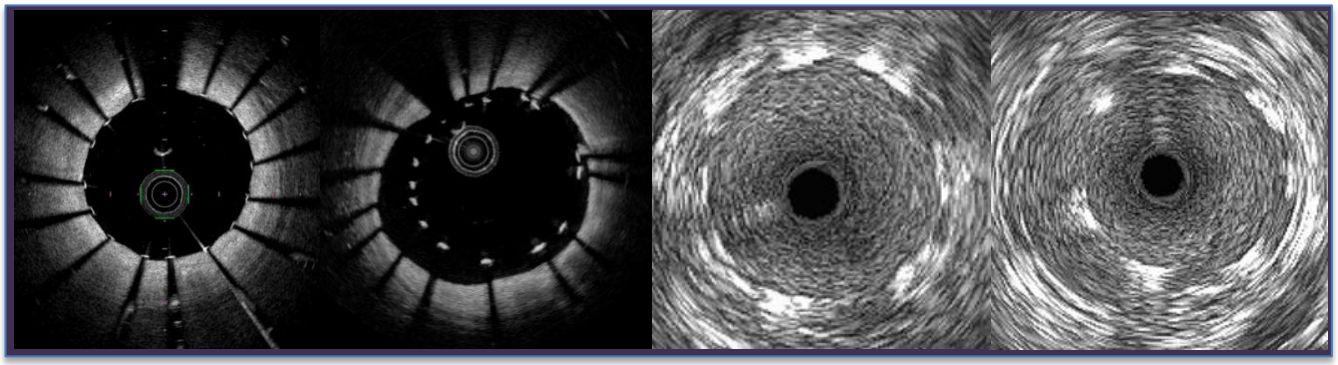
23rd CardioVascular Summit-TCTAP 2018

Imaging & Physiology

April 28, 2018 12:40 PM ~ 12:48 PM Room 104, Level 1

OCT vs. IVUS for Guiding PCI: OPINION Trial and Updated Meta-analysis



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Disclosure statement of financial interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship	Company
• Grant/Research Support	• No
• Consulting Fees/Honoraria	• Abbot vascular, Terumo
• Major Stock Shareholder/Equity	• No
• Royalty Income	• No
• Ownership/Founder	• No
• Intellectual Property Rights	• No
• Other Financial Benefit	• No

IVUS/OCT in ESC guideline 2014

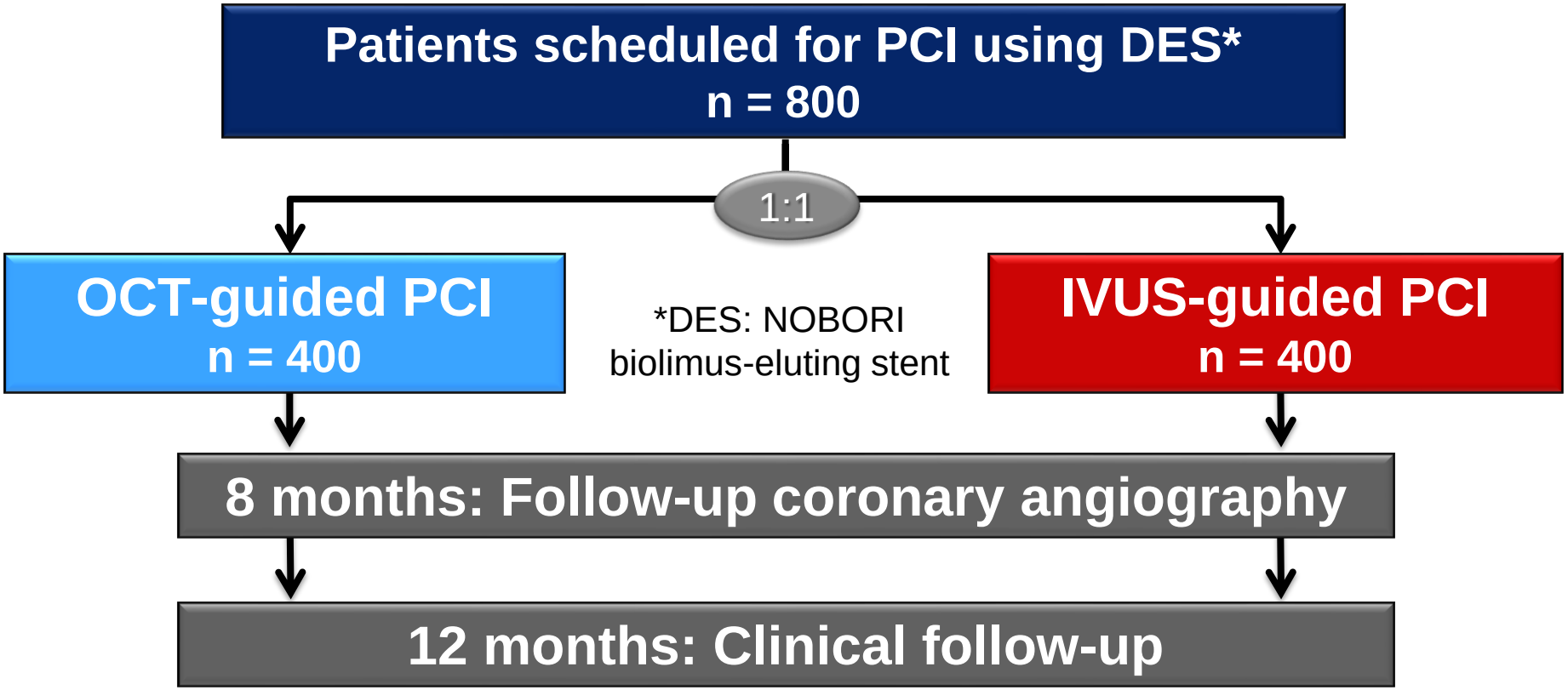
Recommendations	Class	Level
IVUS in selected patients to optimize stent implantation.	**IIa**	**B**
OCT in selected patients to optimize stent implantation.	**IIb**	**C**

