Imaging-guided PCI

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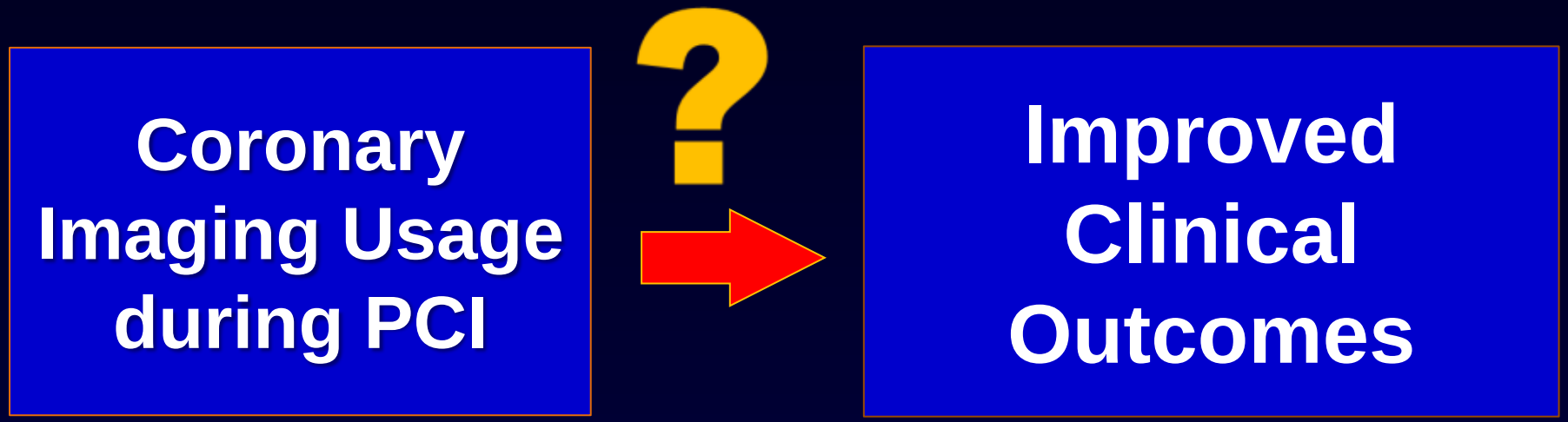
Conflict of Interest

- I have nothing to disclose

2014 ESC/EACTS Guidelines

IVUS in selected patients to optimize stent implantation.	IIa	B
IVUS to assess severity and optimize treatment of unprotected left main lesions.	IIa	B
IVUS or OCT to assess mechanisms of stent failure.	IIa	C
OCT in selected patients to optimize stent implantation.	IIb	C

Evidence for Use of Coronary Imaging



- Recently, many evidences demonstrating the clinical usefulness of coronary imaging have been accumulated since the prior guidelines were released.

Clinical benefit of IVUS-guided PCI

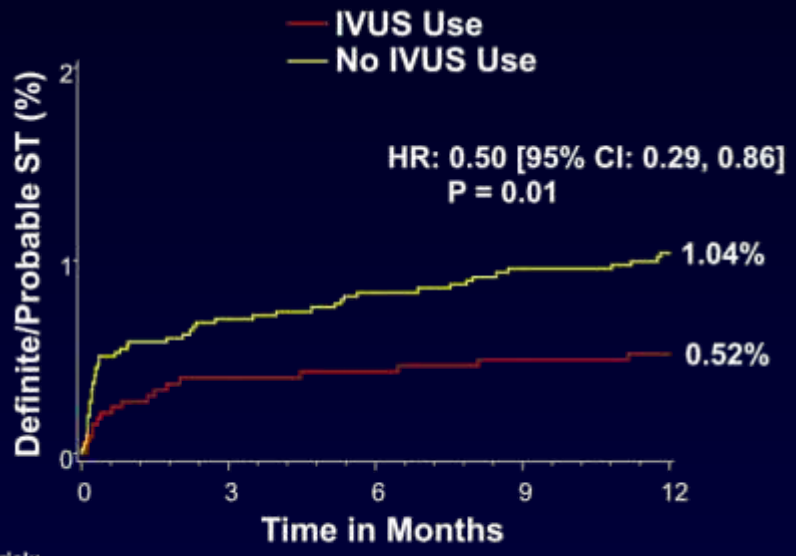
Recent observational studies comparing clinical outcomes between IVUS-guided an angiography-guided PCI

Study	Year	N (IVUS/angio)	Enrolled patients	FU, m	Major findings (IVUS vs. angiography)
Witzenbichler et al.[1]	2014	3349/5234	All comers	12	Definite/probable ST: 0.6% vs. 1.0%, p=0.003 MI: 2.5% vs. 3.7%, p=0.004 Cardiac death, ST, MI; 3.1% vs. 4.7%, p=0.002
Roy et al.[2]	2008	884/884 by matching	All comers	12	Definite ST: 0.7% vs. 2.0%, p=0.014
Park et al.[3]	2013	463/463 by matching	Nearly all comers	12	Cardiac death, MI, TLR: 4.3% vs. 2.4, p=0.047
Kim et al.[4]	2011	487/487 by matching	Non-left main bifurcation	36	Death or MI: 3.8% vs. 7.8%, p=0.03
Hong et al.[5]	2014	201/201 by matching	Chronic total occlusion	24	Definite/probable ST: 0% vs. 3.0%, p=0.014 MI: 1.0% vs. 4.0%, p=0.058
de la Torre Hernandez et al.[6]	2014	505/505 by matching	Left main lesions	36	Cardiac death, MI, TLR: 11% vs. 16%, p=0.04 Definite/probable ST: 0.6% vs. 2.2%, p=0.04

(1) Witzenbichler B, et al. Circulation. 2014;129:463-470
(2) Roy P, et al. Eur Heart J. 2008;29:1851-1857
(3) Park KW et al. Int J Cardiol. 2013;167:721-726
(4) Kim JS, et al. . Am Heart J 2011;161:180-187
(5) Hong SJ et al. Am J Cardiol. 2014;114:534-540
(6) de la Torre Hernandez JM et al. JACC Cardiovasc Interv. 2014;7:244-254

