OCT- or IVUS-Guided PCI for Complex Coronary Lesions : Key Analysis from OCTIVUS Trial

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Disclosure Statement

- I, Do-Yoon Kang, DO NOT have any relevant financial relationships to disclose.
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Background

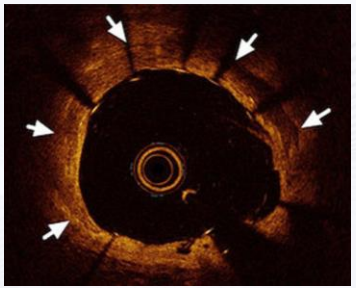
- Intracoronary imaging-guided PCI for complex coronary-artery lesions showed superior clinical outcomes compared to angiography-guided PCI.[1-4]
- Optical coherence tomography (OCT) and intravascular ultrasound (IVUS) have shown comparable outcomes in guiding PCI.[5-7]
- However, the comparative effectiveness of OCT or IVUS for guiding PCI in patients with complex coronary-artery lesions remains unclear.

PCI, percutaneous coronary intervention

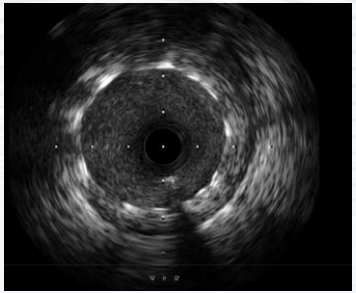
[1]Hong SJ, et al. *JAMA* 2015;314:2155-63. [2]Kim BK, et al. *Circ Cardiovasc Interv* 2015;8. [3]Zhang J, et al. *J Am Coll Cardiol* 2018;72:3126-37. [4]Lee JM, et al. *New Engl J Med* 2023;388:1668-79. [5]Ali ZA, et al. *Lancet* 2016;388. [6]Kubo T, et al. *Eur Heart J* 2017;38. [7]Kang DY, et al. Circulation 2023;Aug 27.

Background : Current ACC/AHA/SCAI Guidelines

COR	LOE	RECOMMENDATIONS
2a	B-R	1. In patients undergoing coronary stent implantation, IVUS can be useful for procedural guidance, particularly in cases of left main or complex coronary artery stenting, to reduce ischemic events (1-10).
2a	B-R	2. In patients undergoing coronary stent implantation, OCT is a reasonable alternative to IVUS for procedural guidance, except in ostial left main disease (11-13).
2a	C-LD	3. In patients with stent failure, IVUS or OCT is reasonable to determine the mechanism of stent failure (14-17).



OCT



IVUS

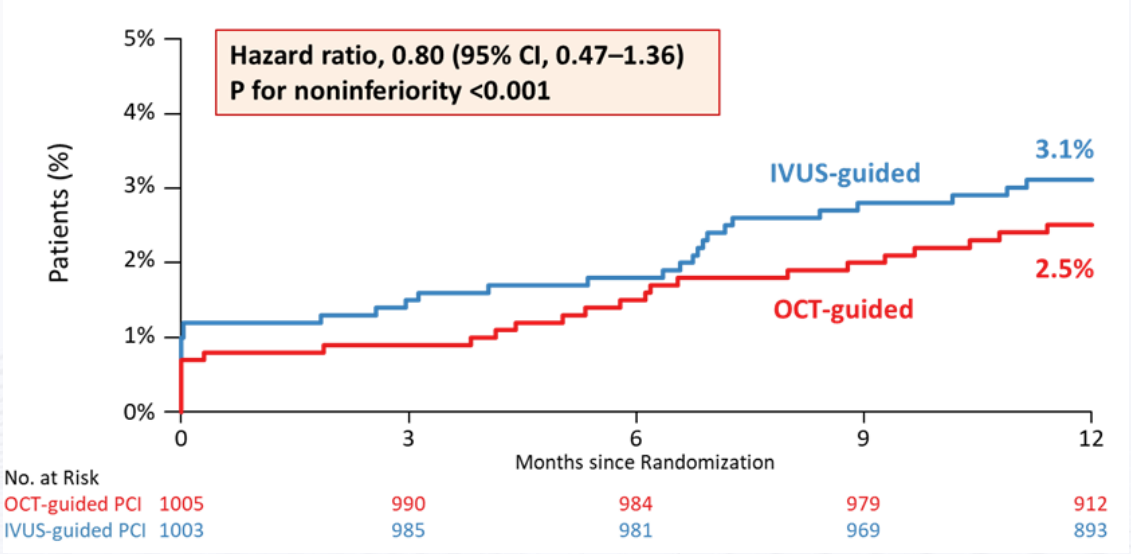
Lawton JS, et al. *J Am Coll Cardiol* 2021.

