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Coronary Artery Disease

Efficacy of Optical Coherence Tomography-Guided Primary Percutaneous Coronary Intervention in Patients with Acute Coronary Syndrome

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Background: Optical coherence tomography (OCT) is currently used as a guide for percutaneous coronary intervention (PCI), however its clinical benefit in comparison with intravascular ultrasound (IVUS) remains unclear in patients with acute coronary syndrome (ACS).

Objectives: The purpose of this study was to evaluate the clinical efficacy of OCT-guided PCI in comparison with IVUS-guided PCI in patients with ACS.

Methods: The study participants comprised 280 consecutive ACS patients who underwent primary PCI for *de novo* culprit lesions under OCT or IVUS guidance.

Results: Compared with the IVUS-guided group, the OCT-guided group had lower Killip classification ($p < 0.001$) and lower creatinine level at baseline (0.80 ± 0.37 mg/dl vs. 1.13 ± 1.29 mg/dl, $p = 0.004$). Fluoroscopy time and total procedure time were significantly shorter in the OCT-guided group than in the IVUS-guided group (32 ± 13 min vs. 41 ± 19 min, $p < 0.001$, and 98 ± 39 min vs. 127 ± 47 min, $p = 0.002$, respectively). The major adverse cardiovascular event-free survival curves were similar between the OCT- and IVUS-guided groups after adjusting for clinical background using propensity score (log-rank $p = 0.328$).

Conclusions: After adjusting for clinical background, OCT-guided PCI could provide comparable clinical outcomes to IVUS-guided PCI in patients with ACS. Shorter fluoroscopy time and total procedure time with OCT may reduce patient radiation exposure and also improve hospital workflow.

Key Words: Acute coronary syndrome • Optical coherence tomography • Percutaneous coronary intervention

Abbreviations

ACS	Acute coronary syndrome
AMI	Acute myocardial infarction
CK	Creatine kinase
Cre	Creatinine
DES	Drug-eluting stent
IABP	Intra-aortic balloon pumping
IVUS	Intravascular ultrasound
MACE	Major adverse cardiovascular events
MLA	Minimum lumen area
NIT	Neointimal thickness
OCT	Optical coherence tomography
OFDI	Optical frequency domain imaging
PCI	Percutaneous coronary intervention
PCPS	Percutaneous cardiopulmonary support
QCA	Quantitative coronary angiography
RCTs	Randomized controlled trials
TLR	Target lesion revascularization

INTRODUCTION

Intravascular ultrasound (IVUS) is the standard method for quantitative measurements of planimetric parameters of coronary artery disease during percutaneous coronary intervention (PCI). The superiority of IVUS-

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guided PCI over angio-guided PCI in terms of reducing major adverse cardiovascular events (MACE) and ischemia-driven target lesion revascularization (TLR) following implantation of a drug-eluting stent (DES) has been confirmed in several randomized controlled trials (RCTs) and meta-analyses.[1-3] A relatively new intravascular imaging system, optical coherence tomography (OCT), seems to be superior to previous methods in terms of precise assessments of vessel configurations and dimensions with high-resolution image quality.[4,5] However, relatively few studies have compared OCT- and IVUS-guided primary PCI in patients with acute coronary syndrome (ACS). In patients with ACS, the etiology of coronary lumen narrowing and the clinical situation during PCI differ completely from those in elective PCI.[6,7] Furthermore, the effectiveness of the rapid acquisition of high-resolution OCT images with dedicated diagnostic software in a primary PCI setting is still unclear in comparison with IVUS. Therefore, the aim of this study was to investigate the usefulness of OCT in a primary PCI setting regarding clinical background characteristics, PCI-related procedural parameters, and clinical outcomes in comparison with IVUS.

METHODS

Study population

This study was a single-center, observational, retrospective study. Among ACS patients admitted to our hospital and registered in the institutional KIBIDAN-GO (Kawasaki BioImaging DAtabase for loNg term cardiovascular proGnOsis) database from January 2012 to November 2016, those who underwent PCI for a de novo culprit lesion with guidance by OCT/optical frequency domain imaging (OFDI) or IVUS were enrolled. We excluded patients with ACS who underwent PCI without intravascular imaging (either OCT or IVUS) and patients on hemodialysis, and a total of 280 ACS patients including 196 with acute myocardial infarction (AMI) and 84 with unstable angina were enrolled. A flow chart of patient participation is shown in Figure 1.

The study protocol was approved by the Institutional Review Board of Kawasaki Medical School (IRB number: 3181), and this study was conducted in accordance with the Declaration of Helsinki with regards to investigations in humans.