OCT is becoming increasingly widespread as an adjunctive intravascular diagnostic technique in PCI, because of its ability to visualize coronary structures at high resolution.

Clinical and prognostic implication of OCT guidance in PCI has not been established yet.

The OPINION study design

Prospective, multi-center (n=42), randomized (1:1), non-inferiority trial comparing OCT-guided PCI with IVUS-guided PCI



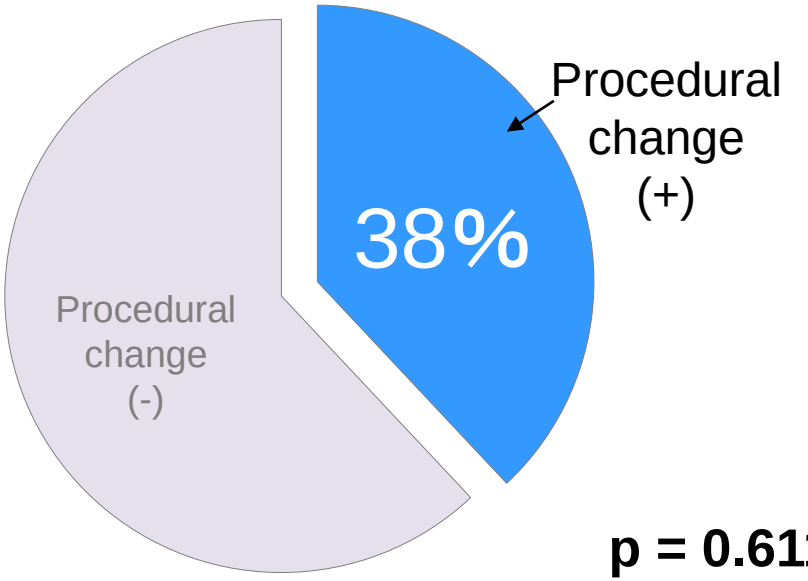
Primary Endpoint: Target Vessel Failure (TVF) at 12 months after PCI

