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ORIGINAL RESEARCH

Single-Session Versus Staged Multivessel Optimal IVUS-Guided PCI in Patients With CCS or NSTE-ACS

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ABSTRACT

BACKGROUND There are no studies comparing single-session vs staged multivessel intravascular ultrasound (IVUS)-guided percutaneous coronary intervention (PCI) in patients with chronic coronary syndrome (CCS) or non–ST-segment-elevation acute coronary syndrome (NSTE-ACS).

OBJECTIVES The authors aimed to compare single-session vs staged multivessel IVUS-guided PCI in patients with CCS or NSTE-ACS.

METHODS The OPTIVUS-Complex PCI study multivessel cohort was a prospective multicenter single-arm trial enrolling 1,021 patients with CCS or NSTE-ACS undergoing multivessel PCI including left anterior descending coronary artery using IVUS aiming to meet the prespecified OPTIVUS criteria for optimal stent expansion. We compared single-session vs staged multivessel PCI. The primary endpoint was a composite of death, myocardial infarction, stroke, or any coronary revascularization.

RESULTS There were 246 patients (24.1%) undergoing single-session multivessel PCI, and 775 patients (75.9%) undergoing staged multivessel PCI. There was a wide variation in the prevalence of single-session multivessel PCI across the participating centers. The staged multivessel PCI group more often had complex coronary anatomy such as 3-vessel disease, chronic total occlusion, and calcified lesions requiring an atherectomy device compared with the single-session multivessel PCI group. The rates of PCI success, procedural complications, and meeting OPTIVUS criteria were not different between groups. The cumulative 1-year incidence of the primary endpoint was not different between single-session and staged multivessel PCI groups (9.0% vs 10.8%, log-rank $P = 0.42$). After adjusting confounders, the effect of single-session multivessel PCI relative to staged multivessel PCI was not significant for the primary endpoint (HR: 0.95; 95% CI: 0.58-1.55; $P = 0.84$).

CONCLUSIONS Single-session and staged multivessel IVUS-guided PCI had similar 1-year outcomes.

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ABBREVIATIONS AND ACRONYMS

DAPT = dual antiplatelet therapy

IVUS = intravascular ultrasound

MSA = minimum stent area

PCI = percutaneous coronary intervention

STEMI = ST-segment elevation myocardial infarction

Patients undergoing multivessel percutaneous coronary intervention (PCI) sometimes require multiple procedures to complete revascularization, which is called "staged PCI procedure."[1,2] Completing PCI for all target lesions in a single session would be ideal to avoid multiple procedures and reduce cost. However, there are some clinical and nonclinical reasons to perform staged procedures in real-world practice.[1,2] Among patients with ST-segment elevation myocardial infarction (STEMI) and multivessel disease, several large-scale randomized controlled trials comparing staged PCI of nonculprit lesions with culprit-only PCI have been conducted, suggesting the importance of complete revascularization.[3,4] The benefit of complete revascularization over culprit-only PCI was reported to be consistent irrespective of the timing of nonculprit lesion revascularization.[5] In patients with non-ST-segment elevation acute coronary syndrome (NSTE-ACS), complete revascularization is also recommended in the current European guideline based on the results of several observational studies.[6-8] However, there has been only 1 small randomized controlled trial comparing single-session multivessel PCI with staged multivessel PCI in patients without STEMI,[9] and there are no recommendations about whether we should choose single-session or staged multivessel PCI in patients without STEMI in the current American and European guidelines.[10,11]

The benefit of intravascular ultrasound (IVUS) in reducing ischemic events after PCI was well established in previous randomized controlled trials,[12,13] and it is recommended to use IVUS especially in complex lesions such as multivessel disease.[10] However, one of the drawbacks of IVUS is prolonged procedure time.[13] IVUS-guided PCI might affect choice of single-session or staged multivessel PCI and their outcomes in real-world practice, because the main reasons to choose staged PCI strategy are related to prolonged procedure time leading to patient and operator fatigue, and affecting catheterization laboratory time schedule.[1] Therefore, we aimed to compare single-session vs staged multivessel PCI strategies in patients without STEMI enrolled in a large Japanese IVUS-guided PCI study.

METHODS

STUDY POPULATION. The OPTIVUS-Complex PCI (Optimal Intravascular Ultrasound Guided Complex Percutaneous Coronary Intervention) study multivessel cohort was a prospective multicenter single-arm trial that enrolled patients undergoing multivessel IVUS-guided PCI including a target lesion in the left anterior descending coronary artery. The exclusion criteria were those patients with STEMI, cardiogenic shock, and previous history of coronary artery bypass grafting. The design, patient enrollment, and main results at 1 year were previously reported in detail.[14] The study protocol was approved by the central review board, Kyoto University Certified Review Board, based on the enforcement of the Clinical Trials Act in Japan. Written informed consent was provided from all enrolled patients.

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The authors attest they are in compliance with human studies committees and animal welfare regulations of the authors' institutions and Food and Drug Administration guidelines, including patient consent where appropriate. For more information, visit the Author Center.

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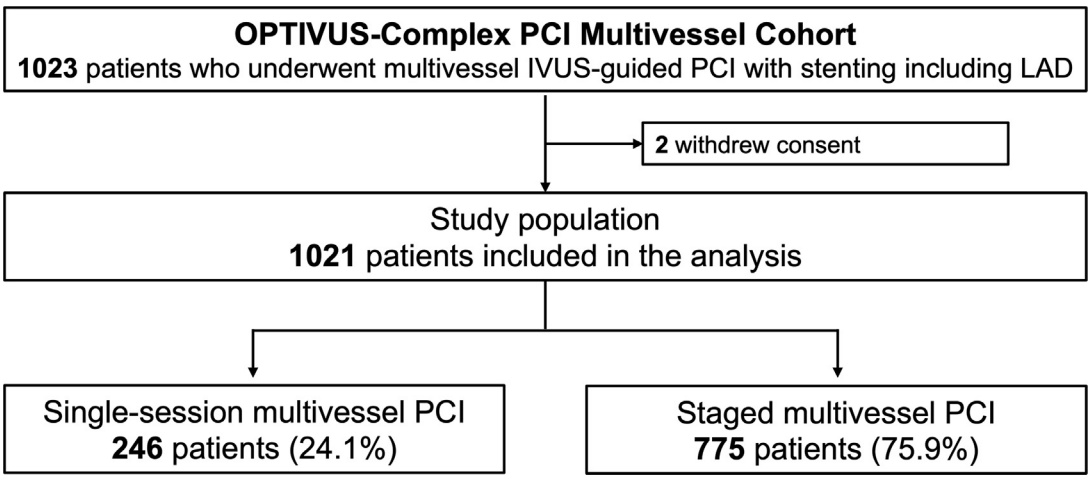
FIGURE 1 Study Flow



In the study population, there were 246 patients (24.1%) who underwent single-session multivessel PCI and 775 patients (75.9%) who underwent staged multivessel PCI. IVUS = intravascular ultrasound; LAD = left anterior descending coronary artery; OPTIVUS = OPTimal IntraVascular UltraSound; PCI = percutaneous coronary intervention.

