Disclosure

- I have nothing to disclose.

Current Guideline for PCI at True Bifurcation

2018 ESC/EACTS guideline vs 2021 ACC/AHA/SCAI Guideline

Recommendations on intravascular imaging for procedural 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

Recommendations for Use of Intravascular Imaging
**Referenced studies that support the recommendations are summarized in Online Data Supplement 25.**

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).

Neumann FJ et al. 2018 ESC/EACTS Guidelines on myocardial revascularization. *Eur Heart J. 2019;40:87-165. doi: 10.1093/eurheartj/ehy394*
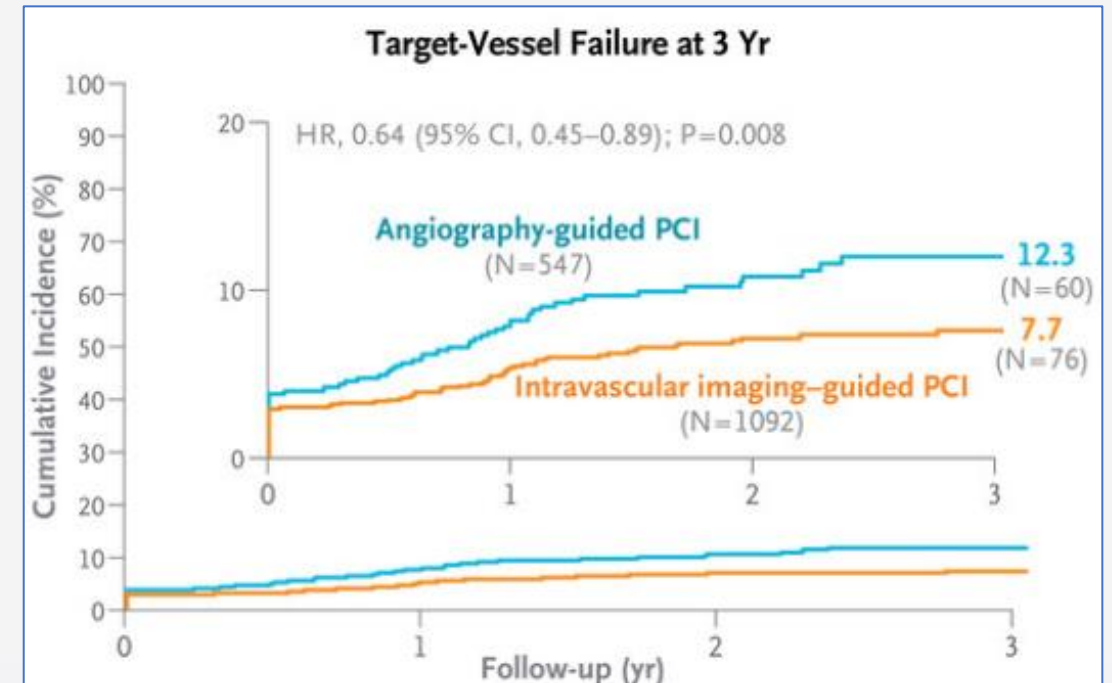
Lawton JS et al. 2021 ACC/AHA/SCAI Guideline for Coronary Artery Revascularization. *Circulation. 2022;145:e18-e114. doi: 10.1161/cir.0000000000001038*

