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Trends and outcomes of optical coherence tomography use: 877 patients single-center experience

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ABSTRACT

Background: Optical-coherence-tomography (OCT) is an emerging invasive coronary imaging with still undefined clinical value. Recent data have underlined daily impact of such technique in several clinical settings such as acute coronary syndromes (ACS) and percutaneous coronary intervention (PCI) guidance. We aimed at assessing the trends and outcomes of OCT use in a high-volume percutaneous coronary interventions (PCI)-center.

Methods: Over 6 years, 1025 coronary artery segments in 877 patients underwent OCT evaluation. Clinical and procedural characteristics were prospectively collected. Clinical setting for OCT was: "*Diagnostic OCT*" (OCT for lesion evaluation after coronary angiography without further PCI); "*PCI-guidance OCT*" (OCT as a guidance for complex PCI, both by intention or after diagnostic OCT). Primary study end-point was the occurrence of target-vessel-failure (TVF) during the follow-up.

Results: Overall, OCT was successful in 99.1% of attempted lesions. Only one complication (coronary dissection requiring urgent PCI) occurred during OCT. After a follow-up of 695 ± 562 days, TVF occurred in 8.2% of cases. Despite similar baseline characteristics, TVF-free survival curves were different in the two populations (5.4% after diagnostic OCT and 9.9% after PCI-guidance OCT). Minimal-lumen-area (MLA) of target lesion was independently associated with TVF (HR 0.7, 95% CI 0.6–0.8). This was mainly driven by a significant impact of MLA in patients not revascularized (HR 0.6, 95% CI 0.4–0.9). TVF did not change according to the study period despite the selection of patients with increasing complexity.

Conclusions: OCT has a good safety profile across a broad spectrum of patients encountered in daily practice. The easy-to-assess MLA parameter may help stratify prognosis of patients undergoing OCT. These data call for further evaluations of OCT clinical impact.

Summary: OCT is a light-based imaging tool which had subvert the quite ordinary world of coronary imaging and the present study evaluates OCT use in a high-volume center. Our results suggest that application of OCT in "real world" patients presenting higher risk has a good safety profile.

Several factors could predict a worse long-term outcome in patients undergoing OCT evaluation, mostly related to more complex clinical conditions. These findings could encourage even low-to intermediate volume centers to improve their OCT use in daily practice.

1. Introduction

Optical coherence tomography (OCT) is an emerging intracoronary imaging technique, which allows high resolution assessment of the various components of atherosclerotic plaques [1,2]. OCT studies carried out in the setting of acute coronary syndrome (ACS) have shed new light on the outcome, showing that the outcome of fissured plaques is worse than that of not fissured plaques [3]. Furthermore, recent observations suggest that OCT-derived coronary lumen dimensions correlate with the functional status of coronary artery lesions. Accordingly, increasing data indicate for OCT a role to guide stent deployment optimization [4–7]. Therefore, beyond its established role for research purposes, OCT looks as an emerging tool to be introduced in "real world" practice when simple angiography is not perceived to provide sufficient information.

In the present study, we sought to assess the trends and outcomes associated with OCT use in a real-world experience.

Abbreviations: OCT, optical coherence tomography; ACS, acute coronary syndrome; PCI, percutaneous coronary interventions; LVEF, left ventricle ejection fraction; CKD, chronic kidney disease; MLA, minimal lumen area; AKI, acute kidney injury; AMI, acute myocardial infarction; TVR, target vessel revascularization; TVF, target vessel failure; HR, hazard ratio; LM, left main artery; IVUS, intravascular ultrasound; STEMI, ST-elevation myocardial infarction.

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2. Methods

2.1. Study population

The study was conducted in a single tertiary center with high interventional volume (1000–1100 percutaneous coronary intervention (PCI) per year) and high OCT use (about 150–200 cases per year). Patient's clinical, angiographic and procedural data were prospectively recorded on a dedicated catheterization laboratory database that has been previously proven to help assessing the role of Euroscore I and II in percutaneous coronary interventions [8,9] and the safety of transradial approach [10]. All patients who underwent OCT assessment between January 2010 and December 2015 were identified from the OCT database of our Institution (approved by the local ethics committee). No exclusion criterion was applied. Left ventricular function was assessed by two-dimensional echocardiography before the procedure and a left ventricular ejection fraction (LVEF) of 50% or more was considered normal. Chronic kidney disease (CKD) was defined as any abnormalities of kidney structure or function, present for >3 months, with GFR <60 ml/min per 1.73 m^2.

Of note CKD was not considered an exclusion criterion for OCT use. Yet, as a general approach at our centre, OCT is not used in patients with advanced CKD or with decompensated heart failure. Indeed, in severe heart failure patients, the risk of haemodynamic instability due to a longer procedure and higher volume of contrast injection should be avoided. Moreover, all patients with reduced renal function were administered by intravenous fluid supplementation before and after intervention. All patients gave written informed consent to the invasive procedure. The study conformed to the Declaration of Helsinki on human research.

