Intravascular Imaging-guided Complex PCI: Which One and Why?

Do-Yoon Kang, MD, PhD.

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



TCTAP, 25 Apr 2024

COI Disclosure

Do-Yoon Kang

The author has no financial conflicts of interest to disclose concerning the presentation

Why Do We Have to Use Intravascular Imaging for Guiding Complex PCI?

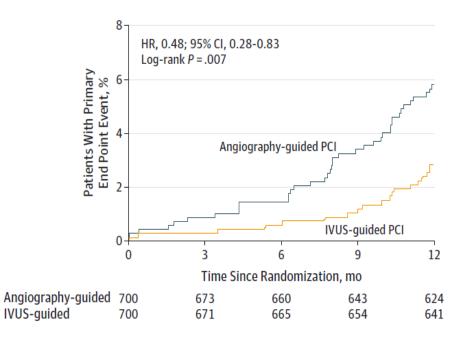




IVUS Improved Clinical Outcomes in Large RCTs

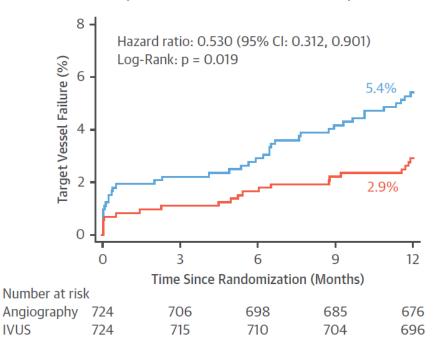
IVUS-XPL (Long lesions)

MACE (CD+TL-MI+ID-TLR)



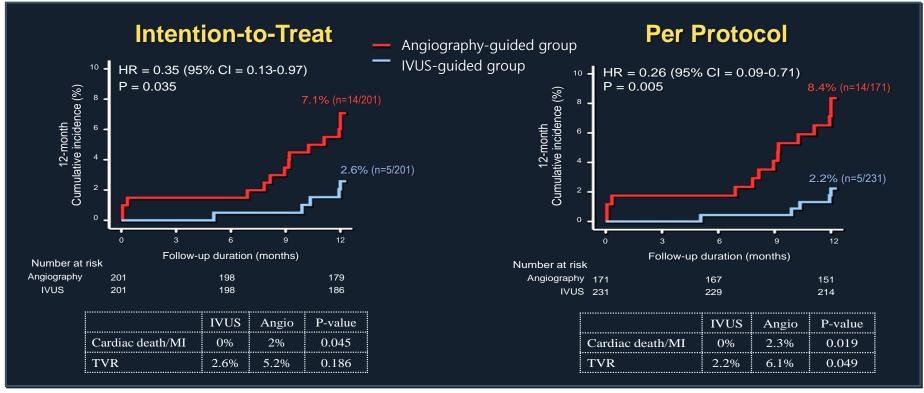
ULTIMATE (All-comer)

TVF (CD+TV-MI+CD-TVR)



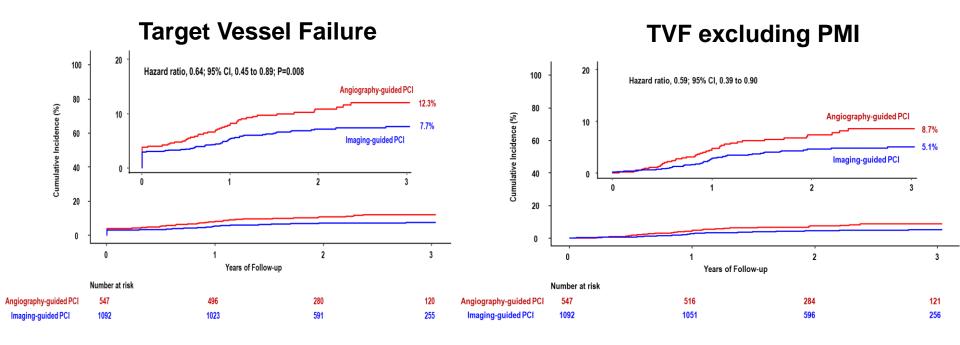
IVUS Improved Clinical Outcomes in CTO PCI

