Doctor of Philosophy

광간섭단층촬영 및 혈관내 초음파를 이용한 스텐트 최적화가 임상 결과에 미치는 영향

Impact of Stent Optimization using Optical Coherence Tomography or Intravascular Ultrasound on Clinical Outcomes

The Graduate School

of the University of Ulsan

Department of Medicine

Hoyun Kim

Impact of Stent Optimization using Optical Coherence Tomography or Intravascular Ultrasound on Clinical Outcomes

Supervisor: Duk-Woo Park

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Hoyun Kim

Department of Medicine
University of Ulsan, Korea

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This certifies that the dissertation of Hoyun Kim is approved.

Committee Chair Dr. Gi-Byoung Nam

Committee Member Dr. Duk-Woo Park

Committee Member Dr. Jung-Min Ahn

Committee Member Dr. Do-Yoon Kang

Committee Member Dr. Cheol Hyun Lee

Department of Medicine

University of Ulsan, Korea

February 2024

ABSTRACT

BACKGROUND The 2018 expert consensus by the European Association of Percutaneous Cardiovascular interventions on the clinical use of intracoronary imaging established uniform criteria for stent optimization assessment. However, data on the impact of achieving all these criteria on clinical outcomes following percutaneous coronary interventions (PCI) are limited.

METHODS We used data from the OCTIVUS (Optical Coherence Tomography-Guided or Intravascular Ultrasound-Guided Percutaneous Coronary Intervention) randomized trial, which compared optical coherence tomography (OCT)-guided to intravascular ultrasound (IVUS)-guided PCI. Patient with inadequate imaging quality for stent optimization assessment were excluded from this analysis. After PCI, patients were classified into an optimized group if they met all the stent optimization criteria, and into a non-optimized group if they did not meet at least one of the criteria. The primary endpoint was a composite of death from cardiac causes, target-vessel myocardial infarction (MI), or ischemia-driven target-vessel revascularization (TVR).

RESULTS Among 1980 patients, 1022 (51.6%) were classified into the optimized group, and 958 (48.4%) into the non-optimized group. Over a median follow-up of 2 years (ranging from 1 to 5 years), the primary composite endpoint occurred in 39 (3.8%) patients in the optimized group and in 72 (7.5%) patients in the non-optimized group (hazard ratio [HR] 0.52; 95% confidence interval [CI] 0.35–0.77; P<0.001). This difference was primarily driven by a reduced rate of target-vessel revascularization in the optimized group.

CONCLUSIONS In patients undergoing OCT-guided or IVUS-guided PCI, achieving all the stent optimization criteria was associated with a lower incidence of the primary composite endpoint of death from cardiac causes, target-vessel MI, or ischemia-driven TVR.

Contents

List of Tables and Figures

Introduction

Coronary angiography, a cornerstone modality to diagnose coronary artery disease (CAD) and to guide percutaneous coronary intervention (PCI), has inherent limitations by only visualizing the lumen.[1] These limitations have been overcome with intravascular imaging such as optical coherence tomography (OCT) or intravascular ultrasound (IVUS) that can guide PCI procedures by assessing target-lesion characteristics, optimizing stent implantation, and minimizing stent-related problems.[2-4] Several randomized trials and meta-analyses have demonstrated that intravascular imaging-guided PCI as compared with angiography-guided PCI achieves a larger minimal stent area or improves clinical outcomes in high-risk or complex lesions.[5-11] Specifically, in intravascular imaging-guided PCI procedures, meeting pre-defined stent optimization criteria was associated with better clinical outcomes.[5,8,12,13] However, there had been a challenge of the lack of a uniform definition of stent optimization about optimal stent expansion (absolute or relative), presence of malapposition, or presence of stent edge dissection. In this clinical context, the 2018 expert consensus by the European Association of Percutaneous Cardiovascular Interventions (EAPCI) on the clinical use of intracoronary imaging including OCT and IVUS suggested the uniform criteria to assess stent optimization.[2] However, there has been still limited data assessing the impact of these stent optimization criteria on clinical outcomes.

Recently, the OCTIVUS (Optical Coherence Tomography-Guided or Intravascular Ultrasound-Guided Percutaneous Coronary Intervention) trial, a randomized trial comparing two imaging strategies of OCT and IVUS for PCI guidance in patients with diverse anatomical or clinical characteristics, provided a wealth of data on the result of OCT- or IVUS-guided PCI.[14] To assess the impact of stent optimization according to the expert consensus on clinical use of intracoronary imaging, we used the contemporary data from the OCTIVUS trial and

compared clinical outcomes between patients who met all stent optimization and those who did not meet at least one of the criteria.

Methods

Study Design and Patient Population

The trial design, methos, and primary results of the OCTIVUS trial have been previously reported.[14,15] In brief, the OCTIVUS trial was an investigator-initiated, prospective, multicenter, randomized, open-label pragmatic trial conducted at 9 hospitals in South Korea. In the OCTIVUS trial, a total of 2008 patients with significant coronary artery lesions were randomly assigned, in a 1:1 ratio, to undergo either an OCT-guided (n = 1005) or IVUS-guided PCI (n = 1003). Of these, 28 patients with not available or not sufficient image quality to allow assessment of stent optimization were excluded, and consequently, a total of 1980 patient were included in the present study. The study patients were then classified into the optimized group for those who met all the stent optimization criteria, and into the non-optimized group for those who did not meet at least one of the criteria.

Patients 19 years of age or older who were undergoing PCI with contemporary drug-eluting stents or drug-coated balloons (only for in-stent restenosis) for significant coronary-artery lesions were eligible for enrollment. Major exclusion criteria were patients with ST-segment elevation myocardial infarction at the hospital admission, those with severe renal dysfunction, those with unstable hemodynamics or decompensated heart failure, those with severely calcified or tortuous lesions, which were expected to not allow a delivery of intracoronary imaging catheter, or those who would be unable to be safely randomized to either arm. Details regarding inclusion and exclusion criteria are provided previoulsy.[14,15]

After providing written informed consent, eligible patients were randomly assigned, in a 1:1 ratio, to undergo either OCT-guided PCI or IVUS-guided PCI after diagnostic coronary

angiography. Randomization was performed by means of an interactive Web-based response system using a computer-generated randomization sequence in a permuted block size of four or six, stratified according to enrollment site. The trial was approved by the institutional review board and ethics committees at each participating center. All the patients provided written informed consent before randomization. The trial has been registered at www.clinicaltrials.gov as NCT03394079.

Imaging-guided PCI, Stent Optimization Criteria, and Follow-Up

Detailed procedures have been described previously.[14,15] PCI procedure was performed using standard techniques. Lesion preparation using a balloon catheter, atherectomy, or other devices, and the choice of a specific drug-eluting stent was left to the discretion of the operators. In each group, either IVUS with rotational transducer (Opticross™ or Opticross™ HD, Boston Scientific Corporation, San Jose, CA, USA) or OCT (C7-XR™ and OPTIS™, Abbott, Santa Clara, CA) was used before, during, and immediately after stent implantation. Stent size, length, and optimization of the stented segment was determined with the use of a predefined common algorithm for IVUS or OCT on the basis of expert consensus.[2] 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 6–12 months at the physician's discretion, according to the clinical indication and procedural complexity.

Imaging-guided PCI optimization criteria (stent optimization criteria) were defined on the basis of the expert consensus.[2] Detailed information of imaging-guided PCI optimization criteria are described in the Supplemental Material (section A). In brief, a distal lumen or external elastic membrane reference-based stent sizing strategy was used; avoidance of a landing zone in a plaque burden >50% and particularly lipid-rich tissue at the stent edge; a relative stent expansion of >80% (minimum stent area [MSA] divided by average reference

lumen area) and in lesions (non-left main lesions) with non-evaluable reference lumen area, optimal stent expansion was defined as an absolute in-stent MSA of >5.5 mm^2 by IVUS imaging and >4.5 mm^2 by OCT imaging; extensive malapposition after stent implantation should be avoided and corrected; and large dissection should be avoided and corrected. If imaging criteria for optimization was not met, additional procedures with a high-pressure balloon or additional stent implantation were performed according to the operators' discretion. A repeat imaging evaluation for final PCI optimization was mandated. In cases of with multivessel disease undergoing staged procedures, the initially allocated imaging tool was used in staged PCI procedures. 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.