Between March 2019 and April 2021, 1,023 patients who underwent IVUS-guided multivessel PCI, including left anterior descending coronary artery target, were enrolled in 90 Japanese centers. Excluding 2 patients who withdrew consent, the study population consisted of 1,021 patients (Figure 1). The study population was divided into 2 groups (single-session multivessel PCI and staged multivessel PCI groups). Single-session multivessel PCI was defined as the PCI for all the target lesions performed during the first index PCI procedure, whereas staged multivessel PCI was defined as multiple PCI procedures comprising the first index PCI and planned staged PCI procedures. Planned staged PCI procedures were not regarded as follow-up events, but included in the index procedure.

STUDY PROCEDURES AND OPTIVUS CRITERIA. The PCI operators were mandated to perform optimal IVUS-guided PCI with a target for the prespecified criteria (OPTIVUS criteria) for optimal stent implantation. The details of the study procedures and all of the OPTIVUS criteria are described in the Supplemental Appendix. The most important OPTIVUS criteria for stent expansion were defined as follows: minimum stent area (MSA) less than the distal reference lumen area if the stent length ≥28 mm, and MSA >0.8 average reference lumen area if the stent length <28 mm (average reference lumen area = [proximal reference lumen area + distal reference lumen area] / 2). The overall achievement rate of OPTIVUS criteria and the association between the OPTIVUS criteria and clinical outcomes were previously reported in detail.[14] Quantitative and qualitative coronary angiography analysis was to be performed in all target lesions, and IVUS analysis was to be performed in all target lesions with stenting by an independent core laboratory (Cardiocore).

In addition to the IVUS-related recommendations, there were other recommendations to adopt the contemporary clinical, procedural, and pharmacological practice. Target lesions were to be selected based on a stress imaging or physiological assessment (fractional flow reserve or instantaneous wave-free ratio). Radial access was recommended as the standard approach. PCI for chronic total occlusion was to be performed by a dedicated chronic total occlusion operator. Use of rotational atherectomy was recommended in severely calcified lesions. Proximal optimization technique was recommended in bifurcation lesions. Kissing balloon inflation was recommended if bifurcation lesions were treated with 2-sent techniques. Scheduled follow-up coronary angiography after PCI was discouraged in asymptomatic patients. Recommended pharmacologic management included use of high-intensity statins therapy with the maximum approved dose of strong statins in Japan,

TABLE 1 Baseline Clinical Characteristics (Per-Patient Basis)

	Single-Session Multivessel PCI (n = 246)	Staged Multivessel PCI (n = 775)	*P* Value
Clinical characteristics			
Age, y	71.5 ± 10.0	71.1 ± 10.0	0.58
≥75[a]	102 (41.5)	325 (41.9)	0.90
Men[a]	197 (80.1)	606 (78.2)	0.53
Body mass index, kg/m^2	23.7 ± 3.3	24.2 ± 3.6	0.07
<25.0	172 (69.9)	494 (63.7)	0.08
Acute coronary syndrome[a]	26 (10.6)	119 (15.4)	0.06
Acute myocardial infarction	11 (4.5)	57 (7.4)	0.11
Unstable angina	15 (6.1)	62 (8.0)	0.33
Hypertension	200 (81.3)	660 (85.2)	0.15
Diabetes mellitus[a]	129 (52.4)	431 (55.6)	0.38
on insulin therapy	28 (11.4)	67 (8.6)	0.20
Current smoking	39 (15.9)	137 (17.7)	0.51
Heart failure[a]	41 (16.7)	137 (17.7)	0.72
Prior hospitalization for heart failure	24 (9.8)	63 (8.1)	0.43
Current heart failure at index hospitalization	25 (10.2)	108 (13.9)	0.13
Left ventricular ejection fraction (%)	57.6 ± 12.2	57.7 ± 12.3	0.93
<40%	25 (10.4)	89 (11.5)	0.64
Mitral regurgitation grade ≥3/4	8 (3.3)	22 (2.8)	0.74
Prior myocardial infarction[a]	64 (26.0)	116 (15.0)	<0.001
Prior stroke[a]	28 (11.4)	91 (11.7)	0.88
Peripheral vascular disease	33 (13.4)	83 (10.7)	0.24
eGFR (mL/min/1.73 m^2)	61.3 ± 23.1	58.6 ± 22.1	0.10
eGFR 30-59 mL/min/1.73 m^2	90 (36.6)	302 (39.0)	0.50
eGFR <30 mL/min/1.73 m^2 or hemodialysis[a]	19 (7.7)	78 (10.1)	0.28
eGFR <30 mL/min/1.73 m^2, without hemodialysis	8 (3.3)	30 (3.9)	0.66
Hemodialysis	11 (4.5)	48 (6.2)	0.31
Atrial fibrillation	19 (7.7)	66 (8.5)	0.70
Anemia (hemoglobin <11.0 g/dL)	23 (9.3)	73 (9.4)	0.97
Thrombocytopenia (platelet <100 × 10^9/L)	4 (1.6)	6 (0.8)	0.24
Malignancy	37 (15.0)	89 (11.5)	0.14
Severe frailty[b]	11 (4.5)	28 (3.6)	0.54
ARC-HBR	125 (50.8)	414 (53.4)	0.48
Baseline medications			

Continued on the next page

and short duration (3 to 6 months) of dual antiplatelet therapy (DAPT) after PCI.

ENDPOINTS. The primary endpoint was a major adverse cardiac and cerebrovascular event defined as a composite of death from any cause, myocardial infarction, stroke, or any coronary revascularization. Myocardial infarction was adjudicated according to the academic research consortium definition.[15] Stroke was defined as ischemic or hemorrhagic stroke with neurological symptoms lasting >24 hours. The definitions of secondary endpoints are described in the Supplemental Appendix. All endpoints were assessed at 1 year (between 335 and 394 days), with censoring on day 366. All clinical events comprising the primary endpoint were adjudicated based on the source documents by an independent clinical event committee.

STATISTICAL ANALYSIS. Categorical variables were presented as number (percentage) and were compared with chi-square test. Continuous variables were expressed as mean ± SD or median (IQR) and were compared using the Student's *t*-test or Wilcoxon rank-sum test depending on their distributions. The cumulative 30-day and 1-year incidences were estimated with the Kaplan-Meier method, and the difference was compared with the log-rank test. The effect of single-session multivessel PCI relative to staged multivessel PCI for the primary and secondary endpoints were expressed as HRs and their 95% CIs estimated by the Cox proportional hazard model. We constructed a multivariable Cox proportional hazard model to assess the effect of single-session multivessel PCI relative to staged multivessel PCI for the primary endpoint at 1 year. The risk-adjusting variables were 11 clinically relevant factors listed in Tables 1 and 2. The covariates in the multivariable Cox proportional hazard model were determined by the clinical relevance without model selection procedure. As a sensitivity analysis, we constructed the Cox proportional hazard model including the participating center as random effect and other risk-adjusting variables as fixed effect for the primary endpoint. In addition, we also conducted a sensitivity analysis of the Cox proportional hazard model adjusting propensity score for the primary endpoint. The detailed methods of the Cox proportional hazard model adjusting propensity score are described in the Supplemental Appendix.