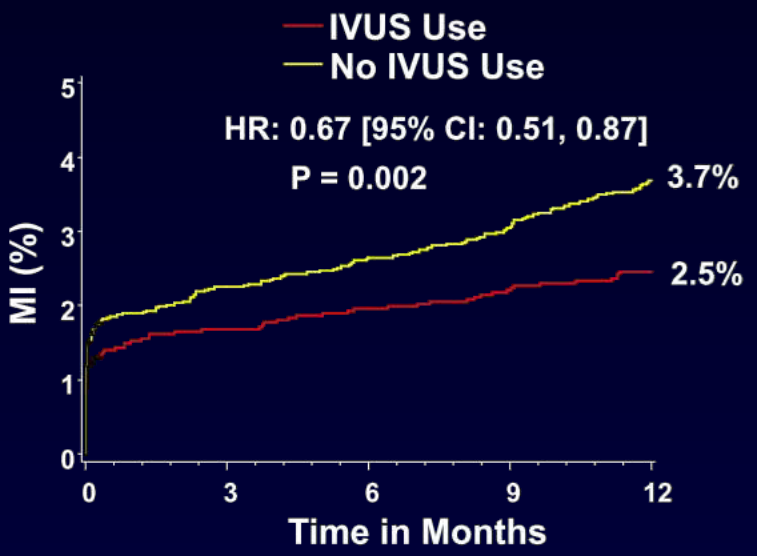
ADAPT-DES substudy (n=8,583 pts, IVUS=3,349 pts and no IVUS=5,234 pts

Definite/Probable Stent Thrombosis



Number at risk:					
IVUS Use	3349	3251	3221	3197	3023
No IVUS Use	5234	5015	4978	4938	4585

MI



Number at risk:					
IVUS Use	3349	3209	3171	3141	2969
No IVUS Use	5234	4932	4882	4830	4460

IVUS guidance during DES PCI may result in less stent thrombosis as well as fewer myocardial infarctions and MACEs

Witzenbichler B, et al. *Circulation* 2014;129: 463-470

Recent randomized studies comparing clinical usefulness between IVUS-guided and angiography-guided PCI

Study	N (IVUS/ angio)	Enrolled patients	FU (m)	Primary endpoint	Major findings
Jakabacin et al.[1]	105/105	Complex and high clinical risk profile	18	Composite of death, MI, TLR	No significant differences (11% vs. 12%).
Chieffo et al.[2]	142/142	Complex lesions	24	Post-procedural MLD	IVUS group had greater MLD (2.70 mm vs. 2.51 mm)
Kim et al.[3]	269/274	Long lesions	12	Composite of cardiac death, MI, ST, or TVR	IVUS group had lower MACE by per-protocol analysis (4% vs. 8%).
CTO-IVUS[4]	201/201	Chronic total occlusion	12	Cardiac death	No differences in primary endpoint; but IVUS group had lower the composite of cardiac death, MI, or TVR.
AIR-CTO[5]	115/115	Chronic total occlusion	12	Late lumen loss	IVUS group had a lesser LLL (0.28 vs. 0.46 mm, p=0.025).
IVUS-XPL[6]	700/700	Long lesions	12	Composite of cardiac death, MI, or TLR	IVUS group had lower primary endpoint (2.9% vs. 5.8%, p=0.007)

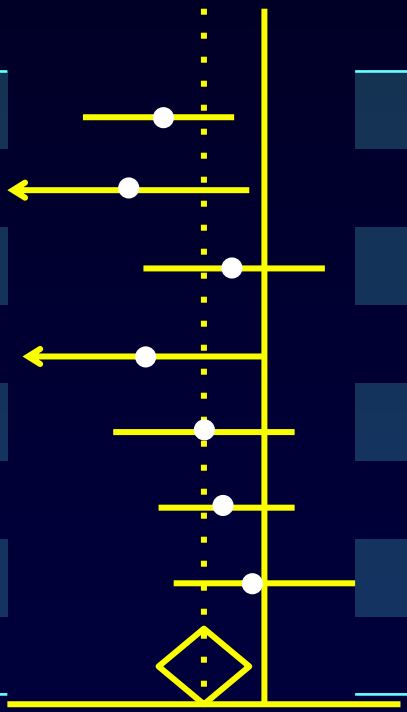
(1) Jakabcin J, et al. Catheter Cardiovasc Interv. 2010;75:578-583
(2) Chieffo A et al. Am Heart J. 2013;165:65-72
(3) Kim JS et al. JACC Cardiovasc Interv. 2013;6:369-376
(4) Kim BK, et al. Circ Cardiovasc Interv 2015:8:e002592
(5) Tian NL et al. EuroIntervention 2015:10:1409-17
(6) Hong SJ, et al. JAMA. 2015;314:2155-2163

Meta-analysis of 7 randomized trials: IVUS vs. angio -guided (first and next-generation) DES implantation

Event: cardiac death, MI, TLR

Study-level meta-analysis

Study	Year	OR	Events: IVUS	Events: Angio
IVUS-XPL	2015	0.49	19/700	39/700
CTO-IVUS	2015	0.37	5/201	14/201
AIR-CTO	2015	0.82	25/115	29/115
Tan et al	2015	0.42	8/61	17/62
Kim et al (RESET)	2013	0.60	12/269	20/274
AVIO	2013	0.67	24/142	33/142
HOME DES IVUS	2010	0.91	11/105	12/105
Overall		0.60	104/1593	164/1599



IVUS better Angio better

Islam Y. Elgendy et al. *Circ Cardiovasc Interv*. 2016;9:e003700

Effect of IVUS vs. Angiography-Guided Everolimus-Eluting Stent Implantation in Long Coronary Lesions: the IVUS-XPL Trial

Patients with long coronary lesions
(Implanted EES stent ≥28 mm in length), N=1400