Laboratory findings were collected before performing PCI. Serum creatinine (Cre) level at 24-72 h after PCI was also collected and compared to baseline serum Cre level. Serial creatine kinase (CK) measurements were obtained every 6-8 h (at least 3 times) until peak CK levels were determined.

Index PCI procedure and intravascular imaging

The patients were given a loading dose of aspirin (200 mg) and ticlopidine (500 mg) or clopidogrel (300 mg) or prasugrel (20 mg) before PCI. After stent implantation, all patients received dual antiplatelet therapy based on the Japanese Circulation Society Guidelines.[8]

For the PCI-related procedural parameters, fluoroscopy time, puncture to balloon time, total procedure time, and total volume of contrast media were evaluated. Regardless of intravascular imaging, all procedures were performed according to standard PCI techniques. OCT (FD-OCT, ILUMIEN^{TM} OPTIS^{TM}; Abbot Vascular, St. Paul, MN, USA and OFDI, LUNAWAVE^{TM}; Terumo Corporation, Tokyo, Japan) and IVUS (ViewIT^{TM} and AltaView^{TM}; Terumo Corporation) were performed and interpreted by the operator. The selection of intravascular imaging modality (OCT or IVUS) was left to the discretion of the operator. Intravascular images were obtained after the administration of nitroglycerin (0.2-0.3 mg). The imaging procedure for OCT was broadly similar to that for IVUS, except that blood had to be displaced by contrast medium during OCT imaging. In cases of vessel occlusion or tight lumen stenosis, obtaining clear OCT images beyond the culprit lesion was difficult because of inade-

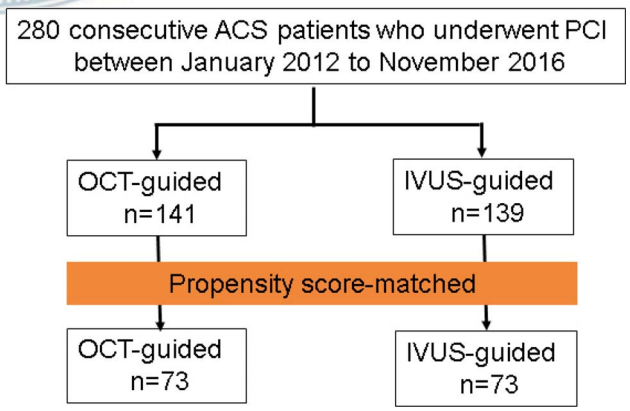

Figure 1. *Study flow chart. ACS, acute coronary syndrome; IVUS, intravascular ultrasound; OCT, optical coherence tomography; PCI, percutaneous coronary intervention.*

quate distal penetration of the contrast medium. In such cases, a thrombus aspiration catheter or pre-dilatation of the culprit lesions with 1.5- or 2.0-mm balloons was required to obtain a clear OCT image distal to the culprit site.

Quantitative coronary angiography analysis

Quantitative coronary angiography (QCA) was performed using images obtained after stent implantation and at follow-up after 6-12 months. Using a guiding catheter for calibration and an edge detection system (QAngio XA 3D 1.0.28.4; Medis Medical Imaging System, Leiden, the Netherlands), the reference lumen diameter, minimum lumen diameter, percent stenosis of the diameter [(1 – minimum lumen diameter/reference lumen diameter) × 100], and lesion length were calculated before the PCI procedure. After the PCI procedure, mean reference lumen diameter, in-stent minimum lumen diameter, in-stent stenosis of the diameter [(1 – in-stent minimum lumen diameter/mean reference lumen diameter) × 100], and acute lumen gain (minimum lumen diameter immediately after PCI – minimum lumen diameter before PCI) were calculated. The stent-to-artery ratio was calculated as the ratio of the diameter of the placed stent to the mean reference lumen diameter.

Routine follow-up coronary angiography was performed at 9-12 months after the index PCI except in the patients who died before coronary angiography, those with severe renal dysfunction, and those with dementia. Follow-up QCA and OCT analyses are shown in the Supplemental Appendix.

Clinical outcomes

Clinical outcomes were investigated through a review of medical records up to 3 years after the PCI, and the results were compared between the OCT-guided and IVUS-guided groups. MACE was defined as the composite of all-cause death, AMI including both target vessel-related myocardial infarction and non-target vessel-related myocardial infarction, and TLR.

Statistical analysis

Data are presented as mean ± standard deviation for continuous variables, and as a frequency for categorical variables. The Student's *t*-test was used to compare continuous variables, and the χ^2 test or Fisher's exact test was used to compare categorical variables. The cumulative incidence of clinical events was estimated using the Kaplan-Meier method, and the curves of the two groups were compared by the log-rank test.

