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Original article

OPtical frequency domain imaging vs. INtravascular ultrasound in percutaneous coronary InterventiON in patients with Acute Coronary Syndrome: Study protocol for a randomized controlled trial

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ABSTRACT

Background: A recent clinical trial demonstrated that optical frequency domain imaging (OFDI) guidance in percutaneous coronary intervention (PCI) is noninferior to intravascular ultrasound (IVUS) guidance in patients with coronary artery disease with regard to target vessel failure (composed of cardiac death, myocardial infarction attributed to the target vessel, and clinically-driven target vessel revascularization) at 12 months. The impact of OFDI guidance in PCI for patients with acute coronary syndrome (ACS) remains uncertain.

Methods: OPINION ACS is a multicenter, prospective, randomized, controlled, open-label, parallel group, non-inferiority trial in Japan. Eligible patients will be randomly assigned to receive either OFDI- or IVUS-guided PCI. PCI is performed using the sirolimus-eluting stent in accordance with certain OFDI and IVUS criteria for optimal stent deployment. All patients will undergo follow-up angiography and OFDI imaging at 8 months. The primary endpoint is the minimum lumen area, as measured by OFDI at 8 months.

Conclusion: The OPINION ACS trial outcomes will provide insights regarding the impact of OFDI-guided PCI on in-stent restenosis at 8 months in patients with ACS.

Introduction

Intravascular ultrasound (IVUS) is the first widely applied clinical imaging technology used to directly visualize atherosclerosis and other pathologic conditions within the vessel wall. Since its ability to image the entire arterial cross-section in real time can improve the precision of interventional procedures, IVUS has become a standard intracoronary imaging technique to guide percutaneous coronary intervention (PCI). Clinical trials have reported that IVUS-guidance results in greater acute lumen gains with reductions in subsequent restenosis, stent thrombosis, repeat revascularization, myocardial infarction, and cardiac death as compared with angiography guidance [1–9].

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In the mid-2000s, optical coherence tomography (OCT) emerged into clinical practice. Based on more than 10 times higher resolution than IVUS, this technology can offer more precise lumen border detection with accurate lumen measurements, which might promote more appropriate stent sizing and implantation during PCI. In addition, OCT is capable of detecting peri-procedural abnormal morphologies during PCI, such as stent edge dissection, intrastent tissue protrusion, incomplete stent apposition, and intra-stent thrombus [10,11]. Optical frequency domain imaging (OFDI; LUNAWAVE™, Terumo Corporation, Tokyo, Japan) is the most recently developed intravascular imaging device based on OCT technology. Recently, we conducted the OPtical frequency domain imaging vs. INtravascular ultrasound in percutaneous coronary InterventiON (OPINION) trial to compare OFDI-guided PCI with IVUS-guided PCI in terms of clinical outcomes. In this trial, OFDI-guided PCI ($n = 414$ patients) was non-inferior to IVUS-guided PCI ($n = 415$ patients) for the primary endpoint of target vessel failure (a composite of cardiac death, target-vessel-related myocardial infarction, and ischemia-driven target vessel revascularization) at 12 months (5.2% vs. 5.1%; $p_{\text{non-inferiority}} = 0.042$, respectively) [12]. In addition, the OPINION imaging study also demonstrated that although the OFDI-guided PCI group had a trend toward a smaller minimum stent area post-PCI, the minimal lumen area (MLA) at the 8-month follow-up was comparable, suggesting that OFDI- and IVUS-guided PCI have similar feasibilities using the current-generation drug-eluting stent (DES) [11]. However, the OPINION trial mainly enrolled patients with stable angina (90%); only 10% had unstable angina, and patients with myocardial infarction were excluded. Since the culprit plaque of acute coronary syndrome (ACS) can be more vulnerable and thrombus-rich, the impact of IVUS and OFDI guidance could be different when treating lesions in patients with stable angina. Therefore, we designed the OPtical frequency domain imaging vs. INtravascular ultrasound in percutaneous coronary InterventiON in patients with Acute Coronary Syndrome (OPINION ACS) trial to evaluate the non-inferiority of OFDI-guided PCI compared with IVUS-guided PCI with regard to the MLA as evaluated by OFDI 8 months after PCI.

