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CORONARY

Proportion and Clinical Impact of Stent Optimization During Imaging-Guided Percutaneous Coronary Intervention

The OCTIVUS Trial

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ABSTRACT

BACKGROUND Data regarding the proportion and clinical impact of achieving stent optimization by intravascular ultrasound (IVUS)– or optical coherence tomography (OCT)–guided percutaneous coronary intervention (PCI) remain limited.

OBJECTIVES The authors assessed the proportion and cardiovascular outcomes in patients with and without stent optimization using imaging guidance.

METHODS This secondary analysis of the OCTIVUS (Optical Coherence Tomography-Guided or Intravascular Ultrasound-Guided Percutaneous Coronary Intervention) trial classified patients into optimized (meeting all prespecified optimization criteria) or nonoptimized groups. The primary endpoint was target vessel failure (TVF), a composite of cardiac death, target vessel myocardial infarction, or ischemia-driven target vessel revascularization.

RESULTS Among 1,980 patients, 1,022 (51.6%) achieved stent optimization, with a lower proportion in the OCT-guided group than in the IVUS-guided group (467 of 967 [48.3%] vs 555 of 1,013 [54.8%]; $P = 0.004$). At a median follow-up of 2.0 years, TVF incidence was lower in the optimized group than in the nonoptimized group (39 of 1022 [3.8%] vs 72 of 958 [7.5%]; HR: 0.52; 95% CI: 0.35-0.77; $P < 0.001$). The effect of stent optimization on TVF appeared more substantial in OCT-guided PCI (14 of 467 [3.0%] vs 38 of 500 [7.6%]; HR: 0.39; 95% CI: 0.21-0.72) than in IVUS-guided PCI (25 of 555 [4.5%] vs 34 of 458 [7.4%]; HR: 0.63; 95% CI: 0.37-1.05), albeit there was no significant interaction between TVF and imaging modalities (P for interaction = 0.30).

CONCLUSIONS Stent optimization was achieved in approximately one-half of patients undergoing imaging-guided PCI and was associated with a better clinical outcome. This effect appeared more pronounced in OCT-guided than in IVUS-guided PCI. (Optical Coherence Tomography Versus Intravascular Ultrasound Guided Percutaneous Coronary Intervention [OCTIVUS]; NCT03394079) (JACC Cardiovasc Interv. 2025;18:1089–1099) © 2025 by the American College of Cardiology Foundation.

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ABBREVIATIONS AND ACRONYMS

CAD = coronary artery disease

DES = drug-eluting stent(s)

IVUS = intravascular ultrasound

MI = myocardial infarction

MSA = minimum stent area

OCT = optical coherence tomography

PCI = percutaneous coronary intervention

QCA = quantitative coronary angiography

TVF = target vessel failure

The widespread adoption of drug-eluting stents (DES) and advances in intravascular imaging modalities, such as intravascular ultrasonography (IVUS) or optical coherence tomography (OCT), have improved cardiovascular outcomes in patients undergoing percutaneous coronary intervention (PCI).[1] This technique using intravascular imaging can guide PCI procedures by allowing an accurate characterization of plaque morphology, providing detailed vessel and stent dimension measurements and minimizing stent-related problems.[2] Several randomized controlled trials and meta-analyses have shown strong evidence supporting intravascular imaging-guided PCI over angiography-guided PCI.[3-10]

For imaging-guided PCI, most previous trials have proposed diverse optimization criteria to optimize PCI using different imaging modalities and achieved stent optimization was associated with better clinical outcomes.[3-6,11,12] Nonetheless, among previous trials using the same intravascular imaging modality,[6,11] conflicting results regarding the clinical effectiveness of imaging-guided PCI have been reported. Although the exact reasons for such discrepant findings remain unclear, it might be partly explained by the nonuniform optimization criteria, completeness of stent optimization, and the clinical impact.

To address this knowledge gap, we used contemporary data from the OCTIVUS (Optical Coherence Tomography-Guided or Intravascular Ultrasound-Guided Percutaneous Coronary Intervention) study, a randomized trial comparing OCT and IVUS for PCI guidance among patients with diverse anatomical or clinical characteristics.[12] We assessed the proportion and predictors of stent optimization with imaging-guided PCI. Most importantly, we assessed whether the risk of cardiovascular outcomes differed in patients with and without stent optimization who received imaging-guided PCI with OCT or IVUS.

METHODS

STUDY DESIGN AND PATIENT POPULATION. The trial design, methods, and primary results of the OCTIVUS (Optical Coherence Tomography versus Intravascular Ultrasound-Guided Percutaneous Coronary Intervention) trial have been previously reported.[12,13] In brief, the OCTIVUS trial was an investigator-initiated, randomized, open-label trial, in which 2,008 patients with significant coronary artery disease (CAD) who were undergoing PCI were randomly assigned, in a 1:1 ratio, to undergo either OCT-guided PCI (n = 1,005) or IVUS-guided PCI (n = 1,003). The trial was approved by the Investigational Review Board or Ethics Committee of each participating center. All patients provided written informed consent before enrollment.

Patients 19 years of age or older who were undergoing PCI with contemporary DES or drug-coated balloons (only for in-stent restenosis) for diverse coronary artery lesions were enrolled. To reflect the pragmatic features of a trial design including a large "all-comer" population of patients, the exclusion criteria were minimal: patients with ST-segment elevation myocardial infarction (MI); those with severe renal dysfunction (estimated glomerular filtration rate <30 mL/min/1.73 m^2); those with unstable hemodynamics or decompensated heart failure (ejection fraction < 30%); those with severely calcified or tortuous lesions, not allowing delivery of intracoronary imaging catheter; or those who cannot be safely randomized to either arm.