To adjust for potential confounding from the choice of intravascular imaging modalities, we evaluated the effects of the OCT-guided PCI strategy relative to the IVUS-guided PCI strategy in a propensity score-matched population. A logistic regression model was used to develop propensity scores for the choice of intravascular imaging with 16 independent variables [age, sex, diagnosis on admission as unstable angina or AMI, Killip class, total amount of contrast, Cre, brain natriuretic peptide, troponin T, peak CK, stent type, stent diameter, stent length, multivessel disease, intra-aortic balloon pumping (IABP) use, percutaneous cardiopulmonary support (PCPS) use, and American College of Cardiology/American Heart Association lesion type B2/C] relevant to the decision regarding intravascular imaging, as listed in Tables 1 and 2. To create the propensity score-matched cohort, patients in the OCT-guided group were matched to those in the IVUS-guided group using a 1:1 greedy matching technique.[9] Cumulative incidence rates of clinical events were compared between the OCT- and IVUS-guided groups in the propensity score-matched cohort. All statistical analyses were conducted using JMP for Mac version 11.0 (SAS Institute, Cary, NC), and a p value < 0.05 was considered significant.

RESULTS

Clinical characteristics

With regards to the clinical characteristics, the OCT-guided group had lower Killip classification (p < 0.001) and lower C-reactive protein levels on admission than the IVUS-guided group (0.7 ± 1.5 mg/L vs. 2.0 ± 4.1 mg/L, p = 0.001) (Table 1). In addition, the OCT-guided group had higher high-density lipoprotein cholesterol levels on admission than the IVUS-guided group (46 ± 12 mg/L vs. 43 ± 13 mg/L, p = 0.020). Serum Cre levels on admission (day 1) were significantly higher in the IVUS-guided group (1.13 ± 1.29 mg/dl) than in the OCT-guided group (0.80 ± 0.37 mg/dl, p = 0.004). However, the change in serum Cre level (Cre level at day 2 – Cre level on admission) did not differ significantly between

Table 1. Clinical characteristics and laboratory data at baseline

	Entire study population			Propensity-matched population		
	OCT-guided (n = 141)	IVUS-guided (n = 139)	p value	OCT-guided (n = 73)	IVUS-guided (n = 73)	p value
Age, years (mean ± SD)	69.7 ± 11.4	70.2 ± 12.5	0.750	69.8 ± 10.8	69.4 ± 11.2	0.805
Male, n (%)	102 (71)	100 (72)	0.941	56 (77)	54 (74)	0.701
BMI (mean ± SD)	23.3 ± 3.6	23.5 ± 3.4	0.776	23.0 ± 3.3	23.8 ± 3.6	0.221
Admission diagnosis, n (%)			0.938			0.599
Unstable angina	42 (30)	42 (30)		26 (36)	23 (32)	
Acute myocardial infarction	99 (70)	97 (70)		47 (64)	50 (68)	
Killip class, n (%)			< 0.001			0.962
I	115 (82)	76 (55)		56 (77)	57 (78)	
II	13 (9)	13 (9)		7 (10)	6 (8)	
III	7 (5)	15 (11)		5 (7)	6 (8)	
IV	6 (4)	35 (25)		5 (7)	4 (5)	
Triglycerides (mg/dl)	127 ± 72	130 ± 78	0.807	123 ± 68	145 ± 82	0.093
HDL-cholesterol (mg/dl)	46 ± 12	43 ± 13	0.020	44 ± 12	43 ± 13	0.441
LDL-cholesterol (mg/dl)	119 ± 35	112 ± 35	0.064	118 ± 35	118 ± 39	0.967
HbA1c (%)	6.3 ± 1.3	6.3 ± 1.3	0.869	6.4 ± 1.4	6.2 ± 1.2	0.369
C-reactive protein (mg/L)	0.7 ± 1.5	2.0 ± 4.1	0.001	0.9 ± 1.8	1.6 ± 4.0	0.143
BNP (pg/ml)	304 ± 704	416 ± 654	0.170	375 ± 898	301 ± 505	0.540
Peak CK (U/l)	1944 ± 2513	2181 ± 3434	0.511	1937 ± 2787	1754 ± 3439	0.722
hs-TnT (ng/ml)	1.44 ± 3.17	1.95 ± 3.84	0.225	1.55 ± 3.18	1.40 ± 2.71	0.754
Cre on admission (day 1) (mg/dl)	0.80 ± 0.37	1.13 ± 1.29	0.004	0.89 ± 0.45	0.96 ± 1.18	0.643
Cre at day 2 (mg/dl)	0.81 ± 0.35	1.15 ± 1.24	0.002	0.89 ± 0.45	0.96 ± 0.86	0.532
ΔCre (mg/dl)	0.02 ± 0.14	0.03 ± 0.76	0.852	-0.01 ± 0.17	-0.01 ± 0.43	0.923