All *P* values were 2-sided and *P* values <0.05 were considered statistically significant. All analyses were performed with R version 4.1.2 (R Foundation for Statistical Computing).

RESULTS

THE PREVALENCE OF SINGLE-SESSION MULTIVESSEL PCI. In the study population, there were 246 patients (24.1%) who underwent single-session multivessel PCI and 775 patients (75.9%) who underwent staged multivessel PCI (Figure 1). There was a wide variation in the prevalence of single-session multivessel PCI across the 90 participating centers (Figure 2). The prevalence of single-session multivessel PCI was 76% to 100% in 7 centers, 51% to 75% in 7 centers, 26% to 50% in 14 centers, and 0% to 25% in 62 centers (Figure 2). There was no apparent association between the number of enrolled patients and the prevalence of single-session multivessel PCI (Figure 2).

BASELINE CHARACTERISTICS. As per-patient analyses, clinical characteristics were not different between single-session and staged multivessel PCI groups, except for the higher prevalence of prior myocardial infarction in the single-session multivessel PCI group than in the staged multivessel PCI group (Table 1). The prevalence of chronic kidney disease was not different between the 2 groups. The prescription rates of aspirin, beta-blockers, and angiotensin-converting enzyme inhibitors or angiotensin II receptor blockers were higher in the staged multivessel PCI group than in the single-session multivessel PCI group (Table 1).

Patients in the single-session multivessel PCI group more often performed coronary computed tomography before index invasive coronary angiography compared with those in the staged multivessel PCI group (Table 2). In the staged multivessel PCI group, 86.7% of the patients underwent 1 staged PCI procedure (Table 2). Median interval from the index PCI to first staged PCI was 21 (IQR: 7-33) days. Among 775 patients in the staged multivessel PCI group, 556 patients (71.7%) underwent only a single PCI during the index hospitalization and 219 patients (28.3%) underwent at least 1 staged PCI during the index hospitalization. The median duration of index hospitalization was 3 days in patients who underwent only a single PCI during the index hospitalization, whereas it was 10 days in patients who underwent at least 1 staged PCI during the index hospitalization.

The prevalence of a radial approach was higher in the staged multivessel PCI group than in the single-session multivessel PCI group (Table 2). The staged multivessel PCI group compared with the single-session multivessel PCI group had more complex coronary anatomy as indicated by the higher prevalence of 3-vessel disease and chronic total occlusion target, and higher SYNTAX score. The total number of target lesions and stents were greater in the staged multivessel PCI group than in the single-session multivessel PCI group, whereas the number of target lesions and stents per procedure were lower in the staged multivessel PCI group than in the single-session multivessel PCI group. Total contrast medium volume was higher in the staged multivessel PCI group than in the single-session multivessel PCI group, whereas contrast medium volume per procedure was lower in the staged multivessel PCI group than in the single-session multivessel PCI group. The rates of PCI success, procedural complications, and meeting OPTIVUS criteria were not different between single-session and staged multivessel PCI groups.

TABLE 1 Continued

	Single-Session Multivessel PCI (n = 246)	Staged Multivessel PCI (n = 775)	*P* Value
Antiplatelet therapy			
$P2Y_{12}$ inhibitors	246 (100)	772 (99.6)	0.33
Clopidogrel	121 (49.2)	442 (57.0)	-
Prasugrel	124 (50.4)	328 (42.3)	-
Aspirin	223 (90.7)	737 (95.1)	0.01
Cilostazol	2 (0.8)	4 (0.5)	0.60
Other medications			
Statins	225 (91.5)	711 (91.7)	0.89
High-intensity statins[c]	84 (34.1)	290 (37.4)	0.35
Beta-blockers	94 (38.2)	360 (46.5)	0.02
ACEIs/ARBs	126 (51.2)	458 (59.1)	0.03
Nitrates	29 (11.8)	119 (15.4)	0.17
Calcium-channel blockers	94 (38.2)	350 (45.2)	0.06
Oral anticoagulants	26 (10.6)	73 (9.4)	0.60
Warfarin	3 (1.2)	16 (2.1)	0.39
DOAC	23 (9.3)	57 (7.4)	0.31
Proton pump inhibitors or histamine type-2 receptor blockers	216 (87.8)	687 (88.6)	0.72
Proton pump inhibitors	210 (85.4)	666 (85.9)	0.82
Histamine type-2 receptor blockers	7 (2.8)	21 (2.7)	0.91

Value are mean ± SD or n (%). Left ventricular ejection fraction was missing in 7 patients. eGFR was missing in 3 patients. [a]Risk-adjusting variables selected for the Cox proportional hazard model. [b]Severe frailty was regarded as present when the hospital chart documented the inability to perform usual activities of daily living. [c]High-intensity statin therapy was defined as the use of maximum approved doses of strong statins in Japan (eg, rosuvastatin 10 mg, atorvastatin 20 mg, or pitavastatin 4 mg).

ACEI = angiotensin-converting enzyme inhibitor; ARB = angiotensin II receptor blocker; ARC-HBR = academic research consortium for high bleeding risk; DOAC = direct oral anticoagulant; eGFR = estimated glomerular filtration rate; PCI = percutaneous coronary intervention.

ANGIOGRAPHIC, IVUS, AND PROCEDURAL CHARACTERISTICS. As per lesion analyses on angiography, lesions in the staged multivessel PCI group more often had complex lesions such as long lesions and calcified lesions compared with those in the single-session multivessel PCI group (Table 3). The prevalence of in-stent restenosis was higher in lesions in the single-session multivessel PCI group than in those in the staged multivessel PCI group. The cutting or scoring balloon and atherectomy device were more often used in lesions in the staged multivessel PCI group than in those in the single-session multivessel PCI group. The rate of postdilation and its maximum balloon inflation pressure were slightly higher in lesions in the single-session multivessel PCI group than in those in the staged multivessel PCI group, whereas the postdilation maximum balloon size was slightly greater in lesions in the staged multivessel PCI group than in those in the single-session multivessel PCI group.

In the postprocedure IVUS analysis in stented lesions, the proximal reference lumen area, MSA, and

TABLE 2 Angiographic and Procedural Characteristics (Per-Patient Basis)