IMAGING-GUIDED PCI. PCI was performed using standard techniques. Lesion preparation using a balloon catheter, atherectomy, or other devices, and the choice of the specific DES was left to the discretion of the operators. In each group, either IVUS with a rotational transducer (OPTICROSS or OPTICROSS HD; Boston Scientific) or OCT (C7-XR and OPTIS; Abbott) was used before, during, and immediately

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after stent implantation. A final intracoronary imaging evaluation after PCI was mandated after stent implantation to determine whether the stented segment was sufficiently optimized. Standard protocols for image acquisition were used with the IVUS or OCT.[14,15]

Procedural anticoagulation was achieved with unfractionated heparin according to the local site protocols. After PCI, all patients were prescribed lifelong aspirin, and a $P2Y_{12}$ inhibitor (clopidogrel, prasugrel, or ticagrelor) was prescribed for at least 6 to 12 months at the physician's discretion, according to the clinical indication and procedural complexity.

STENT OPTIMIZATION CRITERIA. Most participating centers were experienced in the use of intravascular imaging for PCI guidance. At the time of the index PCI procedures, immediate PCI optimization by intracoronary imaging was conducted by investigators at each participating center. Stent size, length, and stented segment optimization were determined using a prespecified algorithm for IVUS- or OCT-guided PCI based on expert consensus,[16] which is the most commonly adopted PCI optimization criteria. Detailed information on imaging-guided PCI optimization criteria are described in the Supplemental Appendix (section A). Briefly, a distal lumen or external elastic membrane reference-based stent sizing strategy was used to achieve a sufficient stent expansion of >80% of the mean reference lumen area. In lesions (non-left main lesions) with non-evaluable reference lumen area, optimal stent expansion was defined as an absolute in-stent minimum stent area (MSA) of >5.5 mm^2 by IVUS and >4.5 mm^2 by OCT. Stent implantation at a landing zone with a plaque burden >50% and a particularly lipid-rich tissue at the stent edge were avoided. Extensive malapposition after stent implantation and large dissection should be avoided and corrected. If imaging criteria for optimization were not met, additional procedures with a high-pressure balloon or additional stent implantation were performed according to the operators' discretion. A repeated intravascular imaging evaluation for final PCI optimization should be mandated.[12,17]

After completion of the PCI procedure, all measurements of quantitative coronary angiography (QCA) and intravascular imaging data were performed by the independent angiographic and imaging core laboratories at the Asan Medical Center.[12] According to the core laboratory-measured stent optimization criteria, the study participants were classified into the optimized group (if they met all the stent optimization criteria) or nonoptimized group (if they did not meet at least 1 of the optimization criteria).

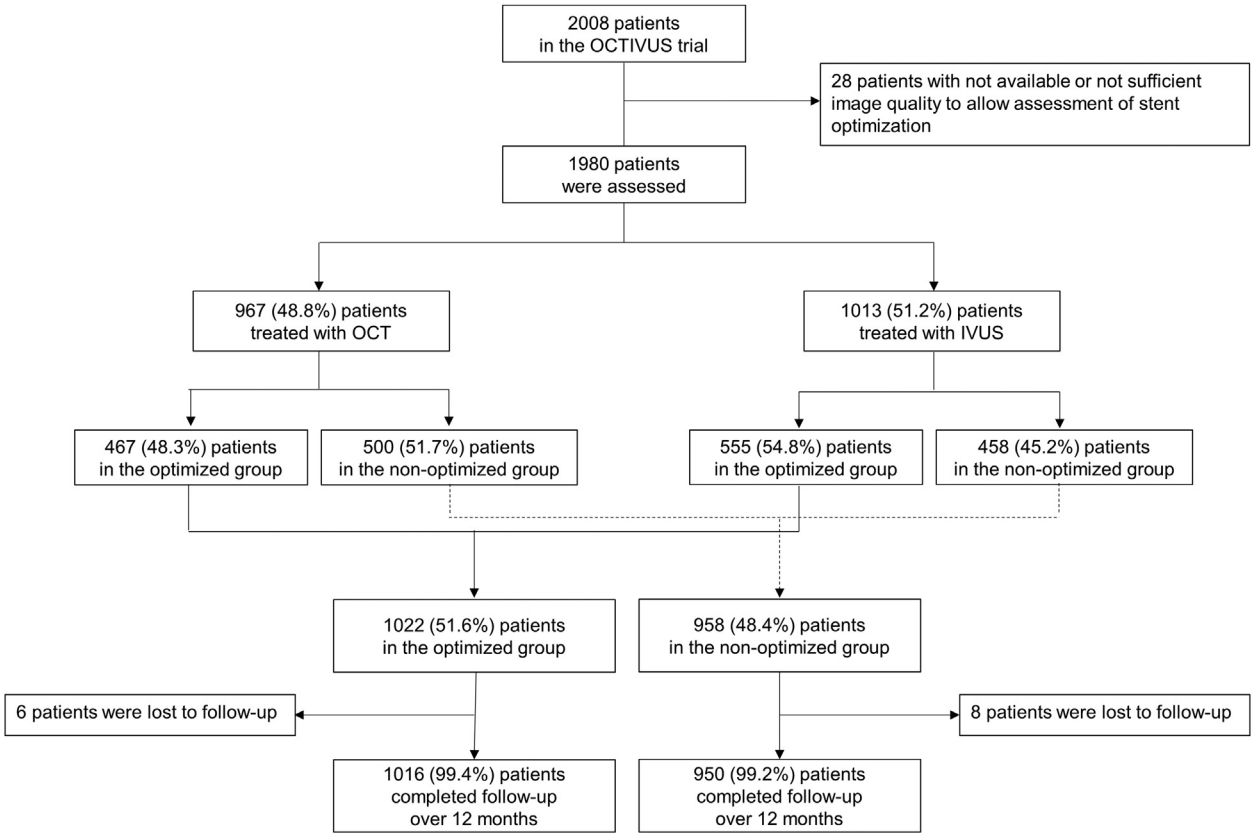
STUDY ENDPOINTS AND FOLLOW-UP. The primary endpoint of the OCTIVUS trial was target vessel failure (TVF), which was defined as a composite of death from cardiac causes, target vessel-related MI, or ischemia-driven target vessel revascularization. Secondary endpoints included individual components of the primary endpoint, target lesion failure (a composite of death from cardiac causes, target vessel MI, or ischemia-driven target lesion revascularization), stent thrombosis, stroke, repeat revascularization, rehospitalization, bleeding events, contrast-induced acute kidney injury, procedural complications requiring active interventions that were related to PCI or intravascular imaging (ie, procedural safety outcomes), and angiographic or imaging-based device success. Definitions of clinical endpoints are summarized in the Supplemental Appendix (section B). All components of clinical endpoints were independently adjudicated by a clinical events committee.