2.2. Optical coherence tomography acquisition technique and analysis

OCT images were acquired with a commercially available system (C7 System and C7 Dragonfly; LightLab Imaging Inc./St. Jude Medical, Westford, MA, USA). Intracoronary isosorbide di-nitrate was administered before OCT probe advancement. During image acquisition, coronary blood flow was replaced by continuous flushing of isoosmolar contrast medium (Iomeprol, Iomeron, Bracco Spa, Milan, Italy) at a rate of 4 ml/s with a power injector (Medrad Avanta, Siemens, Germany) in order to create a virtually blood-free environment. An enhanced contrast flushing protocol was adopted for left main (6 ml/s) [11]. An integrated automated pullback device at 20 mm/s was used and OCT images were digitally stored.

Analyses were performed by intention to use OCT. Accordingly, cases in which the OCT probe entered patient's body but OCT imaging was unsuccessful were categorized as "*OCT failures*". A first "real-time" image analysis was performed when decision whether to perform or not PCI was dependent to OCT evaluation or when OCT was performed as PCI guidance. We systematically obtained during our practice only pre-PCI minimal lumen area (MLA), defined as the cross section with smallest lumen area (mm^2) within the scanned segment before stent implantation [2].

2.3. OCT clinical setting

On the bases of the clinical setting prompting for OCT use, we divided OCT procedures into two main categories:

1. "*Diagnostic OCT*". OCT evaluation selected by the operator in order to better understand the anatomy of coronary segments that were unclear after coronary angiography. In this group, we included only lesions that, on the bases of the combination of OCT results and clinical evaluation, were not revascularized with a conservative management.
2. "*PCI-guidance OCT*". This group comprised all cases in which OCT images were acquired before, during or after PCI to help planning and/or optimizing PCI conduction. When OCT assessment was performed after stent implantation, the following actions were then considered based on operator's experience: 1) no intervention (result accepted); 2) post-dilation; 3) additional stent implantation; 4) side-branch intervention; 5) thrombus-aspiration. In our institution, the decision for post-PCI optimization was made according to single operator online OCT evaluation, as no standard of practice to guide the decision to optimize was previously stated.

2.4. Clinical course after OCT and follow up

In-hospital clinical course was carefully assessed by reviewing clinical records. Acute kidney injury (AKI) was defined according to recent guidelines [12].

All patients were discharged on medical treatment and antiplatelet therapy was recommended according to current guidelines.

After discharge, clinical follow-up was obtained by outpatient visit or telephone interview. A follow-up coronary angiography was performed according to the study protocol in the subgroup of patients receiving OCT due to multicentre research protocols or when clinically indicated.

Clinical events up to the longest available follow-up were considered. Cardiac death was defined as any death without clear non-cardiac cause. Acute myocardial infarction (AMI) was defined as a rise and fall of serum hs-TnT in the presence of ECG signs or symptoms compatible with myocardial ischemia. In the absence of angiographic documentation of a different culprit lesion, any AMI was considered to be related with the vessel investigated by OCT. Target vessel revascularization (TVR) was considered as any surgical or percutaneous revascularization needed during the follow-up on the vessel investigated by OCT.

2.5. Study end-points

In order to emphasize the specificity of the analysis and in keeping with large recent trials [13] we selected a device-oriented primary endpoint of the study. Thus, the primary composite endpoint was target vessel failure (TVF) defined as cardiac death and/or AMI not clearly related to other than investigated vessel and TVR (either percutaneous or surgical).

The individual components of primary end-points constituted the secondary study end-points.

2.6. Statistical analysis

Data were analysed using IBM SPSS Statistics version 22.0 software (IBM, Armonk, NY, USA). Continuous variables were presented as mean ± SD, whereas categorical variables were described with absolute and relative (%) frequencies. Independent samples *t*-test was used to compare continuous variables and Fisher's exact test to compare categorical variables between different groups based on clinical indication to OCT. All tests were two-sided and a p value of <0.05 was considered statistically significant. One-way ANalysis Of VAriance (ANOVA) with post-hoc multiple comparison (Tukey) was used to compare continuous and categorical variables between more than two groups. To assess the possible impact of OCT experience in its use and clinical outcomes, the study population was divided in three two-years periods (2010–2011, 2012–2013, 2014–2015).

Kaplan-Meier estimates of survival free from TVF and secondary endpoints were constructed and compared between different categories of patients using the Mantel-Cox (log-rank) test. Cox regression analysis was performed to assess the predictors of TVF and other secondary endpoint (TVR, vessel related myocardial infarction and cardiovascular death) during follow-up period. Hazard ratios (HR) with corresponding 95% confidence intervals (95% CI) were also calculated. Variables associated with endpoint at the $p < 0.10$ level on univariate analysis were included in multivariate Cox regression analysis. A p value < 0.05 was considered statistically significant.

3. Results

3.1. Characteristics of the study population

During the study period, a total of 1025 "target lesions" in 877 patients with both stable or unstable coronary artery disease underwent OCT evaluation.

Patients' characteristics are reported in Table 1. Briefly, mean age was 66.4 years, 24.8% had diabetes, and 6.2% had CKD. Regarding the clinical presentation, more than half of the patients had ACS and, among these, 57.0% were diagnosed with non-ST-elevation acute coronary syndromes, while the other patients had ST elevation myocardial infarction both presenting within first 24 h or after the first day. The "target lesion" comprised a wide range of de novo lesions or previously stented coronary segments and were located in all coronary tree (Table 1). Left main (LM) OCT evaluation was performed in 135 patients (15.4% of overall population) and main characteristics of such population are summarized in Table 2.