	Single-Session Multivessel PCI (n = 246)	Staged Multivessel PCI (n = 775)	*P* Value
Performing coronary CT before index invasive coronary angiography	43 (17.5)	88 (11.4)	0.01
Number of staged PCI			
1	-	672 (86.7)	-
2	-	101 (13.0)	-
3	-	2 (0.3)	-
Interval from index PCI to first staged PCI (days)	-	21 (7-33)	-
Performing only single PCI during index hospitalization	246 (100)	556 (71.7)	-
Duration of index hospitalization (days)	3 (2-5)	3 (2-4)	0.94
Performing at least 1 staged PCI during index hospitalization	-	219 (28.3)	-
Duration of index hospitalization (days)	-	10 (6-19)	-
Pre-procedure noninvasive test	61 (24.8)	154 (19.9)	0.10
Stress electrocardiogram	28 (11.4)	76 (9.8)	0.48
SPECT	27 (11.0)	67 (8.6)	0.27
Cardiac magnetic resonance	2 (0.8)	7 (0.9)	0.90
Stress echocardiography	1 (0.4)	2 (0.3)	0.71
FFR-CT	2 (0.8)	8 (1.0)	0.76
Invasive FFR or iFR use	70 (28.5)	234 (30.2)	0.60
IVUS use	246 (100)	775 (100)	
Radial artery approach	202 (82.1)	691 (89.2)	0.004
Extent of coronary artery disease[a]			<0.001
2-vessel disease	234 (95.1)	579 (74.7)	
3-vessel disease	12 (4.9)	196 (25.3)	
SYNTAX score	16.4 ± 6.2	18.6 ± 7.4	<0.001
Low <23	206 (84.4)	588 (76.7)	0.02
Intermediate 23-32	33 (13.5)	140 (18.3)	
High ≥33	5 (2.0)	39 (5.1)	
Number of target lesions	2.3 ± 0.6	2.6 ± 0.8	<0.001
Number of target lesions per procedure	2.3 ± 0.6	1.2 ± 0.4	<0.001
Total number of stents	2.5 ± 1.0	3.1 ± 1.3	<0.001
Total number of stents per procedure	2.5 ± 1.0	1.5 ± 0.5	<0.001
Total stent length (mm)	66.8 ± 28.5	84.3 ± 39.0	<0.001
Total stent length per procedure (mm)	66.8 ± 28.5	39.5 ± 17.2	<0.001
Target of proximal LAD[a]	242 (98.4)	767 (99.0)	0.45
Target of chronic total occlusion[a]	24 (9.8)	127 (16.4)	0.01
Target of bifurcation	148 (60.2)	468 (60.4)	0.95
Bifurcation with 2 stents	6 (2.4)	16 (2.1)	0.73
New-generation DES use	246 (100)	775 (100)	-
Contrast medium volume	157 ± 61	251 ± 107	<0.001
Contrast medium volume per procedure	157 ± 61	117 ± 45	<0.001
PCI procedure success (per patient)[b]			
Complete success	241 (98.0)	758 (97.8)	0.88
Partial success	5 (2.0)	17 (2.2)	0.88

Continued on the next page

distal reference lumen area were greater in lesions in the staged multivessel PCI than in those in the single-session multivessel PCI, whereas the rate of meeting OPTIVUS criteria was not different between lesions in the single-session and staged multivessel PCI groups.

DAPT DISCONTINUATION. The cumulative incidence of DAPT discontinuation was higher in the single-session multivessel PCI group than in the staged multivessel PCI group (at 60 days: 29.3% vs 13.6%, at 180 days: 48.4% vs 33.9%, and at 1 year: 72.1% vs 67.6%, log-rank $P < 0.001$) (Supplemental Figure 1). In patients who were on oral anticoagulants at discharge from the index PCI hospitalization, the cumulative incidence of DAPT discontinuation was higher in the single-session multivessel PCI group than in the staged multivessel PCI group (at 60 days: 100% vs 76.7%, at 180 days: 100% vs 91.8%, and at 1 year: 100% vs 95.9%, log-rank $P < 0.001$) (Supplemental Figure 2)

FOLLOW-UP CORONARY ANGIOGRAPHY. The cumulative incidence of follow-up coronary angiography at 1 year was not different between the single-session and staged multivessel PCI groups (15.3% vs 19.1%, log-rank $P = 0.15$) (Supplemental Figure 3). The cumulative incidence of clinically driven follow-up coronary angiography at 1 year was not different between the single-session and staged multivessel PCI groups (5.3% vs 4.6%, log-rank $P = 0.65$) (Supplemental Figure 4), whereas that of scheduled follow-up coronary angiography at 1 year was lower in the single-session multivessel PCI group than in the staged multivessel PCI group (9.1% vs 13.8%, log-rank $P = 0.046$) (Supplemental Figure 5).

CLINICAL OUTCOMES. Complete 1-year clinical follow-up was achieved in 1,015 (99.4%) patients (single-session multivessel PCI: n = 246 [100%], and staged multivessel PCI: n = 769 [99.2%]). Follow-up data were collected from the hospital charts in 831 patients (81.3%), were obtained by contacting the patients and/or their relatives in 105 patients (10.3%), and were obtained by referring physicians in 85 patients (8.3%).

The cumulative 30-day incidence of the primary endpoint was not different between single-session and staged multivessel PCI groups (0.8% vs 1.0%; HR: 0.79; 95% CI: 0.17-3.71; $P = 0.76$) (**Table 4**). The cumulative 30-day incidences of the secondary endpoints were also not different between single-session and staged multivessel PCI groups.

The cumulative 1-year incidence of the primary endpoint was not different between single-session and staged multivessel PCI groups (9.0% vs 10.8%, log-rank $P = 0.42$) (**Figure 3**). After adjusting confounders, the effect of the single-session multivessel PCI group relative to the staged multivessel PCI group was not significant for the primary endpoint (HR: 0.95; 95% CI: 0.58-1.55; $P = 0.84$). There was no apparent association between the number of enrolled patients and the cumulative 1-year incidence of the primary endpoint (**Figure 2**). The cumulative 1-year incidences of the secondary endpoints were also not

different between single-session and staged multivessel PCI groups.

In the sensitivity analysis including the participating center as the random effect, the results were fully consistent with those in the main analysis (Supplemental Table 1). In the sensitivity analysis of the Cox proportional hazard model adjusting the propensity score, the results were fully consistent with those in the main analysis (Supplemental Table 2).

DISCUSSION

The main findings of this prospective study enrolling patients who underwent optimal IVUS-guided multivessel PCI were as follows: 1) the prevalence of patients who underwent single-session multivessel PCI was 24.1%, and there was a wide variation in the prevalence of single-session multivessel PCI across the participating centers; 2) patients who underwent staged multivessel PCI more often had complex coronary anatomy such as 3-vessel disease, chronic total occlusion, and calcified lesions requiring atherectomy device compared with those who underwent single-

