Outcomes From the Bifurcation Subgroup of OCTIVUS Trial

Do-Yoon Kang, MD, PhD for the OCTIVUS Investigators

Division of Cardiology, Asan Medical Center,
**University of Ulsan College of Medicine, Seoul, Korea**

CVRF

Disclosure

Background: Current European Guideline

- Recommendations for intravascular imaging for PCI optimization

Recommendations	Class[a]	Level[b]
IVUS or OCT should be considered in selected patients to optimize stent implantation.[603,612,651–653]	IIa	B
IVUS should be considered to optimize treatment of unprotected left main lesions.[35]	IIa	B
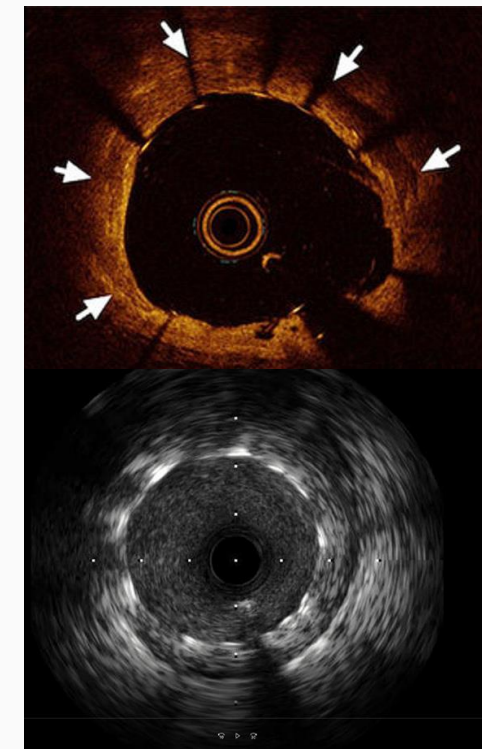
OCT

IVUS

IVUS, intravascular ultrasound; OCT, optical coherence tomography

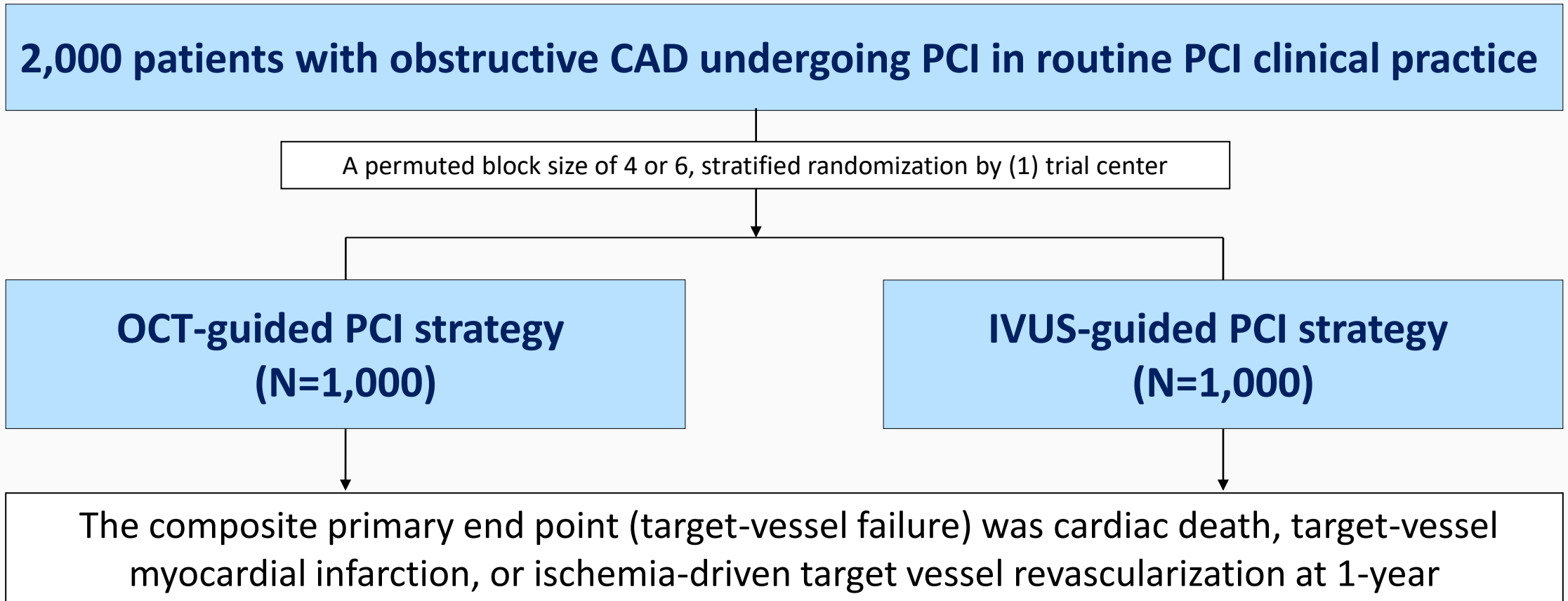Neumann FJ et al. *Eur Heart J* 2019;40:87-165

