

OCT Versus IVUS for Complex PCI

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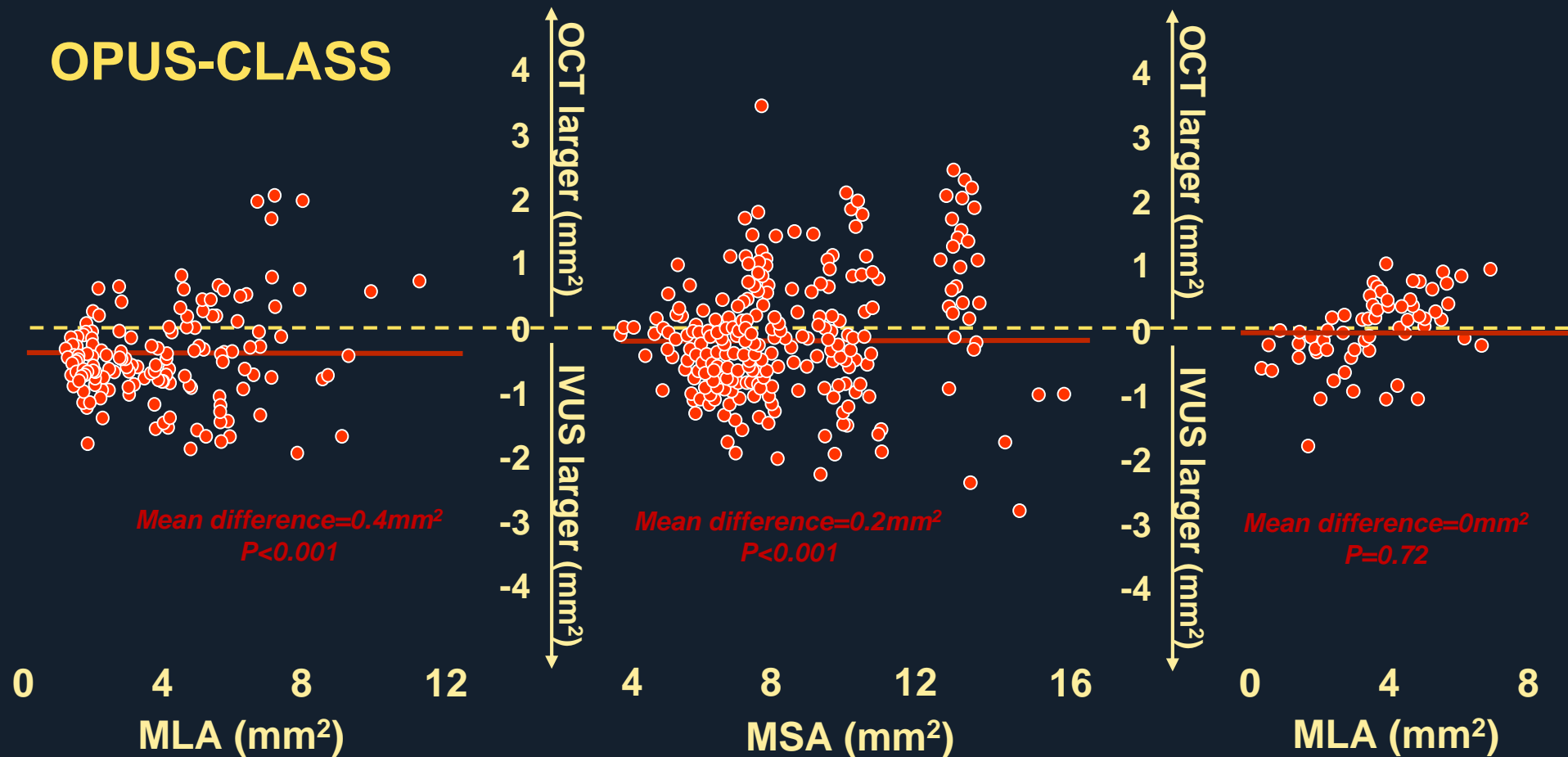
2018 ESC Guideline for Intravascular Imaging

	COR	LOE
➤ IVUS or OCT should be considered in selected patients to optimize stent implantation	IIa	B
➤ IVUS should be considered to optimize treatment of unprotected left main lesions	IIa	B
➤ IVUS and/or OCT should be considered to detect stent-related mechanical problems leading to restenosis	IIa	C

OCT vs. IVUS

	OCT	IVUS
Wave source	Near-infrared light	Ultrasound
Axial resolution, μm	15-20	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

In vivo comparison of OCT vs IVUS



Kubo et al. JACC Cardiovasc Imaging 2013;6:1095-104

Kim et al. Int J Cardiol 2016;221:860-6

Kobayashi et al. Cardiovasc Interv and Ther 2016;31:79-88

OCT vs. IVUS for Morphologic Evaluation

	Morphologic Evaluation	OCT	IVUS
Pre-PCI	Severity of Calcium	★★★	★★
	Stent Sizing by Vessel Wall	★★	★★★
	Stent length by Normal Vessel	★★★	★★★
Post-PCI	Stent Expansion	★★★	★★★
	Stent Malapposition	★★★	★★
	Stent Deformation at Ostium	★★	★★
	Edge Dissection	★★★	★★
	Residual Disease at Edge	★★★	★★★
At follow-up	Old Stent Expansion	★★★	★★★
	Neointimal Hyperplasia	★★★	★★★
	Neoatherosclerosis	★★★	★★
	Stent Fracture	★★	★★
	Positive Remodeling of Vessel Wall	★	★★★

***OCT-guided vs. IVUS-guided PCI,
Which is better ?***

OCT- vs. IVUS- guided PCI

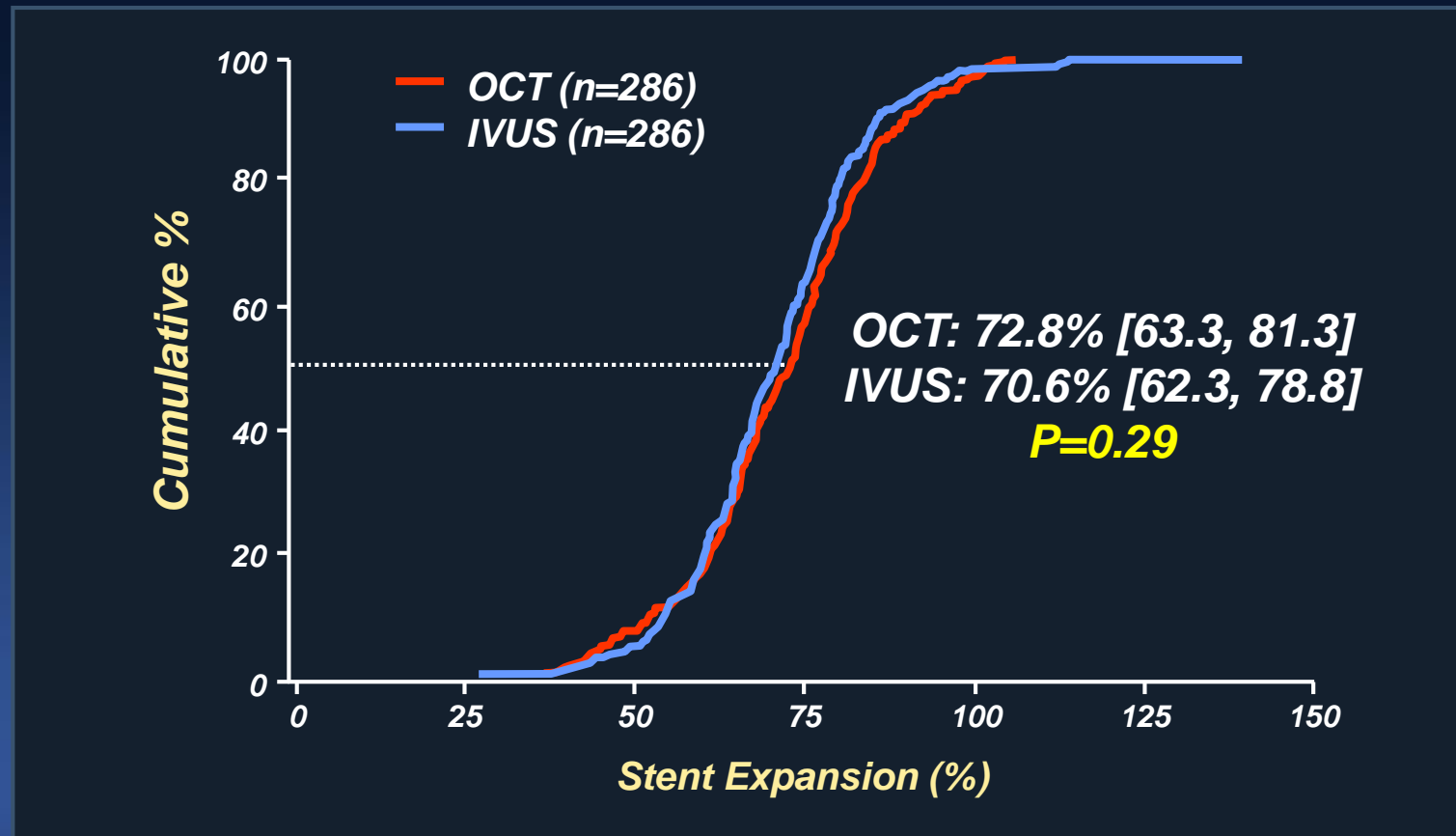
Randomized 70 patients with short, single lesion

Primary endpoint: stent expansion by IVUS

	OCT (n=35)	IVUS (n=35)	P Value
Stent length, mm	16.5±4.2	17.6±5.4	0.33
Stent diameter, mm	3.1±0.5	3.0±0.4	0.78
Stent deployment pressure, atm	9.8±2.4	14.2±3.4	<0.001
Post-procedure IVUS Analysis			
Minimum stent area, mm ²	6.1±2.2	7.1±2.1	0.04
Mean stent area, mm ²	7.5±2.5	8.7±2.4	0.04
Focal stent expansion, %	64.7±13.7	80.3±13.4	0.002
Diffuse stent expansion, %	84.2±15.8	98.8±16.5	0.003

ILUMIEN II

OCT-guided PCI in ILUMIEN I
matched to IVUS-guided PCI in ADAPT-DES



OCT- vs. IVUS- guided PCI

: in propensity-matched population
From 2 Tertiary Hospital in Korea

	OCT (n=114)	IVUS (n=114)	P Value
Age, years	61.5 ± 10.2	61.7 ± 10.2	0.89
Male gender (%)	84 (73.7)	89 (78.1)	0.44
Diabetes (%)	21 (18.4)	21 (18.4)	1.0
Hypertension (%)	50 (43.9)	51 (44.7)	0.89
Stable angina (%)	36 (31.6)	38 (33.3)	0.86
Ejection fraction, %	57.0 ± 10.8	56.2 ± 12.0	0.62
One-Vessel Disease	70 (61.4%)	72 (63.2%)	0.67
LAD target vessel	81 (71.1%)	70 (61.4%)	0.22
Stent size	3.21 ± 0.42	3.18 ± 0.39	0.61
Stent length	25.2 ± 9.3	25.0 ± 11.1	0.90
Overlapped stent (%)	13 (11.4%)	12 (10.5%)	0.83
Contrast dose, mL	297.9 ± 119.6	241.0 ± 105.9	<0.001