The OCTIVUS Trial

Design

- **DESIGN**: a prospective, multi-center, randomized, open-label trial
- **OBJECTIVE**: To compare OCT-guided and IVUS-guided strategies in patients who underwent PCI for diverse coronary-artery lesions
- **HYPOTHESIS**: OCT-guided PCI is non-inferior to IVUS-guided PCI with respect to 1-year target vessel failure.
- **PARTICIPANTS**: 2,008 patients from 9 centers in Korea were randomized to OCT-guided and IVUS-guided PCI.

Primary End Point: Cardiac Death, TV-MI, or TVR at 1 year



Kang DY, Ahn JM, Park DW et al. Circulation 2023 Aug 27.

A Key Subgroup Analysis of OCTIVUS Trial

- ***Objective***

  To compare the clinical efficacy and safety of OCT-guided and IVUS-guided strategies in patients who underwent PCI for ***complex coronary-artery lesions***

Kang DY, Ahn JM, Park DW et al. JACC 2023 Oct 23.

Inclusion and Exclusion Criteria

INCLUSION

1. Men or women at least age ≥ 19 years.
2. Patients with obstructive CAD undergoing PCI under intracoronary imaging guidance.
3. Patients with ***complex coronary lesions*** including,
   - unprotected left main disease,
   - bifurcation disease,
   - aorto-ostial lesion,
   - chronic total occlusion,
   - severely calcified lesion,
   - in-stent restenotic lesion,
   - long diffuse lesion (stent length >38 mm), or
   - multivessel PCI at the index PCI.

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).

CAD, coronary artery disease; PCI, percutaneous coronary intervention

Imaging-guided PCI

- PCI procedure was performed using standard techniques.
- In each group, either IVUS (Opticross™ or Opticross™ HD, Boston Scientific, CA) or OCT (C7-XR™ and OPTIS™, Abbott, CA) was used before, during, and immediately after PCI; a final imaging assessment for PCI optimization was mandated.
- 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 EAPCI expert consensus.[1]
- All intravascular imaging data were measured by the independent imaging core laboratories (the Asan Medical Center, Core-lab).

[1]Raber L, et al. *Eur Heart J* 2018;39:3281-3300.

Study Outcomes

- ***Primary Outcome***

  Target-vessel failure (a composite of death from cardiac cause, target vessel-MI, or ischemia-driven target-vessel revascularization)