In 10 cases only, OCT entered patient's body, but was not performed (OCT failure rate: 0.9%). In particular, in 5 cases OCT probe did not cross the lesions due to calcification or lesion severity, in 4 cases there was an insufficient vessel visualization due to inadequate flushing of contrast media and in 1 case OCT was not performed due to hypotension and angor after probe advancement. In no one of these 10 cases OCT was performed at the end of the procedure. Moreover, only one OCT-induced complication was noticed: in one patient, the attempt to cross a lesion with OCT caused coronary dissection which prompted for urgent PCI which was successfully performed.

OCT settings are summarized in Table 1. A total of 56 lesions (5.5%) only were initially performed according to locally approved protocols (OCTAVIA, IMPACT-CORO) while all other OCT examinations were performed for clinical reasons both for diagnostic assessment or OCT guidance to PCI (Table 3). More specifically, 645 lesions (62.9%) underwent a OCT diagnostic evaluation, and in 324 lesions (31.6%) OCT was

Table 1
Baseline and clinical characteristics.

Characteristics	N (%)
Number of patients investigated by OCT	877
Age (years)	66.4 ± 11.0
Male gender	670 (77.4%)
Risk factors	
- Non-insulin dependent diabetes	169 (19.3%)
- Insulin dependent diabetes	48 (5.5%)
- Hypertension	688 (78.4%)
- Hypercholesterolemia	542 (61.8%)
- Smoke	185 (21.1%)
CKD	54 (6.2%)
Clinical setting	
- STEMI	191 (21.8%)
- NSTEACS	257 (29.3%)
Previous PCI	377 (43%)
Previous CABG	56 (5.5%)
Multi-vessel disease	513 (58.5%)
Reduced LVEF (<50%)	189 (21.6%)
Number of vessel segments investigated by OCT	1025
OCT lesion setting	
- Diagnostic OCT	389 (38.0%)
- OCT guidance for PCI	636 (62.0%)
Target vessel	
- LM	135 (13.2%)
- LAD	534 (52.1%)
- LCx	194 (18.9%)
- RCA	159 (15.5%)
- Graft	13 (1.3%)
Target lesion type	
- de novo	834 (81.4%)
- in-stent restenosis	191 (18.6%)
MLA (mm^2)	3.3 ± 2.0
OCT failure (%)	10 (0.9%)

CKD: chronic kidney disease; STEMI: ST-elevation myocardial infarction; NSTEACS: non ST-elevation myocardial infarction; PCI: percutaneous coronary intervention; CABG: coronary artery by-pass graft; LVEF: left ventricle ejection fraction; OCT: optical coherence tomography; PCI: percutaneous coronary intervention; LM: left main; LAD: left anterior descending artery; LCx: left circumflex artery; RCA: right coronary artery; MLA: minimal lumen area.

Table 2
Diagnostic OCT vs PCI-guidance OCT.

Characteristics	Diagnostic OCT	PCI-guidance OCT	p
Number of patients investigated by OCT	325	552	
Age (years)	66.1 ± 11.9	66.7 ± 10.4	0.469
Male gender	246 (75.7%)	424 (76.8%)	0.651
Risk factors			
- Diabetes	75 (23.1%)	137 (24.8%)	0.613
- Hypertension	248 (76.3%)	440 (79.7%)	0.366
- Hypercholesterolemia	187 (57.5%)	355 (64.3%)	0.072
- Smoke	65 (20.0%)	120 (21.7%)	0.588
- CKD	16 (4.9%)	29 (5.3%)	0.854
Clinical setting			
- ACS	142 (43.7%)	306 (55.4%)	0.001
- Acute STEMI	6 (1.8%)	36 (6.5%)	<0.001
- NSTEACS	81 (24.9%)	176 (31.9%)	0.032
- Recent STEMI	56 (17.2%)	102 (18.5%)	0.688
- Previous MI	44 (13.5%)	75 (13.6%)	0.971
- Previous PCI	146 (44.9%)	231 (41.8%)	0.313
- Previous CABG	16 (4.9%)	30 (5.4%)	0.765
- Multi-vessel disease	165 (50.8%)	348 (63.0%)	<0.001
- Reduced LVEF (<50%)	70 (21.5%)	121 (21.9%)	0.587
Number of vessel segments investigated by OCT	389	636	
Target vessel			
- LM	55 (14.1%)	70 (11.0%)	0.012
- LAD	166 (42.7%)	338 (53.1%)	0.398
- LCx	52 (13.4%)	137 (21.5%)	0.005
- RCA	56 (14.4%)	98 (15.4%)	0.907
- Graft	10 (2.6%)	1 (0.2%)	0.001
MLA (mm^2)	4.2 ± 2.0	2.6 ± 1.8	<0.001

CKD: chronic kidney disease; ACS: acute coronary syndrome; STEMI: ST-elevation myocardial infarction; NSTEACS: non ST-elevation myocardial infarction; MI: myocardial infarction; PCI: percutaneous coronary intervention; CABG: coronary artery by-pass graft; LVEF: left ventricle ejection fraction; LM: left main; LAD: left anterior descending artery; RCA: right coronary artery; MLA: minimal lumen area.

Table 3
LM OCT evaluation: baseline and clinical characteristics.

