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Optical coherence tomography compared with fractional flow reserve guided approach in acute coronary syndromes: A propensity matched analysis

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ABSTRACT

Aim: To compare in patients with ACS (acute coronary syndromes) a PCI (percutaneous coronary intervention) approach based on FFR (fractional flow reserve) vs. one based on OCT (optical coherence tomography).
Methods and results: Consecutive patients admitted for ACS and treated with a PCI approach based on OCT or on FFR (recruited in two different studies) were compared and matched with propensity score analysis. Target Lesion revascularization (TLR) was the primary end point, while major adverse cardiovascular events [MACEs defined as the composite of death from cardiac causes, non-fatal MI, clinically driven target vessel revascularization (TVR), or re-hospitalization due to unstable angina] were the secondary ones. Sub-group analysis was performed for patients with FFR/OCT performed on culprit lesions and not. 285 patients were enrolled in the OCT-guided group and 335 in the FFR-guided group, 197 for each being selected after propensity score. After 25 months (range: 7–39 months), OCT-guided group were exposed to lower incidence of TLR (4.1% vs. 14.2% $p < 0.01$) compared with FFR-guided group without impact on MACEs (14.2% vs. 14.2%, $p = 1$) or all-cause death (3.6% vs. 1.1%, $p = 0.34$). At Kaplan-Maier curve analysis for MACEs OCT-guided and FFR-guided groups showed similar outcomes (HR 1.19, CI 0.65–2.2, $p = 0.54$). Subgroup analysis on culprit and not culprit vessel demonstrated consistent results.
Conclusions: An OCT based approach in ACS patients offers a reduction in TLR when compared to a PCI-FFR driven. These findings should be confirmed in randomized controlled trial.
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1. Introduction

Acute coronary syndromes (ACS) are burdened by a high risk of subsequent adverse cardiovascular events, both due to clinical presentation both to high risk coronary features, despite advance in pharmacological and interventional techniques [1–3].

One of the most fascinating aspects is represented by an accurate as possible evaluation of coronary lesions, in order both to prevent risk of abrupt coronary occlusion due to unstable plaque or the risk of unnecessary stents for low risk coronary lesions.

Two different technologies, FFR (fractional flow reserve) and OCT (optical coherence tomography) have been recently proposed to increase a tailored approach for ACS lesions.

FFR which has the aim to evaluate the ischemic weight of each lesion has been tested in large multicentre randomized controlled trials, offering a reduction of myocardial infarction despite lower use of stents [4]. In ACS setting, the only randomized controlled trial for Non ST Segment Elevation Myocardial Infarction (NSTEMI) have consistently shown a reduction for unnecessary stenting (which was the primary end point, [5]) in the FFR group vs. the angiographic one, despite a not significant trend for increase in risk of recurrent myocardial infarction. Recently FFR in ACS setting have been discussed, due to a potential risk for relevant rates of false negative, due to diffuse vasoconstriction.

From the other side, OCT offers an accurate assessment of coronary lesions [6], evaluating both severity of stenosis with a good correlation with FFR values [7] and kind of plaques. In the only RCT on this topic [8], with a surrogate end point (FFR value), OCT did not show superiority when compared to angiographic group, despite the paper was underpowered to detect clinical difference.

Consequently due to the lack of clinical comparison between FFR and OCT guided PCI procedure we aimed to perform a comparison with propensity score between patients evaluated with one of these two techniques, appraising clinical adverse events as end point.

2. Methods

The present database was derived from two studies, enrolling patients treated for ACS evaluated on culprit or non-culprit lesion with:

- OCT: the OCT-FORMIDABLE register included in a retrospective fashion all consecutive patients in which OCT on culprit and not culprit plaques has been performed in any subset in patients with ACS between January 2014 and October 2015 in 9 centres (see Web Appendix).
- FFR: a multicentre prospective registry evaluating consecutive patients evaluated with FFR on culprit and non-culprit lesion from January 2009 to December 2012 (see Web Appendix).

2.1. Definition of clinical data

For the index admission, diagnosis according to ESC guidelines (STEMI, ST Segment Elevation Myocardial Infarction, NSTEMI Non St Segment and UA Unstable angina) [9].

Diabetes mellitus was defined according to the ADA criteria [10] [fasting blood glucose >126 mg/dL or treated diabetes mellitus (intake of a diabetic diet or oral hypoglycaemic agents)], hypercholesterolemia as the total cholesterol >200 mg/dL or treated hypercholesterolemia and hypertension as systolic blood pressure > 140 mm Hg and/or diastolic blood pressure > 90 mm Hg or treated hypertension.