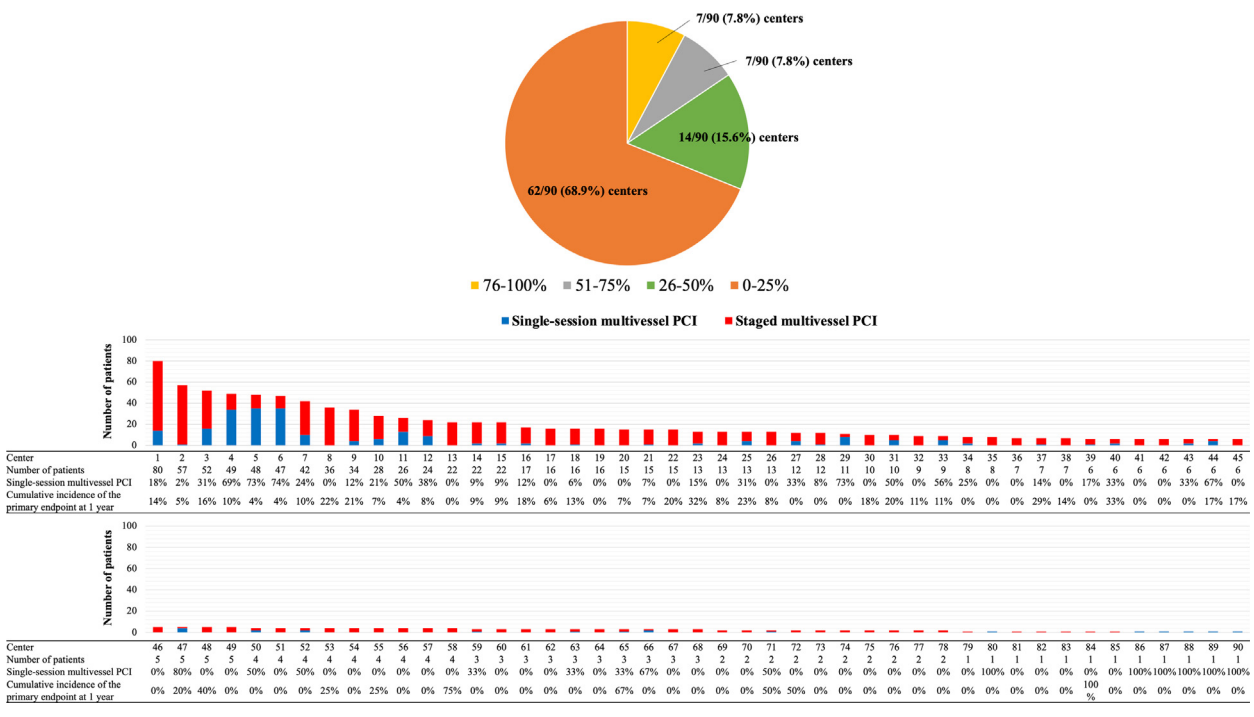
TABLE 2 Continued

	Single-Session Multivessel PCI (n = 246)	Staged Multivessel PCI (n = 775)	*P* Value
Procedural complications	12 (4.9)	55 (7.1)	0.22
Side branch occlusion (post TIMI flow grade ≤2)	6 (2.4)	16 (2.1)	-
Slow flow	5 (2.0)	27 (3.5)	-
Acute occlusion	2 (0.8)	4 (0.5)	-
Perforation	0 (0)	12 (1.5)	-
Cardiac tamponade	0 (0)	0 (0)	-
Stent dislodgement	0 (0)	1 (0.1)	-
Stent thrombosis	0 (0)	0 (0)	-
OPTIVUS criteria			0.15
Meeting in all stented lesions	95 (40.3)	299 (40.1)	
Not meeting in some lesion(s)	87 (36.9)	315 (42.2)	
Not meeting in any lesion	54 (22.9)	132 (17.7)	

Values are n (%), median (IQR), or mean ± SD. SYNTAX score was missing in 10 patients. [a]Risk-adjusting variables selected for the Cox proportional hazard model. [b]PCI procedure success was defined as successful dilatation of target lesion with residual diameter stenosis <50%.

CT = computed tomography; DES = drug-eluting stent(s); FFR = fractional flow reserve; FFR-CT = fractional flow reserve-computed tomography; iFR = instantaneous wave-free ratio; IVUS = intravascular ultrasound; LAD = left anterior descending coronary artery; OPTIVUS = OPTimal IntraVascular UltraSound; PCI = percutaneous coronary intervention; SPECT = stress single photon emission computed tomography; SYNTAX = synergy Between Percutaneous Coronary Intervention With TAXUS and Cardiac Surgery; TIMI = Thrombolysis In Myocardial Infarction.

FIGURE 2 The Prevalence of Single-Session Multivessel PCI by the 90 Participating Centers



The prevalence of single-session multivessel PCI and the cumulative 1-year incidence of the primary endpoint across the 90 participating centers. PCI = percutaneous coronary intervention.

TABLE 3 Angiographic, Procedural, and IVUS Characteristics in the Core Angiographic and IVUS Laboratory (Per Lesion Basis)

	Single-Session Multivessel PCI (557 Target Lesions)	Staged Multivessel PCI (2,038 Target Lesions)	*P* Value
Angiographic and procedural characteristics			
Number of lesions with angiographic evaluation in the core angiographic laboratory	501	1,798	
Preprocedure			
Lesion length (mm)	22.0 ± 12.1 (n = 461)	23.9 ± 14.1 (n = 1611)	0.01
Reference vessel diameter (mm)	2.6 ± 0.5 (n = 501)	2.6 ± 0.6 (n = 1794)	0.02
Minimum lumen diameter (mm)	0.8 ± 0.4 (n = 501)	0.8 ± 0.4 (n = 1795)	0.68
Percent diameter stenosis (%)	68.5 ± 13.2 (n = 501)	68.8 ± 14.3 (n = 1795)	0.60
Thrombus	8/501 (1.6)	45/1,796 (2.5)	0.23
Total occlusion	30/501 (6.0)	144/1,796 (8.0)	0.13
In-stent restenosis	28/501 (5.6)	53/1,796 (3.0)	0.01
Bifurcation	238/501 (47.5)	854/1,796 (47.6)	0.99
Moderate or severe calcification	133/501 (26.5)	589/1,796 (32.8)	0.01
Index procedure			
Invasive FFR or iFR use	93/557 (16.7)	320/2,038 (15.7)	0.57
IVUS use	546/557 (98.0)	1,983/2,038 (97.3)	0.34
Stent use	514/557 (92.3)	1,865/2,038 (91.5)	0.56
PCI procedure success[a]	552/557 (99.1)	2,019/2,038 (99.1)	0.94
Number of stents used per lesion	1.2 ± 0.4 (n = 514)	1.3 ± 0.5 (n = 1863)	<0.001
Stent length per lesion (mm)	32.0 ± 15.4 (n = 514)	35.1 ± 19.2 (n = 1863)	0.001
Minimum stent diameter (mm)	2.75 (2.5-3.0) (n = 514)	2.75 (2.5-3.0) (n = 1863)	0.04
Cutting or scoring balloon use	125/557 (22.4)	758/2,038 (37.2)	<0.001
Rotational atherectomy use	26/557 (4.7)	145/2,038 (7.1)	0.04
Orbital atherectomy use	1/557 (0.2)	41/2,038 (2.0)	0.002
Direct stenting	45/514 (8.8)	138/1,863 (7.4)	0.31
Maximum stent inflation pressure (atm)	12.6 ± 3.1 (n = 511)	12.8 ± 3.1 (n = 1,861)	0.31
Postdilation	415/514 (80.7)	1423/1863 (76.4)	0.04
Maximum balloon size (mm)	3.1 ± 0.6 (n = 415)	3.2 ± 0.6 (n = 1,423)	0.01
Maximum balloon inflation pressure (atm)	18.5 ± 4.1 (n = 412)	17.9 ± 4.3 (n = 1,422)	0.01
Postprocedure			
Minimum lumen diameter (mm)			
In-stent	2.5 ± 0.4 (n = 501)	2.5 ± 0.5 (n = 1,798)	0.01
In-segment	2.1 ± 0.5 (n = 501)	2.2 ± 0.6 (n = 1,798)	0.04
Percent diameter stenosis (%)			
In-stent	14.4 ± 6.4 (n = 501)	14.5 ± 6.8 (n = 1798)	0.83
In-segment	23.6 ± 10.0 (n = 501)	23.8 ± 9.9 (n = 1798)	0.68
Acute gain (mm)			
In-stent	1.7 ± 0.5 (n = 501)	1.7 ± 0.5 (n = 1795)	0.04
In-segment	1.3 ± 0.5 (n = 501)	1.4 ± 0.6 (n = 1795)	0.08
Procedural complications	12/557 (2.2)	63/2038 (3.1)	0.24
Side branch occlusion (post TIMI flow grade ≤2)	6/557 (1.1)	17/2038 (0.8)	
Slow flow	5/557 (0.9)	31/2038 (1.5)	
Acute occlusion	2/557 (0.4)	4/2038 (0.2)	
Perforation	0/557 (0)	13/2038 (0.6)	
Cardiac tamponade	0/557 (0)	0/2038 (0)	
Stent dislodgement	0/557 (0)	1/2038 (0.001)	
Stent thrombosis	0/557 (0)	0/2038 (0)	