EES implantation with IVUS guidance, n=700

EES implantation with angiography guidance, n=700

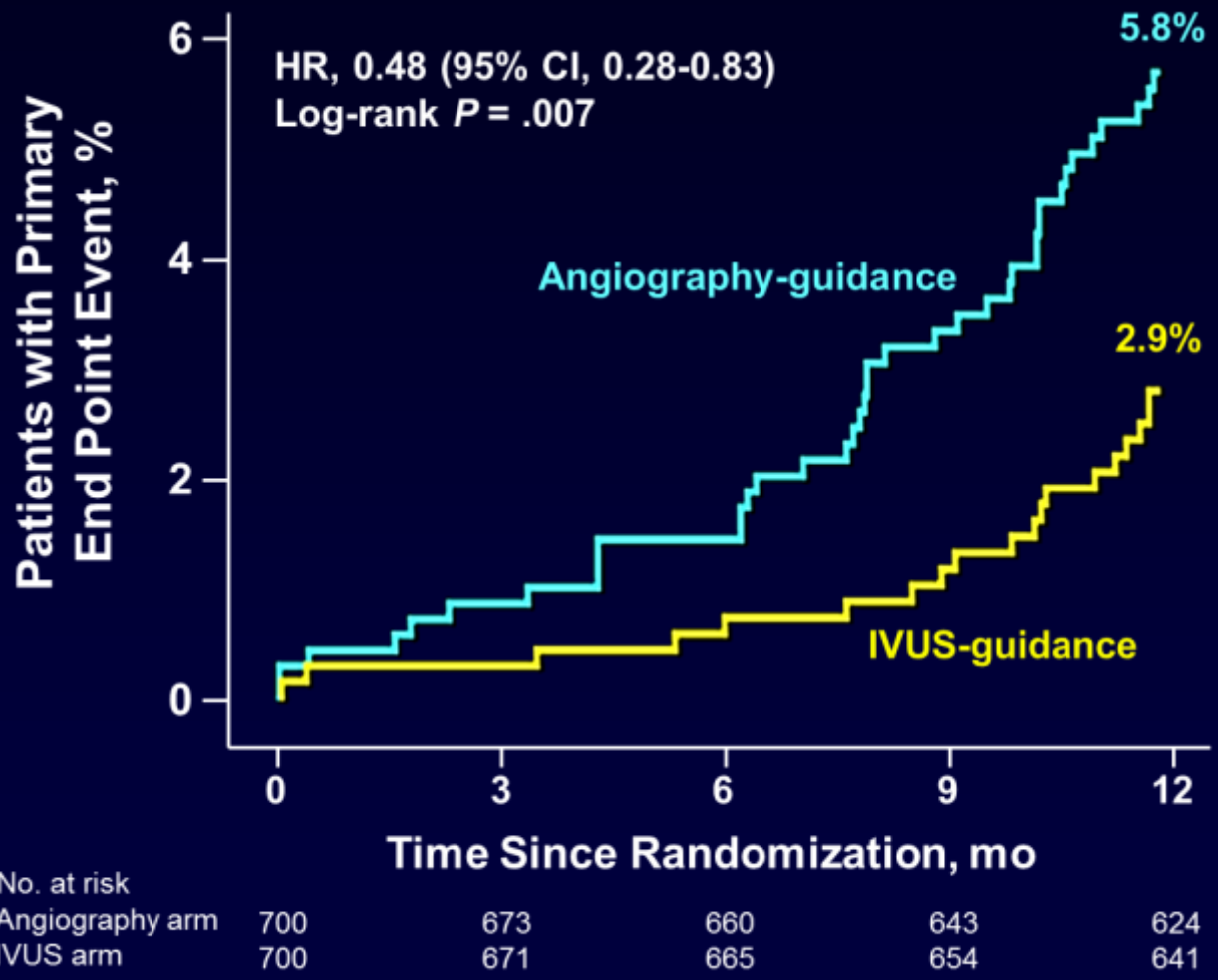
Clinical follow-up at 12 months
Primary end point: MACE

Cardiac death, target-lesion related MI, and ischemia-driven TLR

Hong SJ, Kim BK, Hong MK (corresponding author). *JAMA* 2015;314:2155-63 and 2015 AHA Late Breaking Clinical Trials

IVUS-XPL: Randomized Trial

MACE: Cardiac death, MI, or TLR



Hong SJ, Kim BK, Hong MK (corresponding author). JAMA 2015:314:2155-63

IVUS-XPL: Randomized Trial

	IVUS-guidance (n=700)	Angiography-guidance (n=700)	Hazard ratio (95% CI)	Log-Rank *P* value
Primary End Point				
MACE	19 (2.9%)	39 (5.8%)	0.48 (0.28–0.83)	.007
Secondary End Point				
Cardiac death	3 (0.4%)	5 (0.7%)	0.60 (0.14-2.52)	.48
Target lesion related MI	0	1 (0.1%)	-	.32
Ischemia-driven TLR	17 (2.5%)	33 (5.0%)	0.51 (0.28-0.91)	.02
Stent thrombosis	2 (0.3%)	2 (0.3%)	1.00 (0.14-7.10)	1.00
Acute	1 (0.1%)	1 (0.1%)	-	-
Sub-acute	1 (0.1%)	0	-	-
Late	0	1 (0.1%)	-	-

Hong SJ, Kim BK, Hong MK (corresponding author). JAMA 2015 :314:2155-63

From the IVUS-XPL Trial

- Can IVUS reduce **only TLR**?
- Can IVUS improve **HARD CLINICAL OUTCOMES** such as cardiac death, MI, or stent thrombosis?
- Is there **patient-level** meta-analysis with **second-generation DES alone**?

Patients level meta-analysis: 3 RCTs with 2,345 Patients

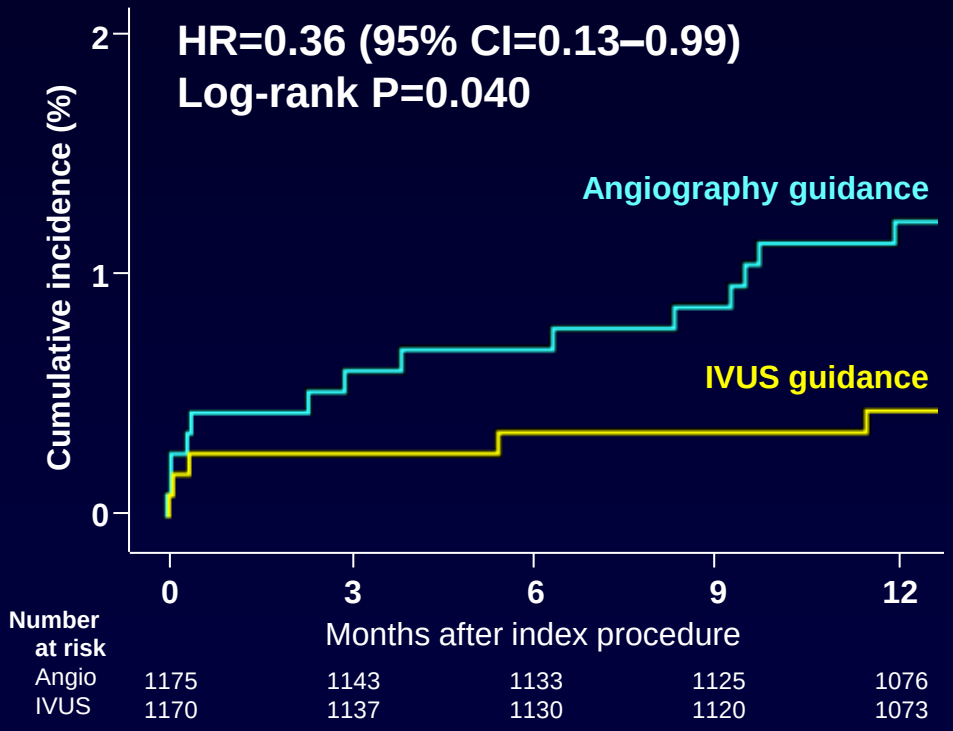
Trials (Year)	No. of patients		Lesion characteristics	Primary endpoint
	IVUS-group	Angio-group		
RESET-IVUS (2013)	269	274	Long lesions	MACE (Composite of cardiac death, MI, TVR, or stent thrombosis)
CTO-IVUS (2014)	201	201	CTO	Cardiac death
IVUS-XPL (2015)	700	700	Long lesions	MACE (Composite of cardiac death, target-lesion related MI, and ischemia-driven TLR)
	1170	1175		