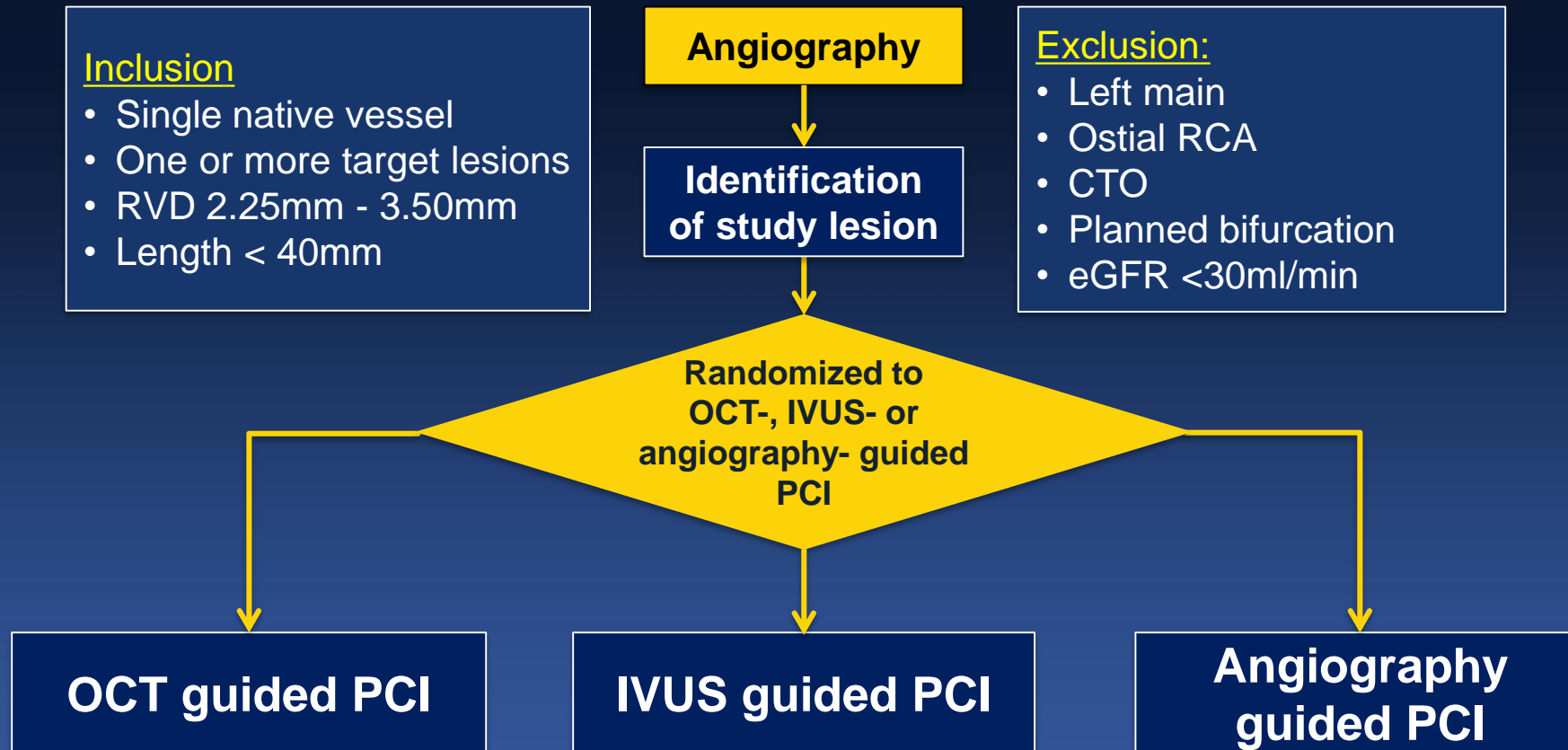
OCT- vs. IVUS- guided PCI

: in propensity-matched population
From 2 Tertiary Hospital in Korea

	OCT (n=114)	IVUS (n=114)	P Value
Stent optimization, %	102 (89.5)	105 (92.1)	0.49
Minimum stent area, mm ²	6.32 ± 2.06	6.34 ± 1.88	0.93
1-year clinical outcomes			
Cardiac death, %	2 (1.8)	3 (2.6)	1.00
Myocardial infarction, %	0	1 (0.9)	1.00
TLR, %	2 (1.8)	1 (0.9)	1.00
MACE, %	4 (3.5)	4 (3.5)	1.00
Stent thrombosis, %	0	1 (0.9)	1.00

ILUMIEN III – OPTIMIZE PCI

Randomized OCT vs. IVUS vs. Angiography



ILUMIEN III – OPTIMIZE PCI

Randomized OCT vs. IVUS vs. Angiography

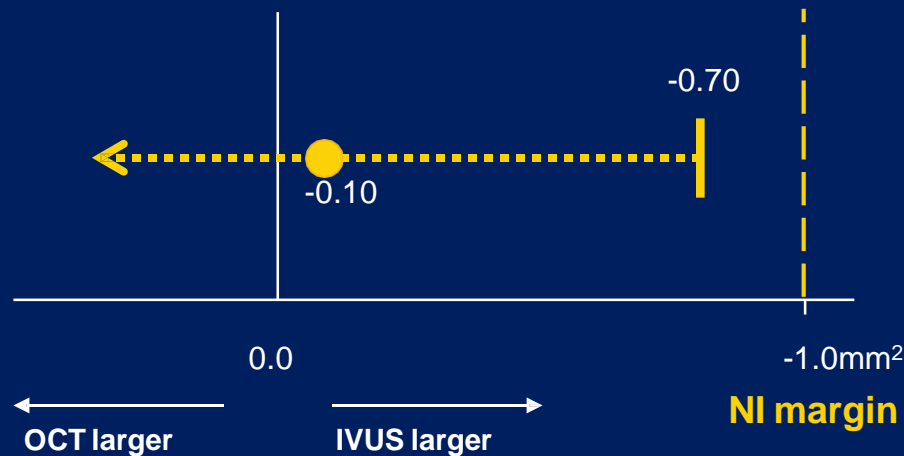
Primary endpoint: Final post-PCI MSA by OCT

OCT 5.79 mm² [4.54, 7.34]

IVUS 5.89 mm² [4.67, 7.80]

97.5% one-sided CI: [-0.70, -]

$P_{noninferiority} = 0.001$



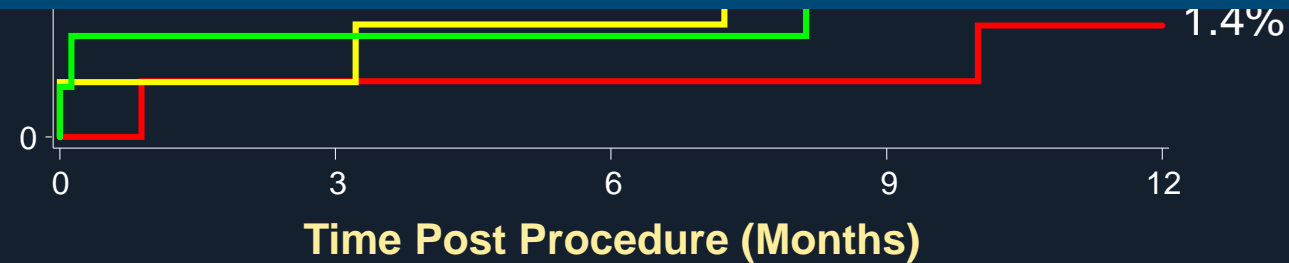
ILUMIEN III: Expansion Endpoints

	OCT (n=140)	IVUS (n=135)	Angio (n=140)	P OCT vs IVUS	P OCT vs Angio
Minimal stent area, mm ²	5.79 [4.54,7.34]	5.89 [4.67,7.80]	5.49 [4.39, 6.59]	0.42	0.12
Min stent expansion, %	88 ± 17	87 ± 16	83 ± 13	0.77	0.02
Mean stent expansion, %	106 [98, 120]	106 [97, 117]	101 [92, 110]	0.63	0.001
<u>Stent expansion</u>					
- Optimal (>95%)	26%	25%	17%	0.84	0.07
- Acceptable (90 - <95%)	16%	12%	3.7%	0.42	0.0008
- Unacceptable (<90%)	59%	63%	79%	0.45	0.0002

ILUMIEN-III: 1-Year TLF Cardiac Death, TV-MI, or ID-TLR



Underpowered to detect differences of clinical outcomes ...



Number at risk:

Angiography	146	141	141	141	53
IVUS	146	137	135	133	59
OCT	158	152	152	150	59

The OPINION RCT: Design

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

Patients scheduled for PCI using DES*
n = 800

1:1

OCT-guided PCI
n = 400

*DES: NOBORI
biolimus-eluting stent

IVUS-guided PCI
n = 400

8 months: Follow-up coronary angiography

12 months: Clinical follow-up

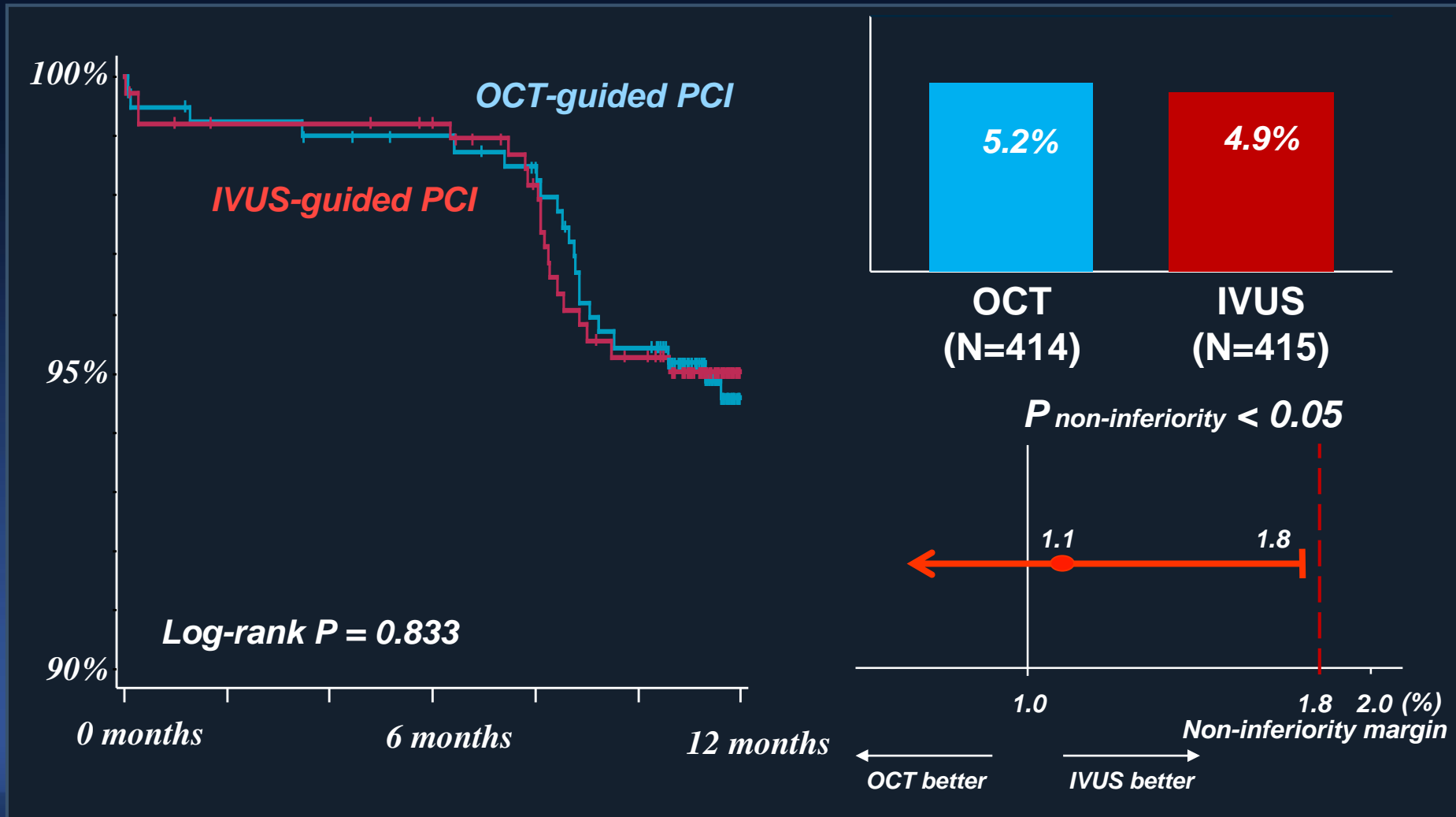
Primary Endpoint: Target Vessel Failure (TVF) at 12 months after PCI