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session multivessel PCI; 3) the rates of PCI success, procedural complications, and meeting OPTIVUS criteria were not different between patients who underwent single-session and staged multivessel PCI; and 4) single-session and staged multivessel PCI had similar 1-year outcomes (**Central Illustration**).

There are some potential clinical and nonclinical reasons to perform staged procedures.[1] Examples of

TABLE 3 Continued

	Single-Session Multivessel PCI (557 Target Lesions)	Staged Multivessel PCI (2,038 Target Lesions)	*P* Value
IVUS analysis postprocedure[b]			
Number of lesions with IVUS evaluation in the core IVUS laboratory	454	1592	
Proximal reference vessel area (mm^2)	15.5 ± 5.7 (n = 372)	16.2 ± 5.6 (n = 1312)	0.02
Proximal reference lumen area (mm^2)	8.0 ± 3.4 (n = 454)	8.4 ± 3.3 (n = 1592)	0.03
Minimum stent area (mm^2)	5.4 ± 1.8 (n = 454)	5.7 ± 2.1 (n = 1592)	<0.001
Distal reference vessel area (mm^2)	8.9 ± 4.4 (n = 436)	10.0 ± 5.2 (n = 1538)	<0.001
Distal reference lumen area (mm^2)	5.4 ± 2.2 (n = 454)	5.9 ± 2.7 (n = 1592)	<0.001
Thrombus or protrusion	60/454 (13.2)	201/1592 (12.6)	0.74
Incomplete stent apposition[c]	170/454 (37.4)	575/1592 (36.1)	0.60
Dissection	19/454 (4.2)	77/1592 (4.8)	0.56
Meeting OPTIVUS criteria	274/453 (60.5)	972/1591 (61.1)	0.82
Stent length ≥28 mm	145/263 (55.1)	519/965 (53.8)	0.70
Stent length <28 mm	129/190 (67.9)	453/626 (72.4)	0.23

Values are mean ± SD, n/N, or median (IQR). [a]PCI procedure success was defined as successful dilatation of target lesion with residual diameter stenosis <50%. [b]IVUS analyses were to be performed in all target lesions with stenting. [c]Incomplete stent apposition was defined as the presence of blood flow between stent struts and vessel wall.

FFR = fractional flow reserve; iFR = instantaneous wave-free ratio; IVUS = intravascular ultrasound; OPTIVUS = OPTimal IntraVascular UltraSound; PCI = percutaneous coronary intervention; TIMI = Thrombolysis In Myocardial Infarction.

TABLE 4 Clinical Outcomes

	Single-Session Multivessel PCI (n = 246)	Staged Multivessel PCI (n = 775)	Crude HR (95% CI)	*P* Value	Adjusted HR (95% CI)	*P* Value
	No. of Patients With Event (Cumulative Incidence, %)					
30-day outcomes						
Primary endpoint: A composite of death, myocardial infarction, stroke, or any coronary revascularization	2 (0.8)	8 (1.0)	0.79 (0.17-3.71)	0.76		
Secondary endpoints						
All-cause death	0 (0)	0 (0)	NA			
Cardiovascular death	0 (0)	0 (0)	NA			
Cardiac death	0 (0)	0 (0)	NA			
Sudden cardiac death	0 (0)	0 (0)	NA			
Noncardiovascular death	0 (0)	0 (0)	NA			
Myocardial infarction	2 (0.8)	6 (0.8)	1.05 (0.21-5.21)	0.95		
Spontaneous	0 (0)	0 (0)	NA			
Periprocedural	2 (0.8)	6 (0.8)	1.05 (0.21-5.21)	0.95		
Definite stent thrombosis	0 (0)	0 (0)	NA			
Stroke	0 (0)	0 (0)	NA			
Ischemic stroke	0 (0)	0 (0)	NA			
Hemorrhagic stroke	0 (0)	0 (0)	NA			
Major stroke[a]	0 (0)	0 (0)	NA			
Hospitalization for heart failure	1 (0.4)	0 (0)	NA			
Major bleeding						
BARC type 3, 4, or 5	3 (1.2)	4 (0.5)	2.37 (0.53-10.60)	0.26		
BARC type 3 or 5	3 (1.2)	4 (0.5)	2.37 (0.53-10.60)	0.26		
BARC type 5	0 (0)	0 (0)	NA			
Target-lesion revascularization	0 (0)	2 (0.3)	NA			
Clinically driven target-lesion revascularization	0 (0)	2 (0.3)	NA			
Target-vessel revascularization	0 (0)	2 (0.3)	NA			
Clinically driven target-vessel revascularization	0 (0)	2 (0.3)	NA			
Any coronary revascularization	0 (0)	2 (0.3)	NA			
Clinically driven any coronary revascularization	0 (0)	2 (0.3)	NA			
A composite of death, myocardial infarction, or stroke	2 (0.8)	6 (0.8)	1.05 (0.21-5.21)	0.95		
A composite of cardiovascular death, target-vessel myocardial infarction, or clinically driven target-lesion revascularization	2 (0.8)	8 (1.0)	0.79 (0.17-3.71)	0.76		