Shin DH, Hong SJ, Hong MK (corresponding author). JACC Intv 2016:9; 2232-9

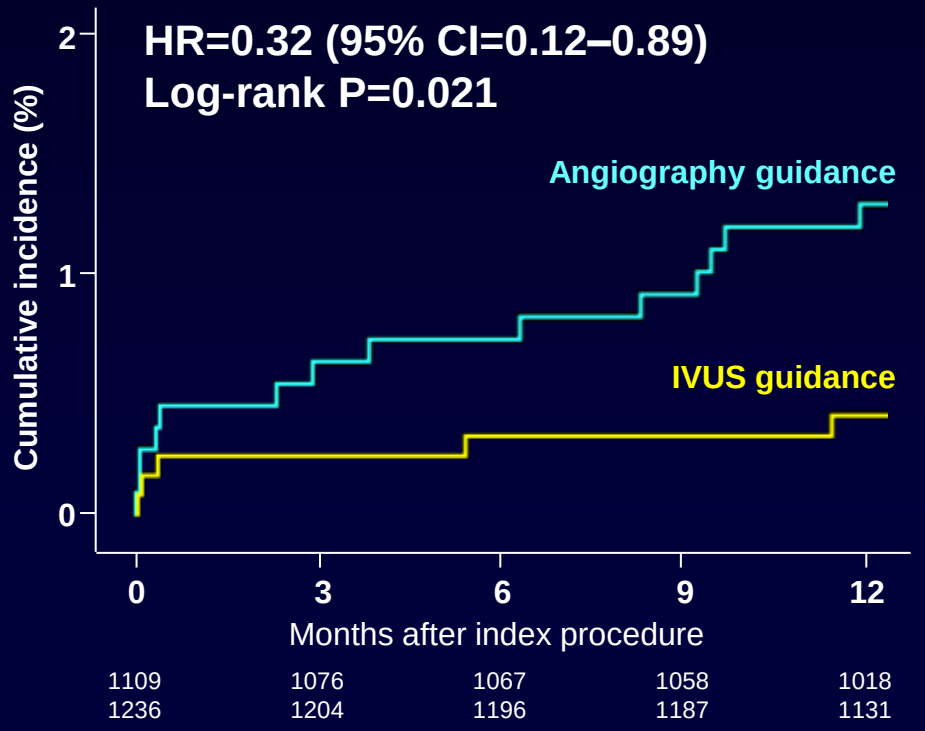
Primary Endpoint: MACE

MACE (cardiac death, MI, or stent thrombosis)

Intention-to treat analysis



Per-protocol analysis



Shin DH, Hong SJ, Hong MK (corresponding author). JACC Intv 2016:9; 2232-9

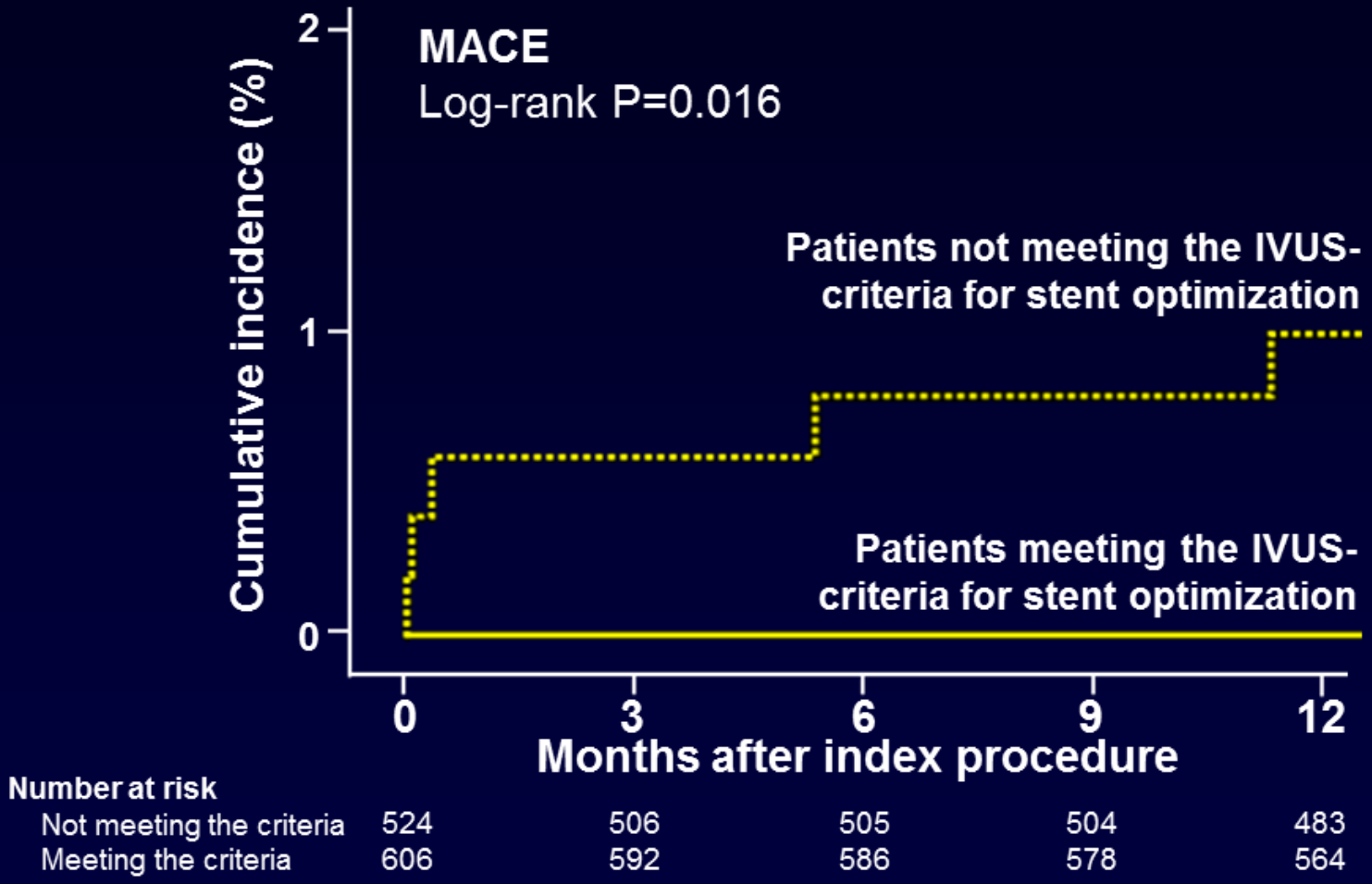
Stent optimization by IVUS

Trial (Year)	IVUS-criteria for stent optimization	% of patients meeting the criteria
RESET-IVUS (2013)	• Minimal CSA ≥ CSA at distal reference segments	49% (126/256)
CTO-IVUS (2014)	• Minimal stent area ≥distal reference lumen area • Stent area at CTO ≥5 mm^2 as far as vessel area permits • Complete stent apposition	60% (117/196)
IVUS-XPL (2015)	• Minimal CSA ≥ CSA at distal reference segments	54% (363/678)
Overall		54% (606/1130)