Materials and methods

Study design

The OPINION ACS is a multicenter, prospective, randomized, controlled, open-label, parallel group, non-inferiority trial comparing OFDI-guided PCI with IVUS-guided PCI. Patients were randomly assigned to one of two groups, who received either OFDI-guided or IVUS-guided PCI with a second-generation DES. In addition to the post-PCI imaging by an allocated imaging modality, the OFDI-guided PCI group underwent post-PCI IVUS, while the IVUS-guided PCI group underwent post-PCI OFDI. Both groups underwent follow-up angiography with OFDI 8 months after the index procedure at participating cardiovascular centers. Investigators will follow up the subjects for 12 months at participating centers and will conduct medical examinations and blood testing. The recommended antiplatelet regimen was aspirin (>81 mg daily; indefinitely) and thienopyridine (75 mg clopidogrel daily, until the 8-month follow-up OFDI).

OPINION ACS is being performed according to the principles derived from the Declaration of Helsinki and from the International Conference on Harmonization Guidelines for Good Clinical Practice, as well as according to all applicable laws, rules, and regulations. The trial protocol was approved by the institutional review board of Kobe University Hospital. All patients who agree to participate will be enrolled only after they have provided written informed consent. This study has been registered with Japan Registry of Clinical Trials (trial identifier: jRCTs052190093), according to the statement of the International Committee of Medical Journal Editors.

Study population

OPINION ACS employs the following eligibility criteria: (1) 20–85 years of age; (2) ACS patients indicated for PCI using a drug-eluting stent to treat a de novo native coronary artery lesion; (3) patients who provided written informed consent; (4) patients whose target vessel diameter was between 2.25 and 3.5 mm (Table 1). ACS includes acute ST-elevation myocardial infarction (STEMI), non-ST-elevation myocardial infarction (NSTEMI), and unstable angina. The OPINION ACS exclusion criteria are listed in Table 2. The eligible patients will give written informed consent and will be then randomly assigned to receive either OFDI- or IVUS-guided PCI using a web-based randomization software conducted at the Translational Research Informatics Data Center, Kobe, Japan (Fig. 1). In this study, we will use minimization, which is a dynamic randomization method that can balance groups with respect to both the numbers in each treatment arm and the characteristics of each group. The randomization will be stratified by (1) STEMI, (2) history of diabetes, and (3) participating cardiovascular centers. Diabetes was considered present if the fasting plasma glucose level was ≧126 mg/dl, the glucose level was >200 mg/dl at 2 h after a 75-g oral glucose tolerance test, the casual plasma glucose level was >200 mg/dl, or the patient was taking antidiabetic medication. In each group, either OFDI or IVUS will be used before, during, and immediately after PCI. Also, medical treatment after PCI were left to the physician's discretion; but were recommended to follow the JCS 2018 Guideline on Diagnosis and Treatment of Acute Coronary Syndrome [13].

OFDI-imaging

OFDI imaging will be performed using the LUNAWAVE™ imaging system and FastView™ imaging catheter (Terumo Corporation) as previously described [12]. A bolus intracoronary injection of nitroglycerin will be administered before OFDI imaging. Following a calibration adjustment, an OFDI catheter will be advanced distally to the target lesion over a 0.014-in. conventional angioplasty guidewire. After the catheter has been placed at the desired location, contrast media will be flushed through the guiding catheter at a rate of 2–4 mL/s for 3–6 s using an injector pump. When blood has been completely removed from the vessel segment to be scanned, the OFDI scan will be initiated

Table 1
Inclusion criteria.

1.	ACS patients indicated for PCI using drug-eluting stent to a de novo native coronary artery lesion
2.	Aged 20–85 years at the time of their consent
3.	Patients whose target vessel diameter between 2.25 and 3.5 mm
4.	Patients who agree to be enrolled in the trial giving signed written informed consent

ACS, acute coronary syndrome; PCI, percutaneous coronary intervention.