Continued on the next page

TABLE 4 Continued

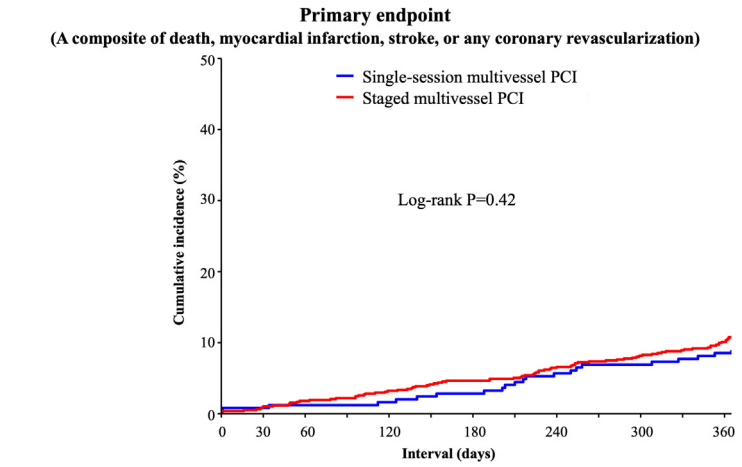
	Single-Session Multivessel PCI (n = 246)	Staged Multivessel PCI (n = 775)				
	No. of Patients With Event (Cumulative Incidence, %)		Crude HR (95% CI)	*P* Value	Adjusted HR (95% CI)	*P* Value
1-year outcomes						
Primary endpoint: A composite of death, myocardial infarction, stroke, or any coronary revascularization	22 (9.0)	83 (10.8)	0.82 (0.52-1.32)	0.42	0.95 (0.58-1.55)	0.84
Secondary endpoints						
All-cause death	5 (2.0)	17 (2.2)	0.92 (0.34-2.49)	0.87		
Cardiovascular death	1 (0.4)	8 (1.0)	0.39 (0.05-3.13)	0.38		
Cardiac death	1 (0.4)	6 (0.8)	0.52 (0.06-4.34)	0.55		
Sudden cardiac death	0 (0)	3 (0.4)	NA			
Noncardiovascular death	4 (1.6)	9 (1.2)	1.39 (0.43-4.51)	0.58		
Myocardial infarction	3 (1.2)	10 (1.3)	0.94 (0.26-3.43)	0.93		
Spontaneous	1 (0.4)	4 (0.5)	0.78 (0.09-6.98)	0.82		
Periprocedural	2 (0.8)	6 (0.8)	1.05 (0.21-5.21)	0.95		
Definite stent thrombosis	1 (0.4)	1 (0.1)	3.13 (0.20-49.98)	0.42		
Stroke	3 (1.2)	3 (0.4)	3.14 (0.63-15.57)	0.16		
Ischemic stroke	2 (0.8)	2 (0.3)	3.14 (0.44-22.30)	0.25		
Hemorrhagic stroke	1 (0.4)	1 (0.1)	3.13 (0.20-50.00)	0.42		
Major stroke[a]	2 (0.8)	3 (0.4)	2.09 (0.35-12.53)	0.42		
Hospitalization for heart failure	6 (2.5)	12 (1.6)	1.57 (0.59-4.19)	0.36		
Major bleeding						
BARC type 3, 4, or 5	13 (5.3)	23 (3.0)	1.79 (0.91-3.54)	0.09		
BARC type 3 or 5	12 (4.9)	23 (3.0)	1.65 (0.82-3.32)	0.16		
BARC type 5	0 (0)	0 (0)	NA			
Target-lesion revascularization	8 (3.3)	36 (4.7)	0.69 (0.32-1.49)	0.34		
Clinically driven target-lesion revascularization	8 (3.3)	35 (4.6)	0.71 (0.33-1.53)	0.38		
Target-vessel revascularization	10 (4.1)	51 (6.7)	0.61 (0.31-1.19)	0.15		
Clinically driven target-vessel revascularization	10 (4.1)	50 (6.6)	0.62 (0.31-1.22)	0.16		
Any coronary revascularization	14 (5.7)	57 (7.5)	0.76 (0.42-1.36)	0.36		
Clinically driven any coronary revascularization	14 (5.7)	56 (7.4)	0.77 (0.43-1.39)	0.39		
A composite of death, myocardial infarction, or stroke	11 (4.5)	30 (3.9)	1.15 (0.58-2.30)	0.69		
A composite of cardiovascular death, target-vessel myocardial infarction, or clinically driven target-lesion revascularization	10 (4.1)	51 (6.7)	0.61 (0.31-1.20)	0.15		

Values are n (%) unless otherwise indicated. Cumulative 30-day and 1-year incidences were estimated with Kaplan-Meier method. The effects of single-session multivessel PCI relative to staged multivessel PCI for the primary and secondary endpoints were expressed as HRs and their 95% CIs estimated by the Cox proportional hazard model. We constructed multivariable Cox proportional hazard model to assess the effect of single-session multivessel PCI relative to staged multivessel PCI for the primary endpoint at 1 year. The risk-adjusting variables were 11 clinically relevant factors listed in Table 1 and 2. Definitions of the endpoints are described in the Supplemental Appendix. [a]Major stroke was defined as modified Rankin scale ≥2.

BARC = bleeding academic research consortium; NA = not applicable; PCI = percutaneous coronary intervention.

clinical reasons for favoring staged PCI are as follows: 1) high contrast medium or radiation exposure; 2) lesion complexity such as calcified lesions requiring atherectomy device, chronic total occlusion, or complex bifurcation lesions; 3) unexpected long procedure time; 4) patient fatigue or agitation; and 5) procedural complications or patient instability.[1] Nonclinical reasons include operator fatigue, catheterization laboratory time schedule, and reimbursement (economic reasons).[1] In this study population reflecting contemporary real-world practice, lesion complexity might be one of the reasons to perform staged procedures, because the staged multivessel PCI group more often had 3-vessel disease, chronic total occlusion, and calcified lesions requiring atherectomy device compared with the single-session multivessel PCI group. In proportion to the high lesion complexity, total contrast medium volume was greater in the staged multivessel PCI group than in the single-session multivessel PCI group, although the contrast medium volume per procedure was lower in the staged multivessel PCI group than in the single-session multivessel PCI group. However, there was a wide variation in the prevalence of single-

FIGURE 3 **Kaplan-Meier Curve for the Primary Endpoint**



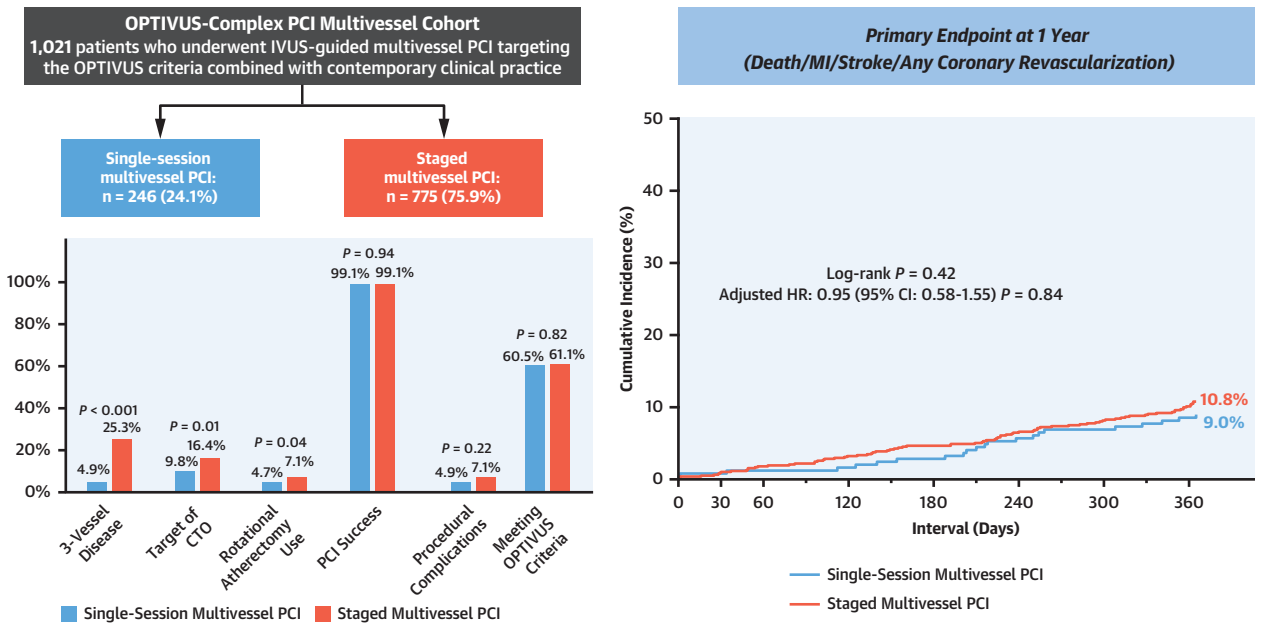
Interval	0	30	60	120	180	240	300	365
Single-session multivessel PCI								
Number of patients with event		2	3	4	7	14	17	22
Number of patients at risk	246	244	243	242	239	232	229	216
Cumulative incidence (%)		0.8	1.2	1.6	2.8	5.7	6.9	9.0
Staged multivessel PCI								
Number of patients with event		8	14	25	36	51	63	83
Number of patients at risk	775	767	760	748	737	721	707	670
Cumulative incidence (%)		1.0	1.8	3.2	4.7	6.6	8.2	10.8