Circulation

Optical Coherence Tomography–Guided or Intravascular Ultrasound–Guided Percutaneous Coronary Intervention: The OCTIVUS Randomized Clinical Trial

Do-Yoon Kang, MD*; Jung-Min Ahn, MD*; Sung-Cheol Yun, PhD; Seung-Ho Hur, MD; Yun-Kyeong Cho, MD; Cheol Hyun Lee, MD; Soon Jun Hong, MD; Subin Lim, MD; Sang-Wook Kim, MD; Hoyoun Won, MD; Jun-Hyok Oh, MD; Jeong Cheon Choe, MD; Young Joon Hong, MD; Yong-Hoon Yoon, MD; Hoyun Kim, MD; Yeonwoo Choi, MD; Jinho Lee, MD; Young Won Yoon, MD; Soo-Joong Kim, MD; Jang-Ho Bae, MD; Duk-Woo Park, MD; Seung-Jung Park, MD; for the OCTIVUS Investigators

Pragmatic Trial Design

Optical Coherence Tomography–guided versus IntraVascular UltraSound–guided percutaneous coronary intervention

OCTIVUS Trial

2,000 patients with obstructive CAD undergoing PCI in routine PCI clinical practice

A permuted block size of 4 or 6, stratified randomization by (1) trial center

OCT-guided PCI strategy (N=1,000)

IVUS-guided PCI strategy (N=1,000)

The composite primary end point (target-vessel failure) was cardiac death, target-vessel myocardial infarction, or ischemia-driven target vessel revascularization at 1-year

Kang DY, Park DW et al. *Am Heart J* 2020;228:72-80
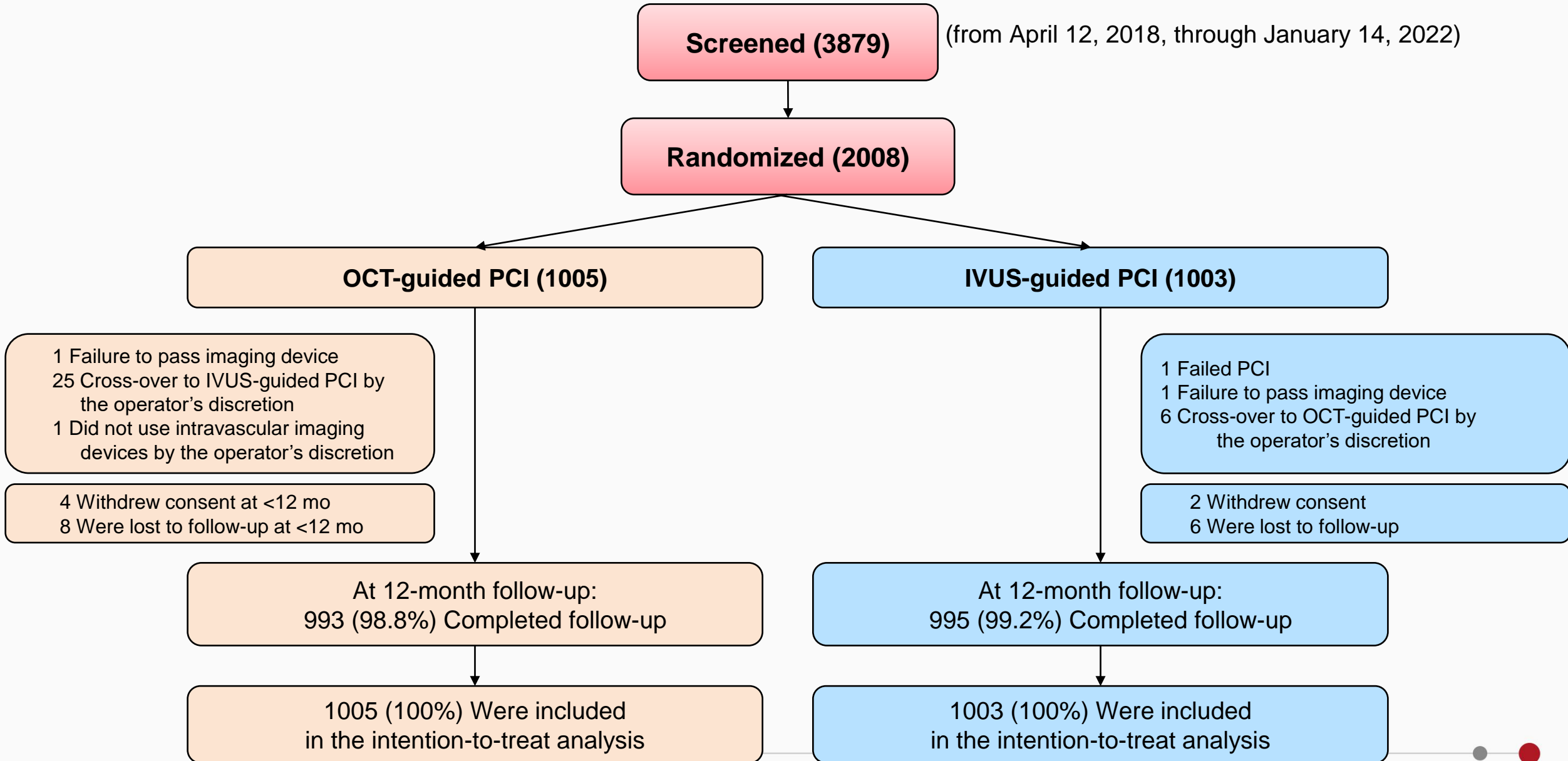
Inclusion and Exclusion Criteria