Shin DH, Hong SJ, Hong MK (corresponding author). JACC Intv 2017:10; 418

Stent optimization by IVUS

MACE (cardiac death, MI, or stent thrombosis)



Shin DH, Hong SJ, Hong MK (corresponding author). JACC Intv 2017:10; 418

Clinical benefit of OCT-guided PCI

OCT-guided PCI (CLI-OPCI Study)

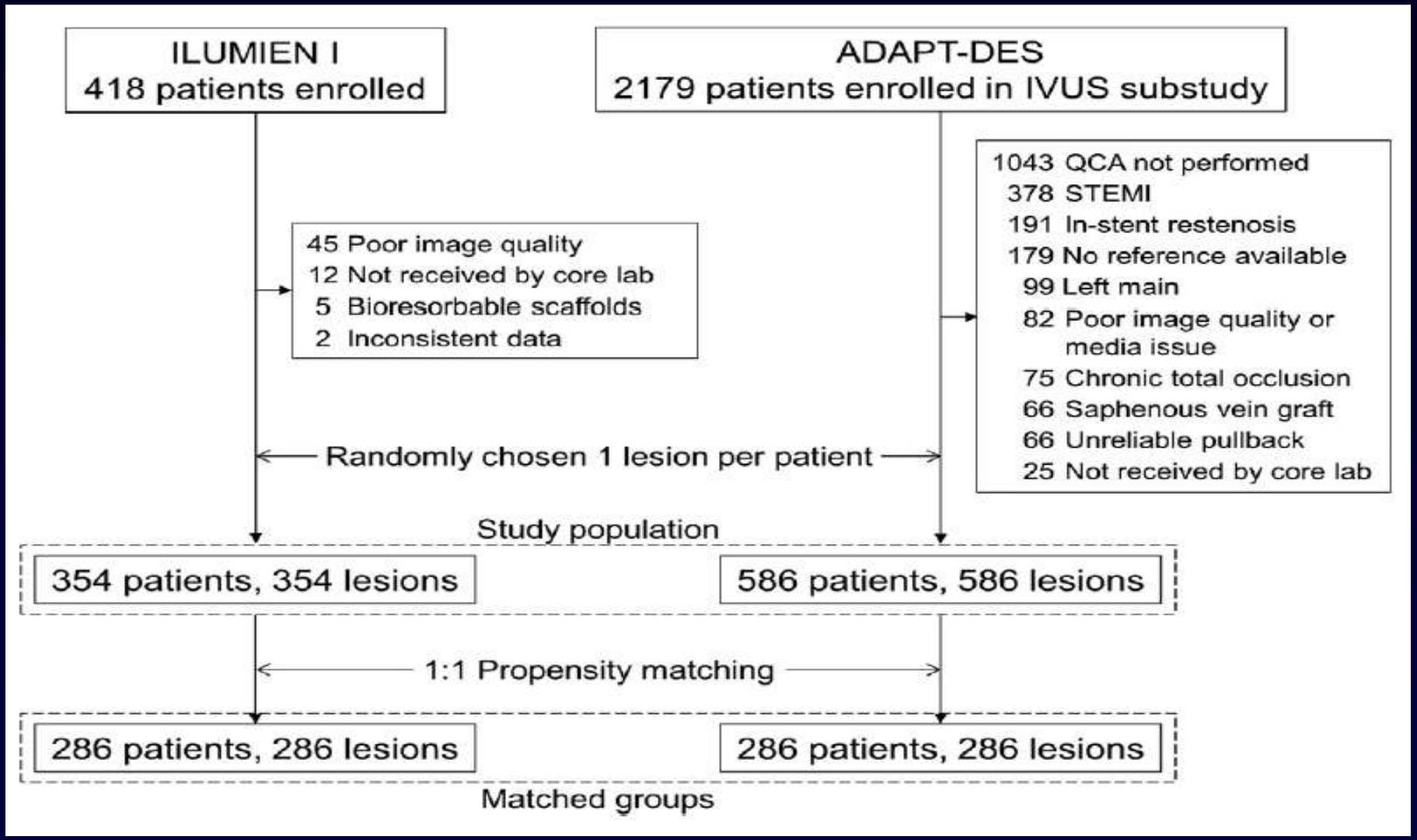
Multi-Center Retrospective Observational Study

	Angiographic guidance group (n=335)	Angiographic plus OCT guidance group (n=335)	*p*-value
In-hospital events			
Cardiac death	3 (0.9%)	2 (0.6%)	1.0
Non-fatal myocardial infarction	22 (6.5%)	13 (3.9%)	0.118
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
[illegible] or repeat revascularisation	50 (15.1%)	32 (9.6%)	0.034

OCT guidance on top of angiography was associated with significant clinical benefits, specifically a reduction in the 1-year rate of cardiac death or MI

Prati F, et al, EuroIntervention 2012; 8:823–829

Comparison of Stent Expansion
ILUMIEN II (OCT vs. IVUS)