OCT / IVUS criteria for optimal stent deployment

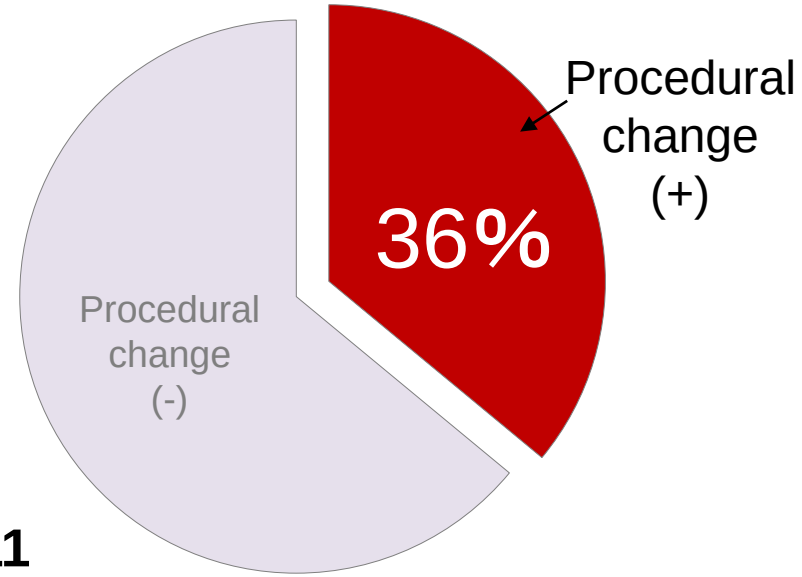
	OCT-guided PCI	IVUS-guided PCI
Reference site	• Most normal looking • No lipidic plaque	• Largest lumen • Plaque burden < 50%
Determination of stent diameter	• By measuring lumen diameter at proximal and distal reference sites	• By measuring vessel diameter at proximal and distal reference sites
Determination of stent length	• By measuring distance from distal to proximal reference site	
Goal of stent deployment	• In-stent minimal lumen area ≥ 90% of the average reference lumen area • Complete apposition of the stent over its entire length against the vessel wall • Symmetric stent expansion defined by minimum lumen diameter / maximum lumen diameter ≥ 0.7 • No plaque protrusion, thrombus, or edge dissection with potential to provoke flow disturbances	