INCLUSION

1. Men or women at least age ≥ 19 years.

2. Patients with obstructive coronary artery disease (native or restenotic) undergoing PCI with contemporary drug-eluting stents or drug-coated balloons (only for in-stent restenotic lesion) under intracoronary imaging guidance.

3. The patient or guardian agreed to the study protocol and the schedule for clinical follow-up, and provided informed written consent, as approved by the appropriate Institutional Review Board/Ethical Committee of the respective clinical site.

EXCLUSION

1. ST-elevation myocardial infarction.

2. Severe renal dysfunction (eGFR <30 mL/min/1.73 m^2), unless patient is on renal replacement therapy.

3. Cardiogenic shock or decompensated heart failure with severe left ventricular dysfunction (left ventricular ejection fraction < 30%).

4. Life expectancy < 1 years for any non-cardiac or cardiac causes.

5. Any lesion characteristics resulting in the expected inability to deliver the intracoronary imaging catheter during PCI (e.g., severe vessel calcification or tortuosity).

PCI, percutaneous coronary intervention

Patient Flow and Follow-Up

Screened (3879)   (from April 12, 2018, through January 14, 2022)

Randomized (2008)

OCT-guided PCI (1005)

IVUS-guided PCI (1003)

1 Failure to pass imaging device
25 Cross-over to IVUS-guided PCI by
  the operator's discretion
1 Did not use intravascular imaging
  devices by the operator's discretion

1 Failed PCI
1 Failure to pass imaging device
6 Cross-over to OCT-guided PCI by
  the operator's discretion

4 Withdrew consent at <12 mo
8 Were lost to follow-up at <12 mo

2 Withdrew consent
6 Were lost to follow-up

At 12-month follow-up:
993 (98.8%) Completed follow-up

At 12-month follow-up:
995 (99.2%) Completed follow-up

1005 (100%) Were included
in the intention-to-treat analysis

1003 (100%) Were included
in the intention-to-treat analysis

Primary Endpoint of TVF: Cardiac Death, TV-MI, or TVR

Hazard ratio, 0.80 (95% CI, 0.47–1.36)
P for noninferiority <0.001

IVUS-guided 3.1%

OCT-guided 2.5%

Patients (%)