Exclusion:

- 3VD, LM disease
- Ostial Lesion
- CTO
- Bypass graft
- In-stent restenosis
- CHF
- eGFR <30ml/min

RCT: OPINION Trial: OCT vs. IVUS

1-Year TVF (Cardiac Death, TV-MI, or ID-TVR)



RCT: OPINION Trial: OCT vs. IVUS

Procedure Results

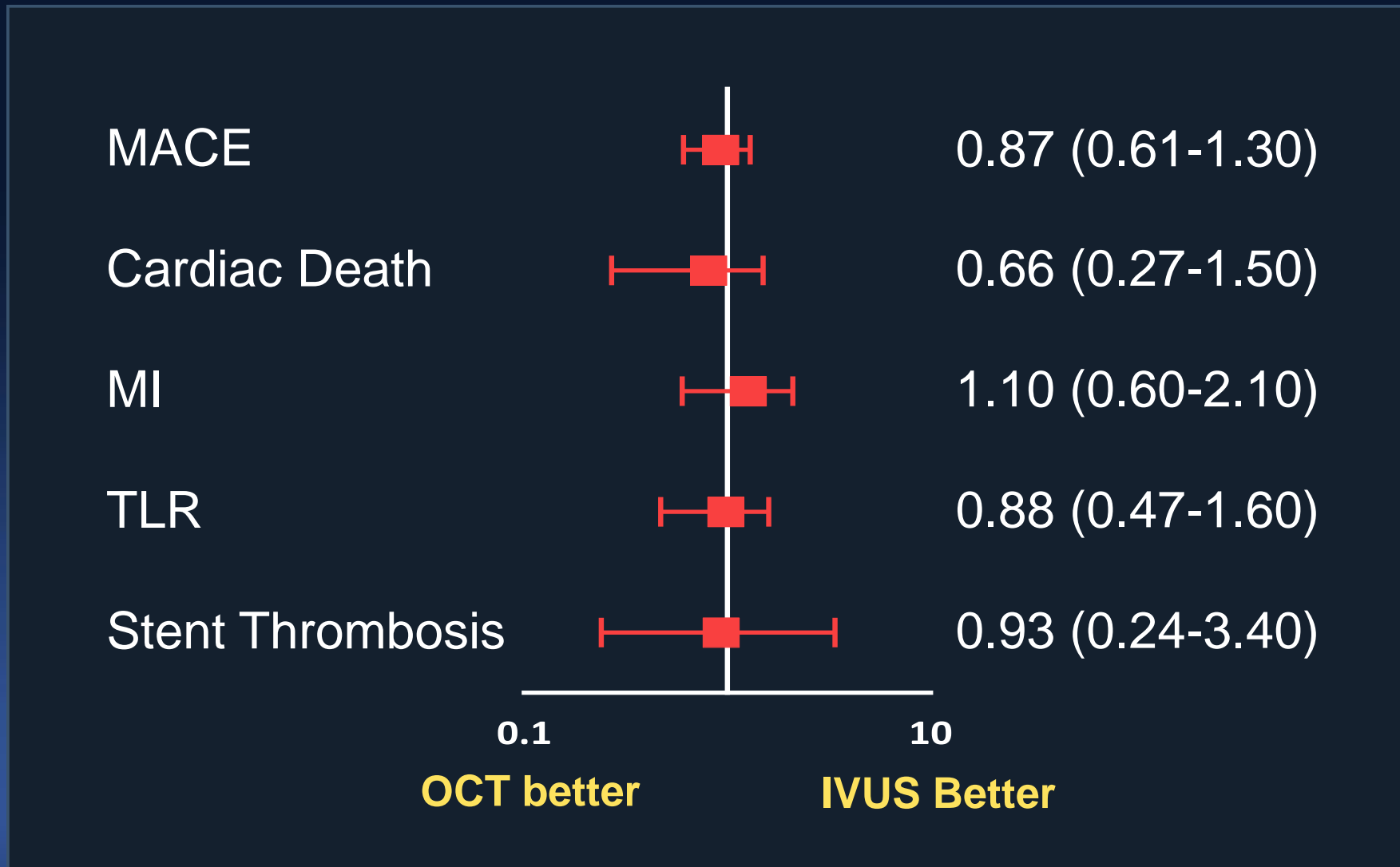
	OCT-guided (412 pts)	IVUS-guided (405 pts)	P value
Stent diameter, mm	2.92 ± 0.39	2.99 ± 0.39	0.005
Total stent length, mm	25.9 ± 13.2	24.8 ± 13.2	0.06
Multiple stenting	16.5%	14.6%	0.50
Pre-dilatation	76.7%	78.0%	0.67
Post-dilatation	76.7%	75.1%	0.62
Max. balloon diameter, mm	3.1 ± 0.8	3.3 ± 1.2	0.06
Max. inflation pressure, atm	16.0 ± 4.2	16.0 ± 4.2	0.06
No. of OCT/IVUS procedure	3.0 ± 1.1	3.0 ± 1.1	0.14
OCT/IVUS related complication	0.7%	0.3%	0.62
Total amount of contrast, mL	164 ± 66	138 ± 56	<0.001

RCT: OPINION Trial: OCT vs. IVUS

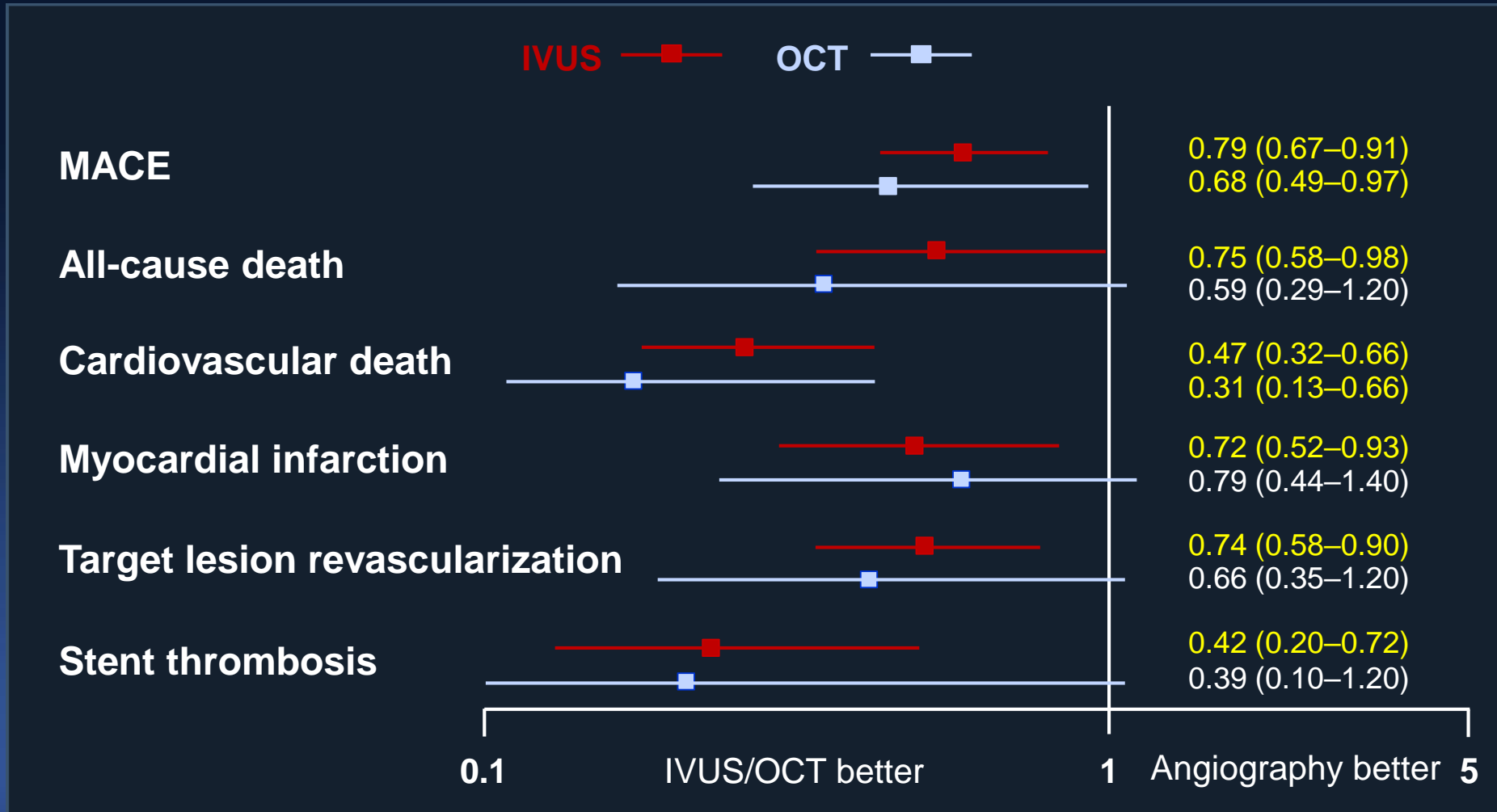
QCA Results

	OCT-guided	IVUS-guided	P value
Post-PCI	409 patients	400 patients	
In-segment RVD, mm	2.86 ± 0.56	2.89 ± 0.56	0.63
In-segment MLD, mm	2.25 ± 0.53	2.27 ± 0.52	0.78
In-segment DS, %	22 ± 10	22 ± 9	0.89
In-segment acute gain, mm	1.32 ± 0.54	1.38 ± 0.54	0.15
8-month FU	369 patients	365 patients	
In-segment RVD, mm	2.82 ± 0.53	2.85 ± 0.56	0.59
In-segment MLD, mm	2.16 ± 0.56	2.17 ± 0.55	0.75
In-segment DS, %	24 ± 13	24 ± 12	0.54
In-segment acute gain, mm	0.10 ± 0.46	0.10 ± 0.44	0.72

OCT vs. IVUS: Meta-analysis



OCT / IVUS vs. Angiography-guided PCI : Meta-analysis



***OCT-guidance vs. IVUS-guidance
for Complex PCI,
Which is better ?***

No Definitive Evidence Yet !!