Follow-up was performed at hospital discharge; at 1, 6, and 12 months; and yearly thereafter. During follow-up, guideline-directed medical therapy and management of risk factors for intensive secondary prevention according to contemporary clinical guidelines were highly recommended. At each visit, all information regarding clinical events and cardiovascular medications were systematically collected. Survival status was reconfirmed through the national death registry of the Korean National Health Insurance Service database.[18]

STATISTICAL ANALYSIS. Main analyses were performed in the as-treated population (Figure 1). Summary statistics are presented as percentages for categorical variables and as mean ± SD for continuous variables. Baseline characteristics, procedural data, and imaging characteristics were compared between the optimized and nonoptimized groups using the Student's *t*-test for continuous variables and chi-square or Fisher exact test for categorical variables, as appropriate.

Cumulative-event probabilities were estimated using Kaplan-Meier methods and were compared with the log-rank test. In time-to-first-event analyses, HRs and 95% CIs were calculated using crude and multivariable Cox proportional hazards models. In the adjusted Cox models, clinically relevant variables were included, such as age, sex, body mass index, diabetes, hypertension, dyslipidemia, smoking, family history of premature CAD, previous MI, previous

FIGURE 1 Study Flow Diagram



Study flow diagram of patients stratified by stent optimization status. IVUS = intravascular ultrasound; OCT = optical coherence tomography; OCTIVUS = Optical Coherence Tomography-Guided or Intravascular Ultrasound-Guided Percutaneous Coronary Intervention.

PCI or coronary artery bypass grafting, previous stroke, congestive heart failure, chronic pulmonary disease, peripheral vascular disease, atrial fibrillation, end-stage renal disease, and left ventricular ejection fraction. The proportional hazards assumption was evaluated with a 2-sided score test of the scaled Schoenfeld residuals at the 0.05 level.[19]

To determine the predictors of core laboratory-measured stent optimization, univariable and multivariable logistic regression analyses were performed. Among clinical, angiographic, and procedural factors, variables for the multivariable model were selected based on their clinical relevance, informed by existing literature and biological plausibility.[20] Correlations between variables have been expressed as ORs with 95% CIs. All the models were adjusted for participating center (stratification factors). All reported P values were 2-sided, and $P < 0.05$ was considered significant for all tests. The 95% CIs for secondary outcomes were not adjusted for multiple comparisons, and therefore the intervals should not be used to infer definitive treatment effects. All statistical analyses were performed using SAS software version 9.4 (SAS Institute) and R software version 4.0 (R Foundation for Statistical Computing).

RESULTS

STUDY POPULATION AND BASELINE CHARACTERISTICS. Of the 2,008 randomized patients enrolled in the OCTIVUS trial, 28 patients who did not have sufficient image quality to allow assessment of final stent optimization at the central core laboratory were excluded. Therefore, 1,980 patients with valid information on stent optimization were included in the final study population (Figure 1). Among them, 967 (48.8%) patients underwent OCT-guided PCI, whereas 1,013 (51.2%) underwent IVUS-guided PCI. Of the 967 patients who underwent OCT-guided PCI, 467 (48.3%) achieved all stent optimization criteria,

whereas 500 (51.7%) did not. Of the 1,013 patients who underwent IVUS-guided PCI, 555 (54.8%) met all optimization criteria, whereas 458 (45.2%) did not. Overall, 1,022 (51.6%) patients were classified into the optimized group and 958 (48.4%) into the nonoptimized group. Each component of the stent optimization criteria in the overall group, OCT-guided group, and IVUS-guided group is shown in Supplemental Table 1. Among these criteria, not achieving optimal stent expansion was the most common mechanistic criterion in the nonoptimized group. Also, a higher detection of major stent malapposition and large dissection by OCT may contribute to the lower rate of stent optimization achieved in the OCT-guided group.

The baseline characteristics of patients in the optimized and nonoptimized groups are summarized in **Table 1**. Compared with patients in the optimized group, those in the nonoptimized group were older and more likely to have higher-risk comorbidities or risk factors (diabetes, previous MI, previous PCI, previous coronary artery bypass grafting, peripheral vascular disease, and end-stage renal disease). This pattern was similar in each group of OCT- and IVUS-guided PCI (Supplemental Table 2).

TABLE 1 Baseline Characteristics of the Patients According to Stent Optimization Status

	Overall (N = 1,980)	Optimized (n = 1,022)	Nonoptimized (n = 958)	*P* Value
Age, y	64.7 ± 10.4	64.1 ± 10.5	65.1 ± 10.5	0.006
Female	426 (21.5)	214 (20.9)	212 (22.1)	0.52
Body mass index, kg/m^2	25.0 ± 3.1	25.0 ± 3.1	25.0 ± 3.1	0.783
Diabetes mellitus	656 (33.1)	311 (30.4)	345 (36.0)	0.008
Insulin-treated diabetes mellitus	65 (3.3)	22 (2.2)	43 (4.5)	0.004
Hypertension	1,265 (63.9)	640 (62.6)	625 (65.2)	0.226
Dyslipidemia	1,660 (83.8)	846 (82.8)	814 (85.0)	0.186
Current smoking	398 (20.1)	198 (19.4)	200 (20.9)	0.404
Family history of premature CAD[a]	108 (5.5)	52 (5.1)	56 (5.8)	0.458
Previous myocardial infarction	138 (7.0)	49 (4.8)	89 (9.3)	<0.001
Previous PCI	420 (21.2)	173 (16.9)	247 (25.8)	<0.001
Previous CABG	51 (2.6)	18 (1.8)	33 (3.4)	0.018
Previous stroke	135 (6.8)	59 (5.8)	76 (7.9)	0.057
Congestive heart failure	44 (2.2)	19 (1.9)	25 (2.6)	0.258
Chronic pulmonary disease	54 (2.7)	24 (2.3)	30 (3.1)	0.285
Peripheral vascular disease	59 (3.0)	20 (2.0)	39 (4.1)	0.006
Atrial fibrillation	65 (3.3)	33 (3.2)	32 (3.3)	0.89
End-stage renal disease on dialysis	44 (2.2)	14 (1.4)	30 (3.1)	0.008
Left ventricular ejection fraction, %	60.4 ± 7.2	60.5 ± 6.9	60.2 ± 7.6	0.381
Clinical indication for index PCI				0.197
Silent ischemia	218 (11.0)	114 (11.2)	104 (10.9)	
Chronic coronary syndrome	1,305 (65.9)	677 (66.2)	628 (65.6)	
Unstable angina	265 (13.4)	145 (14.2)	120 (12.5)	
NSTEMI	192 (9.7)	86 (8.4)	106 (11.1)	