Characteristics	N (%)
Number of patients	135
Age (years)	67.1 ± 11.9
Male gender	106 (78.5%)
Risk factors	
- Non-insulin dependent diabetes	35 (25.9%)
- Insulin dependent diabetes	7 (5.2%)
- Hypertension	105 (77.8%)
- Hypercholesterolemia	79 (58.5%)
- Smoke	17 (12.6%)
CKD	11 (8.1%)
Clinical setting	
- STEMI	3 (2.2%)
- NSTEACS	63 (46.7%)
Previous PCI	56 (41.5%)
Previous CABG	7 (5.2%)
Multi-vessel disease	91 (67.4%)
Reduced LVEF (<50%)	33 (24.4%)
MLA (mm^2)	4.6 ± 2.8
OCT failure (%)	2 (1.5%)

CKD: chronic kidney disease; STEMI: ST-elevation myocardial infarction; NSTEACS: non ST-elevation myocardial infarction; PCI: percutaneous coronary intervention; CABG: coronary artery by-pass graft; LVEF: left ventricle ejection fraction; OCT: optical coherence tomography; PCI: percutaneous coronary intervention; LM: left main; MLA: minimal lumen area.

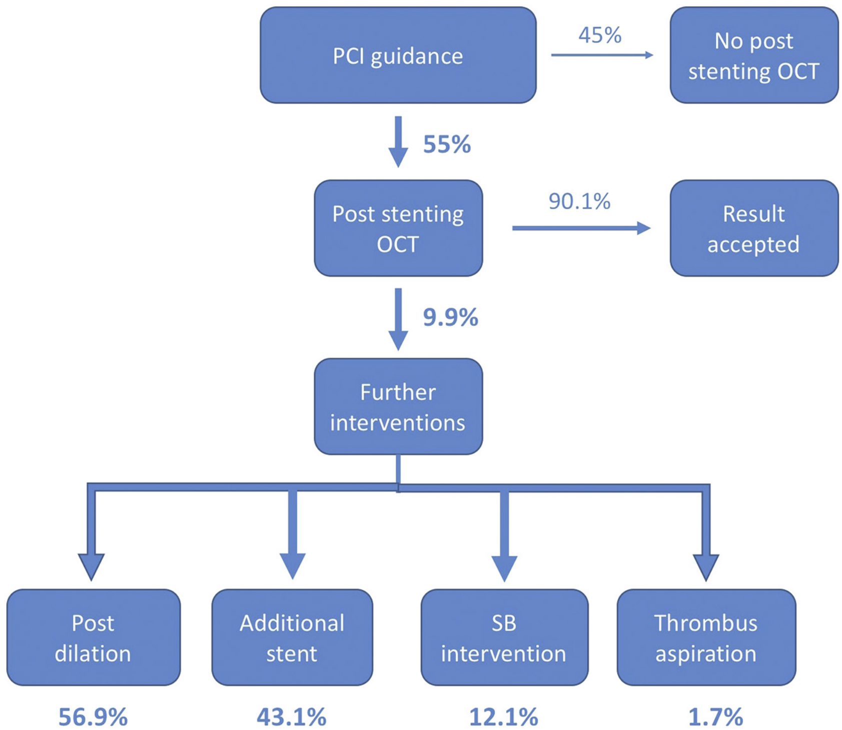

Fig. 1. PCI guidance OCT – Further interventions incidence on the basis of OCT post-PCI findings.

performed by intention as a guidance for PCI. Among lesions with diagnostic OCT, 45.9% were judged to require myocardial revascularization (282 patients underwent PCI and 14 patients went to surgery), while 54.1% were managed conservatively.

Therefore, a total of 636 lesions (62.0%), both directly or after diagnostic assessment, underwent OCT guidance for PCI. Among these, post-PCI OCT evaluation was performed in 333 lesions (55% of cases) and, out of these, PCI optimization was performed in 60 cases (9.9% of total pre-PCI OCT). PCI optimization was performed due to major complications and also due to stent malapposition and/or geographical miss (see Fig. 1 for details).

3.2. Clinical outcomes

All patients were discharged alive. Among the 51 patients with CKD, only 4 patients (0.4% of overall population) had laboratory documentation of AKI and none of them had to undergo new dialytic therapy. During the study, after a mean follow-up of 695 ± 562 days, TVF occurred in 84 (8.2%) of OCT cases (7 cases of cardiovascular death, 77 cases of TVR and/or AMI not clearly related to other than investigated vessel). Of note, TVF occurred in 38 patients (4.3%) within year. Diagnostic OCT and PCI-guidance OCT patients showed significant difference in baseline and clinical characteristics (Table 3), resulting in divergent Kaplan-Meyer TVF-free survival curves (Fig. 2). Interestingly, in overall population, clinical setting (stable coronary disease or acute coronary syndrome) did not affect long term survival (Fig. 3).

In PCI-guidance to OCT group, post-PCI optimization did not result into a different outcome when related to patient in which such optimization was not needed. (Fig. 4).