CTO-IVUS (N=402), Primary endpoint : Cardiac death, MI, and TVR



IVUS Improved Clinical Outcomes in Large RCTs

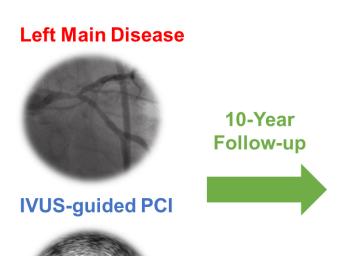
RENOVATE-COMPLEX-PCI (Bifurcation, CTO, LM, Long, MV, ISR, Calcification)

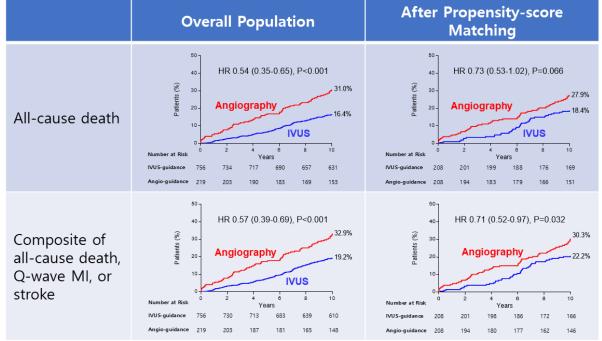


Lee JM, Choi KH et al. NEJM 2023, Mar 5.

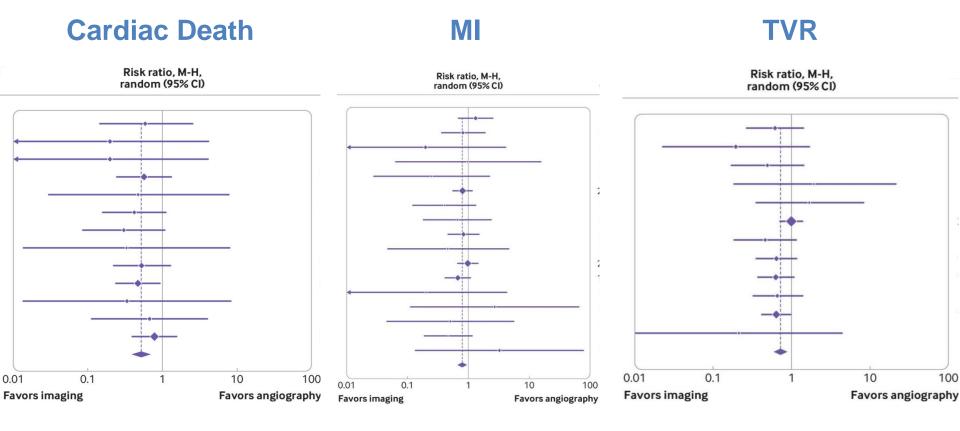
IVUS Improved 10-yr Clinical Outcomes in LM Registry

MAIN-COMPARE Registry





Imaging vs. Angio-guided PCI: Meta-analysis of 20 RCTs



Khan SU et al. BMJ 2023, Nov 16.

Role of Intravascular Imaging for PCI Guidance?

Optimize Acute Stent Results

IVUS-Guided Complex PCI in IRIS-DES Registry

- From IRIS-DES Registry (NCT01186133) Between 2008 and 2017.
- A total 9525 patients with single complex coronary lesions were enrolled in this analysis.
- Complex coronary lesions were included
 - 1. LMCA
 - 2. Bifurcation
 - 3. Diffuse lesion (>30mm)
 - 4. Severely calcified lesion
 - 5. In-stent restenosis
- Primary outcome: composite of cardiac death, target vessel MI and TVR

IVUS-Guided PSP

Under the Intracoronary Imaging Guidance

Inspection of lesion characteristic by IVUS

Calcification
Plaque burden and configuration
Opening of side branch

Selection of stent size and length by IVUS

Stent landing zone configuration
Lesion length
Reference vessel size

Surveillance of stent outcomes

Stent apposition
Stent area
Procedural complications

Post-dilation





Lesion pre-modification for stent delivery and expansion: High pressure balloon Cutting or scoring balloon Rota-ablation





