guidance is associated with superior results compared to PCI without IVUS guidance in lesions of the left major coronary artery.

Using OCT in distal left main stem angioplasty was studied also by Cortese B et al, (22)retrospectivelyassessed cases performed PCI for LMC in three European centres.Cases were classified into two groups: OCT-guidance (pre- and post PCI) and control group (standard angiographic guidance). The study concluded that Systematic OCT guidance during LM-PCI permitted prompt diagnosis and repair of acute stent underexpansion and

malposition.In addition, it was related with indicators of an improved angiographic outcome at the midterm than usual therapy.

The result of the current study showed superiority of OCT in detection of edge dissection and stent malapposition, as statedalso by Fujino Y. et al, (23) in their prospective study which compared OCT with angiography alone or with using IVUSin unprotected left main coronary intervention. That concluded that FD-OCT evaluation of unprotected left main is viable and safe. Direct comparison with IVUS revealed that OCT completed imaging less frequently, but it had greater sensitivity in detection of edge dissection and stent malapposition.

Similarly, Burzotta F. et al, (24) in their study of non-osteal LMC intervention, that was a retrospective study over 54 patients presented for LM PCI. The study concluded that FD-OCT assessment of non-osteal LM disease is feasible and provides high quality images. Also, it stated that OCT is more efficient for distal LM more than osteal lesions.

Another large prospective study which was conducted upon over than 6000 patients for treatment of complex coronary lesion by Choi et al, (5)they concluded that intra-vascular imaging guided PCI (using IVUS or OCT) with DES was related toa lower risk of long-term adverse events than angiography-guided DES implantation in cases with complex coronary artery lesions asmultivessel disease or multiple stent implantation, bifurcation, left main disease, long lesion, CTO, in-stent restenosis, and calcified lesion. These findings indicate that when doing PCI with DES for complicated coronary lesions, intravascular imaging should be utilised to identify lesion features and optimise stent placement.

As was stated by Wijns W. et al, (25) in IUMIEN I study, ILUMIEN I study enrolled 418 patient with presented with stable, unstable angina and NSTEMI presented for PCI. It was found that Pre-PCI and/or post-PCI OCT data influenced operator decision making and procedure strategy in the majority of cases.

Another study conducted by Norihiro Kobayashi et al, (26) comparing OCT and IVUS guidance in treatment of heavily calcific coronary lesions using rotational atherectomy. The study was a retrospective study for 247 patients, with conclusion that OCT-guided rotational atherectomy for heavily calcific coronary lesions leading to a higher percentage stent expansion than IVUS-guided rotational atherectomy. They also recommended OCT-guided atherectomy for therapy of heavily calcific coronary lesions.

In agreement with study done by Sunny Goel et al, (27) They found that there was no difference in procedural, periprocedural and 30 days follow up after using either orbital or rotational atherectomy, except for the reduced fluoroscopy duration associated with orbital atherectomy.

Conclusions:

The increased case/lesion complexity being treated by interventional cardiologists nowadays necessitates a considerably greater precision and safety threshold than in the past. OTCis a very helpful intravascular imaging for optimization of PCI for complex coronary lesion. It significantly changed the decision of the operator for the aim of optimal stent apposition and to reduce complications in complex lesions.

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