Values are mean ± SD or n (%). Percentages may not total 100 because of rounding. [a]A family history of premature CAD was defined as diagnosis of the disease in a male first-degree relative before 55 years of age or in a female first-degree relative before 65 years of age.

CABG = coronary artery bypass grafting; CAD = coronary artery disease; IVUS = intravascular ultrasound; NSTEMI = non-ST-segment elevation myocardial infarction; OCT = optical coherence tomography; PCI = percutaneous coronary intervention.

ANATOMICAL AND PROCEDURAL CHARACTERISTICS. Anatomical and procedural characteristics of patients according to the stent optimization status are presented in **Table 2**. Compared with patients in the optimized group, those in the nonoptimized group showed a higher risk of anatomical and procedural complexity. The mean SYNTAX (Synergy between Percutaneous Coronary Intervention with Taxus and Cardiac Surgery) score was higher in the nonoptimized group than in the optimized group; thus, the total number of treated lesions, number and length of used stents, total amount of contrast dye, and total PCI time were substantially higher in the nonoptimized group. In contrast, no significant differences were observed in the use of high-pressure postdilation and in the rate of procedural complications necessitating active intervention between the optimized and nonoptimized groups. By lesion-level analyses, the proportion of lesion preparation before stenting was higher and the maximum balloon size was larger in the nonoptimized group than in the optimized group (Supplemental Table 3).

Core laboratory-measured QCA and intravascular imaging data are shown in Supplemental Tables 4 and 5, respectively. By QCA analyses, moderate or severe calcification at baseline was more frequent, lesion length was longer, and post-PCI minimal lumen diameter was smaller in the nonoptimized group than in the optimized group. By imaging analysis, the maximum calcium degree was greater and calcium nodules were more frequent in the nonoptimized group than in the optimized group. The degree of stent expansion was commonly smaller in the nonoptimized group than in the optimized group.

CLINICAL OUTCOMES ACCORDING TO STENT OPTIMIZATION. During the entire follow-up period (median 2.0 years [Q1-Q3: 1.1-2.3 years]), ascertainment of the primary and secondary outcomes was completed in 99.4% (n = 1,016 of 1,022) of patients in the optimized group and in 99.2% (n = 950 of 958) in the nonoptimized group, and data on vital status were obtained for all patients (**Figure 1**). Cardioactive

TABLE 2 Anatomical and Procedural Characteristics According to Stent Optimization Status

	Optimized (n = 1,022)	Nonoptimized (n = 958)	*P* Value
Anatomical or lesion characteristics			
Multivessel disease	543 (53.1)	672 (70.1)	<0.001
No. of diseased vessels			<0.001
1	479 (46.9)	286 (29.9)	
2	339 (33.2)	345 (36.0)	
3	204 (20.0)	327 (34.1)	
Treated complex coronary lesions			
Left main disease	75 (7.3)	181 (18.9)	<0.001
Any bifurcation disease	503 (49.2)	541 (56.5)	0.001
Ostial lesion	60 (5.9)	132 (13.8)	<0.001
Chronic total occlusion	43 (4.2)	63 (6.6)	0.019
Severely calcified lesion[a]	51 (5.0)	97 (10.1)	<0.001
In-stent restenotic lesion	51 (5.0)	108 (11.3)	<0.001
Diffuse long lesion[b]	498 (48.7)	660 (68.9)	<0.001
Bypass graft disease	1 (0.1)	2 (0.2)	0.526
SYNTAX score[c]	13.2 ± 8.1	17.9 ± 9.8	<0.001
Category			<0.001
Low, 0-22	884 (86.5)	679 (70.9)	
Intermediate, 23-32	111 (10.9)	201 (21.0)	
High, >32	27 (2.6)	78 (8.1)	
Procedural characteristics			
Imaging modality			0.004
OCT	467 (45.7)	500 (52.2)	
IVUS	555 (54.3)	458 (47.8)	
PCI approach			<0.001
Radial access	733 (71.7)	537 (56.1)	
Femoral access	289 (28.3)	421 (43.9)	
PCI modality			<0.001
Use of drug-eluting stents	1,007 (98.5)	914 (95.4)	
Use of drug-coated balloons (only for in-stent restenotic lesions)	15 (1.5)	44 (4.6)	
Total no. of lesions treated per patient	1.22 ± 0.53	1.48 ± 0.70	<0.001
Mean number of stents per patient	1.40 ± 0.80	1.87 ± 1.17	<0.001
Total stent length per patient, mm	38.7 ± 25.4	57.4 ± 35.9	<0.001
Post dilatation with larger balloon or high-pressure balloon use[d]	952 (93.2)	876 (91.4)	0.153
Total amount of contrast media used, mL	198.5 ± 96.8	240.7 ± 124.5	<0.001
Total PCI time, min	42.7 ± 22.6	52.6 ± 25.2	<0.001
Procedural success			
Angiography based[e]	1,015 (99.3)	940 (98.1)	0.017
Procedural complications requiring active intervention[f]			
Any	25 (2.4)	33 (3.4)	0.188

Values are n (%) or mean ± SD. Percentages may not total 100 because of rounding. [a]Severely calcified lesions were those with encircling calcium seen on angiography. [b]Diffuse long coronary artery lesion was defined as lesion length ≥28 mm or stent length ≥32 mm of the treated segment. [c]The SYNTAX score reflects a comprehensive angiographic assessment of the coronary vasculature. A higher score denotes higher anatomical complexity. Scores were calculated by the core laboratory. [d]Additional poststent larger balloon or high-pressure balloon was used to resolve incomplete stent expansion or incomplete stent apposition. [e]Angiographic device success is defined as successful PCI at the intended target lesion with final in-stent residual stenosis of <30% by quantitative coronary angiography. [f]Procedural complications (eg, major dissection, coronary perforation, vasospasm, thrombus formation, air embolization, slow flow or no reflow, distal embolization, acute closure, ventricular arrhythmia, cardiac tamponade, or cardiogenic shock) requiring active intervention (prolonged balloon inflations, additional stenting required, thrombus aspiration, pericardiocentesis, cardioversion, or use of mechanical circulatory support devices) that were related to PCI or use of intravascular imaging.