Recent RCTs including True Bifurcation PCI

OCTOBER and RENOVATE-COMPLEX
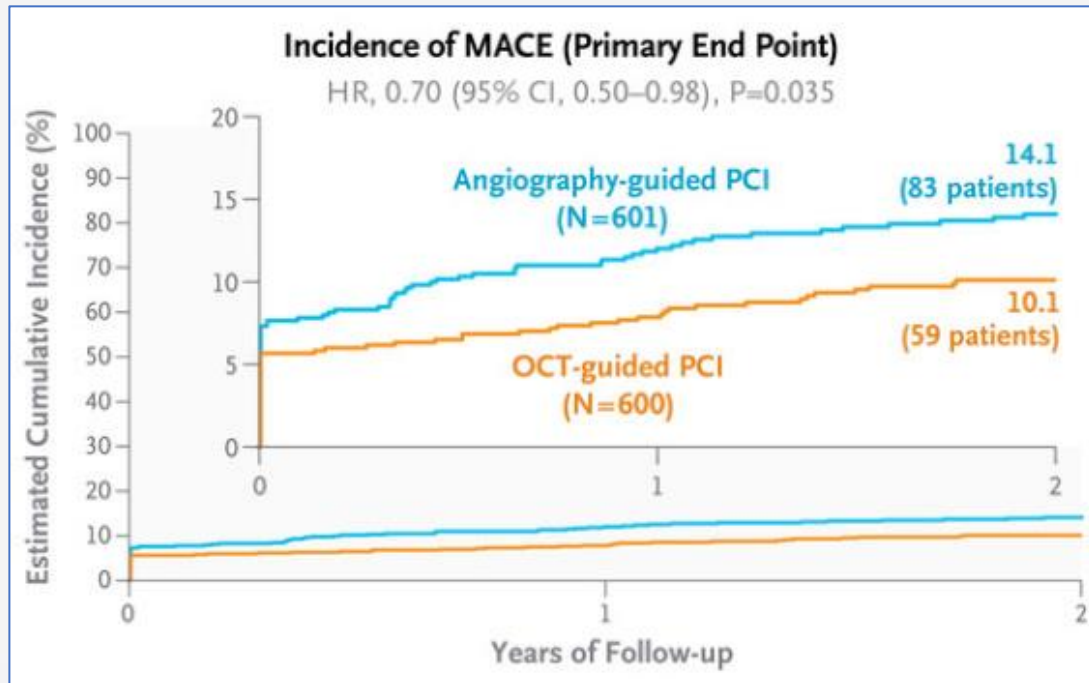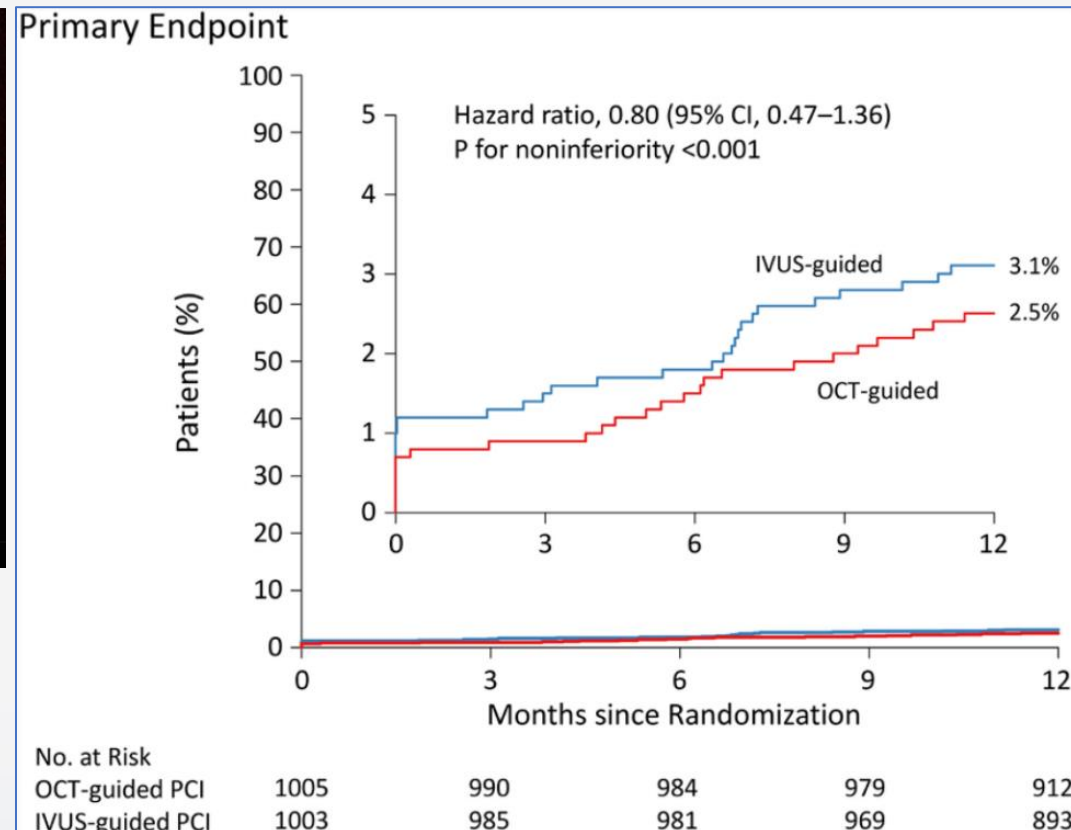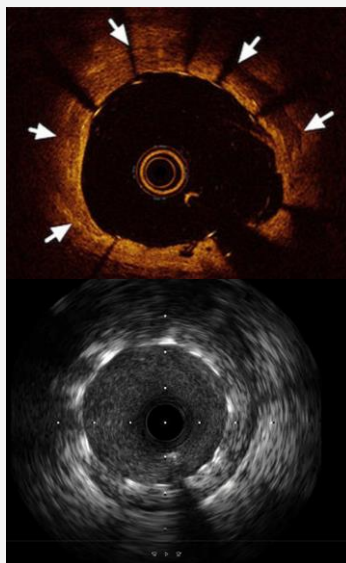