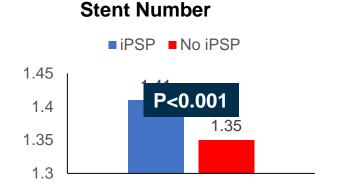


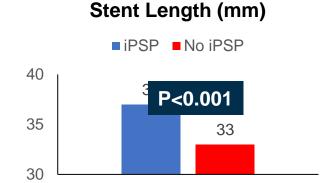




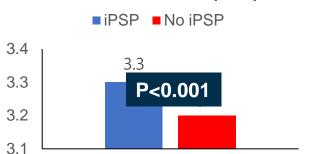
Full lesion coverage Adequate stent size Complete stent apposition
Sufficient stent area
No geographic miss
No procedural complications

IVUS-Guided PSP, What Is Different?

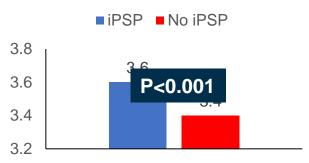




Stent Diameter (mm)



Final Balloon Size (mm)



Park HB et al. JACC Cardiovasc Interv. 2020;13:1403-1413.

Imaging-Guided Complex PCI – Better Clinical Outcome

	Crude cumulative incidence (%)		Multivariate analysis		PS matching		IPTW		
	iPSP	No iPSP	Р	HR (95% CI)	Р	HR (95% CI)	Р	HR (95% CI)	Р
Primary outcome	5.7	8.0	0.001	0.74 (0.61-0.90)	0.003	0.71 (0.56-0.90)	0.005	0.71 (0.63-0.81)	<0.001
Cardiac death	2.3	3.6	0.003	0.73 (0.53-0.99)	0.047	0.78 (0.53-1.15)	0.20	0.62 (0.51-0.75)	0.003
Target vessel MI	0.2	0.5	0.19	0.68 (0.30-1.55)	0.36	0.78 (0.29-2.09)	0.62	0.65 (0.38-1.10)	0.10
TVR	3.4	4.6	0.02	0.73 (0.57-0.94)	0.02	0.68 (0.50-0.92)	0.01	0.74 (0.63-0.87)	<0.001

Post-dilation was the Most Significant Event Predictor Among 3 Components of iPSP

	Univariate analy	sis	Multivariate ana	ılysis*
	HR (95% CI)	P value	HR (95% CI)	P value
Pre-dilation	0.89 (0.69-1.15)	0.374	0.84 (0.64-1.11)	0.216
Stent-sizing	0.79 (0.67-0.93)	0.004	0.89 (0.74-1.07)	0.219
Post-dilation	0.79 (0.67-0.94)	0.006	0.80 (0.67-0.96)	0.016

Post-Balloon Size was Larger With IVUS

Pre-dilation	IVUS	Post-dilation	No. of patients (%)	Stent diameter	Post balloon size (mm)	Annualized event rate	Adjusted HR (95% CI)	P value
No	No	Yes	129 (1.4)	3.04 ± 0.41	3.10 ± 0.81	3.04 %	0.81 (0.35-1.85)	0.613
				Δ+0	.05 (P=0.550)			
Yes	No	Yes	1719 (18.0)	3.08 ± 0.38	3.12 ± 0.86	3.07 %	0.80 (0.53-1.21)	0.297
				Λ +0	04 (P=0.104)			
No	Yes	Yes	309 (3.2)	3.43 ± 0.41	3.79 ± 0.70	2.04%	0.72 (0.39-1.35)	0.306
	Δ +0.35 (P<0.001)							
Yes	Yes	Yes	3374 (35.4)	3.26 ± 0.39	3.58 ₄ ± 0.60	1.98%	0.63 (0.42-0.93)	0.022
				Λ +0.	32 (P<0.004)			

With IVUS,
I Can Implant Bigger Stent,
With Higher Pressure Post-dilation,
Safely.

Small Details Make a Big Difference!