BMI, body mass index; BNP, brain natriuretic peptide; CK, creatine kinase; Cre, creatinine; HbA1c, hemoglobin A1c; HDL, high-density lipoprotein; hs-TnT, high-sensitivity troponin T; IVUS, intravascular ultrasound; LDL, low-density lipoprotein; OCT, optical coherence tomography; SD, standard deviation.

the OCT-guided group (0.02 ± 0.14 mg/dl) and IVUS-guided group (0.03 ± 0.76 mg/dl, p = 0.852). The rate of cardiac arrest requiring cardiopulmonary resuscitation at the time of arrival of emergency medical services tended to be higher in the IVUS-guided group than in the OCT-guided group (3% vs. 7%, p = 0.094). All other baseline characteristics were mostly similar between the OCT-guided and IVUS-guided groups in the entire study population.

Lesion characteristics

In terms of lesion characteristics, the site of the lesion and the prevalence of multivessel disease differed significantly between the two groups for the entire study population (Table 2). The mean stent diameter was significantly larger and the maximum balloon diameter tended to be larger in the IVUS-guided group compared with the OCT-guided group.

PCI-related procedural parameters

Regarding the PCI-related procedural parameters, the total contrast volume in the OCT-guided group (209 ± 50 ml) was significantly larger than in the IVUS-guided group (175 ± 65 ml, p < 0.001). Although the puncture to balloon time was not significantly different between the two groups (OCT-guided group: 41 ± 21 min vs. IVUS-guided group: 45 ± 20 min, p = 0.144), fluoroscopy time and total procedure time were significantly shorter in the OCT-guided group than in the IVUS-guided group (32 ± 13 min vs. 38 ± 19 min, p = 0.001, and 99 ± 36 min vs. 128 ± 54 min, p < 0.001, respectively). These differences in PCI procedure were also observed after adjusting for clinical background using propensity score (fluoroscopy time: OCT-guided group 32 ± 13 min vs. IVUS-guided group 41 ± 19 min, p < 0.001, and total procedure time: OCT-guided group 98 ± 39 min vs. IVUS-guided group 127 ± 47 min, p = 0.002, respectively).

QCA data at baseline are shown in Table 3. Proximal reference diameter before PCI procedure, mean reference diameter, and minimum lumen diameter after the PCI procedure were significantly larger in the IVUS-guided group than in the OCT-guided group.

Clinical outcomes

In the entire study population, the median duration of follow-up after the index PCI procedure was 655 days (interquartile range: 198-1095 days). The cumulative incidence of TLR did not differ significantly between the

Table 2. Lesion and procedural characteristics

	Entire study population			Propensity-matched population		
	OCT-guided (n = 141)	IVUS-guided (n = 139)	p value	OCT-guided (n = 73)	IVUS-guided (n = 73)	p value
Site of stenosis, n (%)			0.011			0.102
Left main	0 (0)	6 (4)		1 (1)	2 (3)	
Left anterior descending	84 (60)	60 (43)		43 (59)	32 (44)	
Left circumflex	19 (13)	23 (17)		5 (7)	16 (22)	
Right coronary artery	37 (26)	46 (33)		23 (32)	22 (30)	
SVG	1 (1)	4 (3)		1 (1)	1 (1)	
Multivessel disease, n (%)	61 (43)	86 (62)	0.003	39 (53)	34 (47)	1.000
Multivessel PCI at the index PCI procedure	18 (13)	23 (17)	0.745	7 (10)	10 (14)	0.411
ACC/AHA lesion type B2/C, n (%)	88 (62)	95 (68)	0.297	23 (32)	27 (37)	0.485
Stent type, n (%)			0.491			0.599
Bare metal stent	27 (19)	22 (16)		11 (15)	15 (21)	
Drug-eluting stent	105 (74)	112 (81)		60 (82)	57 (78)	
POBA only	8 (6)	5 (4)		3 (4)	1 (1)	
Aspiration only	1 (1)	0 (0)		0 (0)	0 (0)	
Total stent length (mm)	28.4 ± 14.3	29.8 ± 16.0	0.474	28.5 ± 14.3	27.2 ± 13.4	0.587
Mean stent diameter (mm)	2.9 ± 0.5	3.0 ± 0.5	0.017	3.0 ± 0.5	3.0 ± 0.7	0.353
Maximum balloon diameter (mm)	3.1 ± 0.7	3.3 ± 0.7	0.055	3.2 ± 0.7	3.3 ± 0.7	0.710
IABP use, n (%)	12 (9)	31 (22)	< 0.001	11 (15)	8 (11)	0.461
PCPS use, n (%)	3 (2)	18 (13)	< 0.001	3 (4)	2 (3)	0.649
Imaging procedure-related complications, n (%)	0 (0)	0 (0)	1.000	0 (0)	0 (0)	1.000
Total volume of contrast (ml)	208 ± 51	176 ± 64	< 0.001	196 ± 51	194 ± 66	0.849
Fluoroscopy time (min)	32 ± 13	38 ± 19	< 0.001	32 ± 13	41 ± 19	< 0.001
Puncture to balloon time (min)	41 ± 21	45 ± 20	0.144	42 ± 21	48 ± 20	0.107
Total procedure time (min)	99 ± 36	128 ± 54	< 0.001	98 ± 39	127 ± 47	0.002