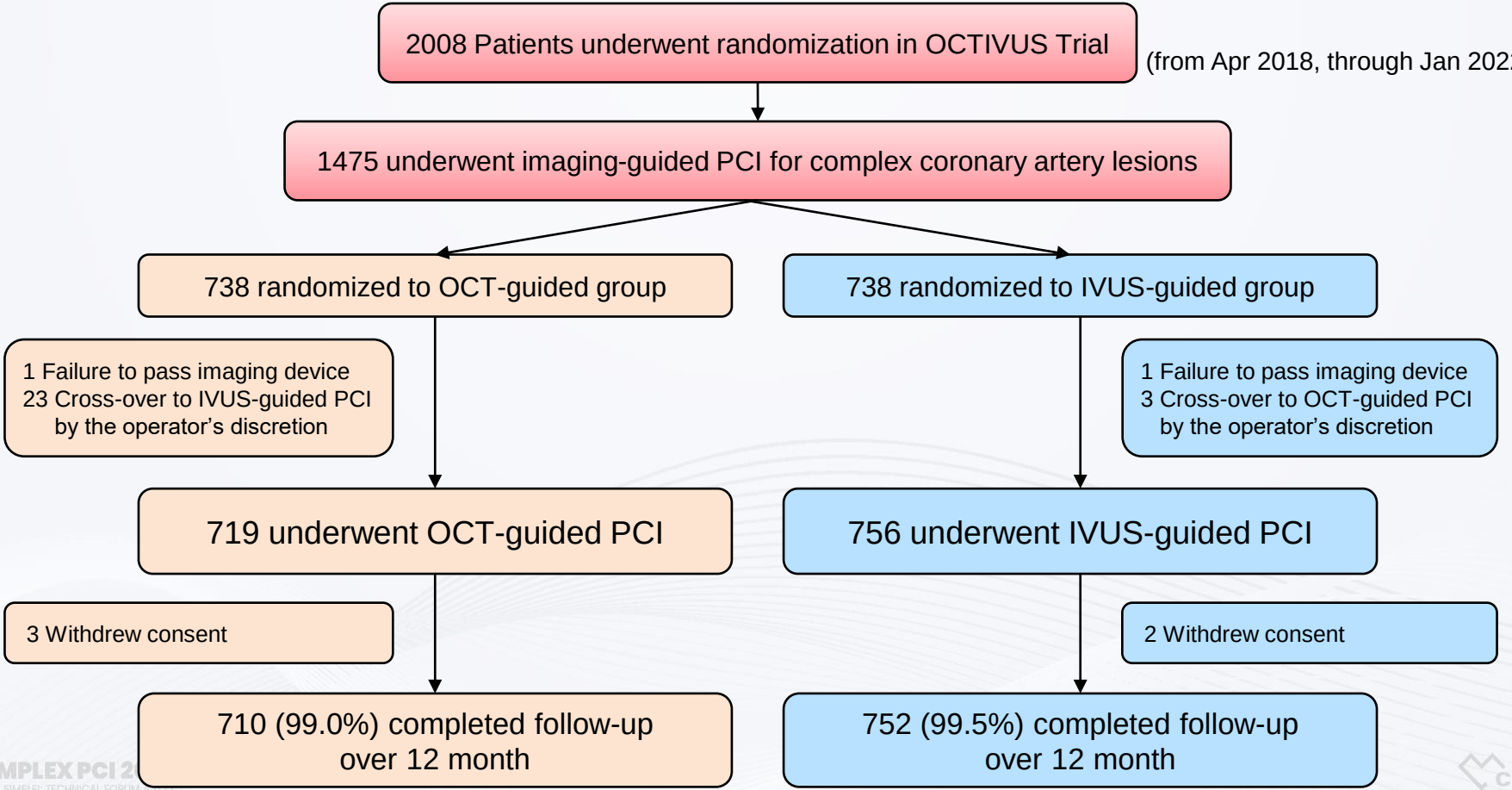
- ***Secondary Outcomes***

  Individual components of the primary outcome,
  Target-lesion failure, Stent thrombosis, Stroke, Repeat revascularization,
  Rehospitalization, Bleeding event, Contrast-induced nephropathy,
  Procedural complications requiring active intervention,
  Angiographic or imaging-based device success.

Statistical Analysis

- Main analyses were performed in the as-treated population
- Cumulative-event probabilities were estimated with the use of the Kaplan–Meier methods. We compared the clinical outcomes between the two groups using Cox proportional hazards models with time-to-first-event analyses.
- Outcomes were also compared with the use of propensity-scores adjustment (IPTW and overlap propensity-score weighting) and weighted Cox proportional hazards regression models to reduce treatment selection bias.

Patient Flow and Follow-Up (Median 2.0 years)



Key Baseline Characteristics

	OCT-guided PCI (N=719)	IVUS-guided PCI (N=756)	P Value
Age [yrs], mean (SD)	64.8±10.1	65.7±10.0	0.06
Female sex	155 (21.6)	158 (20.9)	0.76
Body-mass index	24.8±3.2	24.9±3.0	0.58
Diabetes mellitus — no. (%)	255 (35.5)	275 (36.4)	0.72
Hypertension — no. (%)	465 (64.7)	486 (64.3)	0.88
Dyslipidemia — no. (%)	625 (86.9)	634 (83.9)	0.10
Current smoking — no. (%)	157 (21.8)	143 (18.9)	0.16
Previous PCI — no. (%)	185 (25.7)	159 (21.0)	**0.03**
Previous CABG — no. (%)	22 (3.1)	17 (2.3)	0.33
Previous stroke — no. (%)	19 (2.6)	21 (2.8)	0.87
Left ventricular ejection fraction [%], mean (SD)†	60.4±7.2	60.3±7.2	0.87
Clinical indication for index PCI — no. (%)			0.67
Silent ischemia	81 (11.3)	80 (10.6)	
Stable angina	496 (69.0)	513 (67.9)	
Acute coronary syndrome	142 (19.8)	163 (21.6)	