Intracoronary Imaging for PCI Guidance



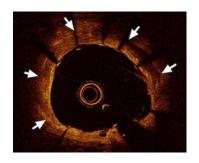
Difference Between OCT and IVUS

	ОСТ	IVUS
Wave source	Near-infrared light	Ultrasound
Axial resolution, µm	1-2	38-46
Penetration depth in soft tissue, mm	1-2	>5
Blood clearance	Needs Contrast	Not required
Plaque burden at lesion	-	+
Aorto-ostial visualization	-	+
Cross-sectional calcium evaluation	Thickness, angle	Angle only
Lipidic plaque evaluation	Lipidic plaque, cap thickness	Attenuated plaque

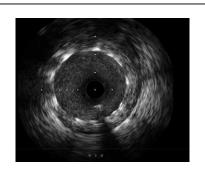
Maehara A et al., J Am Coll Cardiol Img 2017;10:1487-503 Koganti S et al., Interv Cardiol 2016;11:11-16

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

The OCTIVUS Trial

Design

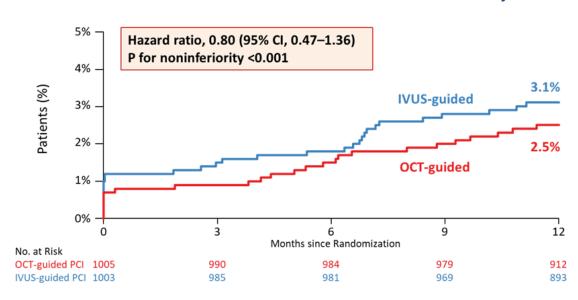
DESIGN: a prospective, multi-center, randomized, open-label trial

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



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

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 m²), 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).

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

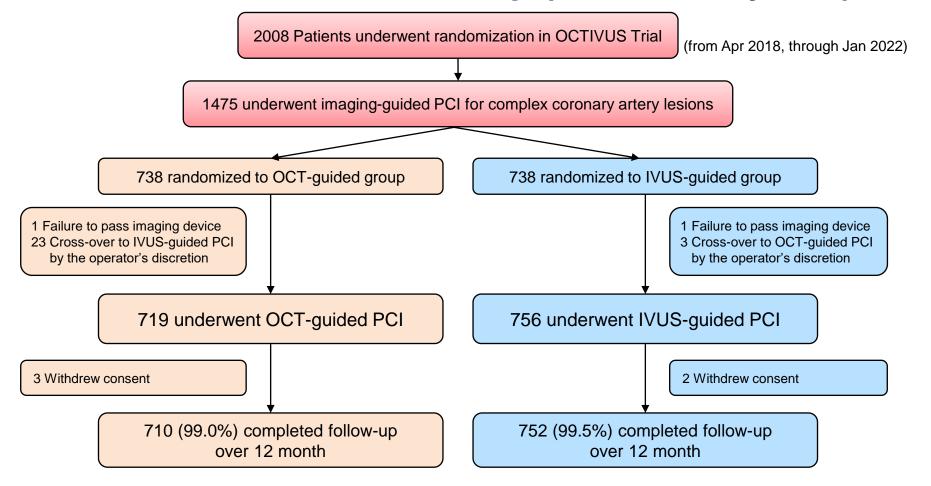
Individual components of the primary outcome,
Target-lesion failure, Stent thrombosis, Stroke, Repeat revascularization,
Rehospitalization, Bleeding event, Contrast-induced nephropathy,
Procedural complications requiring active intervention,

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

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

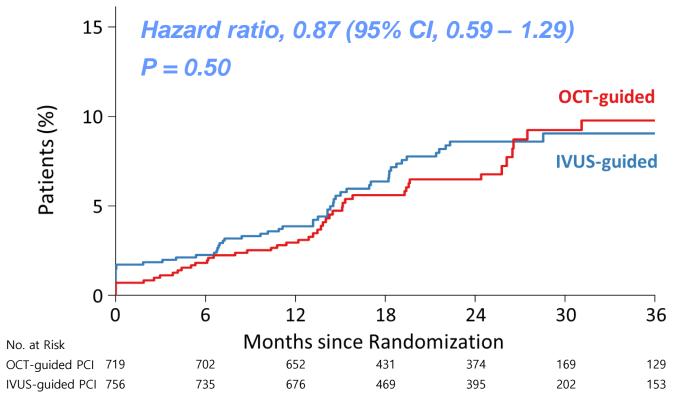
[†]Angiographic device success is defined as successful PCI at the intended target lesion with final in-stent residual stenosis of less than 30% by quantitative coronary angiography. ‡ By patient-level analyses: imaging-based device success is defined as successful PCI at the intended target lesion, 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