Table 2
Exclusion criteria.

1.	Patients with cardiogenic shock
2.	Patients with renal failure (≤estimated glomerular filtration rate 30 mL/min/1.73 m^2 or serum creatinine ≥1.5 mg/dl)
3.	Patients on hemodialysis
4.	Female patients who are pregnant or plan to become pregnant

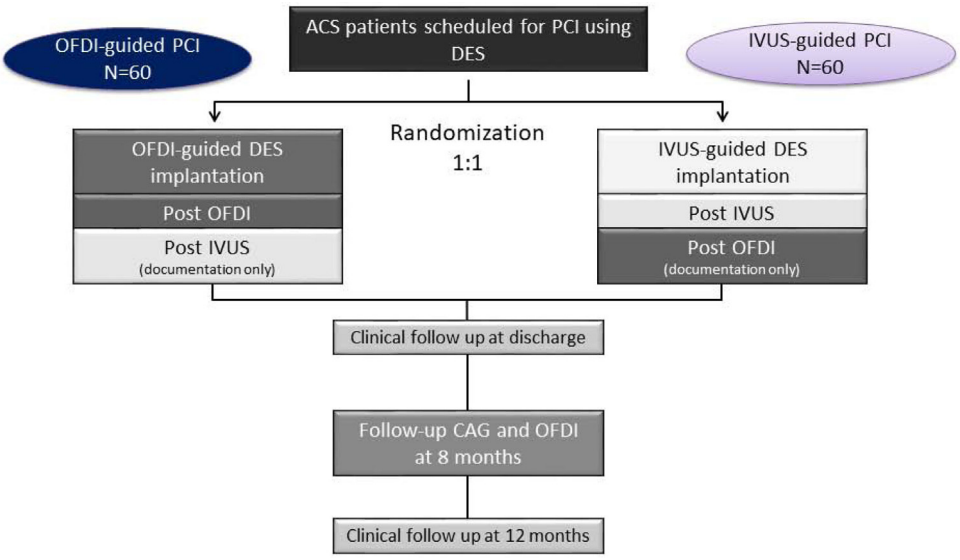

Fig. 1. Flowchart of patient enrolment, allocation, and analysis. ACS, acute coronary syndrome; CAG, coronary angiography; DES, drug-eluting stents; IVUS, intravascular ultrasound; OFDI, optical frequency domain imaging; PCI, percutaneous coronary intervention.

and conducted throughout the entire target lesion at a rate of 20–40 mm/s using an automatic pullback device. The OFDI images will be digitally stored for offline analysis using a dedicated image review system (Terumo Corporation) at the core laboratory (Kobe Cardiovascular Core Laboratory), which is blinded to arm allocation.

PCI procedure

The PCI procedure will be performed in a standard fashion using 6–8 Fr catheters through the femoral, brachial, or radial artery. Use of a sirolimus-eluting stent (SES; Ultimaster, Terumo Corporation) will be recommended. Intravascular imaging of either OFDI or IVUS will be performed before PCI; however, if the imaging catheter fails to pass through the target lesion, balloon dilatation ($\leq$2.5 mm) will be allowed prior to the imaging. Severe calcification may require pre-dilatation with a larger balloon or higher inflation pressure, a rotablator atherectomy, or a cutting balloon angioplasty. Heavily thrombotic lesions may require thrombus aspiration, which will be left to the operator's discretion. Use of distal protection could be considered if the culprit lesion has one of the following: (1) lots of thrombus; (2) a thin-cap fibroatheroma, defined as a plaque with a minimal fibrous cap thickness $<$65 mm [14]; and/or (3), a maximum lipid arc $>$180° degrees. Stent diameter and length will be determined by the obtained images. In OFDI, the reference site will be set at a cross-section adjacent to the target lesion that is most normal looking and free of lipidic plaque (defined as a signal-poor region with a diffuse border). Then, the stent diameter will be determined by measuring the lumen diameter at proximal and distal reference sites, and the stent length will be determined by measuring the distance from the distal to the proximal reference site. In general, the lumen diameter at the distal reference site is smaller than that at the proximal reference site. Stent diameter will be determined to be 0.25–0.50 mm greater than the mean lumen diameter at the distal reference site. In this method, the proximal stent edge may be incompletely opposed to the vessel wall. Therefore, the present study recommends performing post-dilatation by using a balloon with a diameter of 0–0.25 mm greater than the mean lumen diameter at the proximal reference site.