Months since Randomization
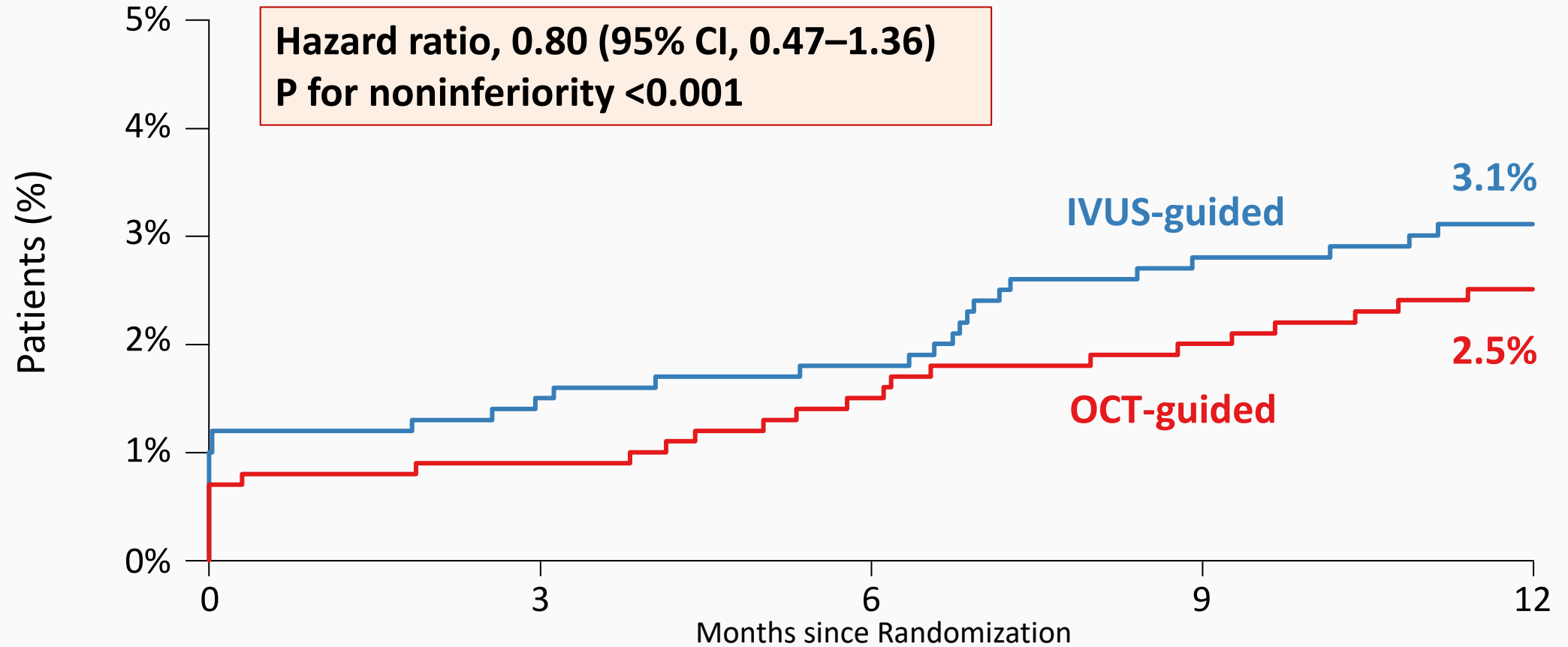
No. at Risk

OCT-guided PCI	1005	990	984	979	912
IVUS-guided PCI	1003	985	981	969	893

CI, confidence interval; TV-MI, target-vessel myocardial infarction; TVR, target-vessel revascularization