CABG, coronary-artery bypass grafting; IVUS, intravascular ultrasound; OCT, optical coherence tomography, PCI percutaneous coronary intervention.
†Data were available for 1216 patients (82.4%) of total patients: 606 patients (84.3%) in the OCT and for 610 (80.7%) in the IVUS-guided PCI group.

Anatomic Characteristics

	OCT-guided PCI (N=719)	IVUS-guided PCI (N=756)	P Value
Treated complex coronary lesions			
Unprotected left main disease — no. (%)	111 (15.4)	153 (20.2)	**0.02**
Any bifurcation disease — no. (%)	503 (70.0)	553 (73.2)	0.18
Aorto-ostial lesion — no. (%)	95 (13.2)	100 (13.2)	0.99
Chronic total occlusion — no. (%)	53 (7.4)	55 (7.3)	0.94
Severely calcified lesion — no. (%)†	69 (9.6)	83 (11.0)	0.38
In-stent restenotic lesion — no. (%)	86 (12.0)	78 (10.3)	0.32
Diffuse long coronary lesions — no. (%)‡	399 (55.5)	424 (56.1)	0.82
Multivessel PCI at index procedure — no. (%)	248 (34.5)	275 (36.4)	0.45
Mean SYNTAX score§	17.0±9.1	18.3±9.1	**0.009**
Median SYNTAX score§	15.0 (10, 22.5)	17.0 (11, 24)	**0.032**

† Those with encircling calcium seen on angiography ‡ Lesion length ≥28 mm or stent length ≥32 mm of treated segment
§SYNTAX, Synergy between Percutaneous Coronary Intervention with Taxus and Cardiac Surgery. Scores were calculated by the core laboratory.

Procedural Characteristics

	OCT-guided PCI (N=719)	IVUS-guided PCI (N=756)	P Value
PCI approach			0.37
Radial access	420 (58.4)	424 (56.1)	
Femoral access	229 (41.6)	332 (43.9)	
PCI modality			0.47
Use of drug-eluting stents	687 (95.6)	728 (96.3)	
Used of drug-coated balloons (only for ISR lesion)	32 (4.5)	28 (3.7)	
Total no. of lesions treated per patient	1.45±0.69	1.47±0.70	0.60
Mean number of stents per patient	1.81±1.12	1.87±1.11	0.32
Total stent length per patient — mm	55.6±34.2	56.2±33.6	0.76
Post-dilatation with larger or high-pressure balloon — no. (%)	672 (93.5)	705 (93.3)	0.87
Total amount of contrast media used — mL	256.2±117.6	219.5±118.0	**<0.001**
Total PCI time — min	48.9±23.8	54.4±25.9	**<0.001**

ISR, in-stent restenosis; PCI percutaneous coronary intervention.

Procedural Outcomes

	OCT-guided PCI (N=719)	IVUS-guided PCI (N=756)	P Value
Procedural success — no. (%)			
Angiography-based†	712 (99.0)	749 (99.1)	0.93
Imaging-based‡	290 / 705 (41.1)	371 / 748 (49.6)	**0.001**
Procedural complications requiring active intervention — no. (%)§			
Any	12 (1.7)	26 (3.4)	**0.03**
IVUS or OCT procedure related complications	0 (0.0)	0 (0.0)	NC

†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.
‡ By patient-level analyses: imaging-based device success is defined as successful PCI at the intended target lesion, which fulfills all optimal criteria for stent implantation by IVUS or OCT. Among patients with multivessel interventions, all treated lesions should be met for optimization criteria.
§Procedural complications requiring active intervention, which were related to PCI or use of intravascular imaging (i.e., procedural safety outcomes).