SYNTAX = Synergy between Percutaneous Coronary Intervention with Taxus and Cardiac Surgery; other abbreviations as in Table 1.

medication use at baseline and during follow-up were mostly similar in the optimized and nonoptimized groups (Supplemental Table 6).

The primary and secondary endpoints of patients between the optimized and nonoptimized groups are summarized in Table 3. Over the entire follow-up period, the incidence of the primary outcome of TVF was significantly lower in the optimized group than in the nonoptimized group (n = 39 of 1,022 [3.8%] vs 72 of 958 [7.5%]; HR: 0.52; 95% CI: 0.35-0.77; $P < 0.001$) (Figure 2). The incidences of target lesion failure and repeat revascularization were also significantly lower in the optimized group than in the nonoptimized group. These findings were consistent after adjustment of clinically relevant covariates (Table 3).

When we assessed outcomes by each imaging modality, the lower risk of TVF event associated with stent optimization was consistent in OCT- and IVUS-guided PCI (Figure 2, Supplemental Table 7). The effect of stent optimization on TVF was graphically substantial in the OCT-guided PCI group (HR: 0.39; 95% CI: 0.21-0.72) than in the IVUS-guided PCI group (HR: 0.63; 95% CI: 0.37-1.05). However, there was no significant interaction between the target vessel revascularization rates and two imaging modalities (P for interaction = 0.30). The risk of TVF according to each component of the imaging-guided optimization criteria in the overall imaging-guided group, OCT-guided group, and IVUS-guided group are shown in Supplemental Figures 1, 2, and 3. Stent expansion and less plaque burden (<50%) at the stent landing zone were significant discriminators for the primary outcome in the OCT-guided group, whereas less plaque burden (<50%) and malapposition at the landing zone were significant discriminators for the primary outcome in the IVUS-guided group. The TVF events according to different criteria of optimal stent expansion in the overall imaging, OCT, and IVUS groups are presented in Supplemental Figures 4, 5, and 6. The relationship between various stent expansion criteria and primary outcome events was different between the OCT- and IVUS-guided groups.

INDEPENDENT PREDICTORS OF STENT OPTIMIZATION. Univariable and multivariable analyses for determining important predictors of stent optimization are summarized in Table 4. In univariable analysis, older age, diabetes, a history of previous MI or PCI, multivessel disease, left main disease, bifurcation disease, ostial lesion, chronic total occlusion, severely calcified lesion, in-stent restenotic lesion, diffuse long lesion, a higher SYNTAX score, longer total stent

TABLE 3 Primary and Secondary Endpoints According to Stent Optimization Status

	Optimized (n = 1,022)	Nonoptimized (n = 958)	HR (95% CI)	*P* Value	Adjusted HR (95% CI)[a]	*P* Value
Primary endpoint						
Target vessel failure (a composite of death from cardiac causes, target vessel MI, or ischemia-driven TVR)	39 (3.8)	72 (7.5)	0.52 (0.35-0.77)	<0.001	0.58 (0.37-0.92)	0.019
Secondary endpoints						
Target-lesion failure[b]	34 (3.3)	64 (6.7)	0.51 (0.33-0.77)	0.001	0.58 (0.36-0.93)	0.023
Death						
From any causes	21 (2.1)	31 (3.2)	0.65 (0.37-1.13)	0.125	0.89 (0.47-1.68)	0.716
From cardiac causes	9 (0.9)	11 (1.1)	0.84 (0.34-2.07)	0.705	1.05 (0.37-2.94)	0.931
From noncardiac causes	12 (1.2)	20 (2.1)	0.55 (0.27-1.13)	0.102	0.79 (0.35-1.79)	0.575
Target vessel MI[c]	10 (1.0)	15 (1.6)	0.62 (0.28-1.39)	0.246	0.69 (0.28-1.68)	0.409
Any MI	11 (1.1)	16 (1.7)	0.64 (0.30-1.38)	0.258	0.72 (0.31-1.67)	0.442
Periprocedural	8 (0.8)	8 (0.8)	0.94 (0.35-2.5)	0.897	0.99 (0.34-2.89)	0.985
Spontaneous	3 (0.3)	8 (0.8)	0.35 (0.09-1.31)	0.120	0.41 (0.08-2.11)	0.288
Stent thrombosis[d]	1 (0.1)	1 (0.1)	0.94 (0.06-14.97)	0.963	NC	0.999
Stroke	7 (0.7)	10 (1.0)	0.65 (0.25-1.72)	0.389	0.74 (0.26-2.14)	0.584
Any repeat revascularization	34 (3.3)	62 (6.5)	0.52 (0.34-0.79)	0.002	0.52 (0.32-0.85)	0.009
TLR	17 (1.7)	42 (4.4)	0.38 (0.22-0.67)	<0.001	0.42 (0.22-0.81)	0.009
TVR	22 (2.2)	50 (5.2)	0.42 (0.25-0.69)	<0.001	0.45 (0.25-0.82)	0.009
Re-hospitalization	148 (14.5)	173 (18.1)	0.8 (0.65-1.00)	0.052	0.84 (0.66-1.08)	0.174
Bleeding event, BARC type 3-5[e]	13 (1.3)	17 (1.8)	0.71 (0.35-1.47)	0.356	0.89 (0.47-1.68)	0.716
Contrast-induced nephropathy[f]	11 (1.1)	17 (1.8)	0.60 (0.28-1.29)	0.193	0.72 (0.31-1.68)	0.451