OCTOBER

RENOVATE-COMPLEX

Lee JM et al. Intravascular Imaging-Guided or Angiography-Guided Complex PCI. *N Engl J Med. 2023;388:1668-1679. doi: 10.1056/NEJMoa2216607*

Holm NR et al. OCT or Angiography Guidance for PCI in Complex Bifurcation Lesions. *N Engl J Med. 2023;389:1477-1487. doi: 10.1056/NEJMoa2307770*

OCTIVUS trial

OCT vs IVUS

- **Design** : a multicenter, progmatic, randomized controlled trial at 9 sites in South Korea

- **Objective** : comparing OCT and IVUS for PCI guidance in patients with diverse coronary artery lesions.

- **Method** : a total of 2008 patients were randomly assigned to OCT-guided PCI (n=1005) and IVUS-guided PCI (n=1003)

- **Primary end point** : a composite of death from cardiac causes, target-vessel myocardial infarction, or ischemia-driven target-vessel revascularization at 1 year.

- **Conclusion** : both OCT and IVUS can be used safely and effectively in the vast majority of procedures, demonstrating comparable acute and long-term outcomes.

Primary Endpoint

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

IVUS-guided — 3.1%
OCT-guided — 2.5%

No. at Risk				
OCT-guided PCI	1005	990	984	979	912
IVUS-guided PCI	1003	985	981	969	893

3.1% in IVUS *vs.* 2.5% OCT guided PCI at 1yr

Kang DY, Park DW et al; The OCTIVUS Randomized Clinical Trial. Circulation. 2023 Oct

Inclusion and Exclusion Criteria in OCTIVUS

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).