Core Lab-QCA Analysis : Lesion-Level Analysis

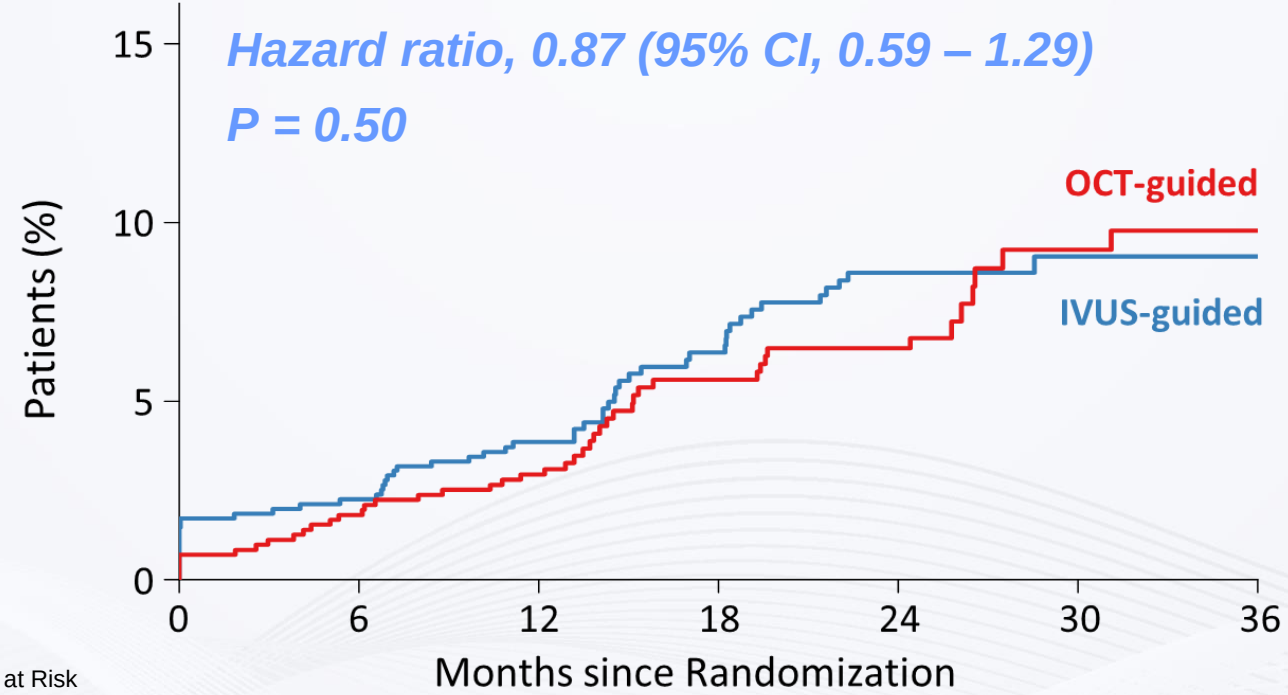
	OCT-guided PCI (N = 719 Patients) (N = 986 Lesions)	IVUS-guided PCI (N = 756 Patients) (N = 1049 Lesions)	P Value
Baseline			
Reference vessel diameter — mm	3.02 ± 0.51	3.01 ± 0.53	0.92
Minimal lumen diameter — mm	0.90 ± 2.86	0.90 ± 2.44	0.98
Diameter stenosis — %	73.1 ± 9.8	72.4 ± 10.1	0.18
Lesion length — mm	34.4 ± 15.3	33.5 ± 15.8	0.31
Final Post-PCI			
Minimum lumen diameter — mm			
In-stent	2.58 ± 0.47	2.57 ± 0.51	0.86
In-segment	2.16 ± 0.49	2.12 ± 0.53	0.07
Diameter stenosis — %			
In-stent	6.0 ± 6.1	5.9 ± 6.5	0.74
In-segment	16.4 ± 10.3	17.8 ± 11.1	**0.004**