Conclusions

In this OCTIVUS trial involving patients who are undergoing PCI for diverse coronary-artery lesions,
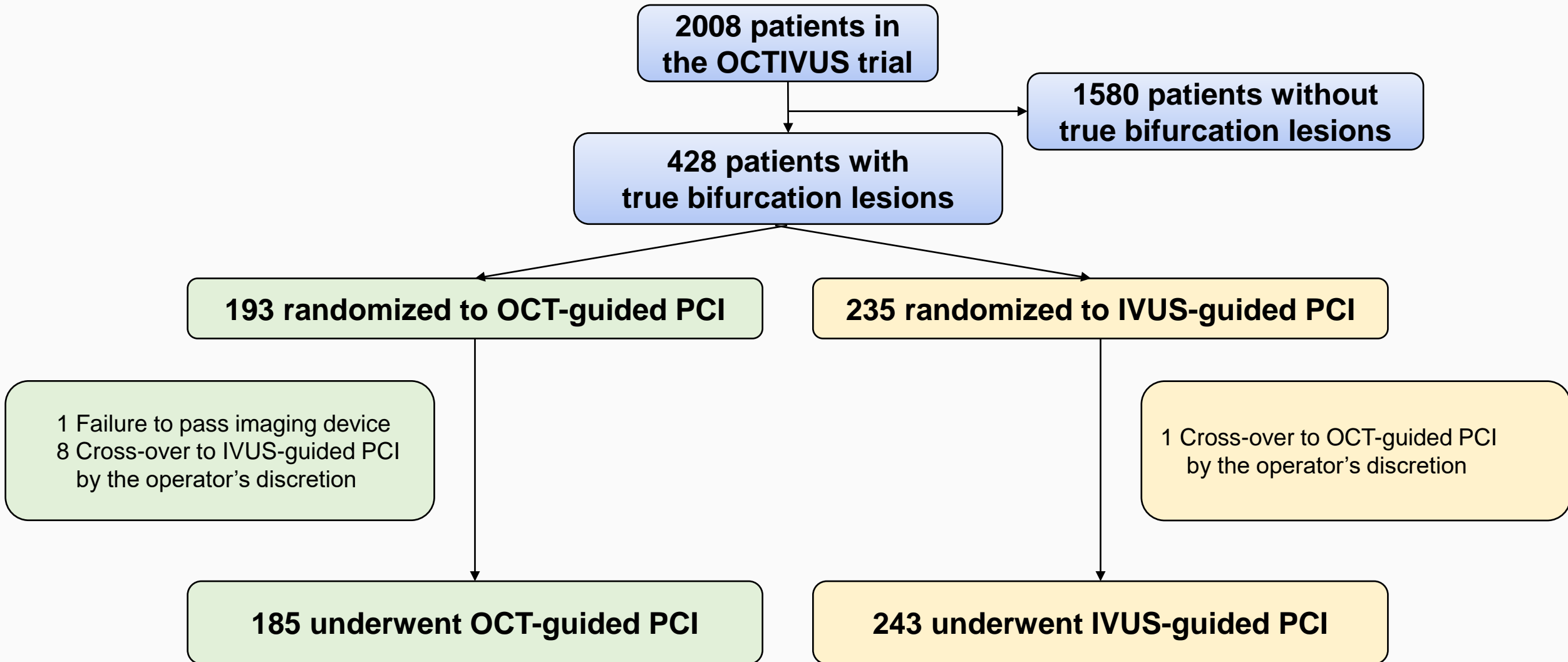
1. **OCT-guided PCI was noninferior to IVUS-guided PCI with respect to a composite of death from cardiac causes, target-vessel myocardial infarction, or ischemia-driven target-vessel revascularization at 1 year.**

2. **However, the selected study population and lower than expected event rates should be considered in interpreting the trial.**