Procedural change by OCT / IVUS guidance

OCT guidance



IVUS guidance

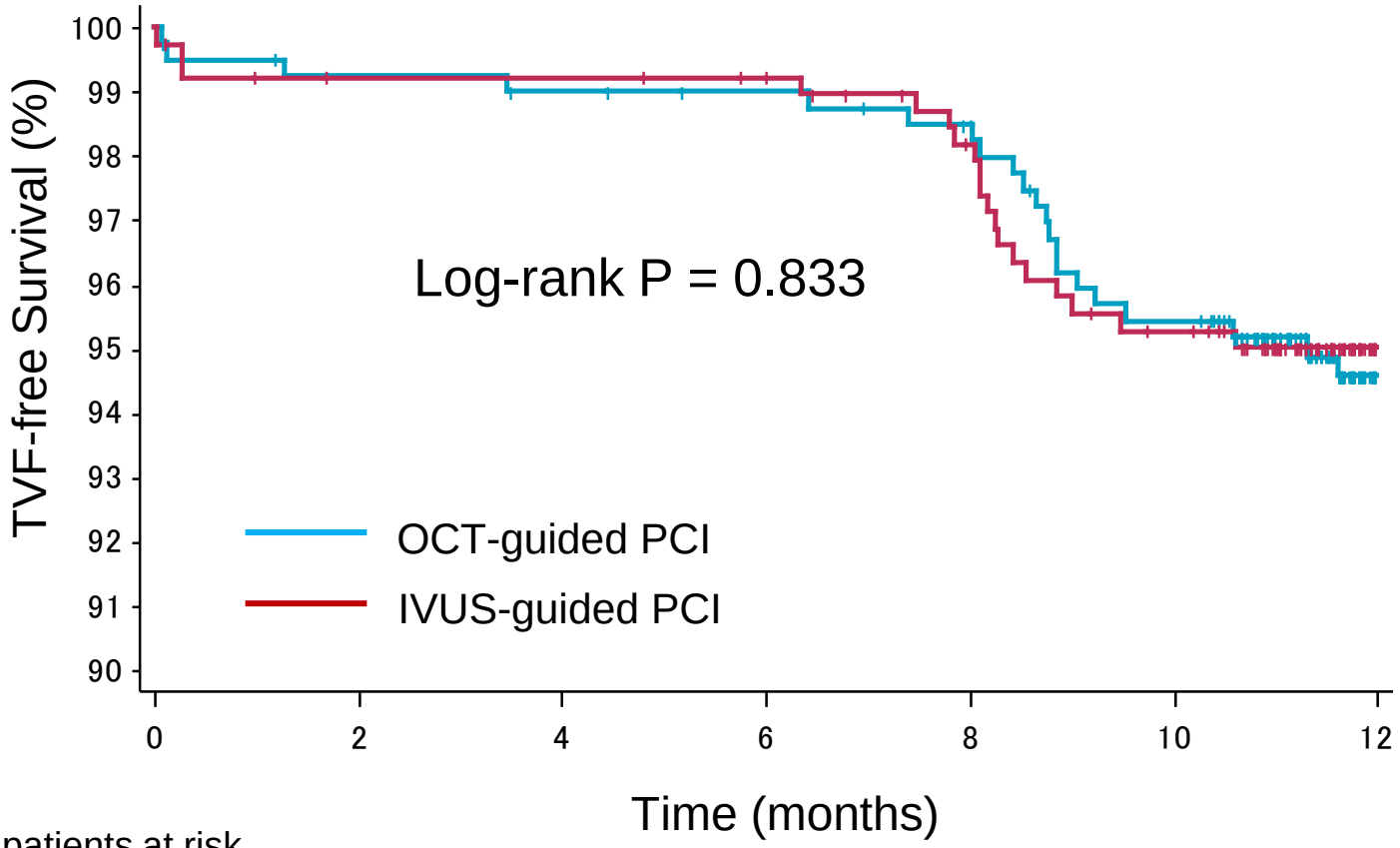


p = 0.611

Pre-dilatation: Balloon size/pressure up (11% vs. 10%)
Rotablator, Cutting balloon (3% vs. 4%)
Distal protection (4% vs. 3%)
Post-dilatation: Balloon size/pressure up (31% vs. 28%)
Additional stent (4% vs. 3%)
Others (1% vs. 2%)

Primary endpoint: TVF

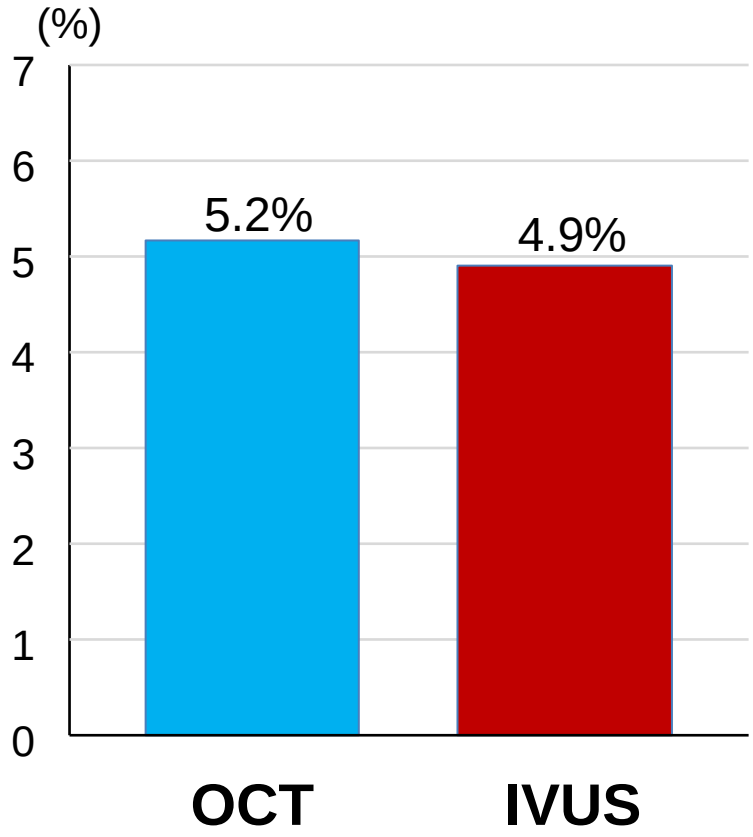
TVF = composite of cardiac death, target vessel-related MI and clinically-driven TVR