Maehara A et al. JACC Cardiovasc Interv 2015;8:1704-8

Comparison of Stent Expansion
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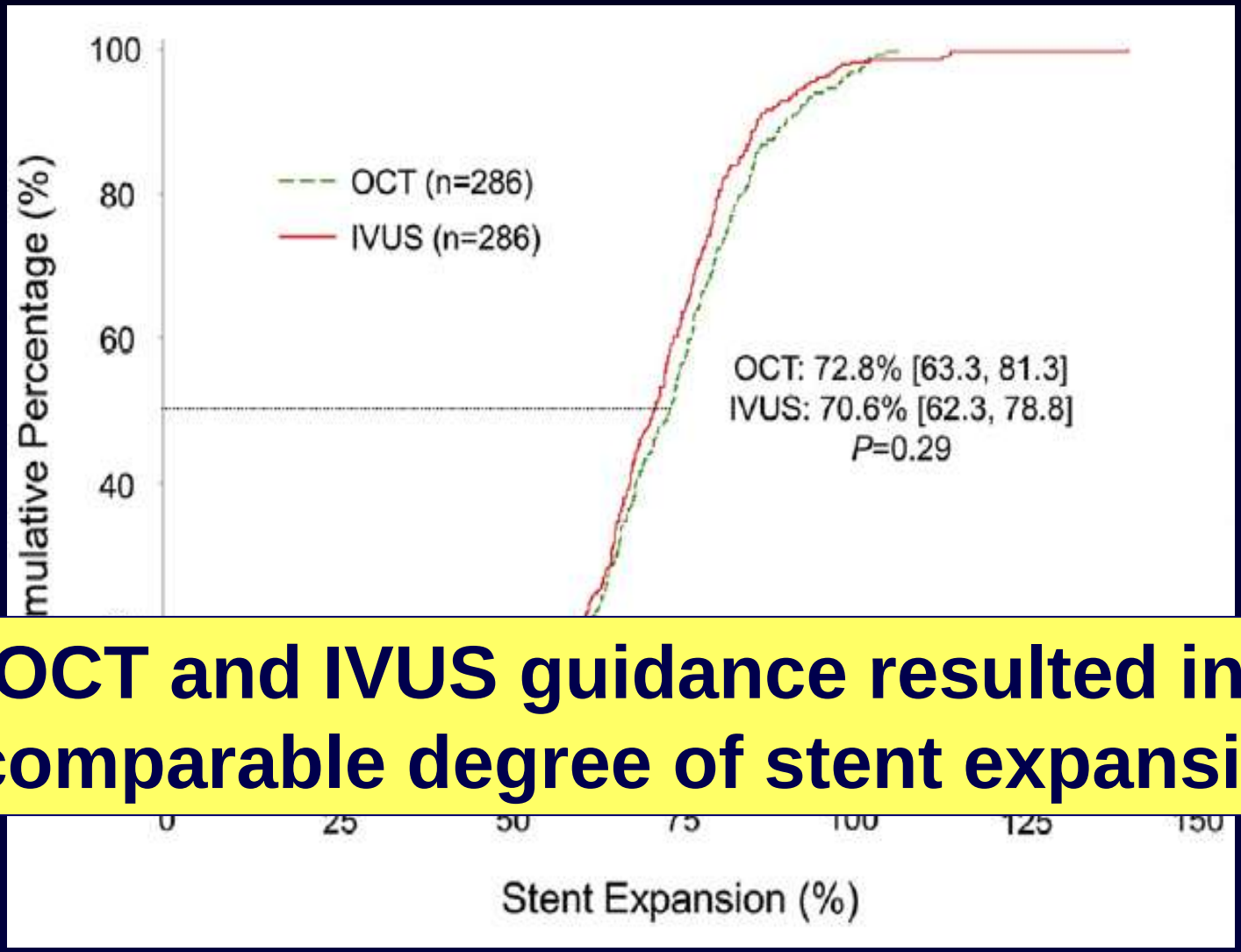
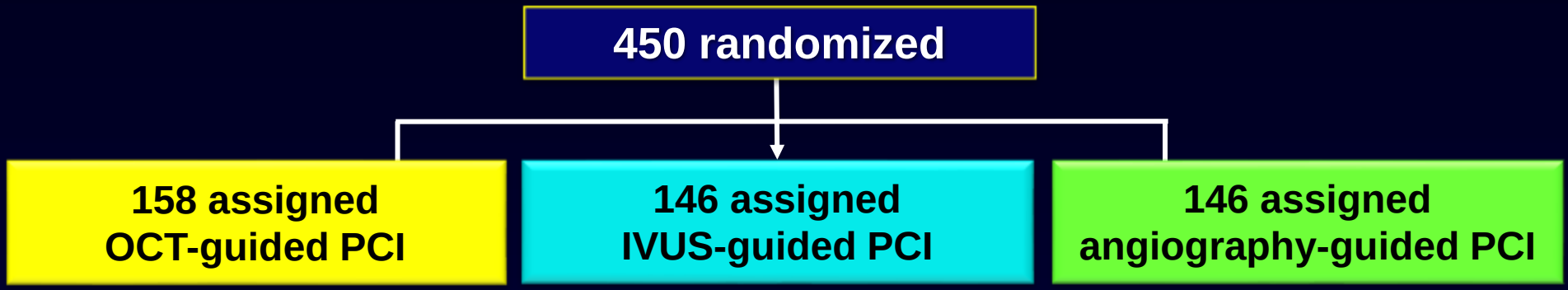


OCT and IVUS guidance resulted in a comparable degree of stent expansion

Maehara A et al. JACC Cardiovasc Interv 2015;8:1704-8

ILUMEIN III

OCT compared to IVUS and Angiography to Guide Coronary Stent Implantation



- **Primary end points:** Post-PCI MSA assessed by OCT

	OCT (n=140)	IVUS (n=135)	Angiography (n=140)	OCT *vs* IVUS p value	OCT *vs* angiography p value
Minimum 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
Minimum stent expansion (%)	87·6% (16·6)	86·5% (15·9)	82·9% (12·9)	0·77	0·02
Mean stent expansion (%)	105·8% (97·8–119·8)	106·3% (96·7–116·6)	101·4% (91·9–110·2)	0·63	0·001

OCT-guided PCI using a specific reference segment external elastic lamina-based stent optimization strategy was safe and resulted in similar minimum stent area to that of IVUS-guided PCI.

Ali et al. Lancet 2016;388:2618-28

Imaging-guided PCI improved outcomes: WHY?

Comparison of Stent Size From Recent Studies

Mean Stent Diameter

	IVUS-guidance N	Angio-guidance N	IVUS-guidance (mm)	Angio-guidance (mm)	P-value
Chieffo et al.[1]	142	142	2.95±0.38	2.86±0.36	0.19
CTO-IVUS[2]	201	201	2.91±0.52	2.85±0.41	0.23
ADAPT-DES[3]	3349	5234	3.4±0.6	3.0±0.7	<0.001
AIR-CTO[4]	115	115	3.05±0.46	2.86±0.37	0.001
Hong et al.[5]	201	201	2.96±0.38	2.83±0.37	0.001
EXCELLENT[6]	463	463	3.21±0.43	3.04±0.42	<0.001

(1) Chieffo A et al, Am Heart J. 2013;165:65-72
(2) Kim BK, et al. Circ Cardiovasc Interv 2015:8:e002592
(3) Witzenbichler B et al. Circulation. 2014;129:463-470
(4) Tian NL et al. EuroIntervention 2015:10:1409-17
(5) Hong SJ, et al. Am J Cardiol. 2014;114:534-540
(6) Park KW. Int J Cardiol. 2013;167:721-726

Frequency of post-adjuvant ballooning From Recent Studies

Frequency of post-adjuvant ballooning

	IVUS-guidance N	Angio-guidance N	IVUS-guidance (mm)	Angio-guidance (mm)	P-value
CTO-IVUS*[1]	201	201	51.2%	41.3%	0.045
Roy et al.[2]	884	884	31.0%	17.7%	<0.001
RESET-IVUS[3]	297	246	54.6%	44.5%	0.03
IVUS-XPL[4]	700	700	76%	57%	<0.001
MOZART[5]	42	42	95.1%	78.6%	0.048

* High pressure poststent dilation

(1) Kim BK, et al. Circ Cardiovasc Interv 2015:8:e002592
(2) Roy P et al. Eur Heart J. 2008;29:1851-1857
(3) Kim JS et al. JACC Cardiovasc Interv. 2013;6:369-376
(4) Hong SJ, et al. JAMA. 2015;314:2155-2163
(5) Mariani J, Jr., et al. JACC Cardiovasc Interv. 2014;7:1287-1293