Core Lab-Imaging Analysis : Lesion-Level Analysis

	OCT-guided PCI (N = 719 Patients) (N = 986 Lesions)	IVUS-guided PCI (N = 756 Patients) (N = 1049 Lesions)	P Value
Core Lab Imaging analysis – final post-PCI			
Minimum stent area — mm^2	5.38 ± 1.90	6.52 ± 2.28	**<0.001**
Minimum stent expansion — %	83.35 ± 17.72	90.04 ± 22.98	**<0.001**
Minimum stent area by distal reference lumen area — %	136.53 ± 49.30	127.93 ± 40.80	**<0.001**
Optimization Imaging-Guided PCI Criteria			
All stent-optimization criteria met — no./total no. (%)	333 / 886 (37.6%)	447 / 971 (46.0%)	**<0.001**
Optimal stent expansion†	429 / 886 (48.4%)	555 / 971 (57.2%)	**<0.001**
Plaque burden at stent landing zone < 50%	596 / 695 (85.8%)	749 / 947 (79.1%)	**0.001**
No major malapposition§	794 / 885 (89.7%)	942 / 970 (97.1%)	**<0.001**
No large dissection¶	798 / 885 (90.2%)	937 / 970 (96.6%)	**<0.001**

†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 and >4.5 mm^2 by OCT. § 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. ¶ 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.

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



No. at Risk							
OCT-guided PCI	719	702	652	431	374	169	129
IVUS-guided PCI	756	735	676	469	395	202	153

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

Kang DY, Ahn JM, Park DW et al. JACC 2023 Oct 23.

Types of CV Outcomes

	OCT-guided PCI (N=719)	IVUS-guided PCI (N=756)	HR (95% CI)†	P Value
Primary composite outcome‡	47 (6.5)	56 (7.4)	0.87 (0.59–1.29)	0.50
Secondary outcomes				
Target-lesion failure§	42 (5.8)	52 (6.9)	0.84 (0.56–1.27)	0.41
Death				
From any cause	22 (3.1)	21 (2.8)	1.10 (0.60–2.02)	0.75
From cardiac cause	11 (1.5)	8 (1.1)	1.40 (0.55–3.54)	0.48
Target-vessel myocardial infarction	6 (0.8)	18 (2.4)	0.35 (0.14–0.88)	**0.03**
Periprocedural	5 (0.7)	12 (1.6)	0.44 (0.15–1.24)	0.12
Spontaneous	1 (0.1)	7 (0.9)	0.16 (0.02–1.26)	0.08
Target-lesion revascularization	25 (3.5)	33 (4.4)	0.81 (0.48– 1.36)	0.43
Target-vessel revascularization	30 (4.2)	37 (4.9)	0.86 (0.53–1.40)	0.55
Contrast-induced nephropathy — no. (%)**	14 (1.9)	11 (1.5)	1.34 (0.61–2.93)	0.46
Stent thrombosis (ARC definite or probable)	0 (0.0)	2 (0.3)	NC	

†Hazard ratios are for the OCT-guided PCI group, as compared with the IVUS-guided PCI group. ‡The primary composite outcome was death from cardiac cause, target-vessel myocardial infarction, or target vessel revascularization. §Target-lesion failure was a composite of death from cardiac causes, target-vessel MI, or ischemia-driven target-lesion revascularization. ** 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.

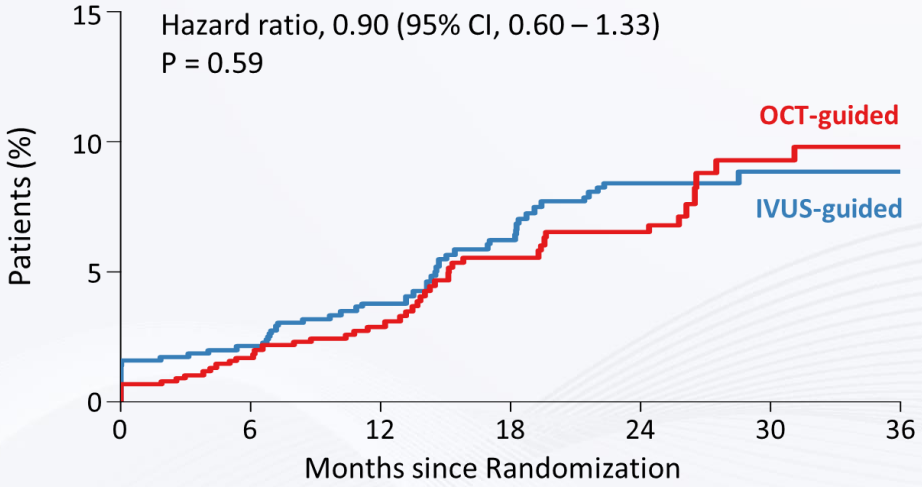
CV Outcomes in Propensity-score Adjusted Population