In IVUS, the reference site will be set at a cross-section adjacent to the target lesion that has the largest lumen and a plaque burden below 50%. Heavily thrombotic lesions may require thrombus aspiration. Use of distal protection could be considered if the culprit lesion has attenuated plaque (defined as hypoechoic or mixed atheroma with ultrasound attenuation but without calcification) $>$5 mm in longitudinal length [15]. Stent diameter will be determined by measuring the vessel diameter (approximated by the external elastic membrane diameter) at proximal and distal reference sites; stent length will be determined by measuring the distance from the distal to the proximal reference sites. In general, the vessel diameter at the distal reference site is smaller than at the proximal reference site. The stent diameter should be equal to or greater than the mean vessel diameter at the distal reference site, and smaller than the mean vessel diameter at the proximal reference site. If there is incomplete stent apposition, the present study recommends performing post-dilatation by using a balloon with a diameter 0–0.25 mm greater than the mean lumen diameter at the proximal reference site.

In addition to the post-PCI imaging by an allocated imaging modality, the OFDI-guided PCI group underwent post-PCI IVUS, while the IVUS-guided PCI group underwent post-PCI OFDI.

Study endpoints

The primary endpoint of the study will be the MLA, as determined by OFDI at the 8-month follow-up. Secondary endpoints will include the minimum stent and lumen areas, the size and numbers of thrombi (defined as a mass protruding beyond the stent strut into the lumen, with marked attenuation behind the mass) and irregular protrusions (defined as protrusion of material with an irregular surface into the lumen between stent struts), edge dissection (defined as disruption of the vessel luminal surface with a visible flap at the stent edge or 5 mm proximal and distal reference segments) and hematomas (defined as hypo-backscattering area related to stent edge dissection) immediately post-PCI, as well as the average neointimal thickness and area, average lumen area, percent of uncovered struts, and percent of malapposed struts at the 8-month follow-up.

Clinical outcomes

The present study will assess the incidence of slow flow/no reflow phenomena and distal embolization during the PCI

procedure. Slow flow/no reflow phenomena was defined as Thrombolysis In Myocardial Infarction (TIMI) flow grade <3 without evidence of dissection, stenosis, or vasospasm during PCI in the target coronary artery with previously normal anterograde flow (TIMI 3). Distal embolization was defined as a distal filling defect with an abrupt 'cut-off' in the main target coronary artery or one of the peripheral coronary branches, distal to the site of angioplasty. Clinical follow-up in the OPINION ACS trial will be scheduled at discharge and at 8 and 12 months after the PCI to evaluate the incidence of cardiac death, myocardial infarction (defined as an increase in levels of cardiac troponin I, according to the third universal definition of myocardial infarction) [16], ischemia-driven target-lesion revascularization, target-vessel revascularization, target-vessel failure (defined as a composite of cardiac death, target-vessel related myocardial infarction, and ischemia-driven target vessel revascularization), and major adverse cardiac events (defined as the composite outcome of cardiac death, myocardial infarction, and ischemia-driven target-lesion revascularization) during the follow-up period.

Sample size calculation

The primary endpoint of this study is to confirm the non-inferiority of OFDI-guided PCI compared with IVUS-guided PCI with regard to the MLA 8 months post-PCI in patients with ACS. Based on the OPINION study [11] conducted in Japan, we assumed the following: (1) a 0 mm^2 between-group difference in the mean MLA 8 months after PCI, (2) a non-inferiority margin of 1.3 mm^2, and (3) a standard deviation of 2.3 mm^2. Using these assumptions, we calculated that 55 patients per groups would be required for the study to have 90% power to confirm the non-inferiority of OFDI-guidance to IVUS-guidance with a one-sided alpha level of 0.05. Assuming that the dropout rate would be 10%, we planned to enroll 120 patients (60 patients per group).