CVRF

METHOD

Inclusion criteria : True bifurcation

- https://www.thecardiologyadvisor.com/ddi/bifurcation-lesion/
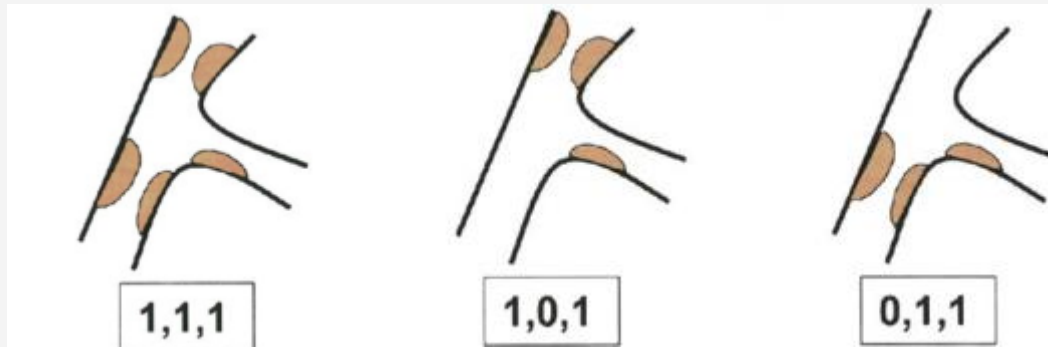
Study Outcomes

Primary outcome and Secondary outcomes

- The primary end-point : Target-vessel failure (a composite of death from cardiac causes, target-vessel-related MI, or ischemia-driven target-vessel revascularization)

- Key secondary end points
    - ✓ Individual components of the primary end-point
    - ✓ Target-lesion failure (a composite of death from cardiac causes, target-vessel MI, or ischemia-driven target-lesion revascularization)
    - ✓ Stent thrombosis
    - ✓ Stroke
    - ✓ Repeat revascularization
    - ✓ Re-hospitalization
    - ✓ Bleeding events

CVRF

Study Flow Diagram

2008 patients in the OCTIVUS trial

→ **1580 patients without true bifurcation lesions**

428 patients with true bifurcation lesions

193 randomized to OCT-guided PCI

235 randomized to IVUS-guided PCI

1 Failure to pass imaging device
8 Cross-over to IVUS-guided PCI by the operator's discretion

1 Cross-over to OCT-guided PCI by the operator's discretion

185 underwent OCT-guided PCI

243 underwent IVUS-guided PCI

CVRF

Baseline Characteristics

Clinical characteristics

	OCT (N = 185)	IVUS (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%)	1.00
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%)	
Unstable angina	18 (9.7%)	22 (9.1%)	
NSTEMI	9 (4.9%)	23 (9.5%)	

Baseline Characteristics

Anatomical characteristics

	OCT (N = 185 patients with 188 lesions)	IVUS (N = 243 patients with 253 lesions)	P-value
Trial bifurcation vessels — no. (%)			0.32
LMCA-LAD-LCX— no. (%)	46 (24.5%)	63 (24.9%)	
LAD-D— no. (%)	112 (59.6%)	149 (58.9%)	
LCX-OM— no. (%)	19 (10.1%)	34 (13.4%)	
RCA-PDA-PLA— no. (%)	11 (5.9%)	7 (2.8%)	
Medina classification(site report) — no. (%)			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%)	

CVRF

Baseline Characteristics

Procedural characteristics

	OCT (N = 185)	IVUS (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			1.00
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 $\pm$ 1.3	2.3 $\pm$ 1.2	0.57
Total stent length per patient — mm	65.0 $\pm$ 40.0	66.7 $\pm$ 37.5	0.67
Stent technique			0.29
1-Stent technique	109 (58.9%)	130 (53.5%)	
2-Stent technique	71 (38.4%)	107 (44.0%)	
Post-dilatation with larger or high-pressure balloon — no. (%)	176 (95.1%)	235 (96.7%)	0.57
Total amount of contrast media used — mL	283.3 $\pm$ 136.1	257.5 $\pm$ 129.5	0.047
Total PCI time — min	56.4 $\pm$ 25.3	64.1 $\pm$ 26.4	0.003

CVRF

Primary Outcome

A composite of Death from cardiac causes, target-vessel-related MI, or ischemia-driven target-vessel revascularization