Follow-up was performed at hospital discharge and at 1, 6, and 12 months and then yearly thereafter. Patients who were unable to attend outpatient clinic visits were contacted by telephone interview. 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.[16]

Study Endpoints and Definitions

The primary endpoint of the OCTIVUS trial was target-vessel failure, which was defined as a composite of death from cardiac causes, target-vessel-related myocardial infarction (MI), or ischemia-driven target-vessel revascularization (TVR). Key secondary endpoints included the individual components of the primary endpoint, target-lesion failure (a composite of death from cardiac causes, target-vessel myocardial infarction, or ischemia-driven target-lesion

revascularization), stent thrombosis, stroke, repeat revascularization, rehospitalization, and bleeding events. Other secondary endpoints included contrast-induced acute kidney injury, procedural complications requiring active intervention, which were related to PCI or intravascular imaging (i.e., procedural safety outcomes), and angiographic or imaging-based device success. All components of clinical endpoints were adjudicated by a clinical events committee whose members were unaware of the treatment assignments.

Standard definitions were used for clinical outcome assessment.[17-21] All deaths were considered cardiac unless an unequivocal non-cardiac cause can be established. The diagnosis of MI was classified as spontaneous or procedural on the basis of the expert consensus document.[18] Repeat revascularization may be either a PCI or a CABG, with TVR defined as repeat revascularization of the entire major coronary vessel proximal and distal to the target-lesion treated during the index procedure. Stent thrombosis was defined according to definite or probable criteria of the Academic Research Consortium.[22] Contrast-induced nephropathy was defined as either a greater than 25% increase of serum creatinine or an absolute increase in serum creatinine of 0.5 mg/dl within 72 hours after PCI. Serious adverse events that were related to PCI or intravascular imaging included procedural complications (e.g., angiographic dissection of at least type B, 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 interventions (prolonged balloon inflations, additional stenting required, thrombus aspiration, pericardiocentesis, cardioversion, or use of mechanical circulatory support devices). Angiographic device success was defined as successful PCI at the intended target-lesion with final in-stent residual stenosis <30% and imaging-based device success was defined as successful PCI at the intended target-lesion, which fulfills the optimal imaging criteria for stent implantation.[14]

Statistical Analysis

All principal analyses were performed on an as-treated basis. Summary statistics were presented as percentages in the case of categorical variables and as means with standard deviations in the case of continuous variables. Baseline characteristics, procedural data, and imaging characteristics were compared between the optimized group and the non-optimized group using the Student's *t*-test for continuous variables and $\chi 2$ or Fisher's exact test for categorical variables. Cumulative-event probabilities were estimated with the use of the Kaplan–Meier methods. In time-to-first-event analyses, hazard ratios (HR) and 95% confidence intervals (CI) were generated with Cox proportional-hazards models. The adjusted HRs were estimated using Cox regression analysis based on the clinical characteristics including age, sex, body mass index, diabetes, hypertension, dyslipidemia, smoking, family history of premature CAD, history of previous MI, history of previous CABG, history of previous stroke, congestive heart failure, chronic pulmonary disease, peripheral vascular disease, atrial fibrillation, end-stage renal disease on dialysis, and left ventricular ejection fraction. To determine the impact of clinical, angiographic, and procedural variables on achieving stent optimization, univariable and multivariable logistic regression analyses were performed. The variables with $P < 0.1$ in univariable analysis were included in the multivariable analysis model. Correlations between variables have been expressed as odds ratios (ORs) with 95% CIs. The proportional hazards assumption was evaluated with a two-sided score test of the scaled Schoenfeld residuals at the 0.05 level.[23] The interaction terms for optimization status and imaging modalities for primary and secondary endpoints were evaluated using formal interaction testing. All reported P values were two-sided, and $p < 0.05$ was considered significant for all tests. All statistical analyses were performed with the use of 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 2008 randomized patients enrolled in the OCTIVUS trial, 28 patients with not available or not sufficient image quality to allow assessment of stent optimization were excluded, and a total of 1980 patient were included in the present study (**Figure 1**). Of those, 967 patients (48.8%) underwent OCT-guided PCI and 1013 (51.2%) underwent IVUS-guided PCI. After undergoing PCI, 1022 patients (51.6%) were classified into the optimized group and 958 (48.4%) into the non-optimized group.

Baseline characteristics of the patients in the optimized and the non-optimized group are presented in **Table 1**. Compared with patients in the optimized group, patients in the non-optimized group were older; were more likely to have histories of diabetes, previous MI, previous PCI, previous CABG, peripheral vascular disease, and end-stage renal disease on dialysis. Baseline characteristics of the patients according to stent optimization status in the OCT group and the IVUS group are shown in **Supplemental Table S1**.

Anatomical and Procedural Characteristics

Anatomical and procedural characteristics according to stent optimization status are presented in **Table 2** and **Supplemental Table S2**. Lesions in the non-optimized group showed a higher prevalence of multivessel disease and a higher prevalence of complex coronary lesions, which included left main disease, bifurcation disease, ostial lesions, chronic total occlusions, severe calcification, in-stent restenosis, and diffuse long lesions compared with lesions in the optimized group. The number of lesions and stents used per patient, and the total stent length per patients were greater in the non-optimized group. In contrast, there were no significant differences in the incidence of high-pressure post-dilation balloon use or in the rate of procedural complications necessitating active intervention between the groups. At the lesion level, lesion preparation using balloons or rotational atherectomy was performed more

frequently, while direct stenting was less common in the non-optimized group. There were no significant differences in the maximum stent diameter or the maximum balloon inflation pressure between the groups. However, the maximum balloon size used was larger in the non-optimized group.

Imaging-guided optimization criteria assessment in overall patient, OCT, and IVUS groups are presented in **Supplemental Table S3**. Core laboratory-measured QCA and imaging analysis by the OCT and the IVUS were detailed in **Supplemental Tables S4 and S5**. There was a common trend toward a higher prevalence of calcified lesions and longer lesion lengths at baseline imaging, accompanied by larger stent areas and greater stent expansion at post-procedure imaging.

Primary and Secondary Endpoints

During the entire follow-up period (median 2.0 years; available for at least 1 year and up to 4.8 years), ascertainment of the primary and secondary outcomes was completed in 99.4% of the patients in the optimized group and 99.2% in the non-optimized group, and data on vital status were obtained for all patients (**Figure 1**). Cardioactive medication use at baseline and during follow-up was similar in the optimized and the non-optimized groups (**Supplemental Table S5**).

The primary and secondary endpoints of patients in the optimized and non-optimized group are presented in **Table 3** and **Figure 2**. Over the entire follow-up period, the primary composite endpoint of death from cardiac causes, target-vessel MI, or ischemia-driven TVR occurred less frequently in the optimized group (39 of 1022 patients, 3.8%) compared to the non-optimized group (72 of 958 patients, 7.5%) (HR, 0.52; 95% CI, 0.35–0.77; P <0.001). After adjusting for clinically significant variables, the incidence of primary composite endpoint remained significantly lower in the optimized group compared with the non-optimized group (**Table 3**). With respect to secondary outcomes, no significant differences

were noted in the incidences of death, target-vessel MI, any MI, stent thrombosis, stroke, rehospitalization, or bleeding events between the optimized and the non-optimized groups. However, repeat revascularization occurred less frequently in the optimized group than in the non-optimized group. The primary and secondary endpoints according to stent optimization status in the OCT group and the IVUS group are shown in the **Supplemental Table S6 and Figure S1**. In the OCT group, the primary composite endpoint occurred less frequently in the optimized group than in the non-optimized group. However, the incidence of primary composite endpoint did not differ significantly between the optimized and the non-optimized groups.

Independent Determinants for Achieving Stent Optimization Criteria

Independent determinants for achieving stent optimization criteria are presented in **Table 4**. In univariable analysis, older age, diabetes, a history of previous MI and previous PCI, multivessel disease, left man 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 length, performing lesion preparation, and larger maximum balloon size were negatively associated with achieving stent optimization. Conversely, performing adjunct post-dilation was positively associated with achieving stent optimization. In the multivariable-adjusted model, factors such as a history of previous MI, left main disease, a higher SYNTAX score, longer total stent length, performing lesion preparation, and a larger maximum balloon size continued to be adversely associated with achieving stent optimization.