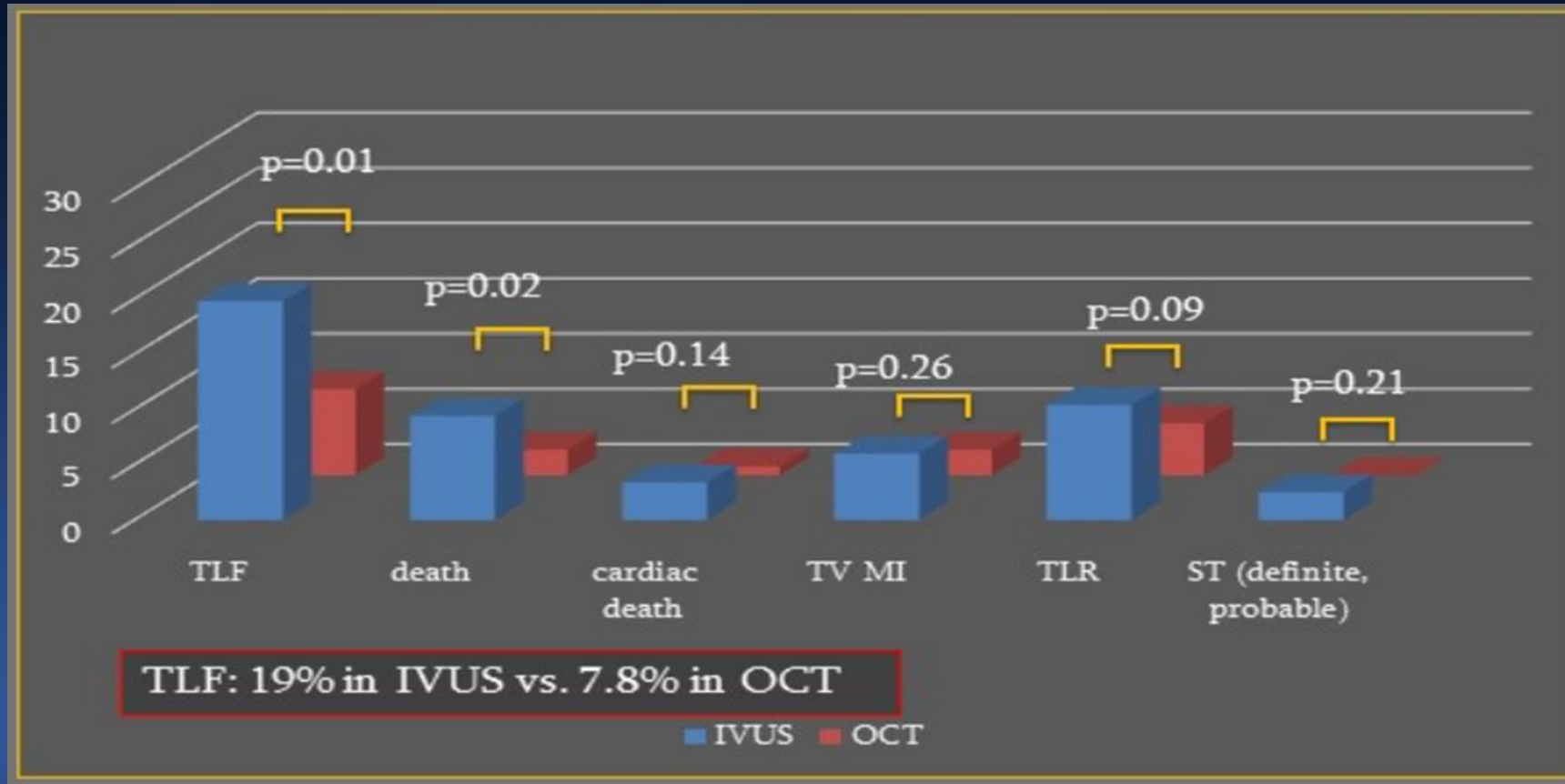
Prior RCTs Excluded Complex Lesions

- **ILUMIEN III**
 - Vessel diameter limited to 2.25-3.5 mm, length <40mm
 - **Complex lesions excluded**
(LM, RCA os, graft, CTO, ISR, planned 2-stent bifurcation)
- **OPINION**
 - **Complex lesions excluded**
(LM or 3VD, ostial lesion, CTO, ISR, bypass graft)

OCT- vs. IVUS- guided PCI in LM PCI

: in Retrospective registry in 13 European centers

246 (41%) of 598 patients used OCT/IVUS, 35 (OCT) 30 (IVUS) Mo FU



OCT is Better for Complex PCI?

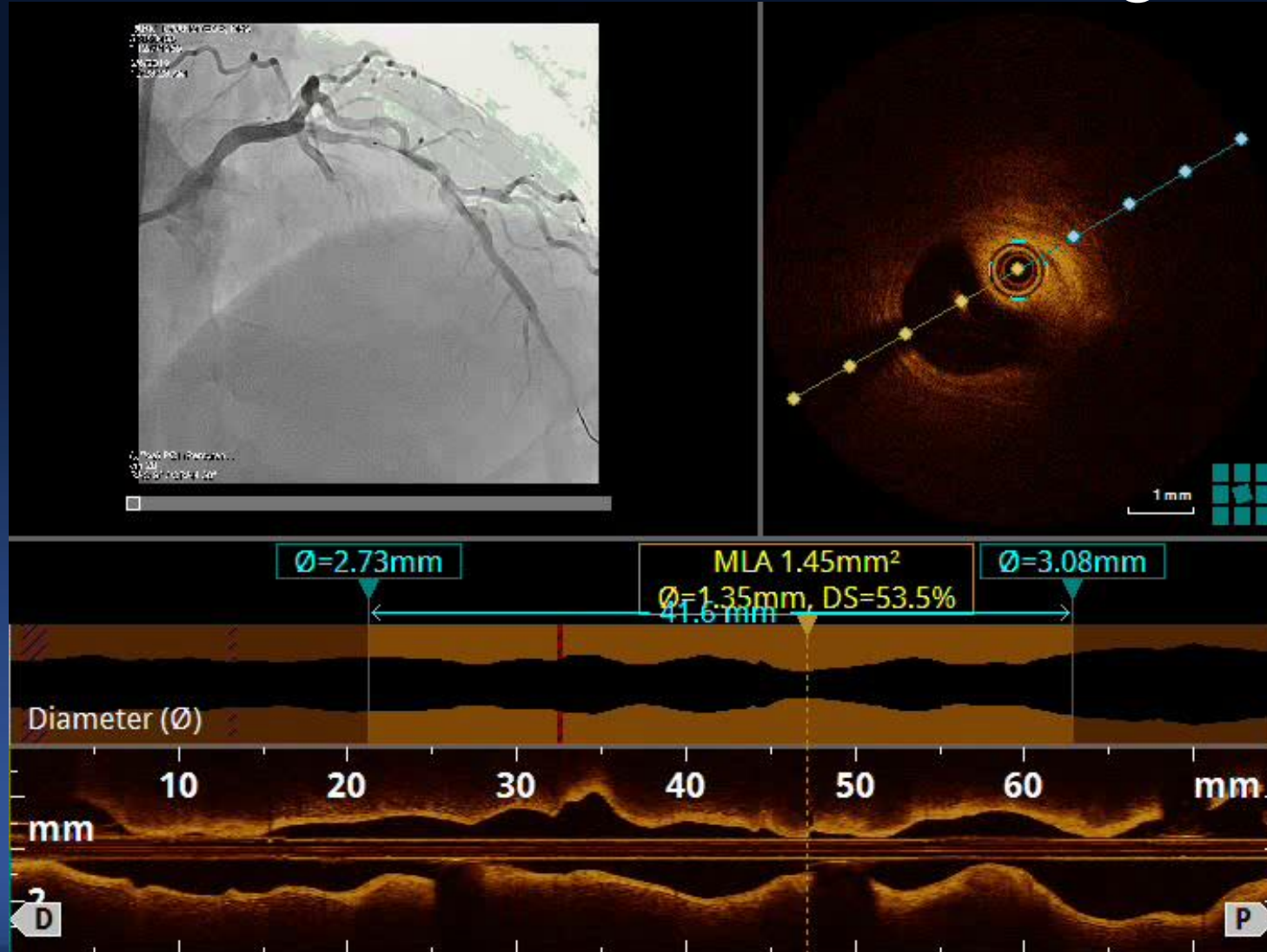
OCT is Better?

Better Spatial Resolution to Detect Acute Complication (ILUMIEN III)

	OCT (n=140)	IVUS (n=135)	P Value
Dissection, any	28%	40%	0.04
Major	14%	26%	0.009
Minor	14%	13%	0.84
Malapposition, any	41%	38%	0.62
Major	11%	21%	0.02
Minor	31%	18%	0.01
Tissue Protrusion, any	67%	74%	0.21
Major	19%	20%	0.88
Minor	48%	54%	0.30