Clinical endpoints were evaluated during the entire follow-up period (ie, from time of randomization to the day of the first occurrence of a primary endpoint event, the day of the last office or telephone visit, or the day of death during follow-up). The listed percentages were estimated as the ratio of the numerator and denominator. HRs are for the optimized group, as compared with the nonoptimized group. Because CIs for secondary outcomes have not been adjusted for multiple comparisons, inferences drawn from these intervals may not be reproducible and should not be used to infer definitive treatment effects for secondary endpoints. [a]In the adjusted Cox models, clinically relevant variables were included, such as age, sex, body mass index, diabetes, hypertension, dyslipidemia, smoking, family history of premature coronary artery disease, previous MI, previous PCI or coronary artery bypass grafting, previous stroke, congestive heart failure, chronic pulmonary disease, peripheral vascular disease, atrial fibrillation, end-stage renal disease, and left ventricular ejection fraction. [b]Target lesion failure was a composite of death from cardiac causes, target vessel MI, or ischemia-driven target lesion revascularization. [c]MI was assessed according to the protocol definition. [d]Stent thrombosis was defined as definite or probable stent thrombosis according to the Academic Research Consortium.[18] [e]Bleeding events were assessed according to the BARC criteria.[19] BARC type 3 to 5 indicates severe bleeding. [f]Contrast-induced nephropathy was defined as either a >25% increase in serum creatinine or an absolute increase in serum creatinine of 0.5 mg/dL from baseline within 72 hours after the index PCI procedure. Event rates of contrast-induced nephropathy are presented as calculated percentages.

BARC = Bleeding Academic Research Consortium; MI = myocardial infarction; NC = not calculated; TLR = target lesion revascularization; TVR = target vessel revascularization.

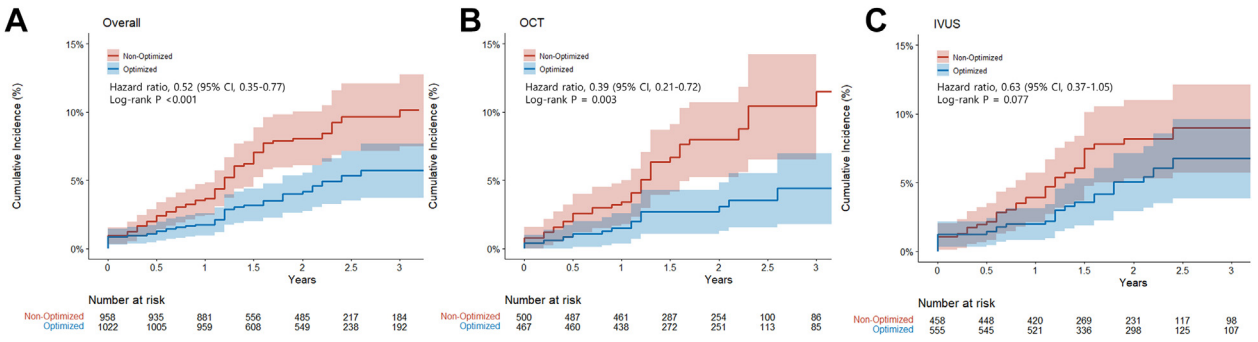
length, performing lesion preparation, and a larger maximum balloon size were negatively associated with achieving stent optimization. Conversely, performing adjunct postdilation was positively associated with achieving stent optimization. In the multivariable-adjusted model, previous MI, left main disease, a higher SYNTAX score, total stent length, lesion preparation, and a maximum balloon size were independent predictors for not achieving stent optimization.

DISCUSSION

In this detailed analysis of the OCTIVUS trial, we evaluated the proportion of achieved stent optimization and its clinical impact in patients who underwent imaging-guided PCI (with either OCT or IVUS). The major findings can be summarized as the following (**Central Illustration**): 1) despite the operators' efforts to achieve stent optimization during imaging-guided PCI, only one-half of the patients finally achieved stent optimization; 2) the proportion that achieved stent optimization was lower in the OCT-guided PCI group than in the IVUS-guided PCI group; 3) stent optimization was significantly associated with a lower risk of TVF, and the effect of stent optimization appeared more pronounced in OCT-guided PCI than in IVUS-guided PCI, albeit there was no significant interaction between TVF and 2 imaging modalities; and 4) several clinical, anatomical, and procedural factors were found as the independent predictors of stent optimization.

Based on cumulative clinical evidence[3-10] and guideline recommendation,[21-23] the use of imaging-guided PCI has substantially increased, especially for complex CAD lesions. In general, stent optimization was defined as sufficient stent expansion without major stent malapposition to the vessel wall or large edge dissection. However, there had been a challenge of the lack of a uniform definition of stent

FIGURE 2 Time-to-Event Curves for the Primary Endpoint According to Stent Optimization Status



Kaplan-Meier curves of the cumulative incidence of the primary endpoint of target vessel failure in the (A) overall, (B) OCT, and (C) IVUS groups are shown. The HR is for the optimized group as compared with the nonoptimized group. Abbreviations as in Figure 1.

optimization with respect to the optimal stent expansion (absolute or relative), the optimal landing zone, and the degree of malapposition or edge dissection. Although several previous studies assessed the impact of each component of stent optimization on acute procedural results or long-term clinical outcomes,[3,4,20,24-27] the recommended optimization criteria and their application pattern were substantially variable. Until recently, no large-scale studies had evaluated the clinical impact of meeting all the stent optimization criteria or failing to meet at least 1 of these common criteria. In the clinical context, the current study can provide more comprehensive understanding of the proportion and mechanism of stent optimization and its clinical impact in contemporary imaging-guided PCI with OCT and IVUS.