Table 1. Baseline Characteristics of the Patients.*

Characteristic	Overall (N = 1980)	Optimized (N = 1022)	Non-Optimized (N = 958)	P value
Age — yr	64.7±10.4	64.1±10.5	65.1±10.5	0.006
Female sex — no. (%)	426 (21.5)	214 (20.9)	212 (22.1)	0.52
Body-mass index†	25.0±3.1	25.0±3.1	25.0±3.1	0.783
Diabetes mellitus — no. (%)	656 (33.1)	311 (30.4)	345 (36.0)	0.008
Insulin-treated diabetes mellitus — no. (%)	65 (3.3)	22 (2.2)	43 (4.5)	0.004
Hypertension — no. (%)	1265 (63.9)	640 (62.6)	625 (65.2)	0.226
Dyslipidemia — no. (%)	1660 (83.8)	846 (82.8)	814 (85.0)	0.186
Current smoking — no. (%)	398 (20.1)	198 (19.4)	200 (20.9)	0.404
Family history of premature CAD — no. (%)‡	108 (5.5)	52 (5.1)	56 (5.8)	0.458
Previous myocardial infarction — no. (%)	138 (7.0)	49 (4.8)	89 (9.3)	<0.001
Previous PCI — no. (%)	420 (21.2)	173 (16.9)	247 (25.8)	<0.001
Previous CABG — no. (%)	51 (2.6)	18 (1.8)	33 (3.4)	0.018
Previous stroke — no. (%)	135 (6.8)	59 (5.8)	76 (7.9)	0.057
Congestive heart failure — no. (%)	44 (2.2)	19 (1.9)	25 (2.6)	0.258
Chronic pulmonary disease — no. (%)	54 (2.7)	24 (2.3)	30 (3.1)	0.285

Peripheral vascular disease — no. (%)	59 (3.0)	20 (2.0)	39 (4.1)	0.006
Atrial fibrillation — no. (%)	65 (3.3)	33 (3.2)	32 (3.3)	0.89
End-stage renal disease on dialysis — no. (%)	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 — no. (%)				0.197
Silent ischemia	218 (11.0)	114 (11.2)	104 (10.9)	
Chronic coronary syndrome	1305 (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)	

* Plus–minus values are means ± SD. Percentages may not total 100 because of rounding. CABG denotes coronary-artery bypass grafting, CAD coronary artery disease, IVUS intravascular ultrasound, NSTEMI non-ST-segment elevation myocardial infarction, OCT optical coherence tomography, and PCI percutaneous coronary intervention.

† The body-mass index is the weight in kilograms divided by the square of the height in meters.

‡ 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.

Table 2. Anatomical and Procedural Characteristics According to Stent Optimization Status.*

Characteristic	Optimized (N = 1022)	Non-Optimized (N = 958)	P value
Anatomical or lesion characteristics			
Multivessel disease — no. (%)	543 (53.1)	672 (70.1)	<0.001
No. of diseased vessels — no. (%)			<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 — no. (%)			
Left main disease — no. (%)	75 (7.3)	181 (18.9)	<0.001
Any bifurcation disease — no. (%)	503 (49.2)	541 (56.5)	0.001
Ostial lesion — no. (%)	60 (5.9)	132 (13.8)	<0.001
Chronic total occlusion — no. (%)	43 (4.2)	63 (6.6)	0.019
Severely calcified lesion — no. (%)†	51 (5.0)	97 (10.1)	<0.001
In-stent restenotic lesion — no. (%)	51 (5.0)	108 (11.3)	<0.001
Diffuse long lesion — no. (%)‡	498 (48.7)	660 (68.9)	<0.001
Bypass graft disease — no. (%)	1 (0.1)	2 (0.2)	0.526

SYNTAX score§			
Mean	13.2±8.1	17.9±9.8	<0.001
Category — no./total no. (%)			<0.001
Low, 0 to 22	884 (86.5)	679 (70.9)	
Intermediate, 23 to 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	1007 (98.5)	914 (95.4)	
Used of drug-coated balloons (only for in-stent restenotic lesion)	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 — no. (%)¶	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 — no. (%)			
Angiography-based‖	1015 (99.3)	940 (98.1)	0.017
Procedural complications requiring active intervention — no. (%)**			
Any	25 (2.4)	33 (3.4)	0.188

* Plus–minus values are means ± SD. Percentages may not total 100 because of rounding. IVUS denotes intravascular ultrasound, OCT optical coherence tomography, and PCI percutaneous coronary intervention.

† Severely calcified lesions were those with encircling calcium seen on angiography.

‡ Diffuse long coronary-artery lesion was defined as lesion length ≥28 mm or stent length ≥32 mm of treated segment.

§ The SYNTAX (Synergy between Percutaneous Coronary Intervention with Taxus and Cardiac Surgery) score reflects a comprehensive angiographic assessment of the coronary vasculature. A higher score denotes higher anatomical complexity. Scores were calculated by the core laboratory.

¶ Additional post-stent larger balloon or high-pressure balloon was used to resolve incomplete stent expansion or incomplete stent apposition.

‖ Angiographic device success is defined as successful PCI at the intended target lesion with final in-stent residual stenosis of less than 30% by quantitative coronary angiography.

** Procedural complications (e.g., 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), which were related to PCI or use of intravascular imaging.

Table 3. Primary and Secondary Endpoints According to Stent Optimization Status.*

Endpoints (n/%)	Optimized (N = 1022)	Non-Optimized (N = 958)	Hazard Ratio (95% CI)	P Value	Adjusted Hazard Ratio (95% CI)	P Value
Primary end point						
Target-vessel failure (a composite of death from cardiac causes, target-vessel myocardial infarction, or ischemia-driven target-vessel revascularization)	39 (3.8)	72 (7.5)	0.52 (0.35–0.77)	<0.001	0.58 (0.37–0.92)	0.019
Secondary end points						
Target-lesion failure†	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 myocardial infarction‡	10 (1.0)	15 (1.6)	0.62 (0.28–1.39)	0.246	0.69 (0.28–1.68)	0.409
Any myocardial infarction‡	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§	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
Target-lesion revascularization	17 (1.7)	42 (4.4)	0.38 (0.22–0.67)	<0.001	0.42 (0.22–0.81)	0.009
Target-vessel revascularization	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¶	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 — no. (%)‖	11 (1.1)	17 (1.8)				

* Clinical end points were evaluated during the entire follow-up period (i.e., 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. BARC denotes Bleeding Academic Research Consortium, CI confidence interval, and NC not calculated.

Hazard ratios are for the optimized group, as compared with the non-optimized group. Because confidence intervals 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 end points.

† Target-lesion failure was a composite of death from cardiac causes, target-vessel myocardial infarction, or ischemia-driven target-lesion revascularization.

‡ Myocardial infarction was assessed according to the protocol definition.

§ Stent thrombosis was defined as definite or probable stent thrombosis according to the Academic Research Consortium.[18]

¶ Bleeding events are assessed according to the Bleeding Academic Research Consortium (BARC) criteria.[19] BARC type 3–5 indicates severe bleeding.

‖ Contrast-induced nephropathy was defined as either a greater than 25% increase of serum creatinine or an absolute increase in serum creatinine of 0.5 mg/dL from baseline within 72 h after the index PCI procedure. Event rates (%) of contrast-induced nephropathy are presented as calculated percentages.

Table 4. Multivariable Analyses for Achieving Stent Optimization Criteria. *

Variable	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 sex	0.98 (0.81–1.20)	0.867		
Diabetes mellitus	0.76 (0.64–0.91)	0.002	0.90 (0.74–1.09)	0.293
Hypertension	0.88 (0.75–1.05)	0.151		
Previous MI	0.53 (0.38–0.73)	<0.001	0.63 (0.41–0.96)	0.033
Previous PCI	0.60 (0.49–0.73)	<0.001	0.88 (0.66–1.19)	0.414
Multivessel disease	0.42 (0.35–0.5)	<0.001	0.90 (0.72–1.13)	0.378
Left main disease	0.34 (0.27–0.44)	<0.001	0.61 (0.43–0.86)	0.005
Bifurcation disease	0.71 (0.60–0.83)	<0.001	1.13 (0.92–1.38)	0.245
Ostial lesion	0.42 (0.32–0.55)	<0.001	1.13 (0.80–1.59)	0.495
Chronic total occlusion	0.62 (0.44–0.89)	0.009	1.43 (0.94–2.18)	0.095
Severely calcified lesion†	0.50 (0.36–0.69)	<0.001	0.73 (0.51–1.05)	0.091
In-stent restenotic lesion	0.43 (0.32–0.58)	<0.001	0.66 (0.41–1.06)	0.088

Diffuse long lesion‡	0.41 (0.34–0.48)	<0.001	0.81 (0.64–1.03)	0.084
SYNTAX score§	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¶	0.54 (0.45–0.65)	<0.001	0.66 (0.53–0.82)	<0.001
Adjunct postdilatation	1.76 (1.29–2.41)	<0.001	0.71 (0.06–8.00)	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		

* CI denotes confidence interval, IVUS intravascular ultrasound, MI myocardial infarction, OR odds ratio, and PCI percutaneous coronary intervention.

† Severely calcified lesions were those with encircling calcium seen on angiography.

‡ Diffuse long coronary-artery lesion was defined as lesion length ≥28 mm or stent length ≥32 mm of treated segment.

§ The SYNTAX (Synergy between Percutaneous Coronary Intervention with Taxus and Cardiac Surgery) score reflects a comprehensive angiographic assessment of the coronary vasculature. A higher score denotes higher anatomical complexity. Scores were calculated by the core laboratory.

¶ Lesion preparation using compliant balloons, non-compliant balloons, scoring or cutting balloons, or rotational atherectomy.