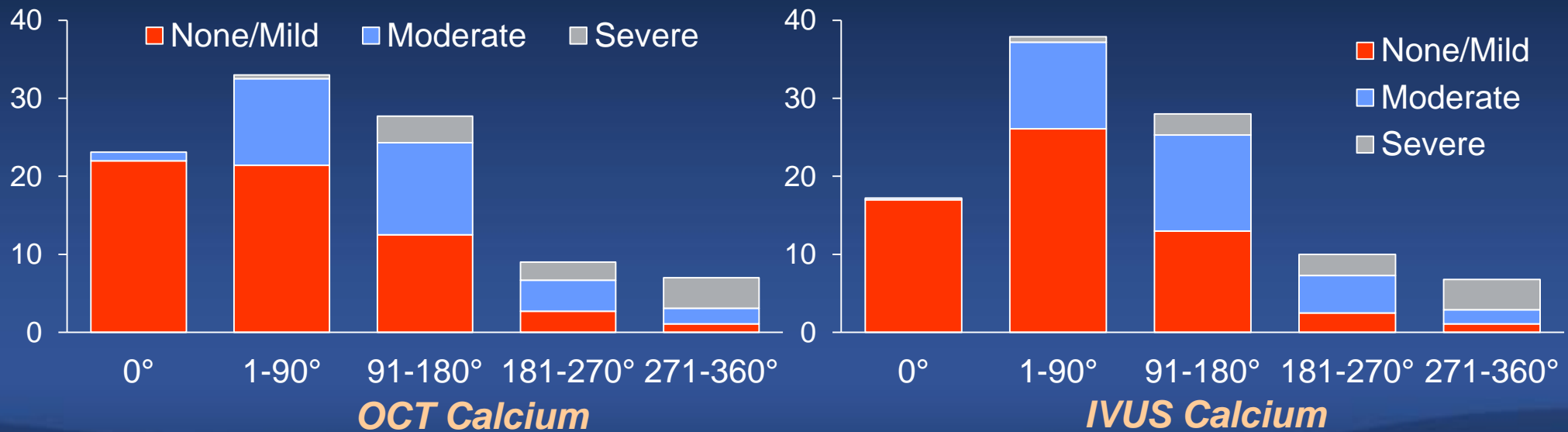
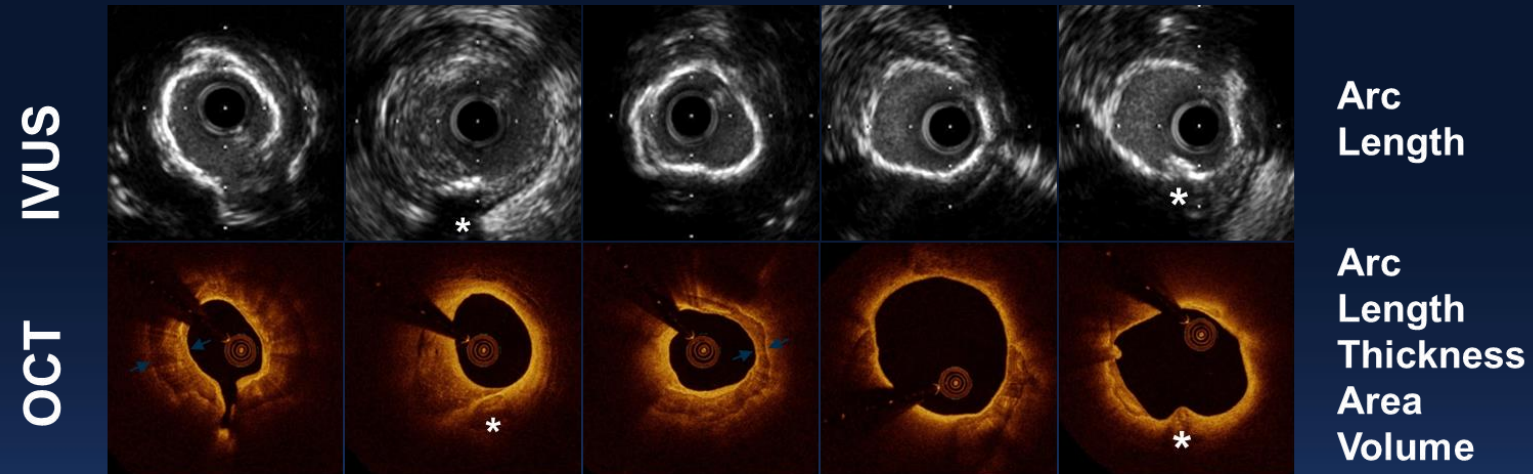
OCT is Better?

Beautiful, Convenient OCT Co-registration



OCT is Better?

Visualization of Calcium with Thickness



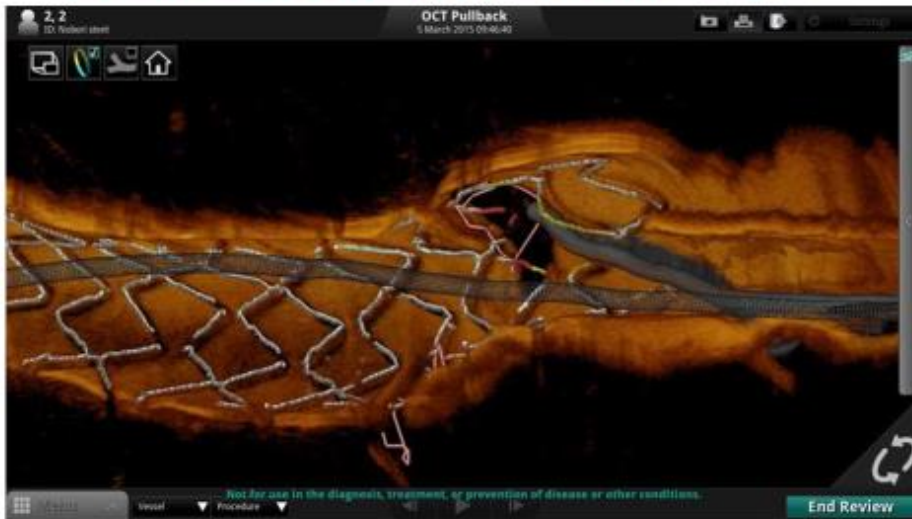
Wang et al. JACC Cardiovasc Imaging 2017;10:869-79

Mintz and Guagliumi. Lancet 2017;390:793-809

OCT is Better?

Delicate Bifurcation PCI with 3D Image

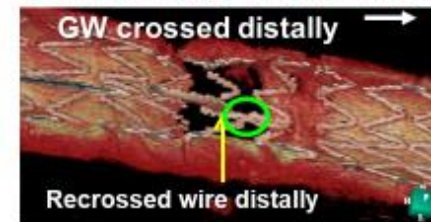
New Development in OCT



Re-crossing wire position in the jailed side branch can be easily identified by newly developed OCT software and improvement of side branch KBT procedure could be expected by the guidance of new OCT.

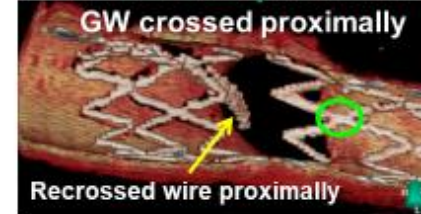
Link connecting to carina type

GW recross distal cell



suboptimal

GW recross proximal cell



Wakayama Medical University

Wakayama Medical University

OCT is Better?

- OCT-Angiography **Co-registration**
- **Faster** Imaging Acquisition
- **Calcium / In-stent Neoatherosclerosis** well visualized
- Delicate **3D-view**, especially for Bifurcation PCI

But,

- Weaker Catheter Tip
- Often can not Visualize Vessel Size
- No Visualization of Ostium
- Need Contrast (Alternatives: Dextran, Saline)

IVUS Better for Complex PCI?

Greater Number of Scientific Evidence

IVUS is Better?

Randomized Trials

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Meta-analyses

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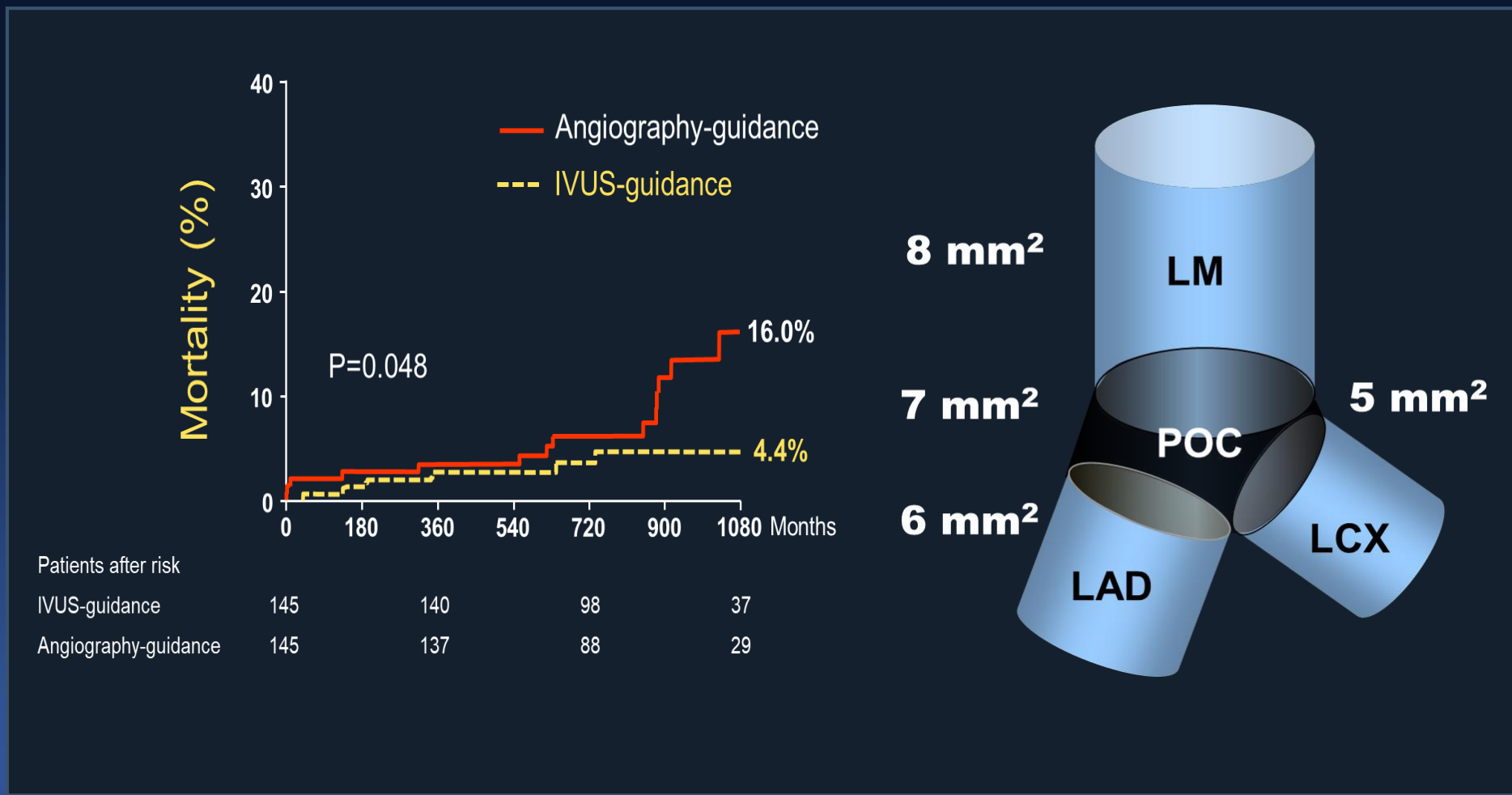


Courtesy of Mintz GS



IVUS is Better?