OCT vs IVUS in Patients with True Bifurcation Lesions

Key Baseline Characteristics

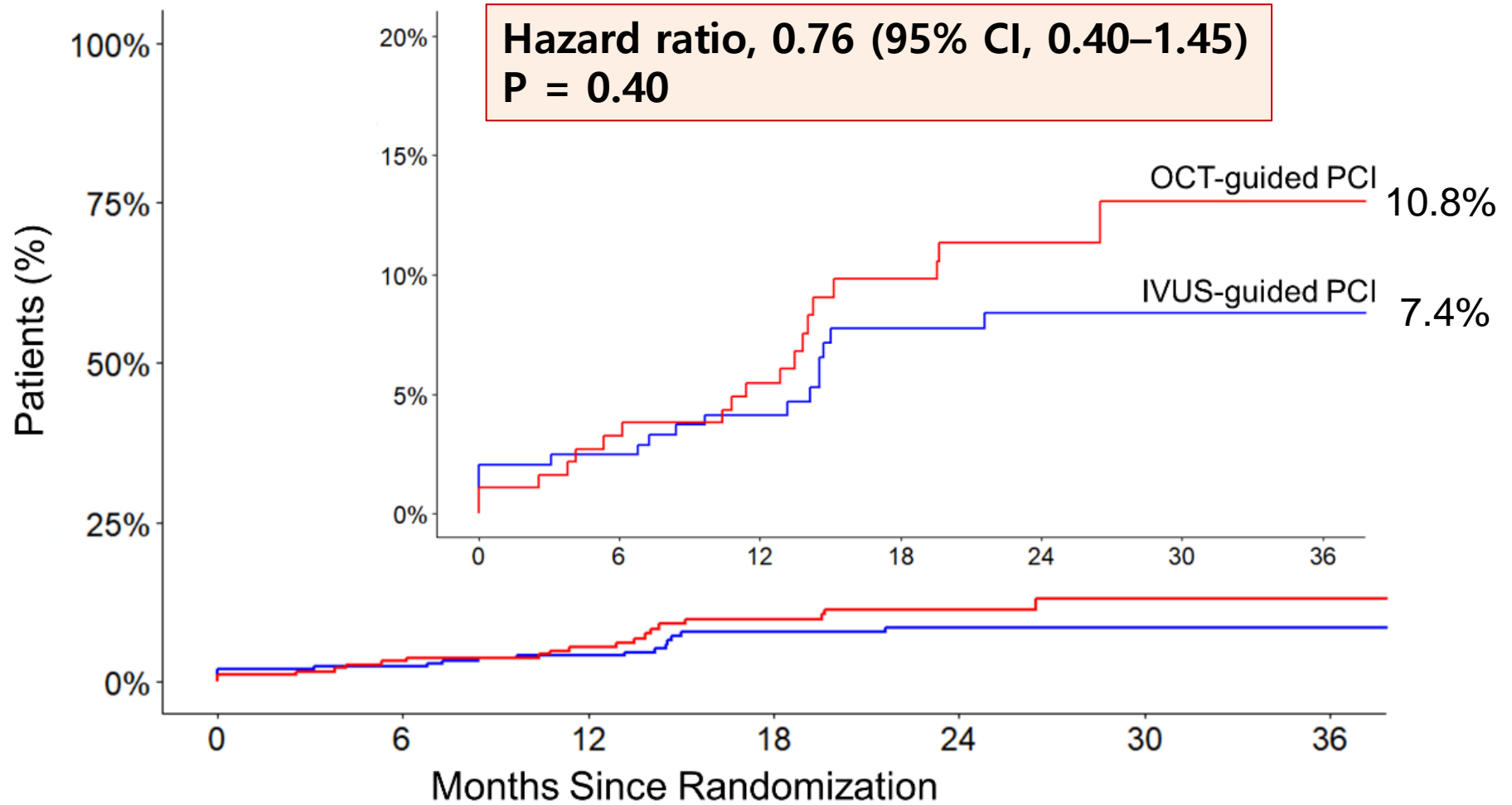|	OCT-Guided PCI (N = 185)	IVUS-Guided PCI (N = 243)	P-value
Age [yrs], mean (SD)	65.5 ± 9.8	65.5 ± 9.7	0.98
Female sex	56 (30.3%)	46 (18.9%)	**0.01**
Body-mass index	24.6 ± 3.2	24.9 ± 2.9	0.33
Diabetes mellitus — no. (%)	72 (38.9%)	87 (35.8%)	0.58
Hypertension — no. (%)	125 (67.6%)	156 (64.2%)	0.53
Dyslipidemia — no. (%)	162 (87.6%)	205 (84.4%)	0.42
Current smoking — no. (%)	35 (18.9%)	53 (21.8%)	0.54
Previous PCI — no. (%)	44 (23.8%)	47 (19.3%)	0.32
Previous CABG — no. (%)	6 (3.2%)	6 (2.5%)	0.85
Previous stroke — no. (%)	11 (5.9%)	19 (7.8%)	0.58
Atrial fibrillation — no. (%)	6 (3.2%)	12 (4.9%)	0.53
End-stage renal disease on dialysis — no. (%)	3 (1.6%)	3 (1.2%)	>0.99
Left ventricular ejection fraction [%], mean (SD)	60.5 ± 7.2	60.7 ± 6.7	0.78
Clinical indication for index PCI — no. (%)			0.54
Silent ischemia	20 (10.8%)	23 (9.5%)	
Stable angina	138 (74.6%)	175 (72.0%)	
Acute coronary syndrome	27 (14.6%)	45 (18.5%)	