ACC/AHA, American College of Cardiology/American Heart Association; IABP, intra-aortic balloon pumping; IVUS, intravascular ultrasound; OCT, optical coherence tomography; PCPS, percutaneous cardiopulmonary support; POBA, percutaneous old balloon angioplasty; SVG, saphenous vein graft.

Table 3. QCA data at baseline

	Entire study population			Propensity-matched population		
	OCT-guided (n = 141)	IVUS-guided (n = 139)	p value	OCT-guided (n = 73)	IVUS-guided (n = 73)	p value
Pre-PCI						
Lesion length (mm)	19.7 ± 9.5	19.8 ± 8.9	0.948	20.0 ± 10.5	18.2 ± 8.1	0.243
Proximal reference diameter (mm)	2.9 ± 0.7	3.1 ± 0.7	0.017	2.9 ± 0.6	3.1 ± 0.7	0.070
Minimum lumen diameter (mm)	0.5 ± 0.4	0.5 ± 0.5	0.892	0.5 ± 0.5	0.5 ± 0.5	0.780
Diameter stenosis (%)	83.3 ± 15.5	84.1 ± 15.7	0.687	82.6 ± 15.7	83.2 ± 16.1	0.798
Post-PCI						
Mean reference diameter (mm)	2.9 ± 0.6	3.0 ± 0.6	0.028	2.9 ± 0.5	3.1 ± 0.6	0.199
Minimum lumen diameter (mm)	2.4 ± 0.6	2.5 ± 0.6	0.041	2.4 ± 0.5	2.5 ± 0.6	0.328
Diameter stenosis (%)	17.9 ± 13.0	17.1 ± 12.2	0.598	17.1 ± 13.2	17.0 ± 12.6	0.979
Acute gain (mm)	1.9 ± 0.1	2.1 ± 0.7	0.070	2.0 ± 0.6	2.1 ± 0.7	0.292
Stent to artery ratio	1.1 ± 0.2	1.1 ± 0.2	0.951	1.1 ± 0.2	1.1 ± 0.2	0.837

IVUS, intravascular ultrasound; OCT, optical coherence tomography; PCI, percutaneous coronary intervention; QCA, qualitative comparative analysis.

OCT-guided group (6%) and IVUS-guided group (5%; p = 0.742) (Table 4). The mortality rate at first hospitalization was significantly lower in the OCT-guided group than in the IVUS-guided group (6% vs. 17%, p = 0.004). The MACE-free survival rate differed significantly between the OCT- and IVUS-guided groups (Figure 2A). On the other hand, after adjusting for clinical background using propensity scores, the rates of all-cause death, TLR, and AMI did not differ significantly (Table 4). MACE-free survival curves were similar between the two groups (Figure 2B).

DISCUSSION

The main results of the present study are that: 1) OCT-guided PCI was preferable for ACS patients with lower Killip classification and preserved renal function than IVUS-guided PCI; 2) OCT-guided PCI was associated with a shorter fluoroscopy time and total procedure time both in the entire study population and after adjusting for clinical background using propensity scores; and 3) the in-hospital mortality rate was significantly lower in the patients with OCT guidance than IVUS guidance because IVUS guidance was used in ACS patients with more severe heart failure, renal dysfunction, and multivessel disease. After adjusting for clinical background using propensity scores, the long-term clinical outcomes were comparable between the OCT- and IVUS-guided groups.