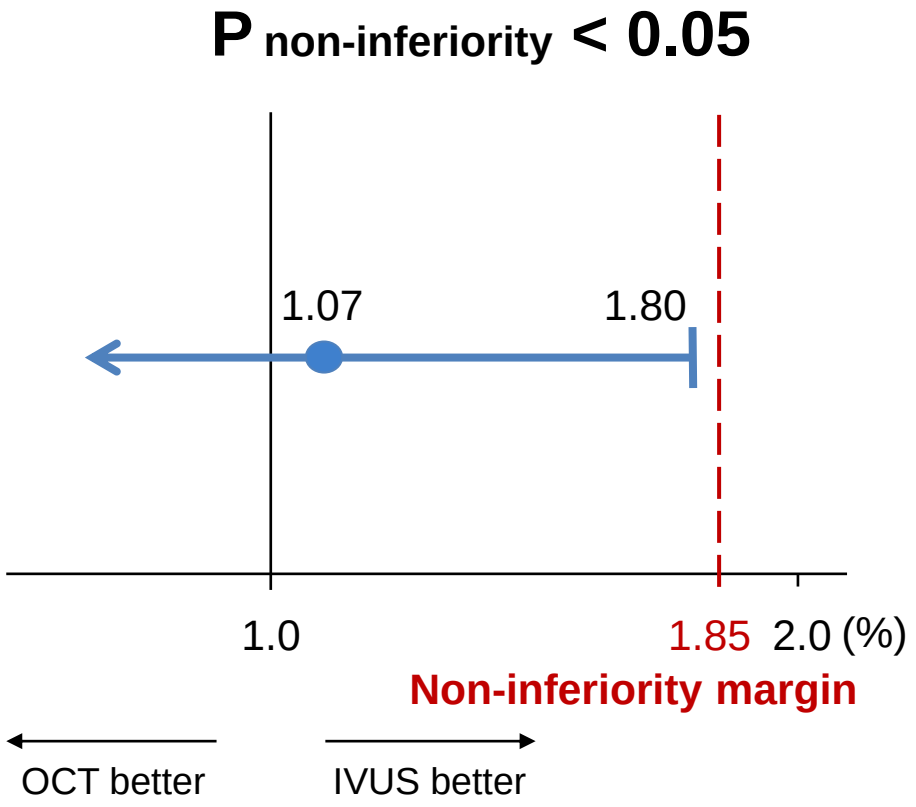


No. of patients at risk

OFDI-guided PCI	401	396	394	392	387	374	265
IVUS-guided PCI	390	384	384	381	373	360	285

Primary endpoint: TVF





The upper 95% confidence interval of the difference in the TVF rate was 1.80%, which was lower than the pre-defined non-inferiority margin. Therefore, non-inferiority of OCT-guided PCI relative to IVUS-guided PCI was demonstrated in terms of TVF.

Secondary endpoints

	OCT	IVUS	*p*-value
Cardiac death	0 (0%)	1 (0.2%)	0.496
MI	2 (0.5%)	3 (0.7%)	0.684
Ischemia-driven TVR			
TLR	11 (2.7%)	12 (3.0%)	0.835
Non-TLR	9 (2.2%)	5 (1.2%)	0.420
Stent thrombosis	1 (0.2%)	2 (0.5%)	0.621
Stroke	4 (1.0%)	1 (0.2%)	0.374
Contrast-induced nephropathy	0 (0%)	0 (0%)	-

QCA results

	OCT	IVUS	*p*-value
Pre-PCI			
Reference vessel diameter, mm	2.62 ± 0.53	2.59 ± 0.57	0.259
Diameter stenosis, %	64 ± 12	65 ± 13	0.156
Post-PCI			
Diameter stenosis, %	12 ± 6	11 ± 6	0.143
8-month follow-up			
Diameter stenosis, %	16 ± 11	15 ± 10	0.948
Binary restenosis (DS>50%)	6 (1.6)%	6 (1.6)%	1.000

OCT results

	OCT	IVUS	*p*-value
Post-PCI			
Mean stent area, mm^2	6.36 (4.95–7.68)	6.68 (5.91–8.79)	0.054
Stent edge hematoma	30 (63)	51 (82)	0.040
Irregular tissue protrusion	25 (48)	33 (73)	0.014
8-month follow-up			
Mean neointima area, mm^2	0.46 (0.36–0.76)	0.62 (0.40–1.06)	0.057
Mean lumen area, mm^2	6.33 (4.77–7.39)	6.34 (5.37–7.87)	0.240

OCT-guided PCI vs. angiography-guided PCI

The CLI-OPCI study retrospectively enrolled 700 patient to compare clinical outcomes between angiographic guidance alone vs. angiographic plus OCT guidance for PCI.