Table 4 shows the results of multivariate Cox regression analysis for TVF in the overall study population, in the subgroup of patients conservatively managed and in OCT-guided PCI. Together with other clinical

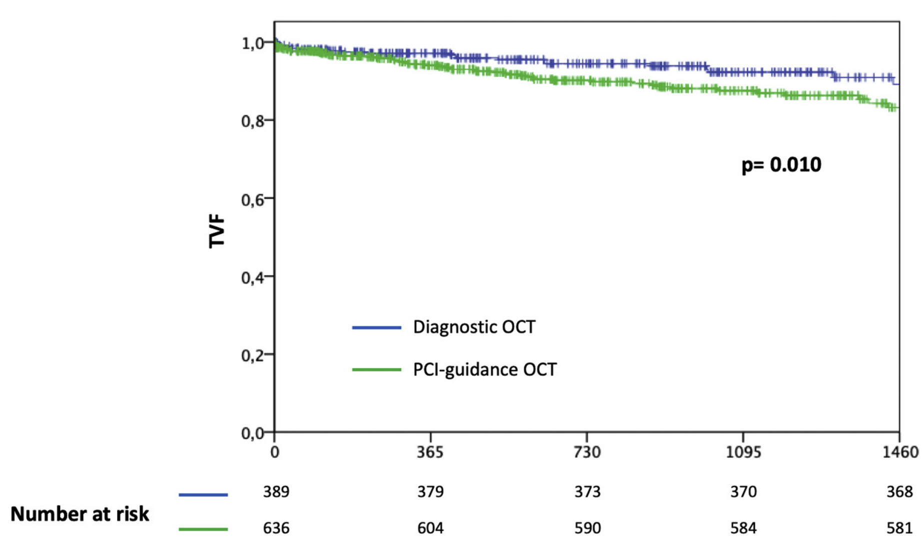

Fig. 2. Survival among clinical groups - Kaplan-Meyer TVF-free survival curve between diagnostic OCT and OCT-guidance to PCI.

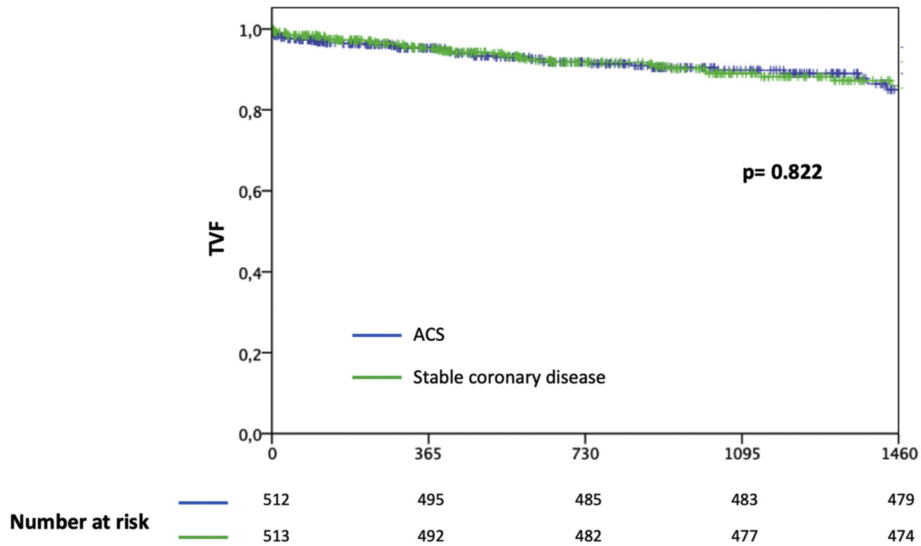

Fig. 3. Survival in different clinical settings - Kaplan-Meyer TVF-free survival curve in ACS and stable coronary disease.

characteristics, MLA was an independent predictor of TVF in the whole study population (HR 0.7, $p < 0.001$) and in both subgroups (HR 0.5, $p = 0.03$ in diagnostic OCT; HR 0.8, $p = 0.04$ in PCI-guidance OCT).

3.3. Temporal trends in OCT use and OCT-associated outcomes

From January 2010 to December 2015 a total of 15,570 coronary angiographies, 5853 PCI, 248 intravascular ultrasound (IVUS), and 1025 OCT were performed at our centre.

Fig. 5 presents trends in OCT and IVUS use in the context of diagnostic and interventional activity. Both diagnostic OCT (panel A) and PCI-guidance OCT (panel B) were stable over time while IVUS examination tended to decrease over time.

Table 5 shows the comparison of baseline, clinical and angiographic characteristics among the three time periods. The use of OCT in the setting of acute ST-elevation myocardial infarction (STEMI) and on lesions previously treated by stent or located in graft decreased over time while its use in LM lesions and patients with reduced LVEF increased. 2-years survival curves free from TVF showed that clinical outcomes were not influenced by study period ($p = 0.574$) (Fig. 6).

4. Discussion

OCT represents an emerging tool for invasive assessment of patients with coronary artery disease. The results of the present, large, single centre experience in which more than one thousand coronary vessels have been investigated show that:

- OCT has similar early and long-term safety in patients with a broad spectrum of clinical and angiographic features.
- MLA, an easy to assess parameter obtained by OCT, is independently associated with clinical outcome (in particular in non-revascularized patients)

Such data provide new clinical evidence supporting the clinical utilization of OCT.