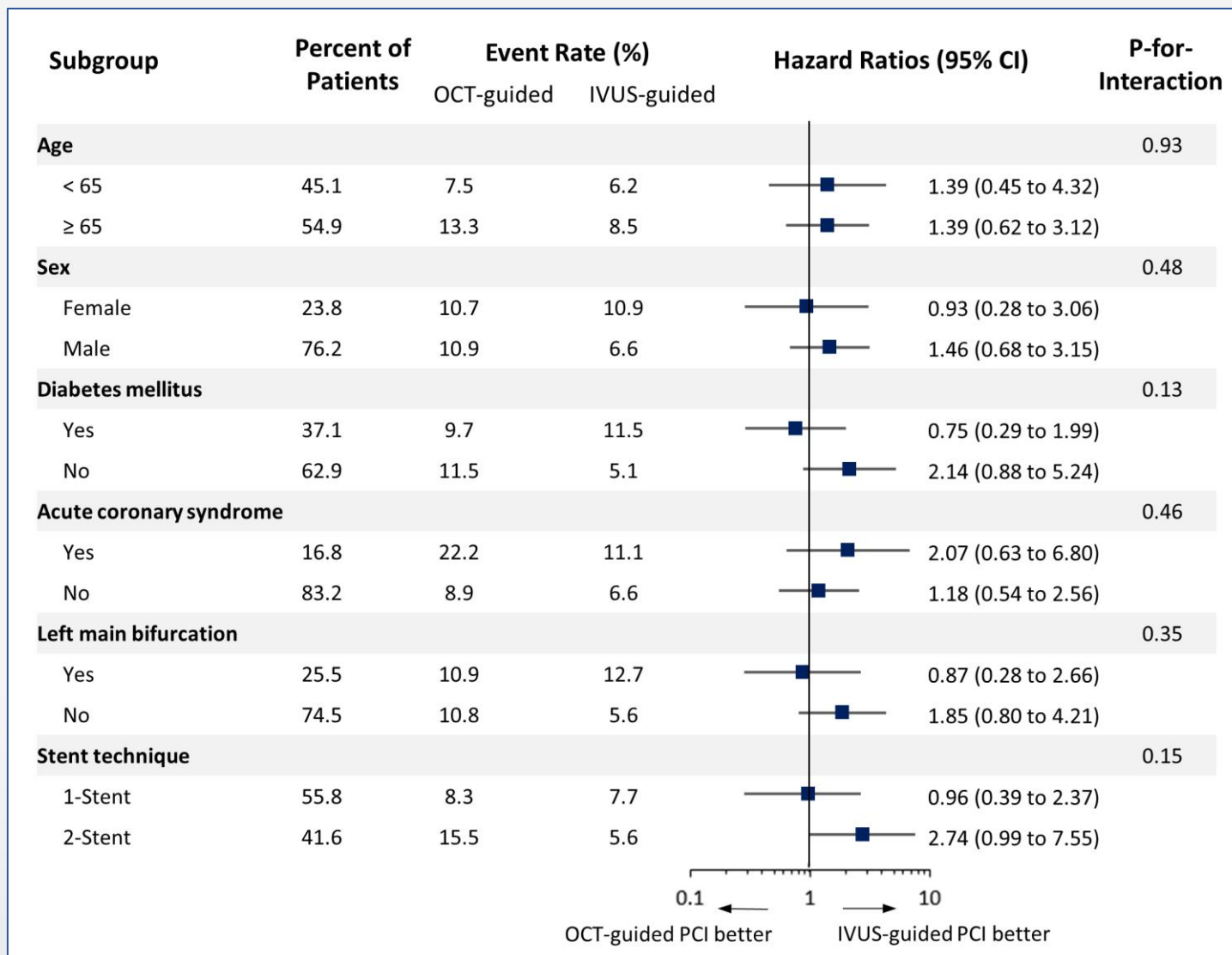HR, 1.32 (95% CI, 0.69-2.52)
P = 0.40
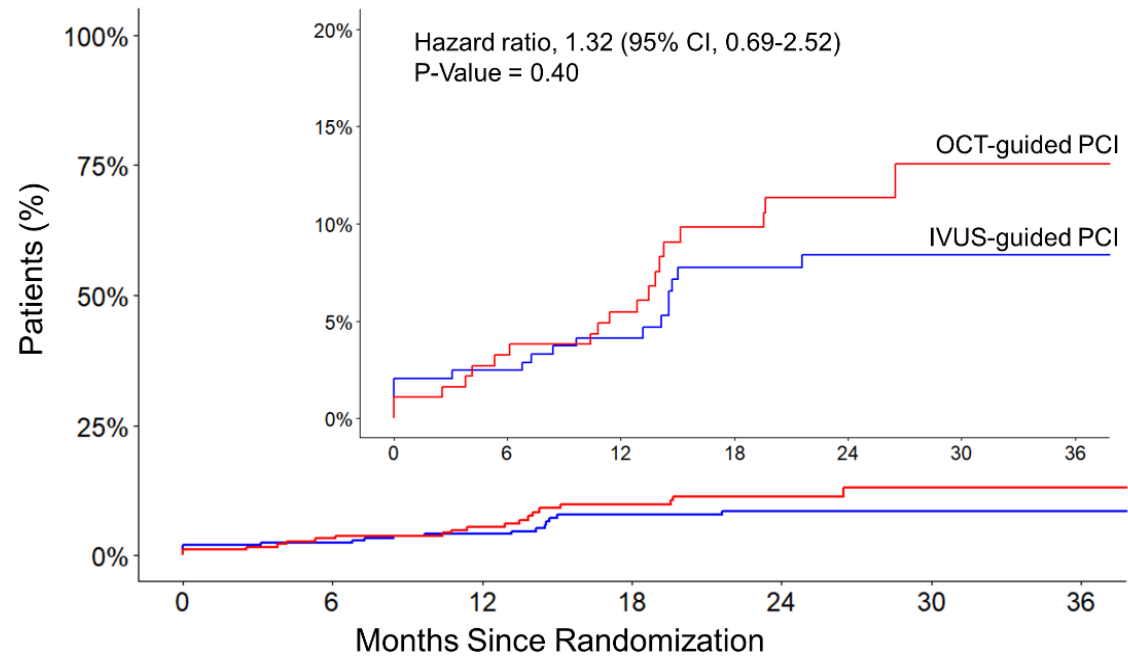
Key Secondary End Points