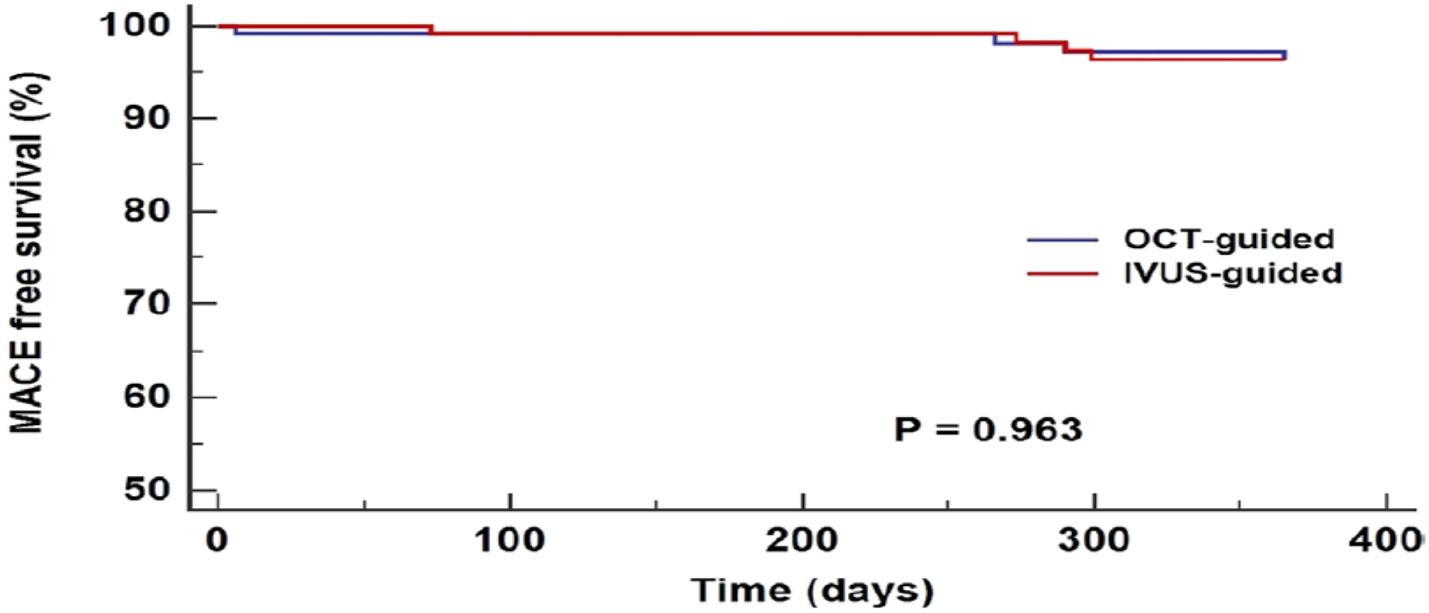
	Angiographic guidance group (n=335)	Angiographic plus OCT guidance group (n=335)	*p*-value
Events at 1-year follow-up			
Death	23 (6.9%)	11 (3.3%)	0.035
Cardiac death	15 (4.5%)	4 (1.2%)	0.010
Myocardial infarction	29 (8.7%)	18 (5.4%)	0.096
Target lesion repeat revascularisation	11 (3.3%)	11 (3.3%)	1.0
Cardiac death, myocardial infarction, or repeat revascularisation	50 (15.1%)	32 (9.6%)	0.034

Conclusion: OCT can improve clinical outcomes of patients undergoing PCI.

OCT-guided PCI vs. IVUS-guided PCI

The study enrolled 290 patients who underwent implantation of a second generation DES under OCT (122 patients) or IVUS (168 patients) guidance. The two groups were compared after 1:1 propensity score matching (114 patients in each group).

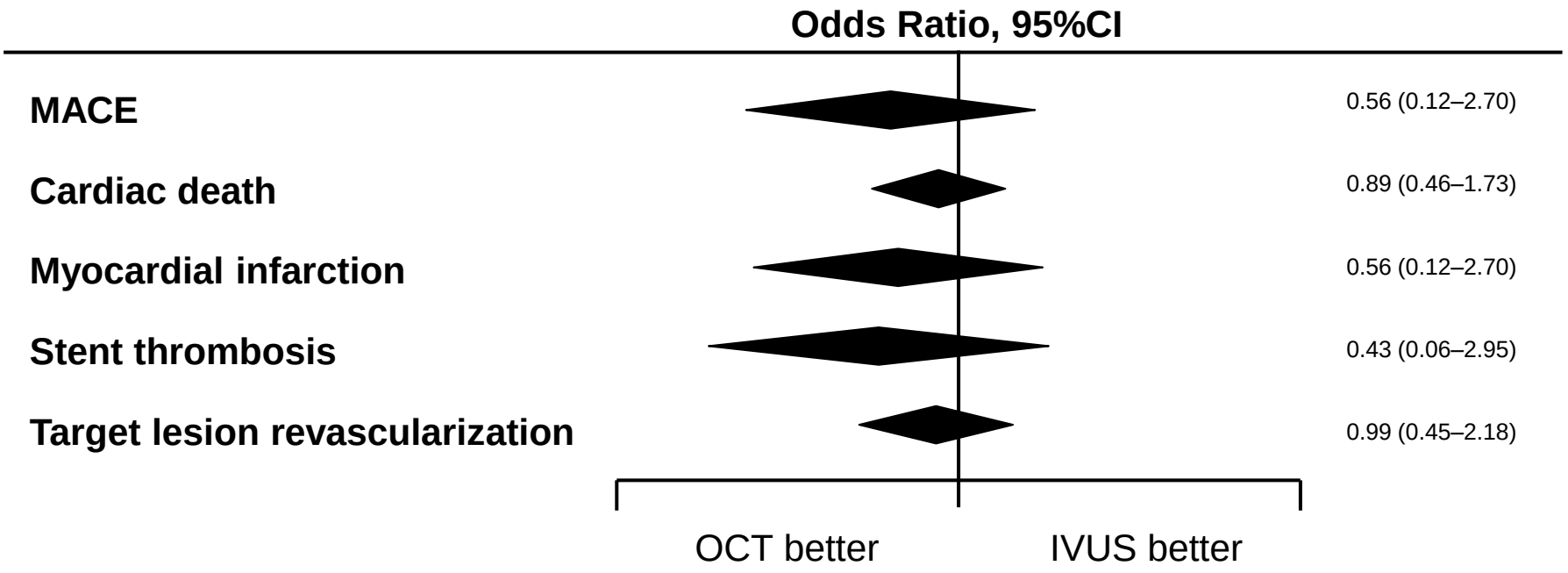
MACE: composite of cardiac death, MI, and TLR