Anatomical Characteristics

	OCT-Guided PCI (N = 185 patients with 188 lesions)	IVUS-Guided PCI (N = 243 patients with 253 lesions)	P-value
Trial bifurcation vessels — no. (%)			0.32
LMCA-LAD-LCX	46 (24.5%)	63 (24.9%)	
LAD-D	112 (59.6%)	149 (58.9%)	
LCX-OM	19 (10.1%)	34 (13.4%)	
RCA-PDA-PLA	11 (5.9%)	7 (2.8%)	
Medina classification(site report)			0.74
(1,1,1)	150 (79.8%)	194 (76.7%)	
(1,0,1)	21 (11.2%)	32 (12.6%)	
(0,1,1)	17 (9.0%)	27 (10.7%)	
SYNTAX score			
Mean	20.6 ± 10.0	21.2 ± 9.4	0.57
Category — no./total no. (%)			0.67
Low, 0 to 22	117 (63.2%)	144 (59.3%)	
Intermediate, 23 to 32	45 (24.3%)	68 (28.0%)	
High, >32	23 (12.4%)	31 (12.8%)	

Procedural Characteristics

	OCT-Guided PCI (N = 185)	IVUS-Guided PCI (N = 243)	P-value
PCI approach			0.90
Radial access	85 (45.9%)	109 (44.9%)	
Femoral access	100 (54.1%)	134 (55.1%)	
PCI modality			>0.99
Use of drug-eluting stents	180 (97.3%)	237 (97.5%)	
Used of drug-coated balloons (only for ISR lesion)	5 (2.7%)	6 (2.5%)	
Mean number of stents per patient	2.2 ± 1.3	2.3 ± 1.2	0.57
Total stent length per patient — mm	65.0 ± 40.0	66.7 ± 37.5	0.67
Stent technique			0.29
1-Stent technique	109 (60.6%)	130 (54.9%)	
2-Stent technique	71 (39.4%)	107 (45.1%)	
Post-dilatation w/ larger or high-pressure balloon	176 (95.1%)	235 (96.7%)	0.57
Total amount of contrast media used — mL	283.3 ± 136.1	257.5 ± 129.5	**0.047**
Total PCI time — min	56.4 ± 25.3	64.1 ± 26.4	**0.003**