Comparison of Final balloon size From Recent Studies

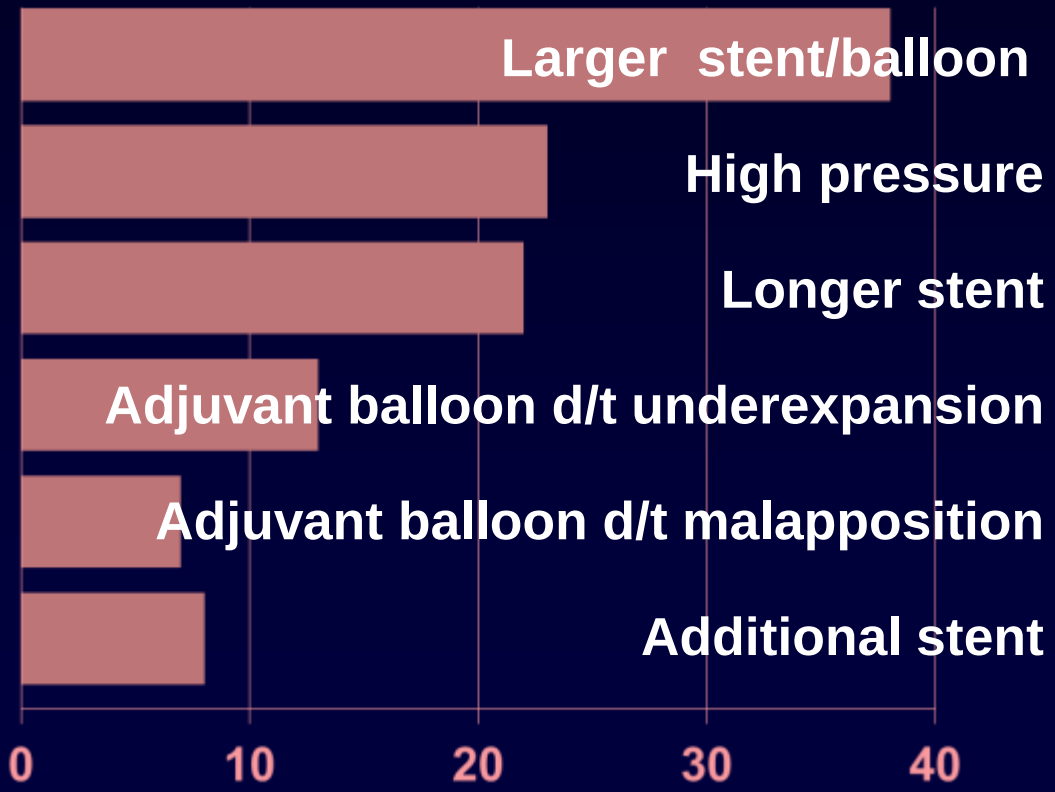
Final Balloon Size or Balloon Pressure*

	IVUS-guidance N	Angio-guidance N	IVUS-guidance (mm or atm*)	Angio-guidance (mm or Atm*)	P-value
Chieffo et al.(1)	142	142	3.39±0.47	3.15±0.40	0.002
CTO-IVUS(2)	201	201	14.6±3.7*	13.8±3.8*	0.040
ADAPT-DES(3)	3349	5234	16.9±3.7*	16.7±3.5*	0.13
RESET-IVUS(4)	297	246	3.2±0.4	3.1±0.3	0.03
IVUS-XPL(5)	700	700	3.14±0.43	3.04±0.42	<0.001

(1) Chieffo A et al, Am Heart J. 2013;165:65-72
(2) Kim BK, et al. Circ Cardiovasc Interv 2015:8:e002592
(3) Witzenbichler B et al. Circulation. 2014;129:463-470
(4) Kim JS et al. JACC Cardiovasc Interv. 2013;6:369-376
(5) Hong SJ, et al. JAMA. 2015;314:2155-2163

How the IVUS information influenced the procedure? From ADAPT-DES Study

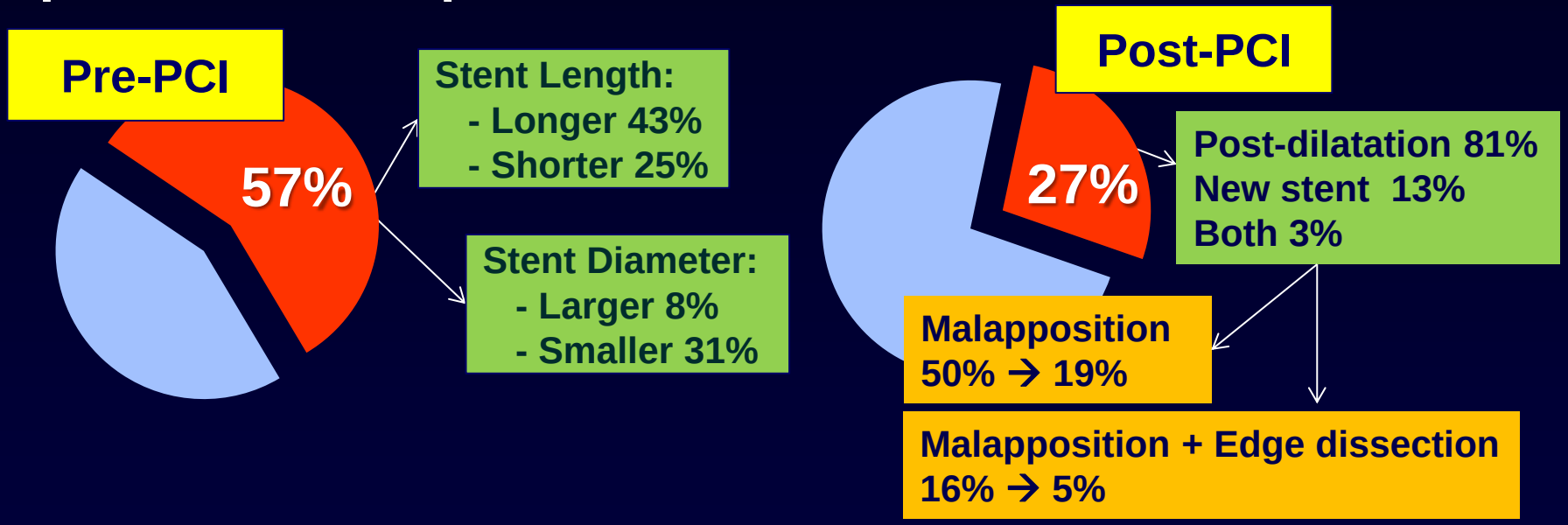
When IVUS was used, the operator was required to report the timing of IVUS imaging (eg, before intervention, after DES, after adjunct balloon inflation) and how the IVUS information influenced the procedure.