	Overlap Weighting Population		IPTW Population	
	HR (95% CI)†	P Value	HR (95% CI)†	P Value
Primary composite outcome‡	0.91 (0.61–1.35)	0.63	0.90 (0.60–1.33)	0.59
Secondary outcomes				
Target-lesion failure§	0.87 (0.57–1.33)	0.52	0.86 (0.57–1.31)	0.48
Death				
From any cause	1.15 (0.63–2.11)	0.66	1.15 (0.63–2.12)	0.65
From cardiac cause	1.51 (0.58–3.91)	0.40	1.53 (0.60–3.95)	0.38
Target-vessel myocardial infarction	0.36 (0.14–0.92)	**0.03**	0.36 (0.14–0.91)	**0.03**
Periprocedural	0.47 (0.16–1.34)	0.16	0.47 (0.16–1.33)	0.15
Spontaneous	0.12 (0.02–0.99)	**0.05**	0.13 (0.02–1.03)	**0.05**
Target-lesion revascularization	0.82 (0.48–1.40)	0.47	0.80 (0.47–1.37)	0.42
Target-vessel revascularization	0.88 (0.54–1.44)	0.61	0.86 (0.53–1.41)	0.55
Contrast-induced nephropathy — no. (%)**	1.42 (0.66–3.08)	0.37	1.51(0.70–3.24)	0.29
Stent thrombosis (ARC definite or probable)	NC		NC	

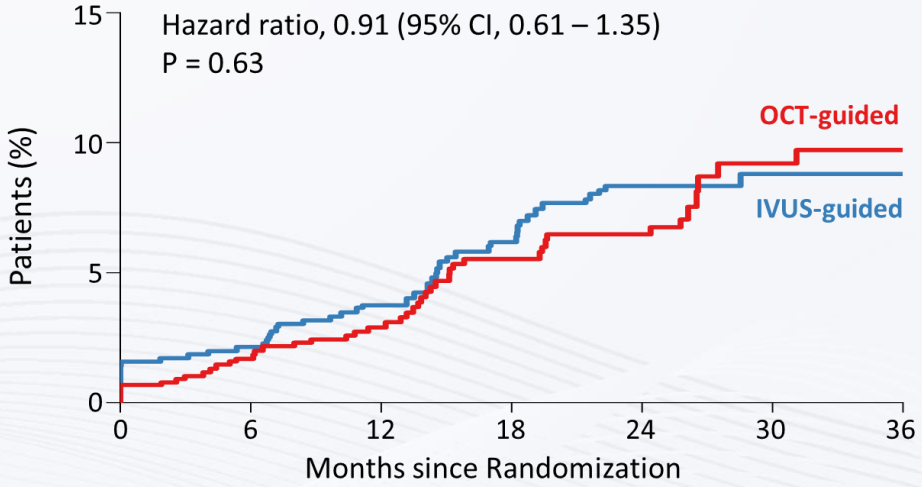
†Hazard ratios are for the OCT-guided PCI group, as compared with the IVUS-guided PCI group. ‡The primary composite outcome was death from cardiac cause, target-vessel myocardial infarction, or target vessel revascularization. §Target-lesion failure was a composite of death from cardiac causes, target-vessel MI, or ischemia-driven target-lesion revascularization. ** 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.

Sensitivity Analysis

IPTW-adjusted Population



Overlap PS weighting-adjusted population



CI, confidence interval; IPTW, inverse-probability-of-treatment weighting; PS, propensity score.