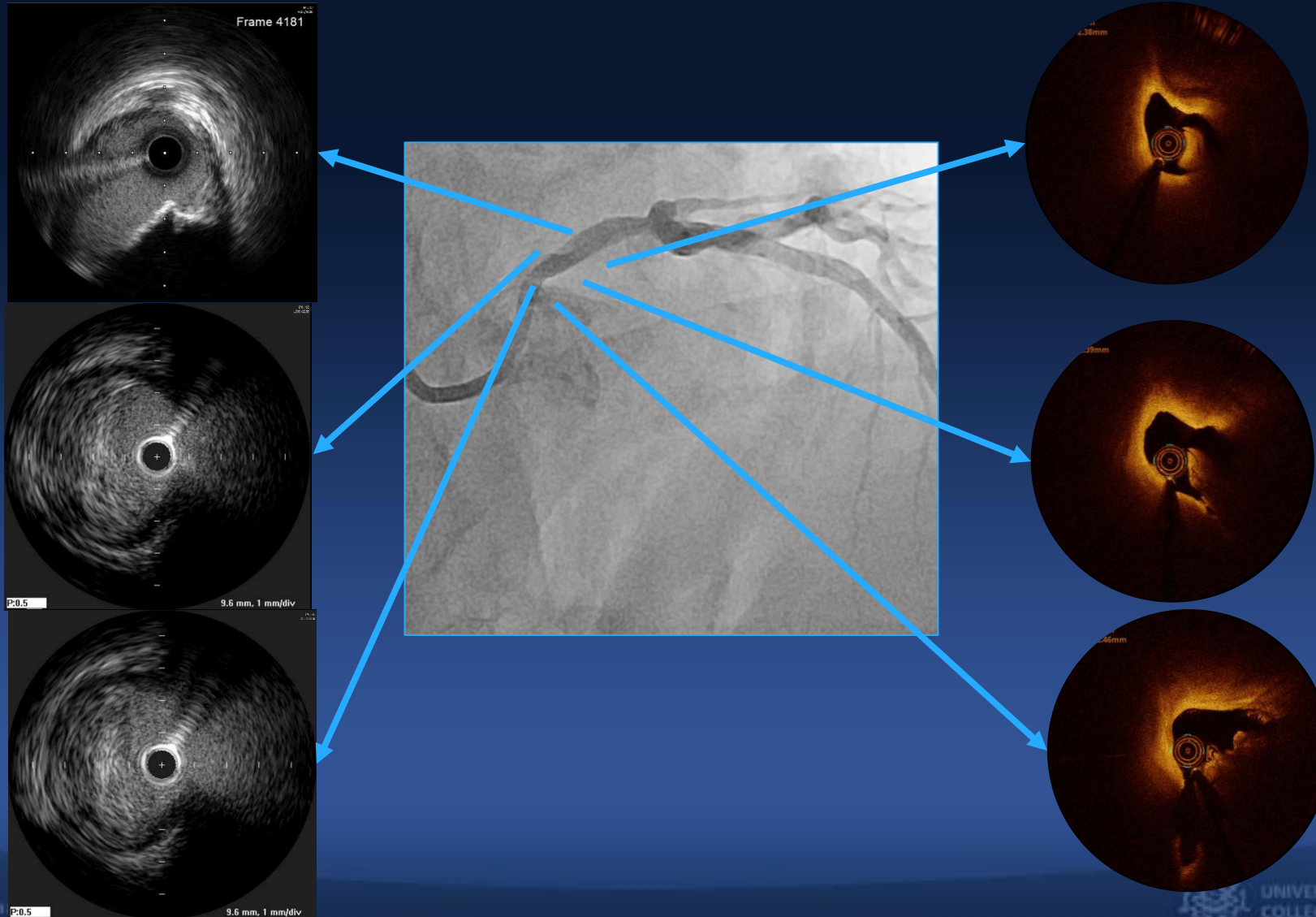
Stronger Scientific Evidence Especially in LM PCI



Park SJ et al, Circ Cardiovasc Interv. 2009;2(3):167-77.

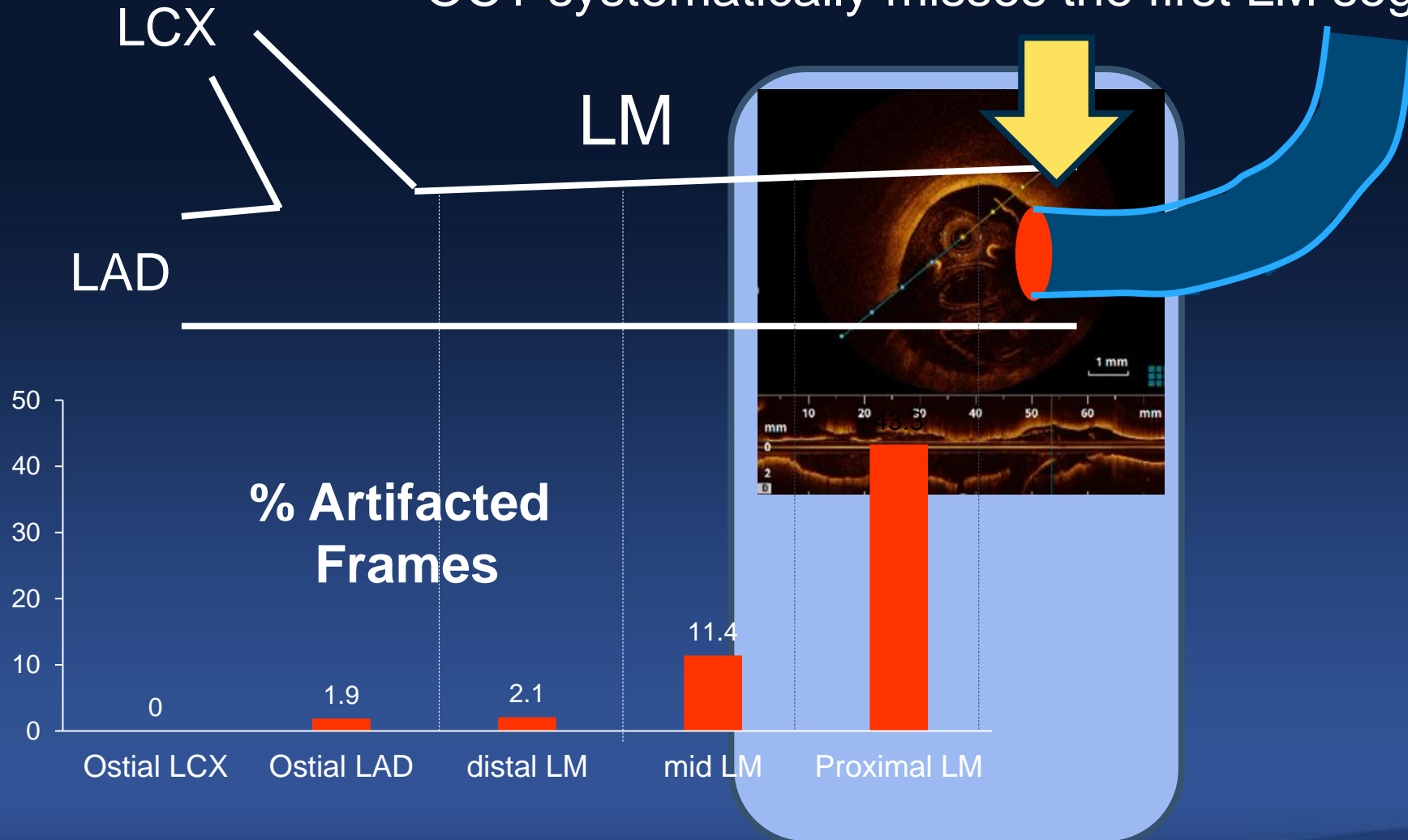
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IVUS is Better? for Left Main Ostium Evaluation



OCT for Left Main

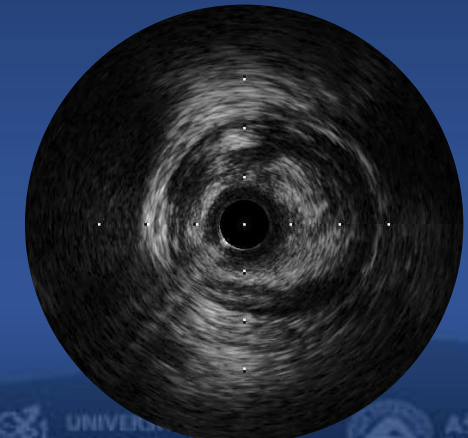
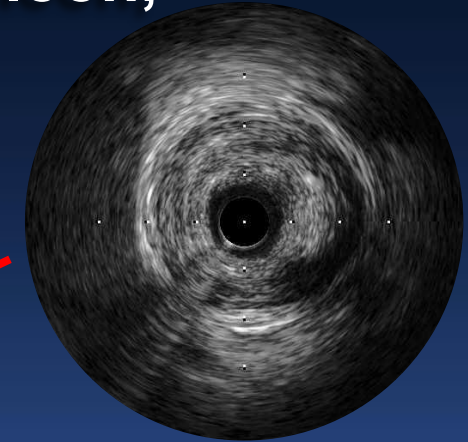
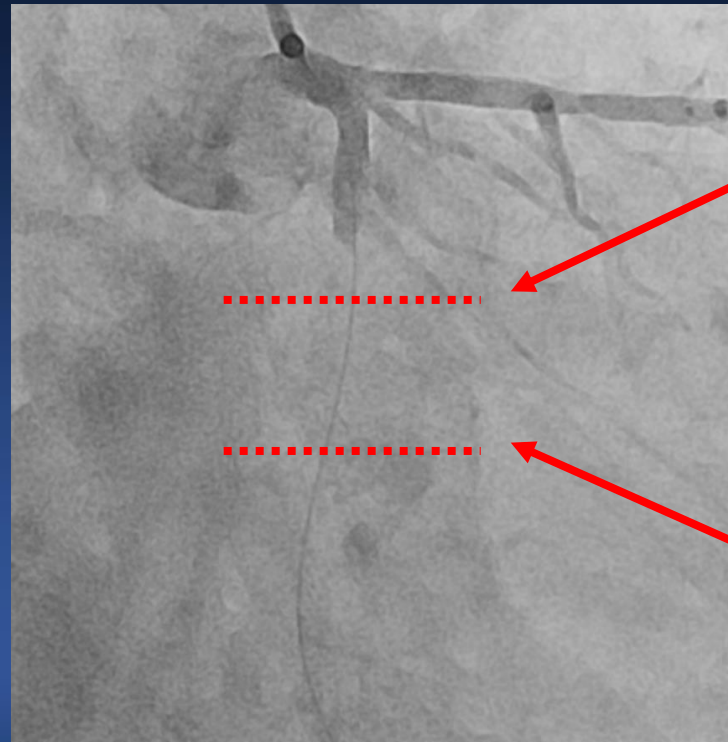
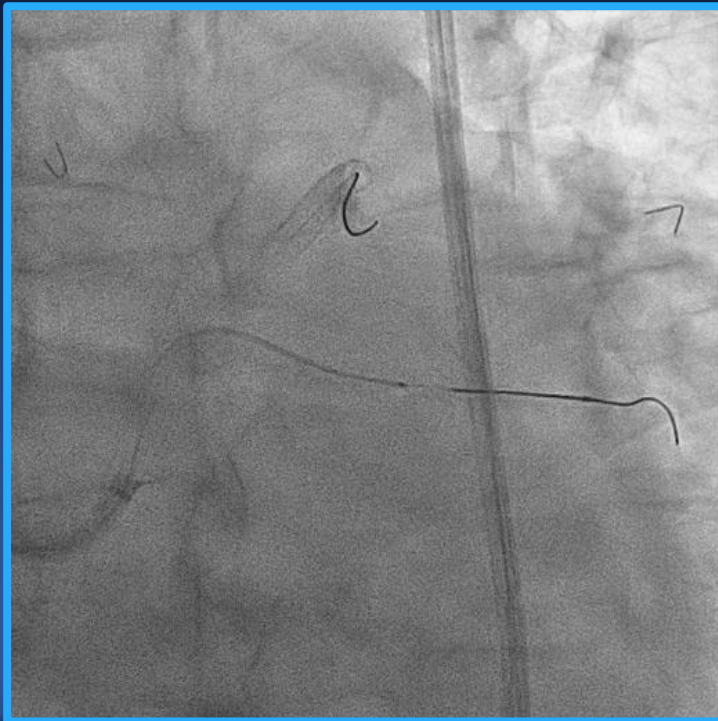
OCT systematically misses the first LM segments



IVUS is Better?