With regards to the operators' selection of IVUS or OCT, operators might prefer IVUS to OCT to avoid contrast volume overload in patients with congestive heart failure or contrast-induced nephropathy in patients with renal dysfunction. The imaging procedure for OCT is similar to that of IVUS, except that blood must be displaced by contrast medium during OCT. An increase in contrast volume is a concern with OCT-guided PCI, particularly in patients with congestive heart failure or renal dysfunction. These factors might affect the operators' decisions on whether to perform OCT-guided or IVUS-guided PCI. However, although the total contrast volume was significantly larger in the OCT-guided group than in the IVUS-

Table 4. Clinical outcomes

	Entire study population			Propensity-matched population		
	OCT-guided (n = 141)	IVUS-guided (n = 139)	p value	OCT-guided (n = 73)	IVUS-guided (n = 73)	p value
Death at first hospitalization, n (%)	8 (6)	23 (17)	0.004	7 (10)	5 (7)	0.547
TLR, n (%)	8 (6)	7 (5)	0.742	0 (0)	2 (3)	0.731
Myocardial infarction, n (%)	2 (1)	4 (3)	0.399	1 (1)	3 (5)	0.172
MACE, n (%)	24 (17)	40 (29)	0.019	11 (15)	11 (15)	0.682

IVUS, intravascular ultrasound; MACE, major adverse cardiac events; OCT, optical coherence tomography; TLR, target lesion revascularization.

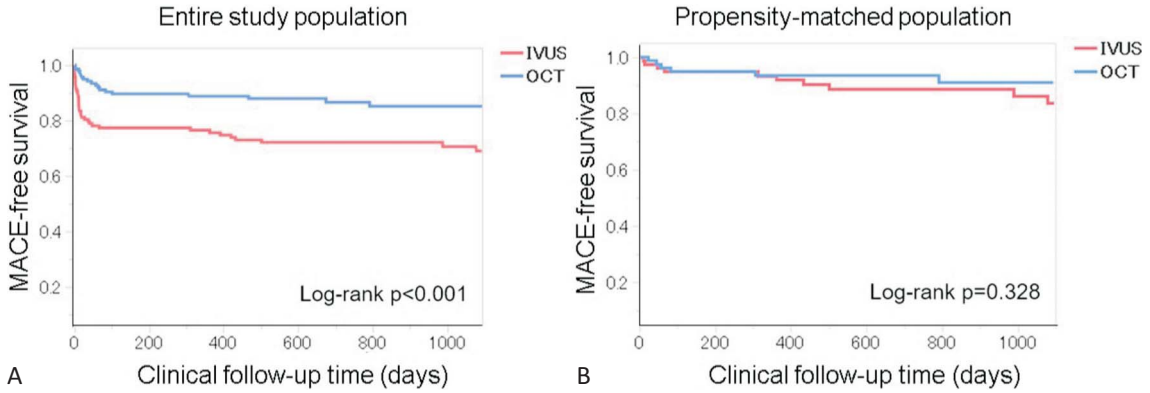

Figure 2. *Kaplan-Meier curves for MACE-free survival rate. The MACE-free survival rate differed significantly between OCT- and IVUS-guided groups in the entire study population (A). On the other hand, after adjusting clinical backgrounds using propensity scores, the MACE-free survival curves were similar between groups (B). IVUS, intravascular ultrasound; MACE, major adverse cardiac events; OCT, optical coherence tomography.*

guided group (208 ± 51 ml vs. 176 ± 64 ml, p < 0.001), the change in serum Cre level at follow-up did not differ significantly between the OCT- and IVUS-guided groups. Regarding lesion characteristics, the mean reference and stent diameters were significantly higher in the IVUS-guided group than in the OCT-guided group. IVUS has a superior depth of penetration than OCT,[10] and therefore operators might prefer IVUS to OCT for lesions in a larger vessel, such as the left main trunk, saphenous vein graft, and proximal right coronary artery.

In this study, OCT-guided PCI required a shorter fluoroscopy time and total procedure time than IVUS-guided PCI, and these results were also observed after adjusting for clinical background using propensity scores. This may be due to the faster pullback speed of OCT (18-40 mm/sec) than that of IVUS (0.5-9 mm/sec), and because high-resolution OCT allowed for visualization of the lesion morphology and abnormal post-stent findings in a shorter time compared with IVUS through automatic quantification of the lumen area and stent parameters by software installed in the OCT system. Furthermore, co-registration of cross-sectional OCT images and angiography allowed for pinpoint visualization of highly accurate lumen morphology on the angiogram, which consequently allowed for an optimized stent implantation strategy by incorporating accurate OCT measurements and angiographic monitoring. Considering these points, OCT may enable operators to rapidly decide the PCI strategy, including lesion preparation, stent sizing, and endpoint of the PCI procedure.