The cumulative 1-year incidence was estimated with the Kaplan-Meier method, and the difference was compared with the log-rank test. The primary endpoint was a composite of death from any cause, myocardial infarction, stroke, or any coronary revascularization.
PCI = percutaneous coronary intervention.

session multivessel PCI across the participating centers, and staged PCI was the preferred strategy in a large proportion of centers. It might suggest the presence of the operator's or center's preference including nonclinical reasons on the choice of single-session or staged multivessel PCI in real-world practice. Indeed, the prevalence of chronic kidney disease was not different between single-session and staged multivessel PCI groups in this study, although chronic kidney disease could be one of the reasons to perform staged procedures aiming to reduce the risk of contrast-induced nephropathy.[1]

In the SMILE (Impact of Different Treatment in Multivessel Non ST Elevation Myocardial Infarction Patients: One Stage Versus Multistaged Percutaneous Coronary Intervention) trial, which was only 1 randomized controlled trial comparing single-session vs staged multivessel PCI in 584 patients without STEMI, the cumulative 1-year incidence of the major adverse cardiovascular and cerebrovascular events was significantly lower in the single-session multivessel PCI group than in the staged multivessel PCI group (13.63% vs 23.19%).[9] The difference was mainly driven by the lower incidence of target-vessel revascularization in the single-session multivessel PCI group compared with the staged multivessel PCI group (8.33% vs 15.20%), for which the authors could not provide adequate explanation. Unlike the SMILE trial, the cumulative 1-year incidences of the primary and secondary endpoints were not different between single-session and staged multivessel PCI groups in this study, although the mean age and SYNTAX score were almost similar in both studies. One of the possible explanations for the discordance might be low event rates in this study compared with those in the SMILE trial. The population in the OPTIVUS-Complex PCI study reflected contemporary PCI practice, such as using new-generation stents, physiology-guided lesion selection, optimal IVUS-guided PCI, refrainment of the scheduled follow-up coronary angiography, and high-intensity statins. The cumulative 1-year incidences of target-vessel revascularization were low in both single-session and staged multivessel PCI groups in this study (4.1% vs 6.7%). The strength of this study was that qualitative coronary angiography and IVUS analyses were performed in all target lesions. The rates of PCI success, procedural complications, and meeting OPTIVUS criteria were not different between patients who underwent

CENTRAL ILLUSTRATION **Single-Session vs Staged Multivessel Optimal IVUS-Guided PCI in Patients With Chronic Coronary Syndrome or Non-ST-Segment-Elevation Acute Coronary Syndrome**



Yamamoto K, et al. JACC: Asia. 2023;3(4):649–661.

Among patients without STEMI in the OPTIVUS-Complex PCI study multivessel cohort (1,021 patients undergoing multivessel PCI using IVUS aiming to meet the prespecified criteria for optimal stent expansion), the prevalence of patients undergoing single-session multivessel PCI was 24.1%, and there was a wide variation in the prevalence of single-session multivessel PCI across the participating centers. Patients undergoing staged multivessel PCI more often had 3-vessel disease, chronic total occlusion, and calcified lesions requiring atherectomy device compared with those undergoing single-session multivessel PCI. Single-session and staged multivessel PCI had similar 1-year outcomes. IVUS = intravascular ultrasound; MI = myocardial infarction; OPTIVUS = OPTimal IntraVascular UltraSound; PCI = percutaneous coronary intervention; STEMI = ST-segment-elevation myocardial infarction.

single-session and staged multivessel PCI in this study, suggesting that the procedural quality of PCI would not be affected regardless of single-session or staged multivessel PCI in contemporary PCI practice. The similar clinical outcomes of staged multivessel PCI despite higher coronary anatomic complexity compared with single-session multivessel PCI might have been brought about by contemporary IVUS-guided PCI practice. Considering the result of this study, single-session multivessel PCI would be a reasonable strategy because of avoidance of multiple procedures and less costly, although staged multivessel PCI might be an acceptable option if there are legitimate reasons.

STUDY LIMITATIONS. First, the observational study design precluded any definitive conclusions due to selection bias and confounders. Because we had no data on the reasons to perform the staged procedure, adjustment with baseline characteristics should be limited. Second, the number of enrolled patients was relatively small. Third, there were no data on total procedure time, radiation exposure, and incidence of contrast-induced nephropathy. Fourth, the present study population might represent selected low-risk patients for a clinical trial. In the Japanese nationwide PCI (J-PCI) registry, the in-hospital mortality rate was 3.9% in patients with non-STEMI and 0.1% to 0.5% in patients with chronic coronary syndrome, although the 30-day mortality rate was 0% in this study.[16,17]

CONCLUSIONS

Single-session and staged multivessel IVUS-guided PCI had similar 1-year outcomes.

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PERSPECTIVES

COMPETENCY IN MEDICAL KNOWLEDGE: We compared single-session vs staged multivessel IVUS-guided PCI in patients without STEMI using the OPTIVUS-Complex PCI study multivessel cohort (1,021 patients undergoing multivessel PCI using IVUS aiming to meet the prespecified criteria for optimal stent expansion). The prevalence of patients undergoing single-session multivessel PCI was 24.1%, and there was a wide variation in the prevalence of single-session multivessel PCI across the participating centers. Patients undergoing staged multivessel PCI more often had 3-vessel disease, chronic total occlusion, and calcified lesions requiring atherectomy device compared with those undergoing single-session multivessel PCI. Single-session and staged multivessel PCI had similar 1-year outcomes.

TRANSLATIONAL OUTLOOK: Considering the result of this study, single-session multivessel PCI would be a reasonable strategy because of avoidance of multiple procedures and less costly, although staged multivessel PCI might be an acceptable option if there are legitimate reasons. Randomized controlled trials are needed to obtain the definitive answer.

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APPENDIX For supplemental material, figures, and tables, please see the online version of this paper.