Figure 1. Study Flow Diagram

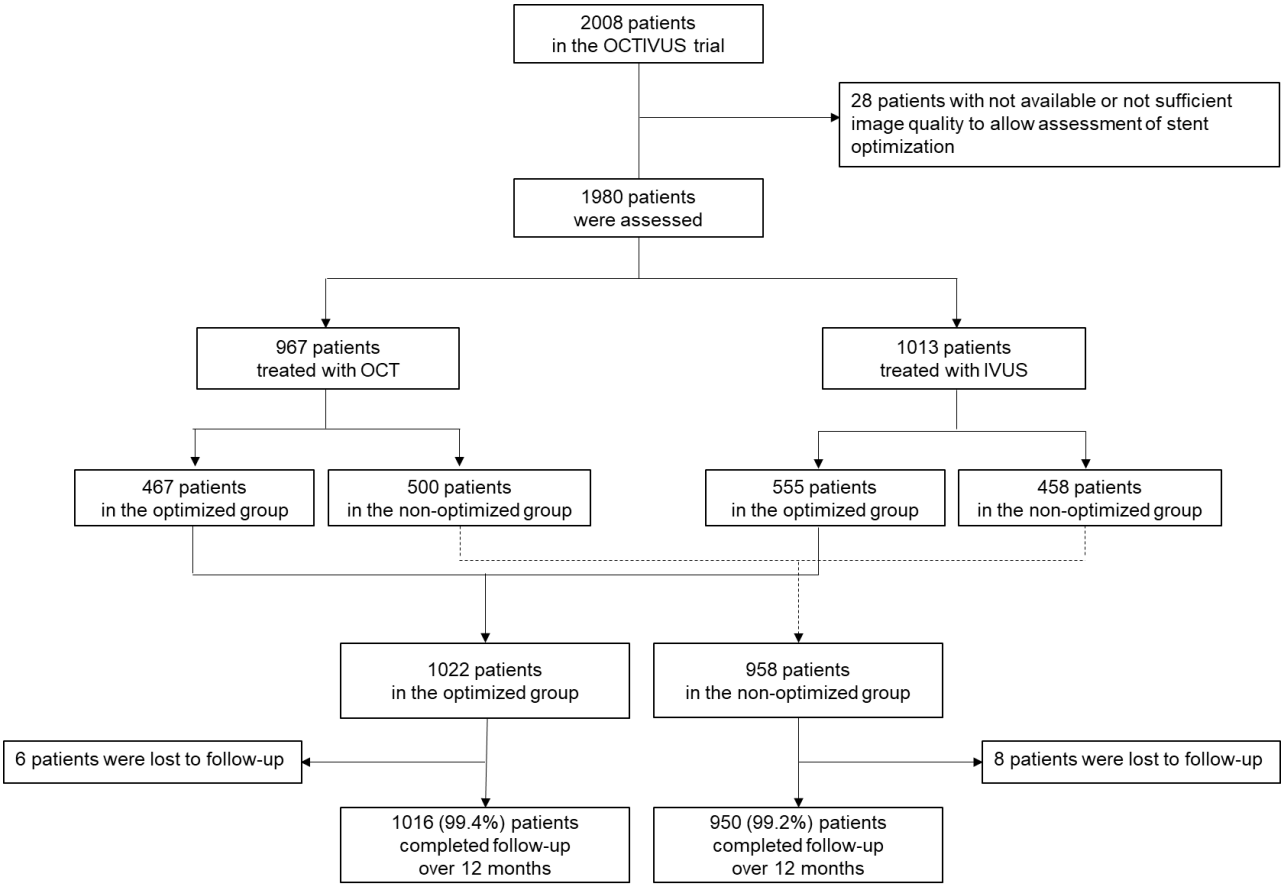
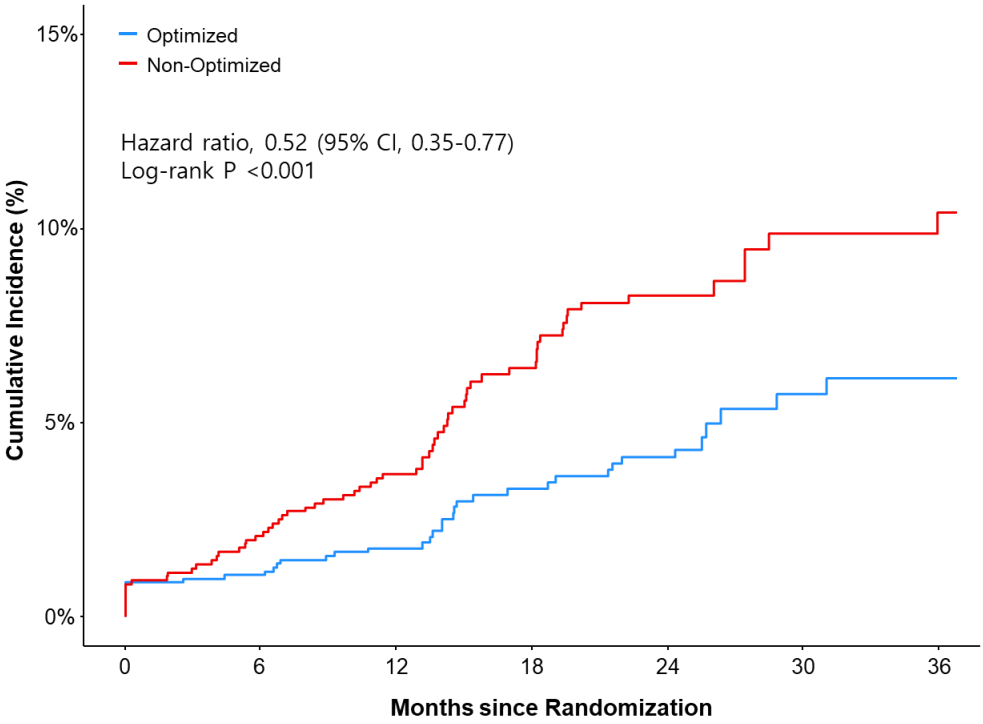


Figure 2. Time-to-Event Curves for the Primary End Point



Number at risk

Optimized	1022	1005	917	607	499	237	172
Non-optimized	958	934	840	555	452	217	168

Discussion

In this post hoc analysis of the OCTIVUS trial, we evaluated the impact of stent optimization on clinical outcomes by comparing patients who met all stent optimization criteria with those who did not meet at least one of these criteria. We observed two major findings. First, over the median follow-up duration of 2 years (ranging from a minimum of 1 year to a maximum of 5 years), achieving all the stent optimization criteria, as suggested by the expert consensus, was associated with a reduced incidence of the primary composite endpoint of death from cardiac causes, target-vessel MI, or ischemia-driven TVR. This was mainly driven by a lower rate of repeat revascularization in the optimized group. Second, despite concerted efforts to achieve stent optimization during PCI procedures, nearly 48% of the patients in the OCTIVUS trial failed to meet the predefined stent optimization targets. This was largely attributable to complex lesion characteristics and procedural factors such as longer stent length, which made it challenging to achieve all the stent optimization criteria.

Previous studies investigating the impact of stent optimization primarily focused on individual components of stent optimization, such as stent expansion (either absolute or relative), malapposition, and significant stent edge dissection.[5,8,13,24-29] These studies assessed the impact of each component of stent optimization on acute procedural results or long-term clinical outcomes. In 2018, the expert consensus on optimization of coronary intervention established comprehensive stent optimization criteria. Until recently, however, there had been no large-scale studies evaluating the clinical impact of meeting all the stent optimization criteria versus failing to meet at least one of these criteria. While the CLI-OPCI II study compared optimal versus suboptimal stent deployment using OCT in a similar manner suggested by the expert consensus, they were limited by small number of enrolled patients and use of bare metal stents, which are associated with a higher incidence of adverse cardiovascular events, in 22% of total patients, which makes its finding less applicable to current practice.[29] In this context, our study stands out for its strength and significance. By utilizing contemporary, large-scale data from the OCTIVUS trial, we evaluated the impact of adhering to all the stent optimization criteria suggested by the expert consensus, providing insights that are directly relevant to current clinical practice.