TVF in Patients with True Bifurcation Lesions

Primary and Secondary Outcomes

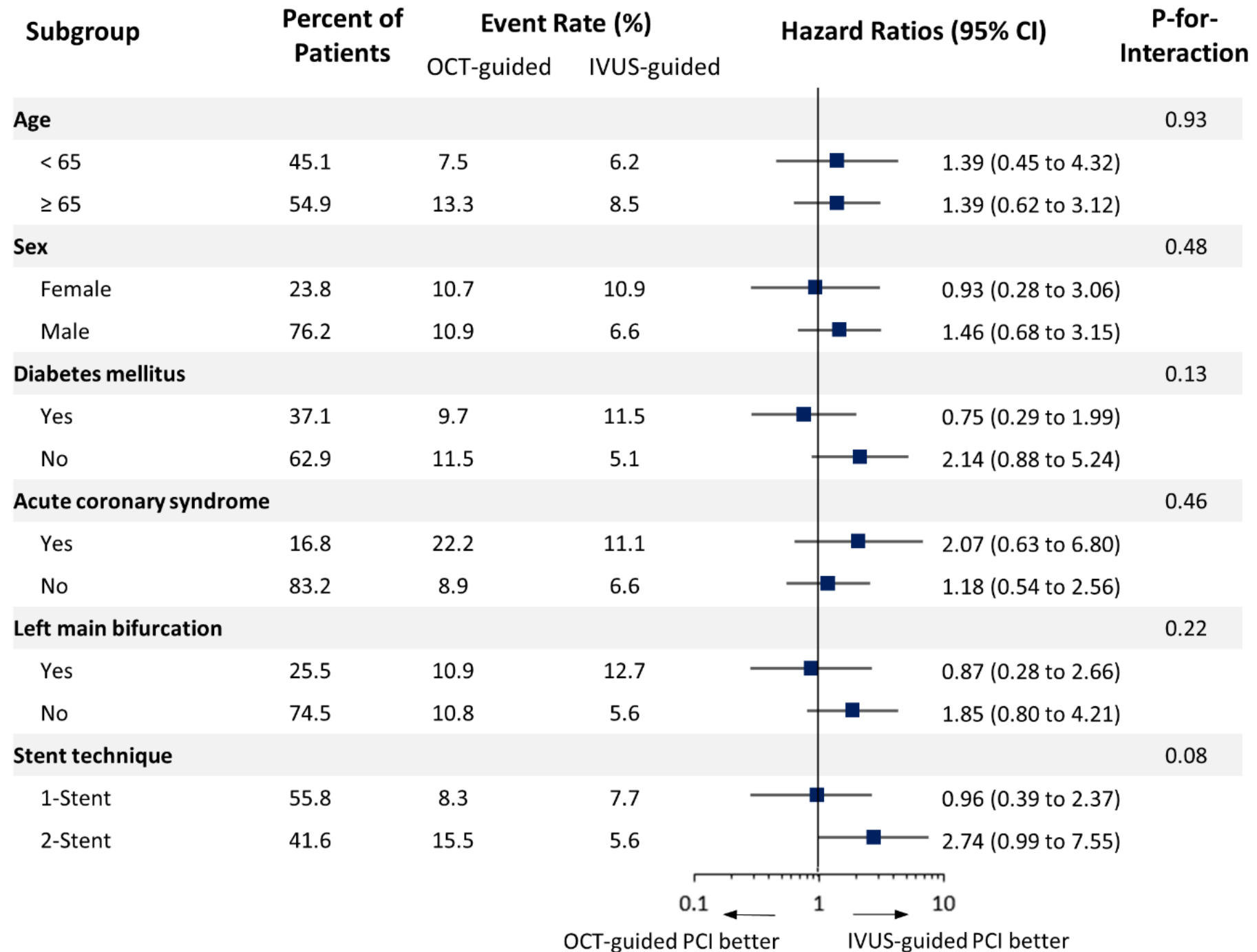|	OCT-Guided PCI (N = 185)	IVUS-Guided PCI (N = 243)	Hazard Ratio (95% CI)	P-value
Target-vessel failure	20 (10.8)	18 (7.4)	1.32 (0.69-2.52)	0.40
Target-lesion failure	18 (9.7)	17 (7.0)	1.24 (0.63-2.44)	0.53
Death from any causes	3 (1.6)	6 (2.5)	0.42 (0.09-2.10)	0.29
Death from cardiac causes	2 (1.1)	2 (0.8)	0.64 (0.06-7.07)	0.72
Target-vessel MI	3 (1.6)	6 (2.5)	0.65 (0.16-2.60)	0.54
Periprocedural	2 (1.1)	4 (1.6)	0.66 (0.12-3.58)	0.63
Spontaneous	1 (0.5)	2 (0.8)	0.64 (0.06-7.09)	0.72
Any revascularization	19 (10.3)	16 (6.6)	1.46 (0.75-2.85)	0.27
Target-lesion revascularization	13 (7.0)	11 (4.5)	1.44 (0.64-3.23)	0.38
Target-vessel revascularization	15 (8.1)	12 (4.9)	1.54 (0.72-3.30)	0.27
Bleeding event : BARC type 3–5	2 (1.1)	5 (2.1)	0.53 (0.10-2.72)	0.44
Contrast-induced nephropathy	3 (1.6)	3 (1.2)	1.00 (0.98-1.03)	0.74

Primary Outcome in the Propensity-Score Adjusted Cohort

IPTW method

Hazard ratio, 1.12 (95% CI, 0.57–2.22)
P = 0.74

Overlap PS weighting method

Hazard ratio, 1.15 (95% CI, 0.16–2.24)
P = 0.69

Key Subgroups Analysis

Subgroup	Percent of Patients	Event Rate (%) OCT-guided	Event Rate (%) IVUS-guided	Hazard Ratios (95% CI)	P-for-Interaction
Age					0.93
< 65	45.1	7.5	6.2	1.39 (0.45 to 4.32)	
≥ 65	54.9	13.3	8.5	1.39 (0.62 to 3.12)	
Sex					0.48
Female	23.8	10.7	10.9	0.93 (0.28 to 3.06)	
Male	76.2	10.9	6.6	1.46 (0.68 to 3.15)	
Diabetes mellitus					0.13
Yes	37.1	9.7	11.5	0.75 (0.29 to 1.99)	
No	62.9	11.5	5.1	2.14 (0.88 to 5.24)	
Acute coronary syndrome					0.46
Yes	16.8	22.2	11.1	2.07 (0.63 to 6.80)	
No	83.2	8.9	6.6	1.18 (0.54 to 2.56)	
Left main bifurcation					0.22
Yes	25.5	10.9	12.7	0.87 (0.28 to 2.66)	
No	74.5	10.8	5.6	1.85 (0.80 to 4.21)	
Stent technique					0.08
1-Stent	55.8	8.3	7.7	0.96 (0.39 to 2.37)	
2-Stent	41.6	15.5	5.6	2.74 (0.99 to 7.55)	

0.1　1　10

← OCT-guided PCI better　　IVUS-guided PCI better →