Coronary angiography represents the gold standard for the diagnosis of coronary artery disease but has recognized resolution limitations. Several intracoronary imaging techniques have been developed and, among these, IVUS has gained in the last decades an established clinical

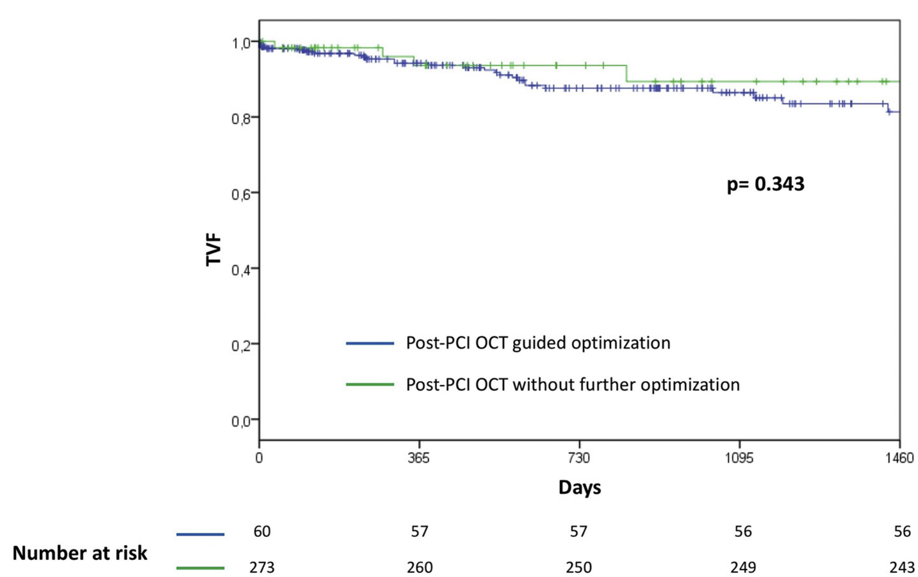

Fig. 4. Survival after post-PCI OCT evaluation - Kaplan-Meyer TVF-free survival curve in patient undergoing an OCT guided post-PCI optimization and patients without further optimization.

Table 4
Predictors of TVF at multivariate analysis.

Whole study population	HR (95%CI)	p
Diabetes	1.6 (1.0–2.6)	0.035
Multivessel disease	2.5 (1.5–4.4)	0.001
LM	1.9 (1.0–3.5)	0.049
in-stent restenosis	2.5 (1.6–4.0)	<0.001
MLA	0.7 (0.6–0.8)	<0.001
Diagnostic OCT	**HR (95%CI)**	**p**
Smoke	3.9 (1.2–12.3)	0.020
LM	5.1 (1.3–19.9)	0.019
MLA	0.5 (0.3–0.8)	0.032
PCI-guidance to OCT	**HR (95%CI)**	**p**
Hypercholesterolemia	2.0 (1.1–4.0)	0.034
MLA	0.8 (0.6–0.9)	0.04

LM: left main; MLA: minimal lumen area; OCT: optical coherence tomography.

role worldwide. More recently, OCT, a higher resolution imaging modality, has become available. OCT was initially utilized for research purposes [2], while the clinical utilization of OCT has been considered controversial for long time. In last few years, several studies have shed new light on OCT clinical impact focusing the attention on its role in post PCI optimization [4–7], thus leading to an upgrade to class IIa in OCT indication for stent optimization in latest 2018 ESC Guidelines for myocardial revascularization [14]. When looking at OCT safety profile, Van der Sijde JN et al. compared for the first time the procedural safety of OCT and IVUS in their experience showing comparable findings [15].

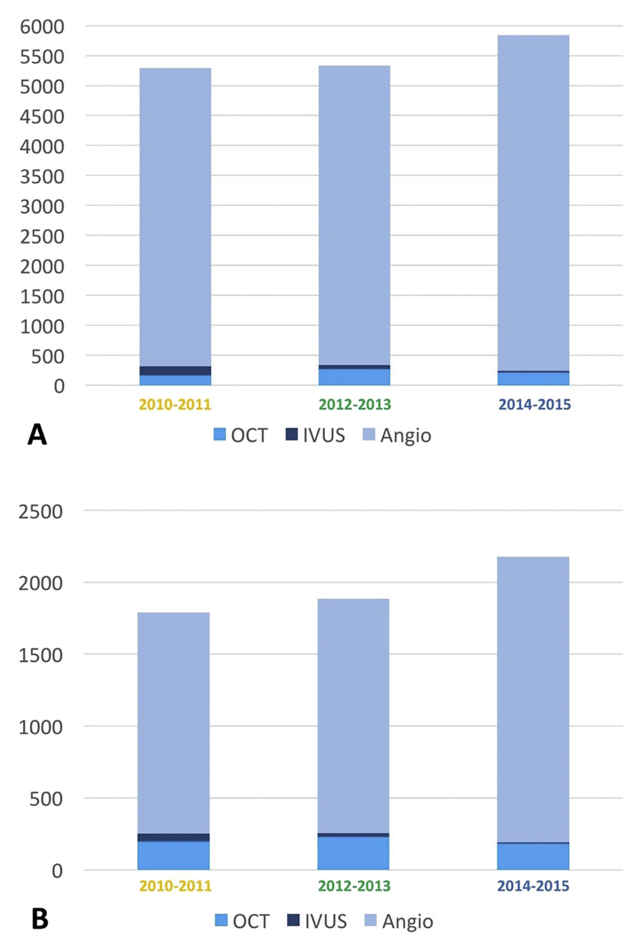

Fig. 5. Temporal trends - OCT and IVUS temporal trends in the setting of diagnostic coronary activity (panel A) and interventional activity (panel B).