Despite dedicated efforts to optimize stent placement, including the selection of appropriate landing zones, lesion preparation with balloons, appropriate stent sizing, adjunctive post-dilation for optimal stent expansion and apposition, and the correction of significant stent edge dissection, nearly 48% of patients in our study were unable to achieve all the stent optimization criteria. A previous study reported that larger reference vessel diameter and larger final balloon size were independent determinants for achieving optimal stent expansion.[13] In the present study, we observed that specific lesion and procedural characteristics, including left main disease, a higher SYNTAX score, and longer total lengths, were independently associated with difficulties in achieving the predefined stent optimization criteria. Interestingly, performing lesion preparation was found to be adversely associated with achieving stent optimization. This could be attributed to the fact that pre-dilation is frequently required for challenging lesion characteristics, such as severe calcification. Therefore, the necessity of lesion preparation in these more complex lesions might contribute to its negative association with achieving stent optimization, and as a result, this could be eventually translated into a matter of baseline lesion characteristics. We believe these baseline lesion characteristics are the key reasons for these difficulties in achieving stent optimization, despite intensive efforts. Consistently, previous trials and meta-analyses have also reported that a substantial proportion of enrolled patients, ranging from approximately 10% to up to 60%, did not reach the predefined targets for stent optimization.[2] Nonetheless, it's important to recognize that imaging-guided PCI with the goal of stent optimization was associated with a reduction in adverse cardiovascular events, which could be attributed to these targets of stent optimization guiding operators in selecting more appropriate stent landing zones, increasing minimum stent area, and effectively addressing malapposition and stent edge dissection when feasible.[2]

It has been consistently demonstrated from previous studies that optimal stent expansion is associated with improved clinical outcomes.[5,8,13,24-29] Stent expansion has been evaluated both as an absolute measure of minimum stent cross-sectional area (MSA) and as a relative measure compared to the proximal, distal, or average reference area. For absolute criteria, MSA thresholds of 4.5 mm^2 for OCT and 5.5 mm^2 for IVUS have been suggested.[24,29] Regarding relative stent expansion, no uniform

criteria have been established with previous studies using various cut-off points, such as MSA exceeding the distal reference area or MSA more than 80% of the average reference area.[5,30] Recognizing the potential limitations of absolute MAS thresholds, which might be small for large vessels and large for small vessels, we initially employed relative stent expansion criteria, turning to absolute criteria only in cases where relative measures were not available. Although there has been some controversy that this relative stent expansion criteria can result in a small MSA in small vessels, considering that reference normal areas in small vessels proximal and distal to disease lesions are small, adopting the relative stent expansion criteria seems reasonable even in small vessels.[31] Interestingly, a prior study noted that an MSA/distal reference area ratio of over 90%, rather than an MSA/average reference area ratio of over 80%, was associated with a reduction in hard clinical outcomes.[13] Nonetheless, as the expert consensus document indicated that achieving over 90% expansion was often unattainable in previous studies, and considering that only 36% of total treated lesion in our study achieved stent expansion over 90% of average reference area, we believe that setting a target of over 80% for MSA relative to the average reference area represents a more practical approach for clinical practice. However, we acknowledge the need for further research to determine the optimal cut-offs for both absolute and relative stent expansion measures.

This study has several limitations. First, as this study is a post hoc analysis of the OCTIVUS trial, there are inherent limitations of the possibility that the study was not powered to specifically address the impact of stent optimization. Nonetheless, our analysis contributes additional evidence on the importance of stent optimization, providing meaningful insights that complement the findings of the OCTIVUS trial. Second, tissue prolapse which can adversely affect clinical outcomes was not evaluated in the present study. Tissue prolapse is known to be adversely related to clinical outcomes in patients with acute coronary syndrome (ACS), rather than in patient with stable CAD.[2] However, its absence may not have significantly influenced our overall findings as the proportion of ACS patients was only 23%. While the inclusion of tissue prolapse evaluation could have provided a more comprehensive analysis, the lack of assessment of tissue prolapse might not substantially alter the interpretation of our results regarding stent optimization. Third, the missing values in lesion-level data

prevented us from fully analyzing factors linked to stent optimization. We were unable to incorporate lesion-level imaging characteristics in our univariable and multivariable analyses due to the missing values in lesion-level data, potentially overlooking some insights. Further research is needed to understand how lesion-level imaging characteristics impact stent optimization.

Conclusions

In this post hoc analysis of the OCTIVUS trial, we observed that achieving all the stent optimization criteria after PCI was associated with a reduced incidence of the primary composite endpoint of death from cardiac causes, target-vessel MI, or ischemia-driven TVR, which was mainly derived from a lower rate of repeat revascularization. Therefore, efforts to achieve all the stent optimization criteria, as suggested by the expert consensus, are required to improve clinical outcomes.

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Supplemental material

Section A. Practical Recommendation for Stent Implantation with Optimization Criteria by IVUS or OCT*

Optimization Criteria by IVUS or OCT
• A distal lumen reference-based (mean distal lumen diameter with up-rounding of stent size [0–0.25 mm]) or EEM reference-based (mean EEM with down-rounding of stent diameter to the nearest 0.25 mm) sizing strategy is recommended.†
• Avoidance of a landing zone in a plaque burden >50% and particularly lipid-rich tissue at the stent edge.
• A relative stent expansion of >80% (MSA divided by average 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 of >5.5 mm^2 by IVUS imaging and >4.5 mm^2 by OCT imaging.‡
• Co-registration of angiography and intracoronary imaging to determine stent length and allow for precise stent placement.
• Extensive malapposition after stent implantation should be avoided and corrected, if anatomically feasible.§
• Large dissection (extensive lateral >60º, longitudinal extension >2mm, and flap extending to media or adventitia) should be avoided and corrected.

* These criteria were based on the expert consensus document with regard to the clinical use of intracoronary imaging including IVUS and OCT.[3] EEM denotes external elastic membrane, IVUS intravascular ultrasound, MSA minimum stent area, and OCT optical coherence tomography.

† For long lesions with a large diameter discrepancy from distal to proximal regions, a more flexible approach using lumen, mid-wall, or EEM is allowed at the treating operator's discretion.

‡ For left main coronary stenoses, an absolute minimum stent area of more than 7 mm^2 for the distal left main coronary artery and more than 8 mm^2 for the proximal left main coronary artery were used as optimization criteria, respectively.[3]

§ Extensive stent malapposition was defined if it meets the criteria for major malapposition (i.e. with unacceptable stent expansion) that further stent expansion be considered. Major stent malapposition was defined as an acute malapposition with the axial distance between the stent struts and the coronary-

artery vessel wall of at least more than 0.4 mm, with longitudinal extension (length) of more than 1 mm.[3]

Table S1. Baseline Characteristics according to Stent Optimization Status and Imaging modalities.*

Characteristic	OCT (N = 967)			IVUS (N = 1013)		
	Optimized (N = 467)	Non-Optimized (N = 500)	P value	Optimized (N = 555)	Non-Optimized (N = 458)	P value
Age — yr	63.3±10.3	65.1±10.3	0.009	64.7±10.6	65.7±10.3	0.127
Female sex — no. (%)	99 (21.2)	107 (21.4)	0.939	115 (20.7)	105 (22.9)	0.397
Body-mass index†	25.0± 3.1	24.9±3.3	0.497	24.9±3.2	25.1±2.9	0.261
Diabetes mellitus — no. (%)	140 (30.0)	172 (34.4)	0.142	171 (30.8)	173 (37.8)	0.02
Insulin-treated diabetes mellitus — no. (%)	11 (2.4)	21 (4.2)	0.109	11 (2.0)	22 (4.8)	0.012
Hypertension — no. (%)	294 (63.0)	327 (65.4)	0.428	346 (62.3)	298 (65.1)	0.37
Dyslipidemia — no. (%)	381 (81.6)	428 (85.6)	0.091	465 (83.8)	386 (84.3)	0.83
Current smoking — no. (%)	96 (20.6)	112 (22.4)	0.486	102 (18.4)	88 (19.2)	0.735
Family history of premature CAD — no. (%)‡	19 (4.1)	33 (6.6)	0.081	33 (5.9)	23 (5.0)	0.522
Previous myocardial infarction — no. (%)	23 (4.9)	52 (10.4)	0.001	26 (4.7)	37 (8.1)	0.026
Previous PCI — no. (%)	79 (16.9)	141 (28.2)	<0.001	94 (16.9)	106 (23.1)	0.014
Previous CABG — no. (%)	11 (2.4)	20 (4.0)	0.147	7 (1.3)	13 (2.8)	0.073
Previous stroke — no. (%)	27 (5.8)	37 (7.4)	0.312	32 (5.8)	39 (8.5)	0.088
Congestive heart failure — no. (%)	14 (3.0)	14 (2.8)	0.855	5 (0.9)	11 (2.4)	0.057
Chronic pulmonary disease — no. (%)	13 (2.8)	15 (3.0)	0.841	11 (2.0)	15 (3.3)	0.195

Peripheral vascular disease — no. (%)	9 (1.9)	18 (3.6)	0.115	11 (2.0)	21 (4.6)	0.018
Atrial fibrillation — no. (%)	4 (3.0)	12 (2.4)	0.566	19 (3.4)	20 (4.4)	0.437
End-stage renal disease on dialysis — no. (%)	4 (0.9)	14 (2.8)	0.025	10 (1.8)	16 (3.5)	0.09
Left ventricular ejection fraction — %	60.5±7.1	60.5±7.1	0.978	60.5±6.8	59.8±8.0	0.195
Clinical indication for index PCI — no. (%)			0.318			0.386
Silent ischemia	314 (67.2)	330 (66.0)		363 (65.4)	298 (65.1)	
Chronic coronary syndrome	69 (14.8)	60 (12.0)		76 (13.7)	60 (13.1)	
Unstable angina	39 (8.4)	54 (10.8)		47 (8.5)	52 (11.4)	
NSTEMI	45 (9.6)	56 (11.2)		69 (12.4)	48 (10.5)	

* Plus–minus values are means ± SD. Percentages may not total 100 because of rounding. CABG denotes coronary-artery bypass grafting, CAD coronary artery disease, IVUS intravascular ultrasound, NSTEMI non-ST-segment elevation myocardial infarction, OCT optical coherence tomography, and PCI percutaneous coronary intervention.