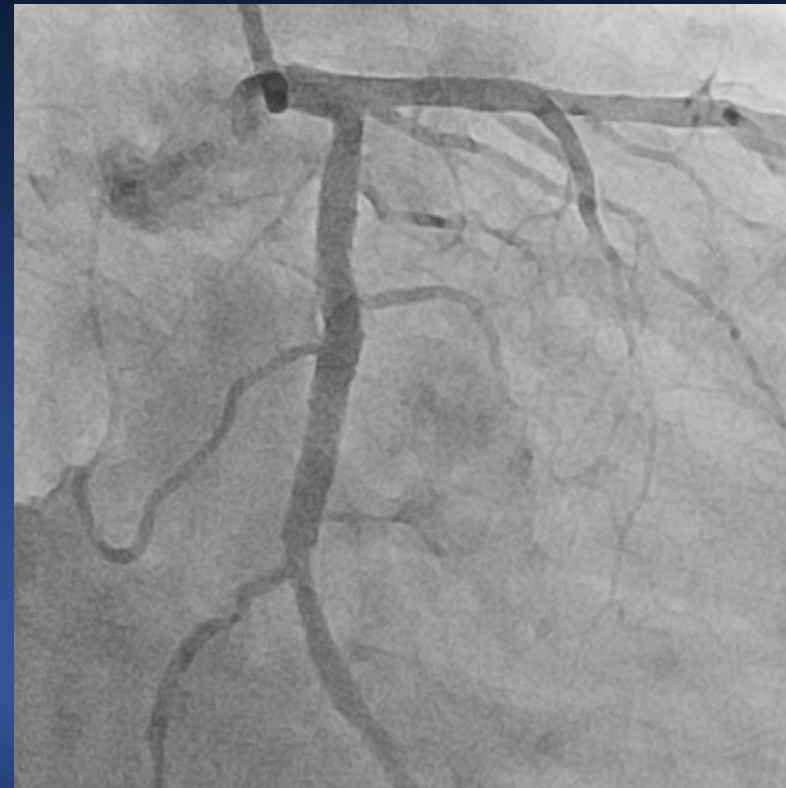
for Non-visualized Vessel (Tight stenosis, Dissection, No-reflow...)

Even I Can Not See Distal Even After Repeated Balloon,
I Can See Vessel by IVUS

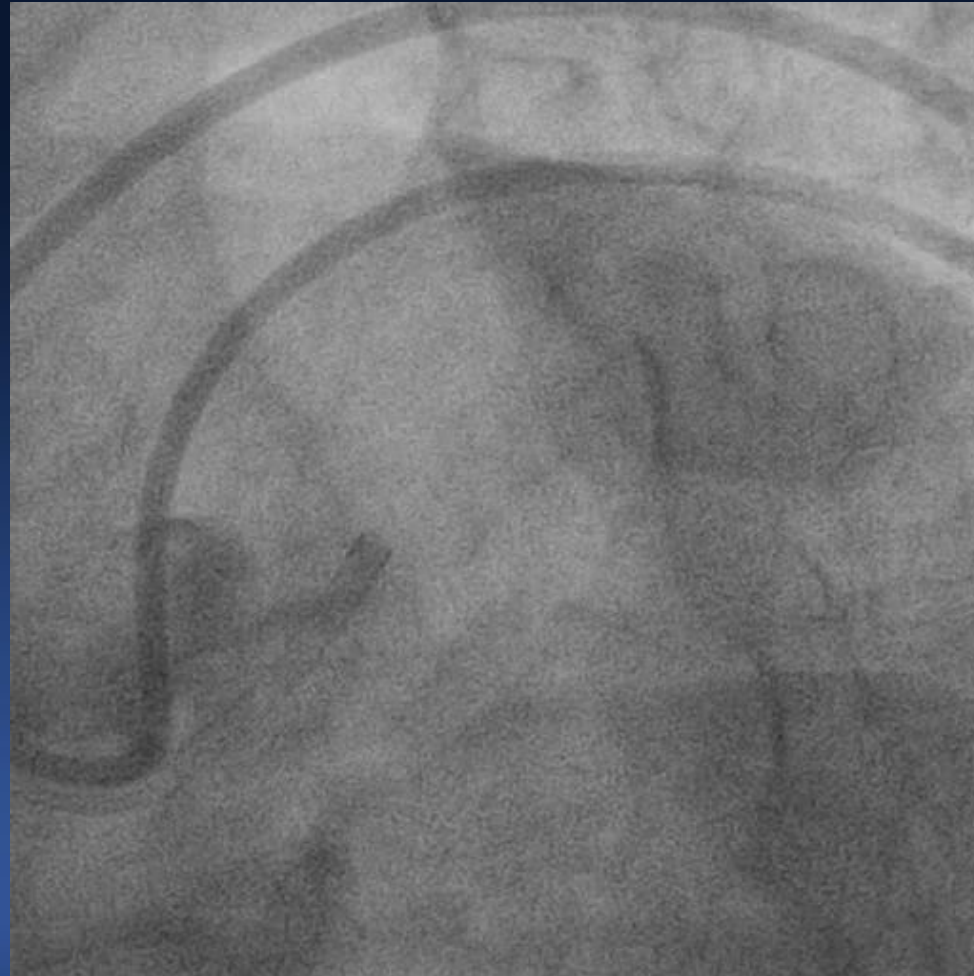


IVUS is Better? for Non-visualized Vessel

Even I Can Not See Distal Even After Repeated Balloon,
I Can See Vessel by IVUS, and Implant Stent

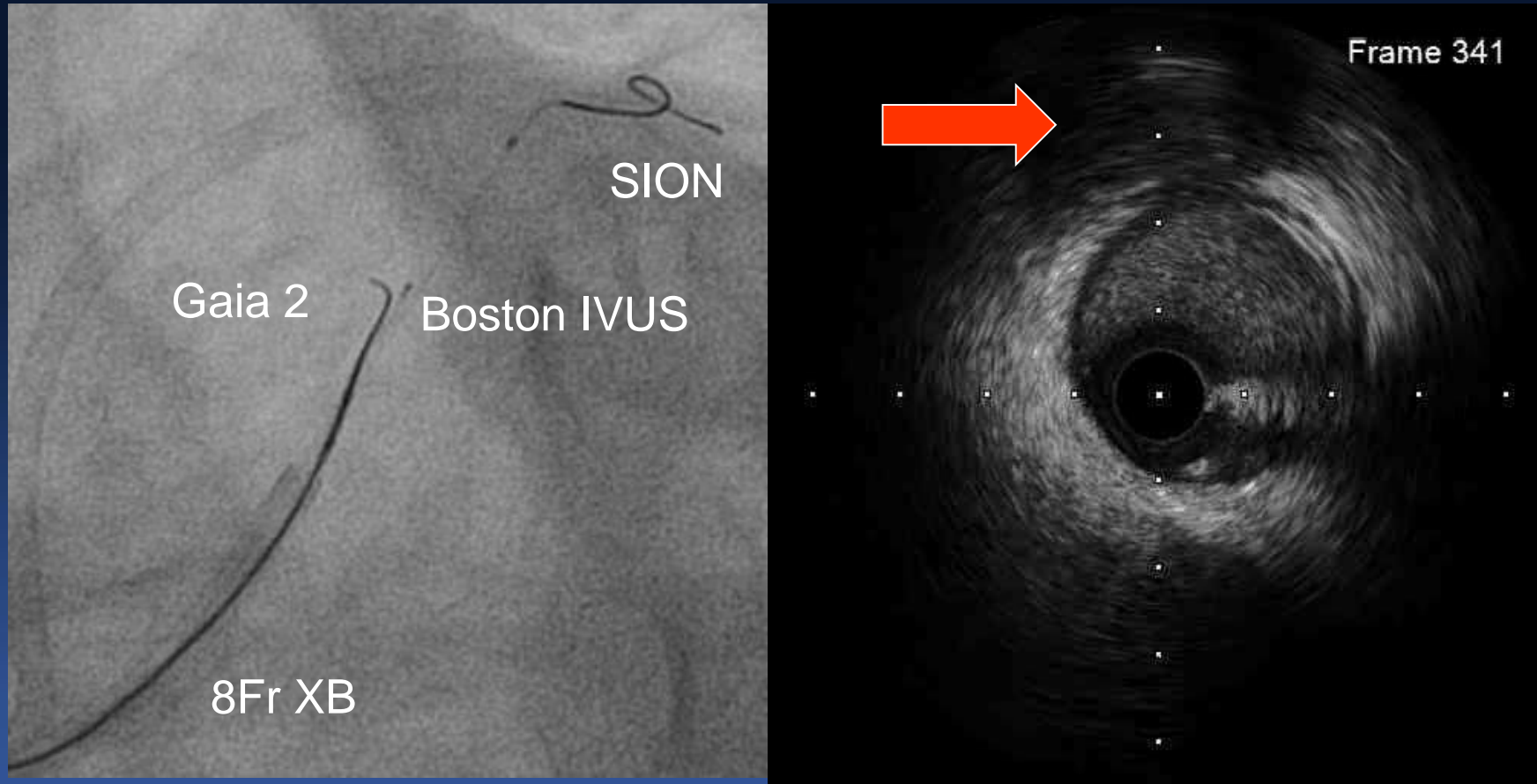


IVUS is Better? for Real-Time Guidance for CTO PCI



Courtesy of SW Lee

IVUS is Better? for Real-Time Guidance



IVUS is Better?

Zero Contrast Procedure Available with IVUS



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Imaging- and pharmacological stress testing in patients with advanced coronary artery disease: a feasibility, safety and efficacy study

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Aims

The feasibility, safety, and efficacy of a 'zero contrast' PCI with intravascular ultrasound (IVUS) in patients with advanced coronary artery disease.

Methods and results

A total of 31 patients with advanced coronary artery disease underwent IVUS-guided PCI. The primary endpoint was the percentage of patients who achieved a proximal-to-distal ratio of $>90\%$ of the mean of the proximal and distal reference areas. The mean proximal-to-distal ratio was $91.2 \pm 10.1\%$ (range 79–100%). The mean proximal-to-distal ratio was $91.2 \pm 10.1\%$ (range 79–100%). The mean proximal-to-distal ratio was $91.2 \pm 10.1\%$ (range 79–100%).