Discussion

IVUS has been widely used as a guide for PCI during elective as well as emergent clinical scenarios. Results from registries, randomized studies [3,7], and meta-analyses [4,5] have shown significant clinical advantages of IVUS-guided PCI over angiography guidance alone to improve clinical outcomes such as cardiac death, myocardial infarction, and target vessel revascularization. Although the majority of such investigations have been conducted in patients with stable coronary artery diseases, the ULTIMATE trial, in which 78.5% of patients had ACS (unstable angina: 65.8%, acute myocardial infarction: 12.7%), also demonstrated a significant reduction in target vessel failure at the 12-month follow-up when PCI procedures using DES were guided by IVUS, compared with angiography-guided procedures [3].

OFDI is the most recent intravascular imaging device based on OCT technology, which has more than 10 times higher resolution than IVUS, and offers more detailed information on microstructural findings (e.g. intra-stent tissue protrusion, incomplete stent apposition, and stent-edge dissection) during PCI [10]. One of the advantages of OFDI over IVUS is that OFDI allows for better visualization of plaque morphology and the detection of thrombi, plaque rupture, and thin-cap fibroatheroma [17–19]. Because ACS culprit lesions are more likely to have such findings, which could induce slow flow/no reflow phenomena and peri-procedural myocardial infarctions, OFDI may be advantageous for PCI guidance in patients with ACS. On the other hand, one of the advantages of IVUS over OFDI is its ability to visualize the whole vessel structure, such as the external elastic membrane border. In a recent imaging sub-study of the OPINION trial, in which the majority of patients had stable angina (stable angina: 88.3%%, unstable angina: 11.7%), we demonstrated that the IVUS-guided PCI group had a slightly but significantly larger stent diameter than the OFDI-guided PCI group. As a result, the IVUS-guided PCI group tended to have a larger minimum stent area post-PCI, with a numerically greater mean stent expansion index than the OFDI-guided PCI group. However, these slight differences had no influence on MLA 8 months after PCI with a second-generation DES [11]; comparable clinical outcomes (target vessel failure) were found between groups 12 months after PCI [12]. Since arterial healing after DES implantation in ACS culprit lesions may be different than in stable angina, it is important to clarify whether these findings could be applied to PCI in patients with ACS.

In the present study, we set MLA 8 months after PCI as a primary endpoint. MLA by IVUS and OCT has been shown to correlate with the presence of ischemia, and smaller MLA is known to be associated with a higher prevalence of cardiovascular events such as in-stent restenosis and target lesion revascularization. Thus, our study design will provide potential impact of IVUS and OFDI-guided PCI not only on post stent setting but on mid-term after stent implantation.

Although the consensus document for the clinical use of intracoronary imaging by the European Association of Percutaneous Cardiovascular Interventions recommends the adjunctive use of intravascular imaging for patients with ACS or for the diagnostic assessment of suspected ACS culprit lesions [20], no randomized studies have compared IVUS-guided PCI versus OCT-guided PCI in patients with ACS. When completed, the OPINION ACS study will help to clarify the impact of IVUS- and OFDI-guided PCI on post-PCI OCT-based findings as well as subsequent vessel healing 8 months after current generation DES implantation.

Conclusions

This prospective randomized study is the first to directly compare OFDI- and IVUS-guided PCI with respect to MLA 8 months after PCI in patients with ACS. The outcomes of the OPINION ACS study will provide insights into the benefits and limitations of these two imaging modalities in patients with ACS who undergo PCI with current generation DESs.

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Conflict of interest

Dr. Otake, Dr. Hibi, and Dr. Sonoda received lecture fees from the Terumo Corporation. Dr. Akasaka received research funds from the Terumo Corporation. All other authors declare that there are no conflicts of interest.

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