TABLE 4 Multivariable Analyses for Not Achieving Stent Optimization Criteria

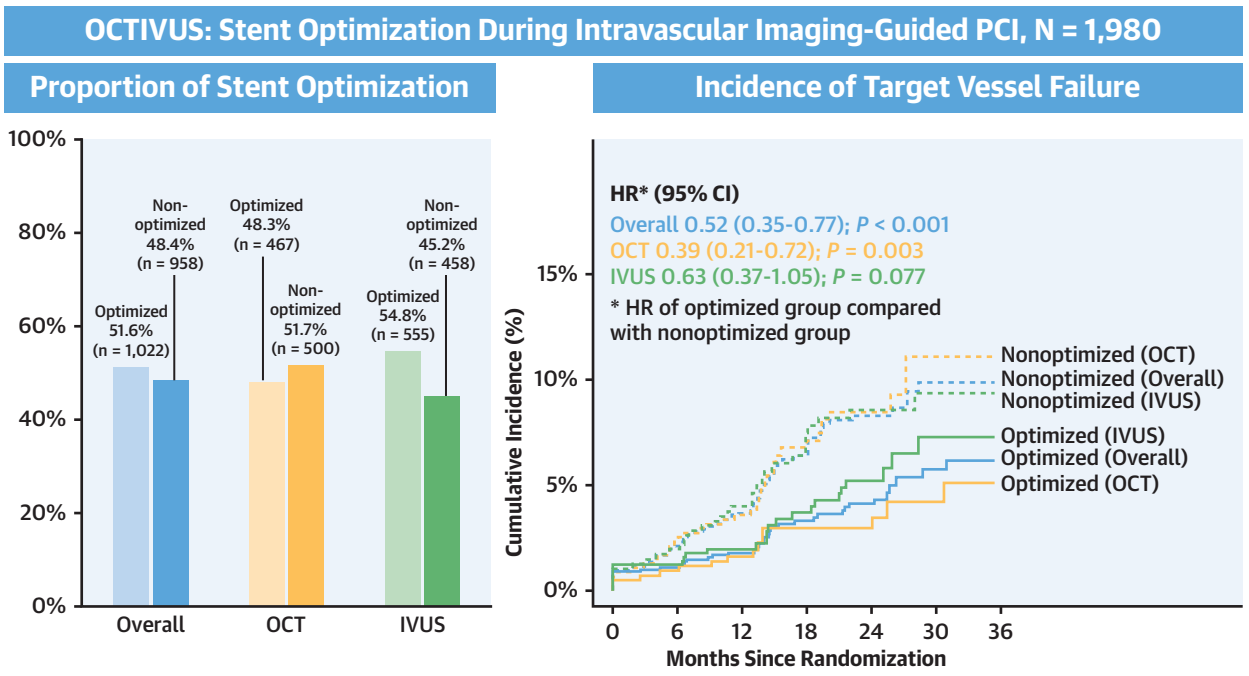
	Univariable Analysis		Multivariable Analysis	
	OR (95% CI)	*P* Value	OR (95% CI)	*P* Value
Age	0.99 (0.98-1.00)	0.007	1.00 (0.99-1.01)	0.753
Male	0.98 (0.81-1.20)	0.867		
Diabetes mellitus	1.31 (1.10-1.55)	0.002	1.11 (0.91-1.35)	0.293
Hypertension	1.13 (0.98-1.34)	0.151		
Previous MI	1.90 (1.36-2.64)	<0.001	1.60 (1.04-2.46)	0.033
Previous PCI	1.66 (1.36-2.03)	<0.001	1.13 (0.84-1.52)	0.414
Multivessel disease	2.37 (1.99-2.83)	<0.001	1.11 (0.88-1.40)	0.378
Left main disease	2.92 (2.26-3.77)	<0.001	1.63 (1.16-2.30)	0.005
Bifurcation disease	1.41 (1.20-1.66)	<0.001	0.89 (0.73-1.09)	0.245
Ostial lesion	2.36 (1.81-3.09)	<0.001	0.89 (0.63-1.25)	0.495
Chronic total occlusion	1.61 (1.13-2.29)	0.009	0.70 (0.46-1.06)	0.095
Severely calcified lesion[a]	2.01 (1.45-2.78)	<0.001	1.37 (0.95-1.98)	0.091
In-stent restenotic lesion	2.34 (1.73-3.17)	<0.001	1.52 (0.94-2.44)	0.088
Diffuse long lesion[b]	2.46 (2.08-2.91)	<0.001	1.23 (0.97-1.55)	0.084
SYNTAX score[c]	0.94 (0.93-0.95)	<0.001	0.98 (0.97-1.00)	0.010
Total stent length per patient	0.98 (0.98-0.98)	<0.001	0.99 (0.98-0.99)	<0.001
Lesion preparation[d]	1.86 (1.54-2.24)	<0.001	1.52 (1.23-1.88)	<0.001
Adjunct postdilatation	0.57 (0.42-0.78)	<0.001	1.41 (0.13-15.88)	0.781
Maximum stent diameter	0.92 (0.77-1.10)	0.358		
Maximum balloon size	0.71 (0.60-0.84)	<0.001	0.70 (0.58-0.85)	<0.001
Maximum inflation pressure	1.00 (0.98-1.03)	0.639		

[a]Severely calcified lesions were those with encircling calcium seen on angiography. [b]Diffuse long coronary artery lesion was defined as lesion length ≥28 mm or stent length ≥32 mm of treated segment. [c]The SYNTAX score reflects a comprehensive angiographic assessment of the coronary vasculature. A higher score denotes higher anatomical complexity. Scores were calculated by the core laboratory. [d]Lesion preparation using compliant balloons, noncompliant balloons, scoring or cutting balloons, or rotational atherectomy.

Abbreviations as in Tables 1-3.

In our study, despite the operators' dedicated efforts to optimize imaging-guided PCI results during the index procedure, nearly 48% of patients did not achieve optimal stent optimization, measured by a core laboratory. Similarly, previous trials and meta-analyses have reported that a substantial proportion of enrolled patients, ranging from approximately 10% to 60%, did not reach the predefined targets for stent optimization.[16] In particular, the significantly low proportion of patients who met the predefined criteria of stent expansion was the main driver of not achieving PCI optimization. Robust prospective studies have demonstrated that optimal stent expansion was significantly associated with better clinical outcomes after imaging-guided PCI.[3,4,20,24-27] Based on these data, the thresholds of stent expansion were suggested as either absolute or relative (to reference lumen diameter) of the final MSA. In our trial, the prognostic impact of differential relative stent expansion (>80% or 90%) or absolute criteria were relatively different for OCT- and IVUS-guided PCI. Similarly, a previous study reported that the long-term benefit of different criteria for

CENTRAL ILLUSTRATION **The Proportion of Stent Optimization and the Cumulative Incidence of the Primary Endpoint**



Kim H, et al. JACC Cardiovasc Interv. 2025;18(9):1089–1099.