	OCT (N = 185)	IVUS (N = 243)	HR (95% CI)	P-value
Primary end point (TVF)	20 (10.8)	18 (7.4)	1.32 (0.69-2.52)	0.40
Secondary end points				
Target-lesion failure	18 (9.7)	17 (7.0)	1.24 (0.63-2.44)	0.53
All cause death	3 (1.6)	6 (2.5)	0.42 (0.09-2.10)	0.29
Cardiac death	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
Stent thrombosis	0 (0.0)	2 (0.8)	NC	
Stroke	1 (0.5)	1 (0.4)	1.48 (0.09-23.74)	0.78
Repeat revascularization	19 (10.3)	16 (6.6)	1.46 (0.75-2.85)	0.27
Re-hospitalization	16 (8.6)	21 (8.6)	0.84 (0.43-1.64)	0.61
Bleeding	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

CVRF

Subgroup Analysis

Subgroup	Percent of Patients	Event Rate (%)		Hazard Ratios (95% CI)	P-for-Interaction
		OCT-guided	IVUS-guided		
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					0.35
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					0.15
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

Conclusion

- In this sub-study of the OCTIVUS trial involving patients with true bifurcation lesions, OCT-guided PCI showed a similar risk of a composite of death from cardiac causes, target-vessel–related MI, or ischemia-driven TVR as compared with IVUS-guided PCI.

- This study supports that both OCT and IVUS can be utilized safely and effectively in patients with true bifurcation lesions who are undergone PCI.