† The body-mass index is the weight in kilograms divided by the square of the height in meters.

‡ 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.

Table S2. Other Procedural Characteristics: Lesion-Level Analysis.*

Characteristic	Optimized (N = 1022 Patients) (N = 1139 Lesions)	Non-Optimized (N = 958 Patients) (N = 1243 Lesions)	P Value
Other procedural characteristics			
Lesion location — no./total no. (%)			<0.001
Left main	65 (5.7)	164 (13.2)	
Left anterior descending	681 (59.8)	561 (45.1)	
Left circumflex	155 (13.6)	187 (15.0)	
Right coronary artery	229 (20.1)	319 (25.7)	
Ramus intermediate	8 (0.7)	11 (0.9)	
Bypass graft	1 (0.1)	1 (0.1)	
Lesion preparation	782 (68.7)	998 (80.3)	<0.001
Use of compliant or non-compliant balloons	779 (68.8)	990 (80.2)	<0.001
Use of scoring- or cutting-balloons	4 (0.4)	16 (1.3)	0.012
Use of rotablation	7 (0.6)	22 (1.8)	0.01
Direct stenting	350 (31.4)	230 (19.1)	<0.001
Adjunct postdilatation — no./total no. (%)	1069 (94.3)	1112 (90.3)	<0.001
Maximum stent diameter — mm	3.32 (0.46)	3.33 (0.45)	0.358
Maximum balloon size — mm	3.67 (0.52)	3.76 (0.50)	<0.001
Maximum inflation pressure — atm	22.26 (4.09)	22.17 (4.45)	0.639

PCI modalities — no./total no. (%)			<0.001
Drug-eluting stent	1115 (97.9)	1159 (93.2)	
Bare-metal stent	1 (0.1)	0 (0.0)	
Drug-coated balloon	22 (1.9)	84 (6.8)	
Plain balloon angioplasty	1 (0.1)	0 (0.0)	
Mean number of stents per lesion	1.2±0.5	1.4±0.7	<0.001
Total stent length per lesion — mm	32.6±16.0	41.6 ± 21.2	<0.001
Type of drug-eluting stents — no./total no. (%)			<0.001
Everolimus-eluting (Xience™, Promus™, or Synergy™)	501 (44.0)	593 (47.7)	
Zotarolimus-eluting (Resolute Onyx™)	434 (38.1)	395 (31.8)	
Sirolimus-eluting (Orsiro® or Ultimaster™)	106 (9.3)	116 (9.3)	
Biolimus-eluting (Nobori™)	33 (2.9)	29 (2.3)	
Novolimus-eluting (DESyne® X2)	40 (3.5)	25 (2.0)	
Others	1 (0.1)	1 (0.1)	
Intracoronary imaging evaluation			
Pre-PCI evaluation	1120 (98.3)	1219 (98.1)	0.631
Post-PCI evaluation	1135 (99.6)	1239 (99.7)	0.901

* Plus–minus values are means ± SD. Percentages may not total 100 because of rounding. IVUS denotes intravascular ultrasound, OCT optical coherence tomography, and PCI percutaneous coronary intervention.

Table S3. Imaging-Guided Optimization Criteria: Lesion-Level Analysis.

Characteristic	Optimized	Non-Optimized
Overall	**1022 Patients (N = 1139 Lesions)**	**958 Patients (N = 1243 Lesions)**
Predefined stent-optimization criteria† — no./total no. (%)		
Optimal stent expansion‡		259/1243 (20.8%)
Plaque burden at stent landing zone < 50%		750/1101 (68.1%)
No major malapposition§		1097/1242 (88.3%)
No large dissection¶		1115/1243 (89.7%)
A relative stent expansion of >90% — no./total no.(%)	660/1086 (60.8%)	164/1185 (13.8%)
OCT	**467 Patients (N = 507 Lesions)**	**500 Patients (N = 639 Lesions)**
Predefined stent-optimization criteria† — no./total no. (%)		
Optimal stent expansion‡		128/639 (20.0%)
Plaque burden at stent landing zone < 50%		386/508 (76.0%)
No major malapposition§		528/639 (82.6%)
No large dissection¶		546/639 (85.4%)
A relative stent expansion of >90% — no./total no.(%)	267/467 (57.2%)	77/597 (12.9%)
IVUS	**555 Patients (N = 632 Lesions)**	**458 Patients (N = 604 Lesions)**

Predefined stent-optimization criteria† — no./total no. (%)		
Optimal stent expansion‡		131/604 (21.7%)
Plaque burden at stent landing zone < 50%		364/593 (61.4%)
No major malapposition§		569/603 (94.4%)
No large dissection¶		569/603 (94.4%)
A relative stent expansion of >90% — no./total no.(%)	393/619 (63.5%)	87/588 (14.8%)

IVUS denotes intravascular ultrasound, OCT optical coherence tomography, and PCI percutaneous coronary intervention.

† Practical recommendations for stent implantation with optimization criteria by IVUS or OCT were described in section F in the supplementary appendix. These criteria were based on the expert consensus document with regard to the clinical use of intracoronary imaging including IVUS and OCT.[3]

‡ Optimal stent expansion was defined as a relative stent expansion of >80% (an in-stent minimum stent area divided by average reference lumen area). In lesions with non-evaluable reference lumen area, optimal stent expansion was defined as an absolute in-stent minimum stent area of >5.5 mm^2 by IVUS imaging and >4.5 mm^2 by OCT imaging.

§ Extensive stent malapposition was defined as an acute stent malapposition of ≥0.4 mm with longitudinal extension >1 mm of the stent over its entire length against the vessel wall, that further stent expansion be considered.

¶ Large dissection was defined as a dissection that occurred 5mm from the edge of the stent, extended to extensive lateral >60º, longitudinal extension >2mm, and flap extending to media or adventitia.

Table S4. Core Laboratory-Measured QCA Analysis: Lesion-Level Analysis.*

Characteristic	Optimized (N = 1022 Patients) (N = 1139 Lesions)	Non-Optimized (N = 958 Patients) (N = 1243 Lesions)	P Value
Core Lab QCA analysis - Baseline			
Presence of thrombus	7 (0.6)	4 (0.3)	0.05
Presence of calcification (moderate to severe)	186 (16.3)	301 (24.2)	<0.001
Presence of ulceration	13 (1.1)	17 (1.4)	0.072
Presence of aneurysm	7 (0.6)	6 (0.5)	0.07
Reference vessel diameter — mm	3.05 ± 0.51	3.60 ± 13.47	0.181
Minimal lumen diameter — mm	0.99 ± 3.51	0.87 ± 2.31	0.356
Diameter stenosis — %	72.4 ± 10.4	73.3 ± 10.1	0.04
Lesion length — mm	27.8 ± 11.8	34.9 ± 16.5	<0.001
Core Lab QCA analysis - Final post-PCI			
Presence of thrombus	2 (0.2)	3 (0.2)	0.726
Presence of spasm	2 (0.2)	3 (0.2)	0.726
Presence of abrupt closure	3 (0.3)	3 (0.2)	0.915
Presence of no reflow	7 (0.6)	6 (0.5)	0.663
Presence of dissection	5 (0.4)	3 (0.2)	0.405

Minimum lumen diameter — mm			
In-stent	2.73 ± 1.02	2.56 ± 0.50	<0.001
In-segment	2.27 ± 0.80	2.19 ± 1.09	0.031
Diameter stenosis — %			
In-stent	5.05 ± 5.42	6.89 ± 7.17	<0.001
In-segment	17.4 ± 10.6	16.9 ± 10.7	0.211
Acute gain — mm			
In-stent	1.76 ± 3.65	1.71 ± 2.37	0.739
In-segment	1.30 ± 3.58	1.34 ± 2.57	0.744

* Plus–minus values are means ± SD. Percentages may not total 100 because of rounding. PCI denotes percutaneous coronary intervention, and QCA quantitative coronary angiography.