2.1.1. Invasive treatment and clinical data collection

All STEMI patients were treated with aspirin (300 mg) plus either clopidogrel (600 mg), prasugrel (60 mg) or ticagrelor (180 mg) on admission to the emergency department. Percutaneous coronary interventions were performed through a radial or femoral access according to operator preference, using a 6 French catheter. A bolus of 5000 IU of heparin was administered. Glycoprotein IIb/IIIa inhibitors were administered after diagnostic angiogram at the start of percutaneous coronary interventions, as well as manual thrombus aspiration according to operator's decision.

All patients with NSTE-ACS received aspirin (300 mg, followed by aspirin 100 mg daily) and were treated with a loading dose of clopidogrel (600 mg) or prasugrel (60 mg) or ticagrelor (180 mg) and fondaparinux or enoxaparin on admission to the emergency department according physician's decision. Use of IIb/IIIa inhibitors was left to operator's decision.

2.1.2. Clinical follow-up and, end-points definitions

Clinical follow-up was assessed by clinical visit each 6 months or by phone call.

The primary endpoint was Target Lesion revascularization (TLR).

Secondary endpoint was major adverse cardiovascular events [MACEs defined as the composite of death from cardiac causes, non-fatal MI, clinically driven target vessel revascularization (TVR), or re-hospitalization due to unstable or progressive angina according to Braunwald Unstable Angina Classification]. Sub-group analysis was performed for patients with FFR/OCT performed on culprit lesions and not.

2.1.3. Statistical analysis

Categorical variables were compared with the Fisher's exact test. Parametric distribution of continuous variables (presented as mean ± SD) was tested graphically and with Kolmogorov–Smirnov test, and the appropriate analyses were used in accordance with the results. For propensity score, first logistic regression analysis was done for all baseline features that differed between provisional and two stent groups and those clinically relevant (age, diabetes mellitus, hyperlipidemia, clinical presentation and multivessel disease) and matching was computed after division into quintiles and methods of nearest neighbor on the estimated propensity score [11]. Calibration was tested with Hosmer–Lemeshow, and accuracy was assessed with Area Under the Curve. Standardized differences were evaluated before and after matching to evaluate performance of the model. In sub-analysis regarding patients in whom culprit plaque underwent FFR assessment STEMI patients was excluded. The Kaplan-Maier survival analysis comparing categorical variables tested by log-rank test was performed. A two-sided p value <0.05 was considered statistically significant; all analyses were performed with SPSS 21.0 (IBM, Armonk, NY, USA).

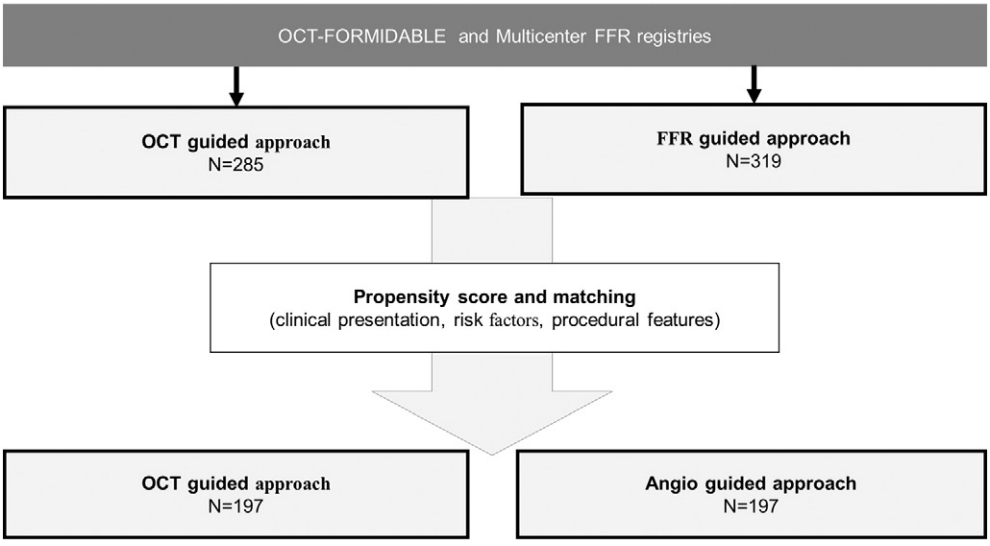

Fig. 1. Study design. OCT: optical coherence tomography, FFR: fractional flow reserve.

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