Subgroup Analysis

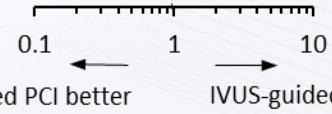
by Anatomical Factors

Subgroup	Percent of Patients	Event Rate (%)		Hazard Ratios (95% CI)	P-for-Interaction
		OCT-guided	IVUS-guided		
Unprotected left main disease					0.56
Yes	17.6	9.0	13.1	0.76 (0.356 to 1.62)	
No	82.4	6.1	6.0	0.99 (0.62 to 1.57)	
Any bifurcation disease					0.20
Yes	71.6	6.8	6.1	1.05 (0.65 to 1.69)	
No	28.4	6.0	10.8	0.61 (0.31 to 1.21)	
True bifurcation disease					0.17
Yes	29.2	10.8	7.4	1.27 (0.7 to 2.44)	
No	70.8	5.1	7.4	0.72 (0.44 to 1.18)	
Aorto-ostial lesion					0.82
Yes	13.2	8.4	9.0	0.79 (0.29 to 2.13)	
No	86.8	6.3	7.2	0.89 (0.58 to 1.36)	
Chronic total occlusion					0.22
Yes	7.3	9.4	5.5	2.06 (0.49 to 8.63)	
No	92.7	6.3	7.6	0.81 (0.54 to 1.22)	
Severely calcified lesion					0.30
Yes	24.8	10.1	13.3	1.18 (0.63 to 2.24)	
No	75.2	6.2	6.7	0.77 (0.47 to 1.27)	

Subgroup Analysis

by Anatomical Factors

Subgroup	Percent of Patients	Event Rate (%) OCT-guided	Event Rate (%) IVUS-guided	Hazard Ratios (95% CI)	P-for-Interaction
Severely calcified lesion					0.30
Yes	24.8	10.1	13.3	1.18 (0.63 to 2.24)	
No	75.2	6.2	6.7	0.77 (0.47 to 1.27)	
In-stent restenotic lesion					0.009
Yes	11.1	10.5	29.5	0.36 (0.17 to 0.78)	
No	88.9	6.0	4.9	1.22 (0.76 to 1.94)	
Diffuse long coronary artery lesion					0.22
Yes	55.8	7.8	7.1	1.07 (0.65 to 1.78)	
No	44.2	5.0	7.8	0.65 (0.35 to 1.21)	
Multivessel PCI					0.066
Yes	35.5	8.1	12.0	0.60 (0.34 to 1.06)	
No	64.5	5.7	4.8	1.27 (0.73 to 2.21)	
SYNTAX score					0.066
Low	72.9	4.6	6.8	0.69 (0.41 to 1.15)	
Intermediate	20.1	8.7	8.3	0.96 (0.43 to 2.17)	
High	7.1	22.0	11.0	3.19 (1.02 to 10.04)	



Limitations

- The observed number of primary-outcome events was lower than expected in the OCTIVUS trial. This subgroup analysis may have inherent limitation of statistical underpower to detect relevant outcomes.
- It was not possible to mask the imaging modalities from the patients and investigators (the possibility of ascertainment or selection bias).
- There would be the possibility of discrepancy on site-determined and core-laboratory measured imaging interpretation.
- The generalizability and reproducibility of the findings may be potentially limited due to the geographic variability in the use of imaging devices.
- We did not perform the cost effectiveness analysis of two modalities.

Summary for the Key Findings

- In this subgroup analysis of the OCTIVUS trial in patients with complex coronary artery lesions, OCT-guided PCI showed a similar risk of target-vessel failure as compared with IVUS-guided PCI.
- The incidence of the target-vessel MI or procedural complications were lower with OCT guidance than with IVUS guidance.
- In anatomical subgroup analysis, OCT showed better clinical performance for treatment of in-stent restenosis.
- The amount of contrast dye used during the procedures was higher in the OCT group than in the IVUS group, but it was not related to an increase of contrast-induced nephropathy.

Conclusions

In this pre-specified analysis of the OCTIVUS trial involving patients with *complex coronary-artery lesions*,

1. OCT-guided PCI showed a similar risk of a composite of death from cardiac causes, target-vessel myocardial infarction, or ischemia-driven target-vessel revascularization compared to IVUS-guided PCI during median 2-year follow-up.

2. However, owing to insufficient statistical power and inherent limitations from subgroup analyses, overall findings should be hypothesis-generating and hence further research is needed in this area.

Thank You for Your Attention !