Table S5. Core Laboratory-Measured Imaging Analysis: Lesion-Level Analysis.*

Characteristic	Optimized	Non-Optimized	P Value
OCT	**467 Patients (N = 507 Lesions)**	**500 Patients (N = 639 Lesions)**	
Baseline			
Presence of fibrous component	324 (63.9)	329 (51.5)	<0.001
Presence of lipid component	298 (58.8)	301 (47.1)	<0.001
Degree of lipid area	267.3 ± 83.5	257.9 ± 86.8	0.179
Presence of thin cap fibroatheroma	24 (4.7)	32 (5.0)	<0.001
Presence of plaque rupture	30 (5.9)	36 (5.6)	<0.001
Presence of thrombus	3 (0.6)	5 (0.8)	0.7
Maximum calcium degree	135.85 ± 90.83	148.29 ± 96.73	0.094
Presence of superficial calcium	255 (50.3)	346 (54.1)	0.195
Presence of deep calcium	25 (4.9)	26 (4.1)	0.482
Presence of calcium nodule	5 (1.0)	11 (1.7)	0.008
Reference lumen area — mm^2	7.35 ± 2.64	7.33 ± 2.75	0.936
Target Segment minimum lumen area — mm^2	1.62 ± 0.79	1.54 ± 0.73	0.178
Lesion length — mm	27.9 ± 10.8	34.9 ± 14.2	<0.001
Final post-PCI			

Minimum stent area — mm^2	6.21 ± 2.01	5.12 ± 1.87	<0.001
Minimum stent expansion — %	96.1 ± 12.0	76.8 ± 16.7	<0.001
Minimum stent area by distal reference lumen area — %	145.2 ± 48.7	126.6 ± 45.9	<0.001
IVUS	**555 Patients (N = 632 Lesions)**	**458 Patients (N = 604 Lesions)**	
Baseline			
Presence of plaque rupture	38 (6.0)	43 (7.2)	0.039
Presence of thrombus	2 (0.3)	6 (1.0)	0.138
Maximum calcium degree	170.3 ± 95.3	197.7 ± 100.3	<0.001
Presence of superficial calcium	335 (53.0)	315 (52.2)	0.764
Presence of deep calcium	51 (8.1)	53 (8.8)	0.655
Presence of calcium nodule	27 (4.3)	35 (5.8)	0.002
Reference lumen area — mm^2	8.39 ± 2.78	8.41 ± 3.00	0.951
Target Segment minimum lumen area — mm^2	2.19 ± 0.86	2.21 ± 1.29	0.864
Lesion length — mm	26.8 ± 11.3	33.1 ± 15.6	<0.001
Final post-PCI			
Minimum stent area — mm^2	7.25 ± 2.35	6.12 ± 2.25	<0.001
Minimum stent expansion — %	101.0 ± 17.1	80.9 ± 21.3	<0.001
Minimum stent area by distal reference lumen area — %	132.9 ± 37.9	119.0 ± 39.2	<0.001

* Plus–minus values are means ± SD. Percentages may not total 100 because of rounding. IVUS denotes intravascular ultrasound, and OCT optical coherence tomography.

Table S6. Relevant Cardiac-Related Medications at Discharge and During Follow-Up.*

Characteristic	Optimized (N = 1022)	Non-Optimized (N = 958)	P value
At discharge — no./total no. (%)	N=1022	N=958	
Aspirin	1011 (98.9)	936 (97.7)	0.034
$P2Y_{12}$ inhibitors†	1015 (99.3)	950 (99.2)	0.700
Oral anticoagulants‡	41 (4.0)	44 (4.6)	0.524
Beta-blockers	660 (64.6)	647 (67.5)	0.165
ACE inhibitor or ARB	323 (31.6)	343 (35.8)	0.048
Calcium-channel blockers	687 (67.2)	668 (69.7)	0.230
Statins	1019 (99.7)	955 (99.7)	0.937
1 Mo (±2 weeks) after randomization — no./total no. (%)	N=1014	N=947	
Aspirin	1008 (99.4)	936 (98.8)	0.174
$P2Y_{12}$ inhibitors†	996 (98.2)	935 (98.7)	0.360
Oral anticoagulants‡	40 (3.9)	46 (4.9)	0.324
Beta-blockers	661 (65.2)	623 (65.8)	0.780
ACE inhibitor or ARB	304 (30.0)	361 (38.1)	<0.001
Calcium-channel blockers	614 (60.6)	608 (64.2)	0.096
Statins	993 (97.9)	928 (98.0)	0.919

6 Mo (±1 Mo) after randomization — no./total no. (%)	N=960	N=900	
Aspirin	881 (91.8)	827 (91.9)	0.926
$P2Y_{12}$ inhibitors†	920 (95.8)	872 (96.9)	0.225
Oral anticoagulants‡	39 (4.1)	45 (5.0)	0.331
Beta-blockers	625 (65.1)	592 (65.8)	0.760
ACE inhibitor or ARB	321 (33.4)	339 (37.7)	0.057
Calcium-channel blockers	557 (58.0)	565 (62.8)	0.036
Statins	938 (97.7)	874 (97.1)	0.417
12 Mo (±2 Mo) after randomization — no./total no. (%)	N=1011	N=937	
Aspirin	528 (52.2)	498 (53.1)	0.684
$P2Y_{12}$ inhibitors†	771 (76.3)	739 (78.9)	0.168
Oral anticoagulants‡	46 (4.5)	44 (4.7)	0.878
Beta-blockers	616 (60.9)	575 (61.4)	0.844
ACE inhibitor or ARB	341 (33.7)	341 (36.4)	0.218
Calcium-channel blockers	515 (50.9)	536 (57.2)	0.006
Statins	950 (94.0)	878 (93.7)	0.809

* Numbers (percentages) are from the intention-to-treat analysis. During the regular follow-up period, patients who were unable to attend outpatient clinic visits were contacted by telephone interview for assessment of adverse clinical events; for whom, collection of exact information on concomitant cardiovascular medications was not available. ACE denotes angiotensin-converting enzyme, ARB angiotensin-receptor blocker, CABG coronary-artery bypass grafting, IVUS intravascular ultrasound, OCT optical coherence tomography, and PCI percutaneous coronary intervention.

† $P2Y_{12}$ inhibitors were clopidogrel, ticagrelor, or prasugrel.

‡ Oral anticoagulants were a vitamin K antagonist or a non–vitamin K antagonist oral anticoagulant.

Table S7. Primary and Secondary Endpoints According to Stent Optimization Status and Imaging modalities. *

Endpoints (n/%)	OCT (N = 967)				IVUS (N = 1013)			
	Optimized (N = 467)	Non-Optimized (N = 500)	HR (95% CI)	Adjusted HR (95% CI)	Optimized (N = 555)	Non-Optimized (N = 458)	HR (95% CI)	Adjusted HR (95% CI)
Primary end point								
Target-vessel failure†	14 (3.0)	38 (7.6)	0.39 (0.21–0.72)	0.48 (0.24–0.97)	25 (4.5)	34 (7.4)	0.63 (0.37–1.05)	0.59 (0.32–1.08)
Secondary end points								
Target-lesion failure‡	11 (2.4)	33 (6.6)	0.36 (0.18–0.71)	0.48 (0.22–1.05)	23 (4.1)	31 (6.8)	0.63 (0.37–1.08)	0.57 (0.31–1.06)
Death								
From any causes	8 (1.7)	19 (3.8)	0.47 (0.20–1.07)	0.71 (0.26–1.95)	13 (2.3)	12 (2.6)	0.87 (0.40–1.91)	1.05 (0.41–2.69)
From cardiac causes	3 (0.6)	7 (1.4)	0.51 (0.13–2.05)	1.22 (0.14–10.76)	6 (1.1)	4 (0.9)	1.23 (0.35–4.35)	1.13 (0.27–4.75)
From noncardiac causes	5 (1.1)	12 (2.4)	0.44 (0.16–1.26)	0.51 (0.15–1.77)	7 (1.3)	8 (1.7)	0.69 (0.25–1.91)	1.26 (0.31–5.06)
Target-vessel myocardial infarction§	2 (0.4)	5 (1.0)	0.43 (0.08–2.20)	0.59 (0.10–3.65)	8 (1.4)	10 (2.2)	0.66 (0.26–1.68)	0.62 (0.22–1.79)
Any myocardial infarction§	2 (0.4)	5 (1.0)	0.43 (0.08–2.20)	0.59 (0.10–3.65)	9 (1.6)	11 (2.4)	0.68 (0.28–1.64)	0.66 (0.25–1.78)
Periprocedural	2 (0.4)	3 (0.6)	0.71 (0.12–4.27)	1.16 (0.11–12.13)	6 (1.1)	5 (1.1)	0.99 (0.30–3.24)	0.87 (0.24–3.15)
Spontaneous	0 (0.0)	2 (0.4)	NC	NC	3 (0.5)	6 (1.3)	0.42 (0.10–1.68)	0.64 (0.10–4.29)