Conclusion: One year cumulative MACE free survival rate was similar between OCT-guided PCI and IVUS-guided PCI.

OCT-guided PCI vs. IVUS-guided PCI

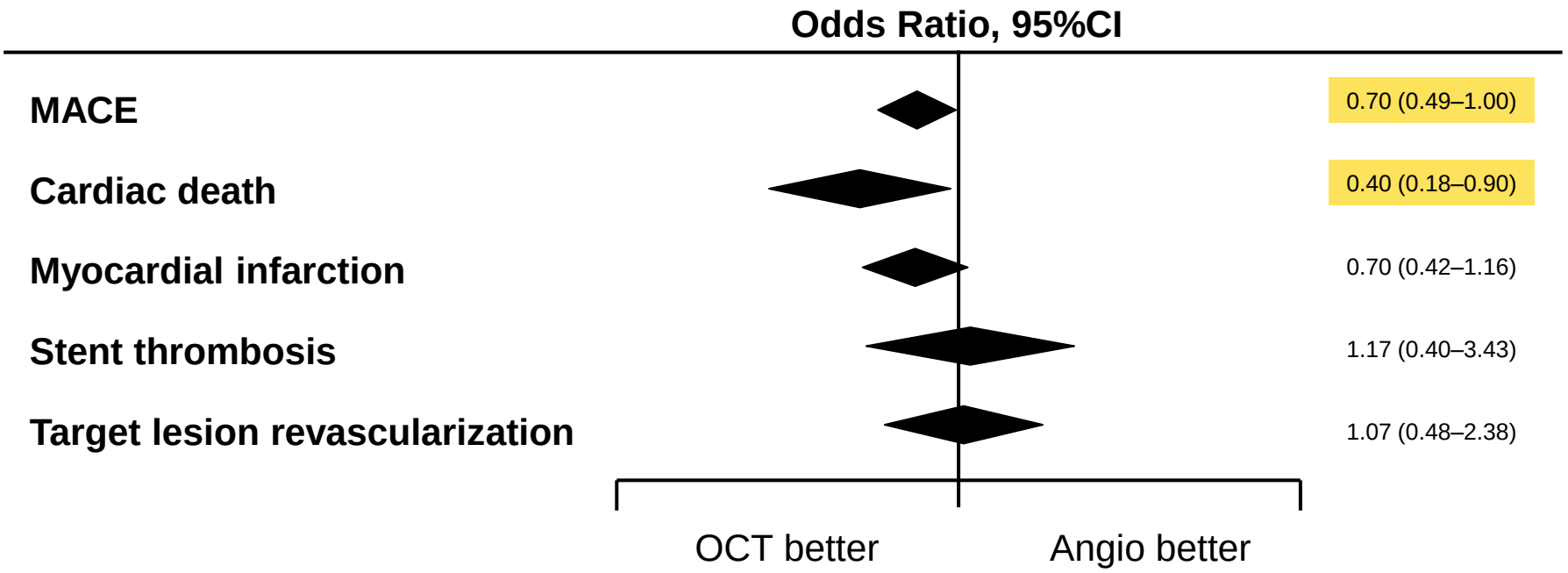
This meta-analysis included 2,781 patients; OCT-guidance vs. angiography guidance (n = 1753) and OCT-guidance vs. IVUS-guidance (n = 1028).