Proportion of stent optimization and the cumulative incidence of the primary endpoint of target vessel failure. IVUS = intravascular ultrasound; OCT = optical coherence tomography; OCTIVUS = Optical Coherence Tomography-Guided or Intravascular Ultrasound-Guided Percutaneous Coronary Intervention.

IVUS-defined optimal stent expansion on hard clinical outcomes was substantially variable.[20] However, although some thresholds of stent expansion were predictive of better outcomes, achieving such criteria could be often unattainable and associated with procedural safety concerns. Further research is warranted to determine practically applicable and optimal thresholds for absolute and relative stent expansion measures.

In the current study, several clinical and anatomical factors were found to be the important predictors of imaging-guided stent optimization. A previous study reported that larger reference vessel diameter and larger final balloon size were independent determinants for achieving optimal stent expansion.[20] In our study, specific lesion and procedural characteristics, including left main disease, a higher SYNTAX score, and longer stent length, were independently associated with difficulties in achieving stent optimization. Interestingly, we observed that conduction of lesion preparation and use of a larger maximum balloon size was associated with lower rates of achieving stent optimization. Given that aggressive lesion preparation and larger balloon size at higher pressures was frequently required in highly anatomically complex lesions, such procedural characteristics might reflect more technical challenges in achieving stent optimization (ie, this relationship are likely association and not causation). Thus, in the practical viewpoint, optimal lesions preparation would be essential part for imaging-guided PCI optimization. Given that imaging-guided PCI with the goal of stent optimization was associated with better long-term outcomes, such key predictors and

precautious during imaging-guided PCI, especially for complex coronary artery lesions, should be reconsidered.

In the current study, stent optimization was associated with better clinical outcomes in both OCT-guided and IVUS-guided PCI. Graphically, the clinical benefit of stent optimization on TVF rates was remarkable in the OCT-guided PCI group than in IVUS-guided PCI group, although there was no statistically significant interaction. The RENOVATE-COMPLEX-PCI trial (The Randomized Controlled Trial of Intravascular Imaging Guidance versus Angiography-Guidance on Clinical Outcomes after Complex Percutaneous Coronary Intervention) confirmed the benefits of intravascular imaging guidance (OCT use in 25% of patients) in the complex PCI setting.[5] These findings, along with the results of the OCTOBER trial (The European Trial on Optical Coherence Tomography Optimized Bifurcation Event Reduction), show the superiority of systematic OCT guidance using a predefined imaging protocol over angiographic guidance for PCI of complex bifurcation lesions.[6] By contrast, in ILUMIEN (OCT Guided Coronary Stent Implantation Compared with Angiography: A Multicenter Randomized Trial in PCI) IV,[11] OCT-guided PCI achieved a significantly larger final MSA, compared with angiography-guided PCI. However, such favorable procedural results did not translate into a significant benefit in a 2-year TVF. Although the exact rate of achieved stent optimization was not reported in ILUMIEN IV, the low proportion of sufficiently met stent optimization, and the very sensitive prognostic effect of OCT-guided PCI and different patient or anatomical characteristics might partly explain the discrepant findings regarding the prognostic effect of OCT-guided PCI among trials. The recent OCCUPI (OCT-guided versus angiography-guided percutaneous coronary intervention for patients with complex lesions) trial confirmed that the group with stent optimization showed a lower occurrence of the primary endpoint than the group with stent suboptimization among patients who underwent OCT-guided PCI.[28] These findings highlight the importance of stent optimization when OCT is used to evaluate stent expansion, apposition, and edge dissection for PCI guidance. However, because PCI optimization for some lesions can be difficult despite maximal efforts, future studies investigating the determinants of stent suboptimization are needed. They would provide insights into which OCT parameters and/or specific actions triggered by OCT evaluation can be associated with better outcomes.

STUDY LIMITATIONS. First, as this study is a subgroup analysis of the OCTIVUS trial, the current study may have been statistically underpowered to detect clinically relevant findings. Therefore, the findings of the present study should be interpreted as being hypothesis generating. Second, during the trial enrollment, all imaging-guided PCI procedures depended largely on the operators' interpretation and reaction to the imaging findings at the participating centers. Therefore, discrepancies on site-determined and core laboratory-measured imaging interpretation and assessment of stent optimization may arise. Third, some lesion-level data values were missing, preventing us from fully analyzing factors linked to stent optimization. Fourth, tissue protrusion, which can adversely affect clinical outcomes,[16] was not evaluated in the present study. Finally, given that considerable geographic variability in the use of imaging-guided PCI in routine clinical practice and that this study included only the East-Asian population, the generalizability and reproducibility of the study findings should be further considered.

CONCLUSIONS

In this detailed core laboratory analysis and its clinical correlation with the OCTIVUS trial, stent optimization was only achieved in approximately one-half of patients who were undergoing imaging-guided PCI. The achieved stent optimization was associated with a better clinical outcome than with nonachieved stent optimization, and such an effect seems to be more pronounced in OCT-guided PCI than in IVUS-guided PCI.

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PERSPECTIVES

WHAT IS KNOWN? Data regarding the relative proportion of achieving stent optimization by intravascular coronary imaging, either IVUS or OCT, and its clinical impact are still limited.

WHAT IS NEW? In patients undergoing intravascular imaging-guided PCI with OCT or IVUS, who were enrolled in the OCTIVUS trial, stent optimization was achieved in approximately one-half of patients and the achieved stent optimization was associated with a better clinical outcome.

WHAT IS NEXT? Further research is required to provide more reliable and clinically applicable algorithm for stent optimization during intravascular imaging-guided PCI.

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KEY WORDS intravascular ultrasound, optical coherent tomography, percutaneous coronary intervention, stent optimization

APPENDIX For expanded Methods and References sections and supplemental tables and figures, please see the online version of this paper.

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