Stent thrombosis¶	0 (0.0)	0 (0.0)	NC	NC	1 (0.2)	1 (0.2)	0.83 (0.05–13.2)	NC
Stroke	4 (0.9)	5 (1.0)	0.85 (0.23–3.16)	2.12 (0.34–13.31)	3 (0.5)	5 (1.1)	0.5 (0.12–2.08)	0.77 (0.15–4.07)
Any repeat revascularization	14 (3.0)	33 (6.6)	0.44 (0.23–0.82)	0.47 (0.23–0.98)	20 (3.6)	29 (6.3)	0.59 (0.33–1.04)	0.49 (0.25–0.99)
Target-lesion revascularization	6 (1.3)	21 (4.2)	0.3 (0.12–0.74)	0.42 (0.15–1.15)	11 (2.0)	21 (4.6)	0.45 (0.22–0.94)	0.36 (0.15–0.90)
Target-vessel revascularization	9 (1.9)	26 (5.2)	0.36 (0.17–0.77)	0.44 (0.19–1.05)	13 (2.3)	24 (5.2)	0.47 (0.24–0.92)	0.41 (0.17–0.95)
Re-hospitalization	52 (11.1)	82 (16.4)	0.67 (0.47–0.95)	0.75 (0.50–1.12)	96 (17.3)	91 (19.9)	0.91 (0.68–1.21)	0.89 (0.64–1.23)
Bleeding event, BARC type 3–5‖	7 (1.5)	7 (1.4)	1.05 (0.37–3.00)	1.94 (0.46–8.11)	6 (1.1)	10 (2.2)	0.49 (0.18–1.34)	0.56 (0.18–1.76)
Contrast-induced nephropathy — no. (%)**	5 (1.1)	8 (1.6)			6 (1.1)	9 (2.0)		

* Clinical end points were evaluated during the entire follow-up period (i.e., 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. BARC denotes Bleeding Academic Research Consortium, CI confidence interval, HR hazard ratio, IVUS intravascular ultrasound, NC not calculated, and OCT optical coherence tomography.

Hazard ratios are for the optimized group, as compared with the non-optimized group. Because confidence intervals 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 end points.

† Target-vessel failure was a composite of death from cardiac causes, target-vessel myocardial infarction, or ischemia-driven target-vessel revascularization.

‡ Target-lesion failure was a composite of death from cardiac causes, target-vessel myocardial infarction, or ischemia-driven target-lesion revascularization.

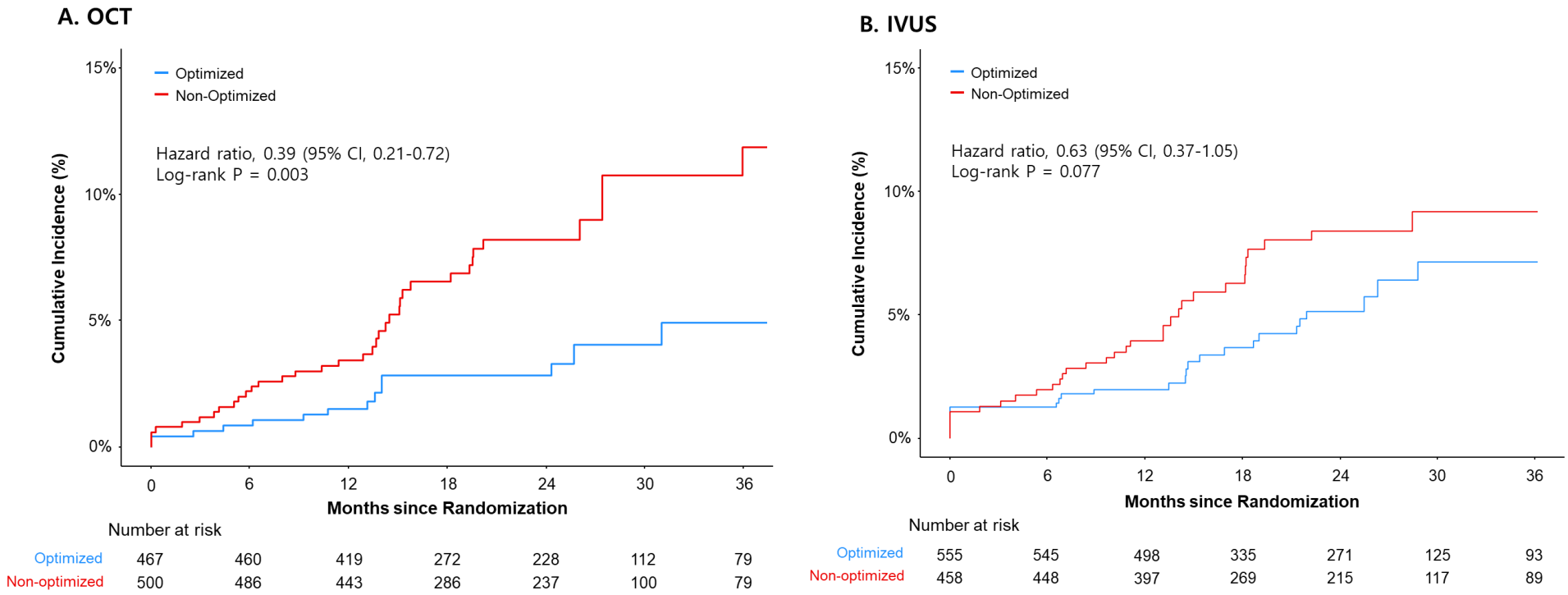
§ Myocardial infarction was assessed according to the protocol definition.

¶ Stent thrombosis was defined as definite or probable stent thrombosis according to the Academic Research Consortium. Only 2 definite thromboses were observed in the IVUS-guided PCI group at 1 day and 95 days after the procedure.

‖ Bleeding events are assessed according to the Bleeding Academic Research Consortium (BARC) criteria, in which BARC type 3–5 indicates severe bleeding.

** Contrast-induced nephropathy was defined as either a greater than 25% increase of serum creatinine or an absolute increase in serum creatinine of 0.5 mg/dL from baseline within 72 h after the index PCI procedure. Event rates (%) of contrast-induced nephropathy are presented as calculated percentages.

Figure S1. Time-to-Event Curves for the Primary Endpoint According to Stent Optimization Status in the OCT and the IVUS groups.



국문요약

배경: 2018 년 유럽 심혈관 중재 전문가 합의는 혈관내 영상을 사용한 스텐트 최적화 평가의 임상적 사용에 대한 통일된 기준을 제시하였다. 그러나 경피적 관상동맥 중재술 이후 이러한 모든 기준을 충족시키는 것이 임상 결과에 미치는 영향에 대한 자료는 제한적이다.

방법: 광간섭단층촬영 또는 혈관내 초음파를 이용한 관상동맥 중재술을 비교한 연구인 OCTIVUS 연구(광간섭단층촬영 또는 혈관내 초음파를 이용한 관상동맥 중재술의 비교에 대한 연구)의 데이터를 사용하여 분석을 진행하였고 스텐트 최적화 여부를 평가하기에 영상이 부적합한 환자는 제외하였다. 관상동맥 중재술 후 환자들은 모든 스텐트 최적화 기준을 충족한 경우에 최적화 그룹으로 분류되었고, 적어도 하나의 기준을 충족하지 못한 경우는 최적화되지 않은 그룹으로 분류되었다. 주요 연구 종점은 심장 원인 사망, 대상 혈관 심근 경색, 또는 허혈 주도 대상 혈관 재관류의 복합 발생률이었다.

결과: 1980 명의 환자 중 1022 명(51.6%)이 최적화 그룹으로, 958 명 (48.4%)이 최적화되지 않은 그룹으로 분류되었다. 2 년의 중위 추적 관찰 기간 동안 최적화 그룹에서 주요 복합 종점이 39 명(3.8%)에서 발생하였고, 최적화되지 않은 그룹에서는 72 명(7.5%)에서 발생하였다 (위험비율 0.52; 95% 신뢰구간 0.35-0.77; P <0.001). 이 차이는 주로 최적화 그룹에서 대상 혈관 재관류가 감소했기 때문이었다.

결론: 광간섭단층촬영 또는 혈관내 초음파를 이용한 관상동맥 중재술을 받은 환자에서 모든 스텐트 최적화 기준을 달성하는 것은 심장 원인 사망, 대상 혈관

심근 경색, 또는 허혈 주도 대상 혈관 재관류의 주요 복합 종점 발생률 감소와 관련이 있었다.

중심 단어: 스텐트 최적화, 광간섭단층촬영, 혈관내 초음파, 관상동맥 중재술