Conclusion: There was no statistically significant difference in clinical outcomes between OCT-guided PCI and IVUS-guided PCI.

OCT-guided PCI vs. angiography-guided PCI

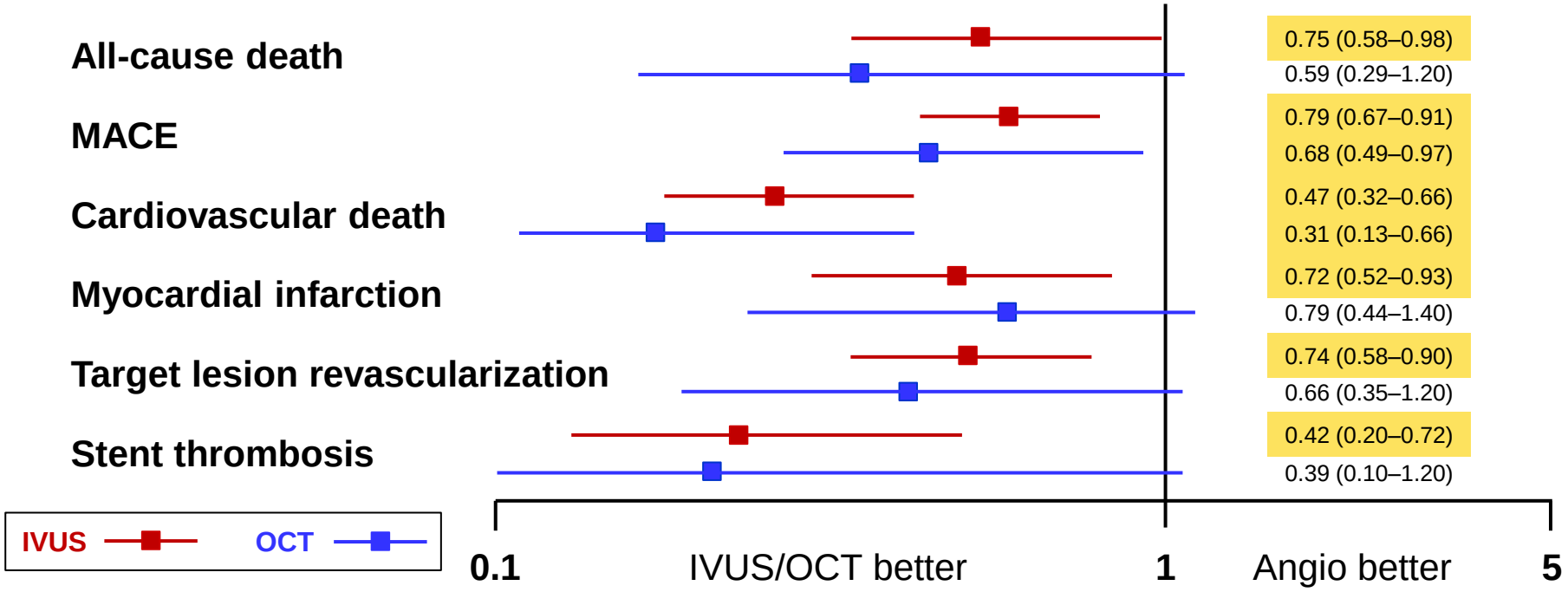
This meta-analysis included 2,781 patients; OCT-guidance vs. angiography guidance (n = 1753) and OCT-guidance vs. IVUS-guidance (n = 1028).



Conclusion: The rate of MACE and cardiac death was significantly lower in OCT-guided PCI compared to angiography-guided PCI.

IVUS/OCT-guided PCI vs. angio-guided PCI

This meta-analysis included 31 studies and 17,882 patients (angiography: 27 studies, 2,875 pts; IVUS: 29 studies, 8,434 pts; and OCT: 7 studies, 1,623 pts).



Conclusion: IVUS/OCT guidance in PCI reduced the risk of MACE and cardiovascular death compared to angiography guidance alone.

Conclusion

1. OCT-guided PCI and IVUS-guided PCI is equivalent in terms of clinical outcome.
2. As compared with angiography-guided PCI, both OCT-guided PCI and IVUS-guided PCI have excellent clinical outcomes, with a low rate of death, MI and repeat revascularization.

Thanks for your attention !