In terms of comparisons between OCT-guided and IVUS-guided PCI, two dedicated RCTs have been reported. The OPINION trial included 829 patients with stable angina pectoris, and found that OCT-guided PCI was non-inferior to IVUS-guided PCI concerning the clinical endpoint of target vessel failure within 12 months (5.2% vs. 4.9%, p for non-inferiority < 0.05).[11] The ILUMIEN-III study included 450 patients of whom 36% had ACS and addressed the question of whether OCT-guided PCI using a specific optimization protocol was comparable to IVUS-guided PCI.[12] The results showed that MSA, as the primary endpoint, with OCT-guided PCI was comparable to that with IVUS-guided PCI. Both the OPINION trial and ILUMIEN-III study showed the non-inferiority of OCT versus IVUS-guided PCI with regards to clinical target vessel failure and MSA, respectively. Both of these studies mainly compared OCT-guided and IVUS-guided PCI among patients who underwent elective PCI. On the other hand, relatively few studies have compared OCT-guided and IVUS-guided primary PCI in patients with ACS with regards to subsequent coronary thrombus formation based on three pathological conditions in the coronary arterial wall: ruptured vulnerable plaque, plaque erosion, or calcified nodules.[6] To the best of our knowledge, this is the first report to compare clinical background characteristics, QCA data, and OCT findings during follow-up and clinical outcomes following OCT-guided versus IVUS-guided PCI in patients with ACS. In patients with ACS, the etiology of coronary lumen narrowing and the clinical situation during PCI are completely different from elective PCI. Considering the benefits of OCT-guided PCI in ACS patients, OCT could be used to assess the etiology of ACS (e.g., plaque rupture, erosion, calcified nodules, and others) which cannot be assessed as accurately using IVUS.[6,13] As mentioned above, OCT during PCI procedures in patients with ACS would offer many benefits. In the present study, OCT-guided PCI in patients with ACS had similar OCT findings during follow-up including neointimal characteristics and neointimal area (Supplemental Results), and clinical outcomes compared with IVUS-guided PCI after adjusting for clinical background using propensity scores. Considering these results, OCT-guided PCI in patients with ACS might be feasible and safe for daily cardiac catheterization laboratory practice, even in emergency settings, and might improve workflow leading to the more efficient use of hospital resources.

Limitations

The present study has several important limitations. First, this registry was a single-center, retrospective, observational study. Therefore, we performed propensity score-matched analysis to adjust for potential confounders. Nevertheless, we could not rule out the presence of unmeasured confounders and selection bias. Second, the sample size was not large enough to evaluate the impact of intravascular imaging on the occurrence of stent thrombosis. Third, OCT-guided PCI was accompanied by a shorter fluoroscopy time and total procedure time than IVUS-guided PCI. However, there is a learning curve for OCT-guided PCI which may affect the fluoroscopy time and total procedure time. Fourth, the fact that four different types of treatment (bare-metal stent, DES, plain

old balloon angioplasty only, or aspiration only) were used in this study has to be taken into account. Fifth, although routine follow-up coronary angiography at 9-12 months after the index PCI was planned, not every patient had follow-up CAG and OCT examinations due to death, severe renal dysfunction, and dementia. This may have led to selection bias. Finally, Killip classification showed more severe heart failure on admission, and IABP/PCPS use rates were significantly higher in the IVUS-guided group than in the OCT-guided group. The rate of cardiac arrest requiring cardiopulmonary resuscitation at the time of arrival of emergency medical services tended to be higher in the IVUS-guided group than in the OCT-guided group (3% vs. 7%, p = 0.094). As a result, the MACE-free survival rate was significantly lower in the IVUS-guided group due to the significantly higher rate of mortality at first hospitalization compared to the OCT-guided group within the entire study population. Considering the results of this study, the usefulness of OCT-guided PCI in ACS patients with heart failure, renal dysfunction, and multivessel disease needs to be established in further studies.

CONCLUSIONS

With proper selection of ACS patients, OCT-guided PCI could provide similar clinical outcomes to IVUS-guided PCI. Shortening the fluoroscopy and total procedure time by using OCT may reduce patient radiation exposure and also improve hospital workflow. Further large-scale studies with long-term follow-up are necessary to investigate the usefulness of OCT in primary PCI settings regarding clinical background characteristics, PCI-related procedural parameters, and clinical outcomes in comparison with IVUS.

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All the other authors have nothing to disclose.

ETHICAL STATEMENT

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. The study protocols of this retrospective analysis were approved by the Kawasaki Medical School Institutional Review Board (Protocol Identification Number: 3181).