Table 5
Temporal trends in OCT use.

Characteristics	2010–2011	2012–2013	2014–2015	p
Age (years)	66.3 ± 10.8	66.3 ± 11.3	66.9 ± 11.3	0.685
Male gender	242 (76.6%)	314 (77.5%)	239 (78.6%)	0.832
Risk factors				
- Diabetes	61 (23.1%)	91 (22.5%)	79 (26.0%)	0.528
- Hypertension	244 (77.2%)	333 (82.2%)	226 (74.3%)	0.039
- Hypercholesterolemia	204 (64.9%)	258 (63.7%)	180 (59.2%)	0.311
- Smoke	62 (19.6%)	85 (21.0%)	62 (20.4%)	0.903
- CKD	22 (7.0%)	30 (7.4%)	9 (3.0%)	0.031
Clinical setting				
- ACS	165 (52.2%)	207 (51.1%)	140 (46.1%)	0.258
- Acute STEMI	21 (6.6%)	13 (3.2%)	9 (3.0%)	0.032
- NSTEACS	84 (26.6%)	123 (30.4%)	90 (29.6%)	0.517
- Recent STEMI	60 (19.0%)	71 (17.5%)	41 (13.5%)	0.145
- Previous MI	43 (13.6%)	62 (15.3%)	36 (11.8%)	0.087
- Previous PCI	131 (41.5%)	206 (50.9%)	119 (39.1%)	0.003
- Previous CABG	31 (9.8%)	16 (4.0%)	9 (3.0%)	<0.001
- Multi-vessel disease	206 (65.2%)	231 (57.0%)	189 (62.2%)	0.203
- Reduced LVEF (<50%)	56 (17.7%)	91 (22.5%)	74 (24.3%)	0.033
Target vessel				
- LM	25 (7.9%)	61 (15.1%)	49 (16.1%)	0.004
- LAD	162 (51.3%)	215 (53.1%)	157 (51.6%)	0.879
- LCx	72 (22.8%)	62 (15.3%)	60 (19.7%)	0.036
- RCA	48 (15.2%)	71 (17.5%)	40 (13.2%)	0.277
- Graft	13 (4.1%)	0 (0.0%)	0 (0.0%)	<0.001
Target lesion				
- previously implanted stent	67 (21.2%)	90 (22.2%)	34 (11.2%)	<0.001
MLA (mm^2)	3.44 ± 2.42	3.23 ± 1.76	3.06 ± 1.88	0.071

CKD: chronic kidney disease; ACS: acute coronary syndrome; STEMI: ST-elevation myocardial infarction; NSTEACS: non ST-elevation myocardial infarction; MI: myocardial infarction; PCI: percutaneous coronary intervention; CABG: coronary artery by-pass graft; OCT: optical coherence tomography; LVEF: left ventricle ejection fraction; LM: left main; LAD: left anterior descending artery; LCx: left circumflex artery; RCA: right coronary artery; MLA: minimal lumen area.

Yet, different clinical settings (including patient selection, research protocols, usage during diagnostic or interventional procedures) could possibly impact long term outcome among patients undergoing OCT evaluation. Thus, to the best of our knowledge, this is the first study investigating the impact of clinical, angiographic and procedural characteristics on the outcome of large series of OCT performed in single high-volume tertiary centre. The collected data show that OCT has progressively become the main invasive imaging modality in our daily practice and is currently utilized in a wide spectrum of clinical settings. In the context of a high-volume experience, OCT technical failures were rare and significant complications like the need for OCT-related urgent PCI or AKI were negligible. Moving from procedural feasibility to clinical impact, in the present study we sought to evaluate the impact of OCT setting on clinical outcome. TVF, a recently validated device-oriented composite end-point [13], was selected as the primary end-point since OCT represents an invasive technique which may influence the management of investigated coronary segments (treating or not, when treating, PCI conduction). After diagnostic OCT, the decision whether to perform PCI or not was based on single operator decision. Recently, a small observational study carried out by our group have demonstrated that the integrated assessment of AS (≥ or <70%), MLA (≥ or <2.5 mm^2) and/or the presence of rupture plaque or thrombus shows high correlation with fractional flow reserve values [16]. However, the clinical impact of this composite OCT assessment on myocardial revascularization is still under investigation in a randomized trial [17].

As a first finding, we noticed that baseline characteristics of patients undergoing OCT pre-PCI evaluation not followed by myocardial revascularization differs from those who patients in which OCT is used as guidance to PCI. These findings are particularly driven by a different clinical complexity of the latter, mainly related to higher incidence of ACS and MV disease. Within the limitation of a single centre experience, this information improved the perception that OCT guidance to PCI could be very useful in complex clinical setting. Moreover, diagnostic