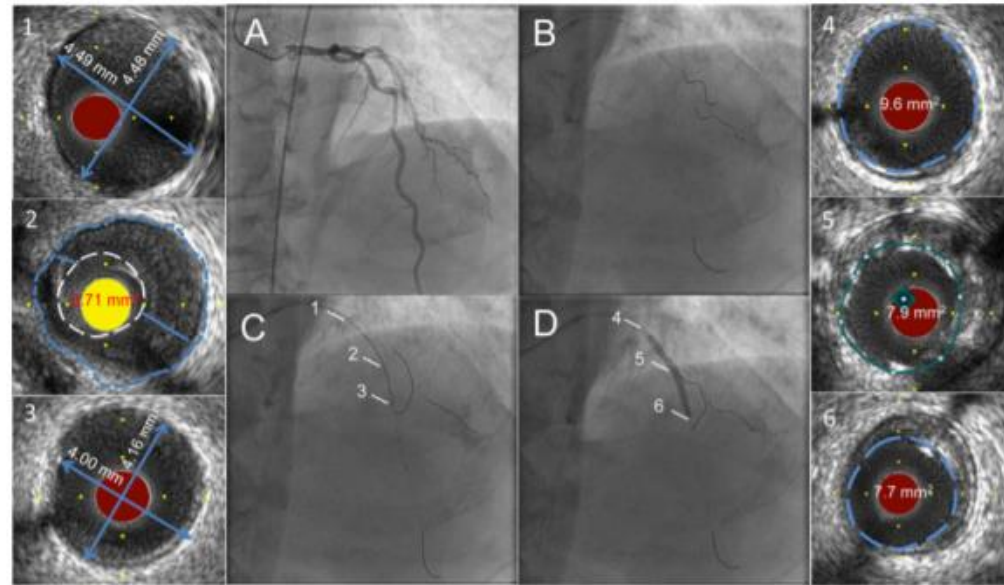
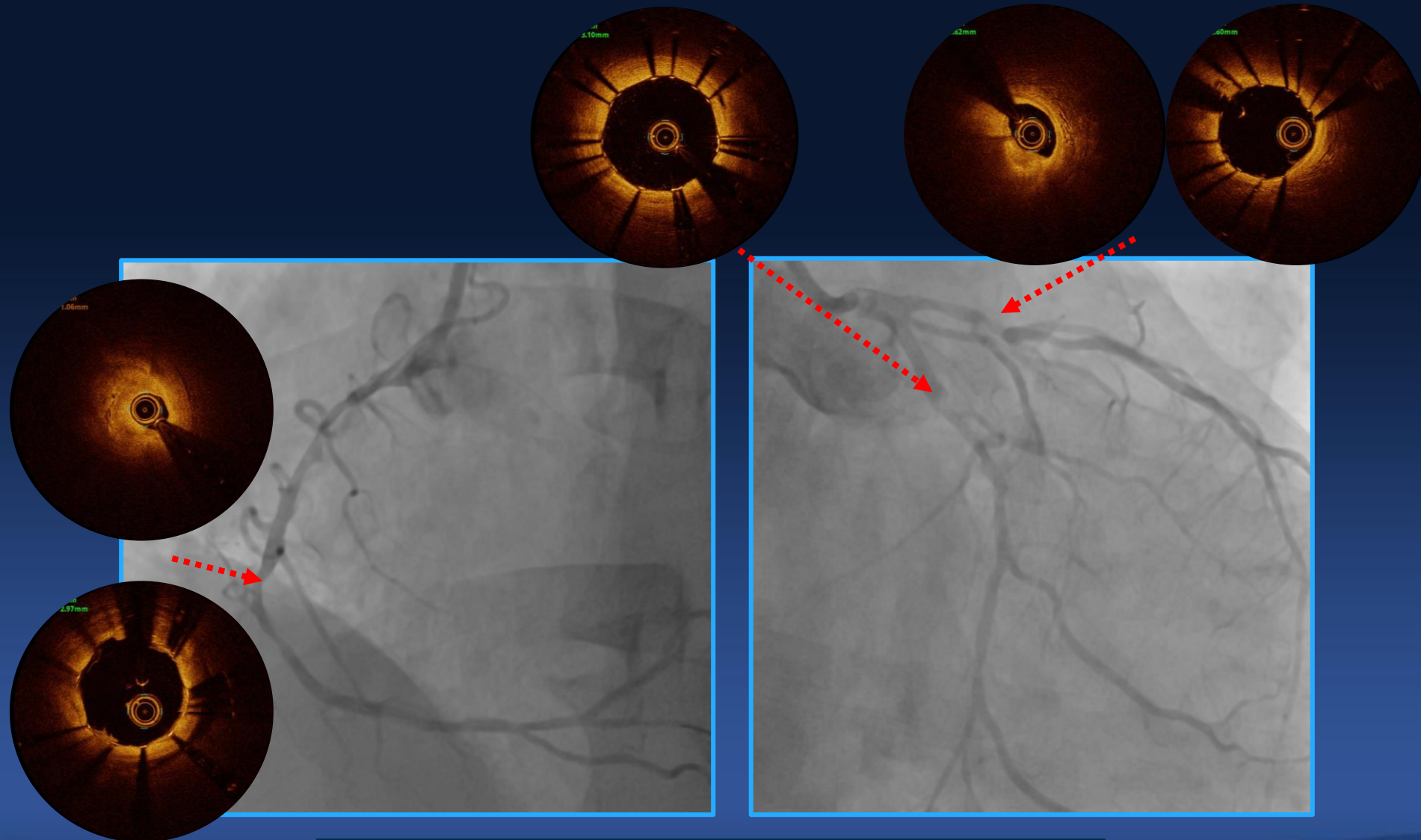


Figure 1 Ultra-low contrast coronary angiography followed by staged percutaneous coronary intervention with zero contrast. Cine images recorded at the initial angiography using ultra-low contrast volume are displayed on adjoining screen during the staged percutaneous coronary intervention (A) and used to guide catheter engagement, coronary guide wire placement in the left anterior descending artery, diagonal branch, and the circumflex artery, thus creating a metallic silhouette of the left coronary system (B). Intravascular ultrasound imaging of the left anterior descending artery is performed with proximal reference diameter (≈ 4.5 mm) (1), minimal luminal area (3.71 mm²) (2), and distal reference diameter (≈ 4.0 mm) (3) measured for selection of the appropriate pre-dilation balloon and stent sizes. The co-registered dry cine image of intravascular ultrasound transducer placed at the distal reference (C) is used to guide the percutaneous coronary intervention. Following preparation of the lesion and deployment of a 3.5×38 mm drug-eluting stent (D), intravascular ultrasound is repeated to assess the result, to determine the proximal (9.6 mm²) (4) and distal (7.7 mm²) (6) reference areas, and to guide post-dilation of under-expanded segments to achieve the pre-determined MSA, defined as $>90\%$ of the mean of the proximal and distal reference areas, (7.9 mm²) (5).

3 vessel PCI with OCT



Total Contrast Volume: 500cc

IVUS is Better?

- Stronger Evidence in Complex Lesions
- Vessel Size, Ostial Visualization
- Visualize Vessel Even without Flow
- Real Time Guidance and Manual Pull-Back
- No Contrast

But,

- Time consuming, No co-registration
- Identification of Thick Calcium or In-Stent neoatherosclerosis is difficult

My Thoughts: OCT vs. IVUS in Complex PCI

	OCT	IVUS
LM disease		Better
Ostial lesion		Better
Bifurcation	Delicate	Convenient
Calcification	Better, as far as it passes the lesion	
Long lesion	It saves time	
CTO		Better
In-stent restenosis	Better	
Renal dysfunction or CHF		Better

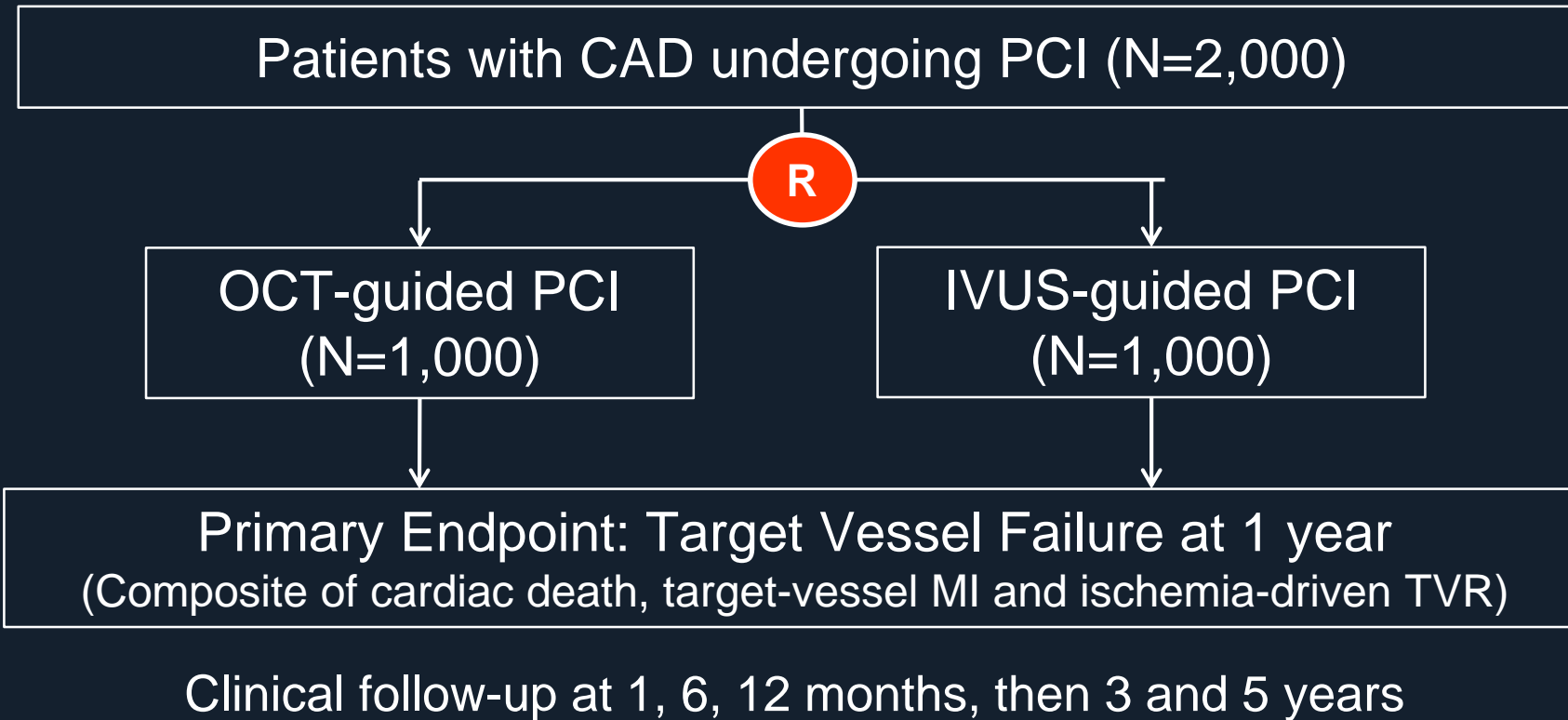
OCTIVUS Trial

*Larger-sized, Pragmatic RCT
To detect differences in Clinical Outcomes
For **All-Comer, including Complex PCI***

*Comparing
OCT-guided and IVUS-guided PCI*

Optical Coherence Tomography versus Intravascular Ultrasound
Guided Percutaneous Coronary Intervention

OCTIVUS Trial



Conclusions

OCT vs. IVUS for Guiding Complex PCI

- OCT-guided and IVUS-guided PCI showed similar procedural benefits.
- Which one is Better for Complex PCI? No Definitive Data yet. They are Different with their own Advantages and Limitations.
- Pragmatic RCT for all-comer PCI, **OCTIVUS** will provide a relative benefit of OCT- vs. IVUS-guided PCI in contemporary PCI practice.