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SUPPLEMENTARY MATERIALS

METHODS

Follow-up QCA and OCT analysis

Routine follow-up coronary angiography at 9-12 months after the index PCI was performed except for patients who died before coronary angiography, severe renal dysfunction and dementia. Late lumen loss was calculated as minimal lumen diameter immediately after PCI – minimal lumen diameter at follow-up. Binary restenosis was defined as an increase in the percent stenosis of the diameter of ≥ 50%.

For the examination of stented segments, the OCT catheter was placed > 10 mm distal to the stented lesion and pulled back using an automatic pullback system. Cross-sectional OCT images of stented segments at 1-mm intervals were analyzed. We evaluated the neointimal coverage of each stent strut, neointimal volume, neointimal tissue characteristics, and presence of thrombus. A covered strut was defined as a neointimal thickness (NIT), representing the distance between the center of the strut and the neointimal surface, > 30 μm.[S1,S2] We classified neointimal tissue characteristics into 4 patterns: homogeneous, heterogeneous, layered or neoatherosclerosis.[S3] We then observed the neointimal characteristics at the site of minimum lumen area (MLA) in the stented segment. Neoatherosclerosis was defined as the presence of lipid, calcification, thin-cap fibroatheroma, neovascularization, or intimal rupture in the neointima, as mentioned in previous studies.[S4,S5] Thrombus was defined as a mass protruding into the lumen with an irregular surface.[S6] These OCT findings were compared between OCT-guided and IVUS-guided PCI groups at follow-up.

RESULTS

Overall, 67.1% of patients in this study underwent follow-up coronary artery angiography irrespective of the presence of symptoms. QCA data at follow-up are shown in Supplemental Table 1. Mean reference diameter and minimum lumen diameter tended to be higher in the IVUS-guided group than in the OCT-guided group. Percent stenosis of the diameter, late loss, and rate of binary restenosis was similar between groups. OCT findings at follow-up (data available in 70 patients) are shown in Supplemental Table 2. Most stent struts were

Supplemental Table 1. QCA data at follow-up

	OCT-guided (n = 109)	IVUS-guided (n = 79)	p value
At follow-up			
Mean reference diameter (mm)	2.8 ± 0.5	3.0 ± 0.6	0.053
Minimum lumen diameter (mm)	2.1 ± 0.6	2.3 ± 0.7	0.082
Diameter stenosis (%)	26.2 ± 16.5	24.1 ± 16.3	0.385
Late loss (mm)	0.3 ± 0.5	0.3 ± 0.6	0.793
Binary restenosis, n (%)	8 (7)	6 (8)	0.947

IVUS, intravascular ultrasound; OCT, optical coherence tomography; QCA, qualitative comparative analysis.

Supplemental Table 2. Optical coherence tomography findings at follow-up

	Overall (n = 70)	OCT-guided (n = 39)	IVUS-guided (n = 31)	p value
Cross-section, n	401	233	168	-
Total struts, n	4108	2437	1671	-
Uncovered strut rate (%)	12.7 ± 13.7	14.0 ± 13.2	10.8 ± 14.2	0.325
ISA rate (%)	0.6 ± 2.1	0.5 ± 1.5	0.8 ± 2.7	0.475
Neointimal characteristics, n (%)				0.499
Homogeneous pattern	313 (78)	180 (77)	133 (79)	
Heterogeneous pattern	74 (18)	46 (20)	28 (17)	
Layered pattern	10 (3)	6 (3)	4 (2)	
Neo-atherosclerosis	4 (1)	1 (0)	3 (2)	
Quantitative analyses of MLA site at baseline				
Stent area (mm^2)	6.3 ± 2.5	6.3 ± 2.6	6.3 ± 2.4	0.995
Lumen area (mm^2)	4.7 ± 2.3	4.7 ± 2.4	4.7 ± 2.1	0.996
Neointimal area (mm^2)	1.6 ± 1.6	1.6 ± 1.6	1.6 ± 1.7	0.998
Per patient analyses				
Presence of thrombus, n (%)	3 (4)	2 (5)	1 (3)	0.693
Presence of neoatherosclerosis, n (%)	4 (6)	1 (3)	3 (10)	0.199

ISA, incomplete stent apposition; IVUS, intravascular ultrasound; MLA, minimum lumen area; OCT, optical coherence tomography.

covered with neointima in both groups. As for neointimal tissue characteristics at the MLA site, no significant differences were evident between groups, with each group predominantly showing a homogeneous pattern. Evidence of thrombus was detected in two cases from the OCT-guided group and one from the IVUS-guided group.

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