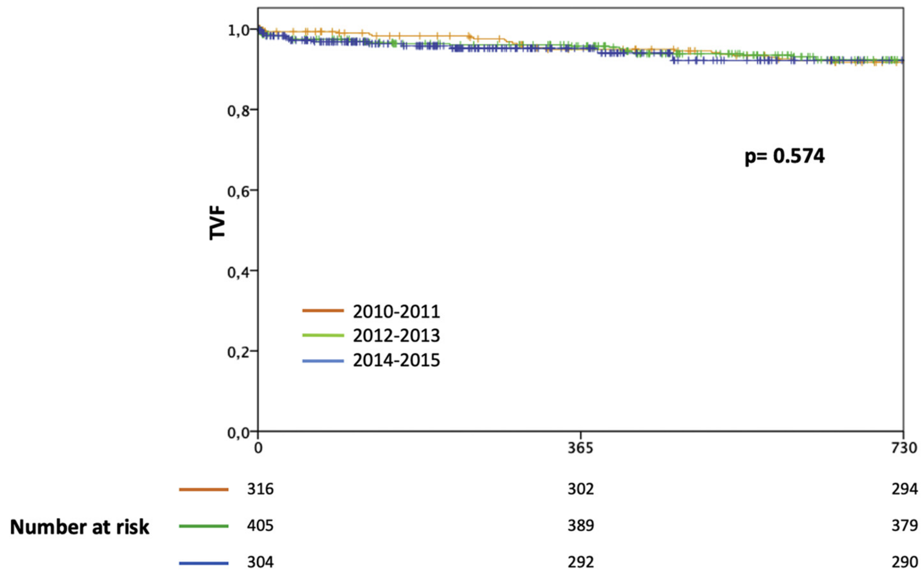

Fig. 6. Survival across time - Kaplan-Meyer 2-years TVF-free survival curves across different time periods.

OCT assessment not followed by myocardial revascularization is associated with better prognosis when compared with OCT-guidance to PCI group. However, these finding may be affected by early and late post-PCI complication in latter group.

Interestingly, we found that, together with well-established risk factors for adverse outcome in coronary artery disease (multivessel disease, LM disease, diabetes), OCT-derived lumen dimension is a predictor of TVF. Indeed, we found that a higher pre-PCI MLA value is associated with reduced TVF in the whole study population and, as expected, this is mainly driven by its impact in patients managed conservatively. Such findings fit with those in IVUS-based studies [18] and reinforce the perception that OCT-derived quantitative measures might have a clinical impact. In such context, efficacy and safety of OCT to guide revascularization decision has been recently investigated in a multicenter clinical trial [7] which showed comparable results between OCT guidance and IVUS guidance with a similar safety profile. However, in this field, a large scale randomized trial is ongoing (ILUMIEN IV [NCT03507777]) and still awaited to finally clarify if OCT guidance results in superior clinical outcomes in patients undergoing PCI.

When performing PCI, OCT high resolution permits detection of features such as malapposition, intrastent plaque/thrombus protrusion or edge dissections [7]. Such findings may be dependent on treated lesion characteristics since we previously observed that in complex lesions like bifurcations, virtually no lesion may be find free from such OCT-detected stent “complications” [19]. The clinical impact of such imperfections detected by OCT is still undefined but the risk of overtreatment is considerable. A prudent interventional attitude aimed at correcting just major OCT-detected stent imperfections seems to have been applied by the operators involved in the study (<10% of OCT-triggered interventions), probably related to lower known data about stent optimization, especially during the first years of OCT utilization in our cathlab. Indeed, only more recently, results from Ilumien I [4] and III [6] and CLIO-PCI [5] studies have emphasized clinical and prognostic importance of routine post-PCI OCT guided optimization. However, it should be underlined that our approach is supported by a recent large multicentre study by Prati et al. [6] suggesting that only major post-stenting suboptimal stent deployment OCT features are associated with an increased risk of adverse events.

Another important opportunity offered by our study design was the possibility to assess the temporal trends in OCT use and outcomes. At our centre, OCT was the main imaging modality while IVUS volume was progressively reduced (finally being considered mainly for aorto-ostial lesions where blood removal with contrast flush is difficult). Yet, experience led to appreciable changes in case selection. In particular, acute STEMI patients were assessed significantly less (probably due to high chances of vessel anatomy masking by intracoronary thrombus). On the contrary, OCT use was expanded to LM lesions (after development of better knowledge of specific procedural settings to optimize image acquisition [11]) in patients without previous revascularization and in patients with lower ejection fraction. Once more, the similar clinical outcomes observed despite changes in patients' selections across years seems to support the safety of OCT application in different settings.

In conclusion, within the limitation of an observational study conducted in single-centre environment, the reported data provides new insights regarding the clinical practice with OCT and support its safety and potential utility across a broad spectrum of patients encountered in the daily practice.

Study limitations

This study is an observational retrospective analysis of a single center experience, so the interpretation of the results should take into account the limitation of a registry.

Clinical follow-up data were missing in 50 patients (4.9%) and there is a wide variation in follow-up time (280 patients have <1 year follow up).

Risk factors for stent thrombosis and disease progression like compliance for medical therapy administered (including dual antiplatelet therapy and statins) have not be assessed.

We included in our database every FD-OCT performed between January 2010 and December 2015, so we feel that the reported results represent our real clinical practice. However, the high level of experience in this single-center study does not mean that reported results can be translated to less experienced centers.

Conflicts of interest disclosure

Dr Dato discloses to have received in the past a research grant from St. Jude. Dr Burzotta, Trani, Niccoli, Leone, Aurigemma and Porto disclose to have received speaker's fees from St. Jude.

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