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



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	

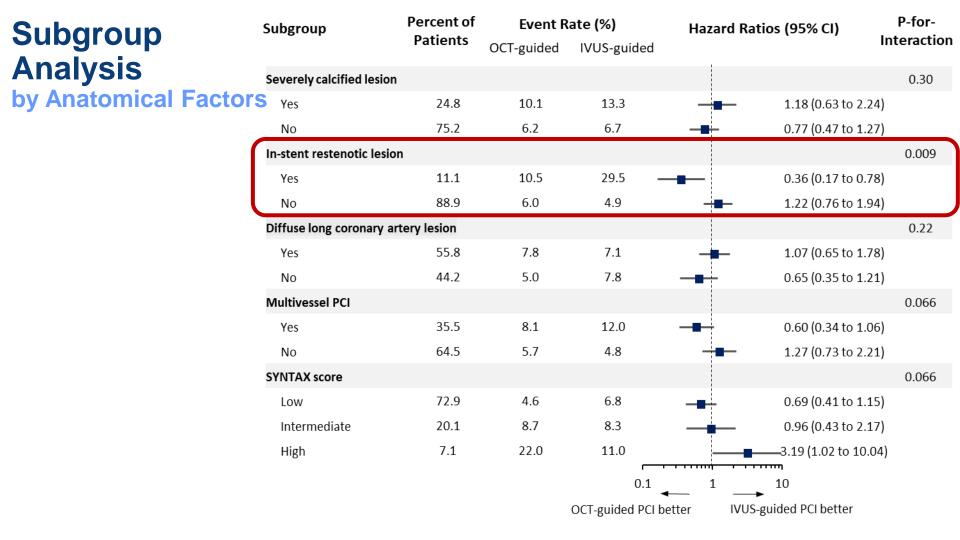
[†]Hazard ratios are for the OCT-guided PCI group, as compared with the IVUS-guided PCI group. ‡The primary composite outcome was death from cardiac cause, target-vessel myocardial infarction, or target vessel revascularization. §Target-lesion failure was a composite of death from cardiac causes, target-vessel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

Subgroup Analysis by Anatomical Fa	Factors	Subgroup	Percent of Patients	Event Rate (%)		Hazard Ratios (95% CI)		P-for-
				OCT-guided	IVUS-guided			Interaction
		Unprotected left main di	sease					0.56
		Yes	17.6	9.0	13.1	-	0.76 (0.356 to 1.6	2)
		No	82.4	6.1	6.0	-	0.99 (0.62 to 1.57	7)
		Any bifurcation disease						0.20
		Yes	71.6	6.8	6.1	-	1.05 (0.65 to 1.69	9)
		No	28.4	6.0	10.8	-	0.61 (0.31 to 1.22	1)
		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	3)
		Aorto-ostial lesion						0.82
		Yes	13.2	8.4	9.0	-	0.79 (0.29 to 2.13	3)
		No	86.8	6.3	7.2	-	0.89 (0.58 to 1.36	5)
		Chronic total occlusion						0.22
		Yes	7.3	9.4	5.5	-	_ 2.06 (0.49 to 8.63	3)
		No	92.7	6.3	7.6	-	0.81 (0.54 to 1.22	2)
		Severely calcified lesion						0.30
		Yes	24.8	10.1	13.3	-	1.18 (0.63 to 2.24	4)
		No	75.2	6.2	6.7	- ■	0.77 (0.47 to 1.27	7)



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 targetvessel 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*,

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

OCT vs. IVUS in My Daily Practice

	ОСТ	IVUS
LM disease		Better
Ostial lesion		Better
Bifurcation	Delicate	Convenient
Long lesion	It saves time	
СТО		Better
In-stent restenosis	Better	
Renal dysfunction or CHF		Better