Witzenbichler B et al. Circulation. 2014;129:463-470

From ILUMEIN I Study

- OCT impacted on PCI procedure in **65% of pts** either pre-PCI and/or post-PCI

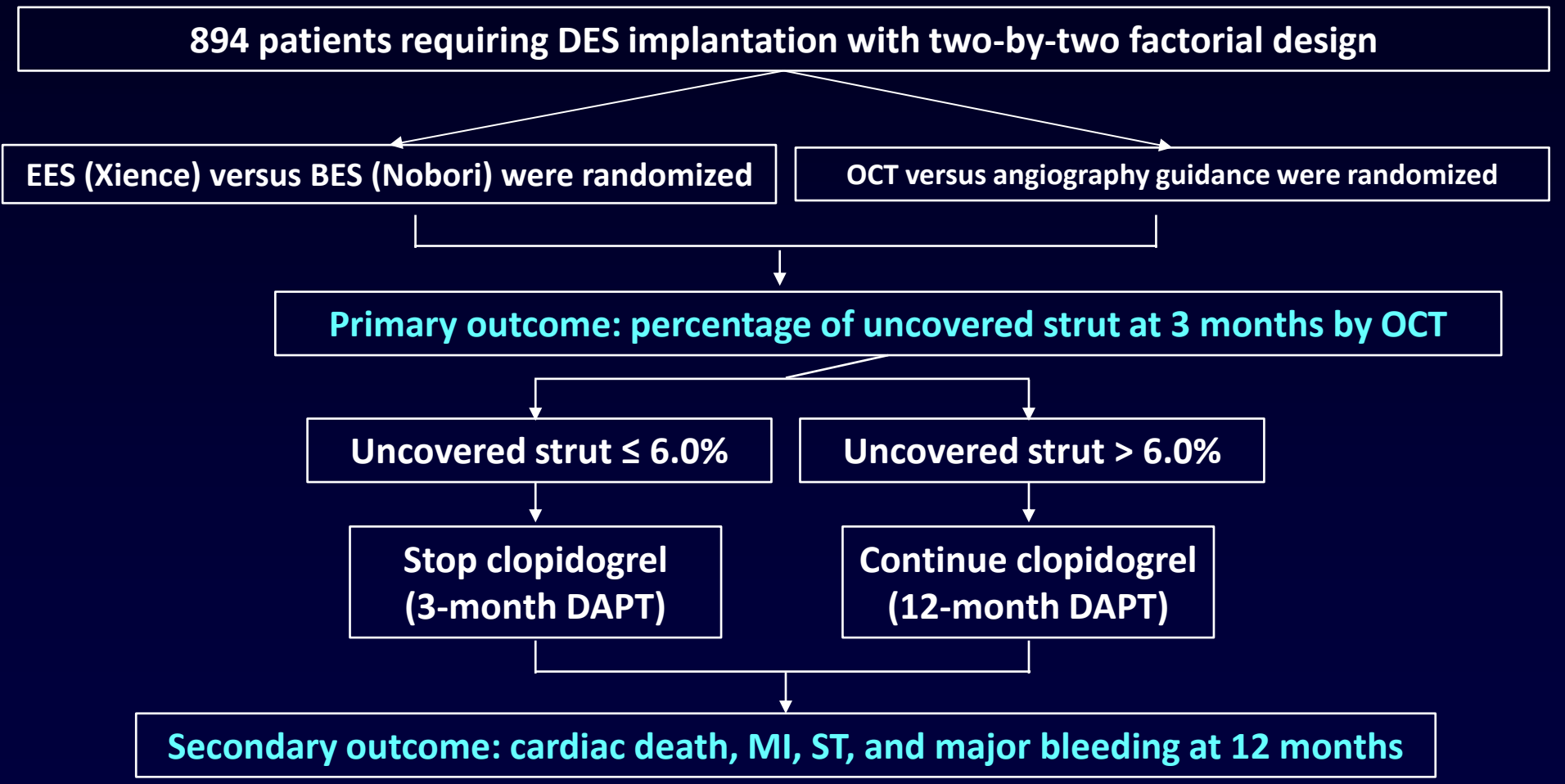


- **Post-PCI FFR** values were significantly different between optimization groups (lower in cases with pre- and post-PCI reaction to OCT) but no longer different after post-PCI stent optimization.
- **MACE events at 30 days** were low: death 0.25%, MI 7.7%, repeat PCI 1.7%, and stent thrombosis 0.25%

Wijns W, et al, Eur Heart J 2105:36:3346-55

Early strut coverage in patients receiving new-generation drug-eluting stents and its implications for dual antiplatelet therapy: a randomized clinical trial

The DETECT OCT trial investigators



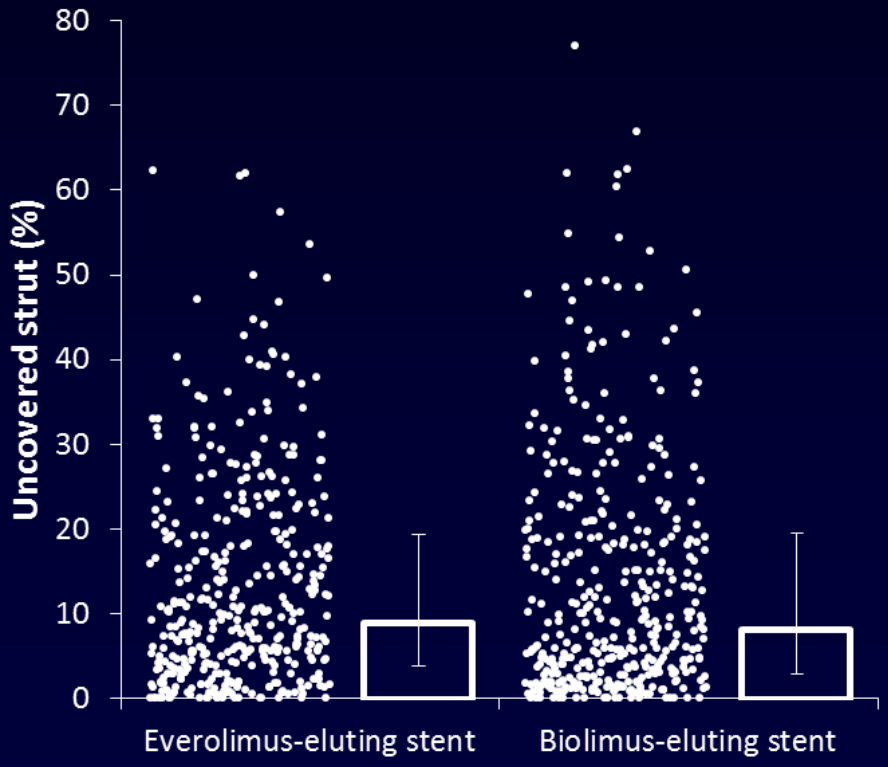
Lee SY, Kim JS, Hong MK (corresponding author), et al. Presented at ESC Late Breaking Science 2017

Primary Outcome: percentage of uncovered strut

EES vs. BES

Mean difference of 0.4%
95% confidence interval, -1.6–2.4
p=0.69

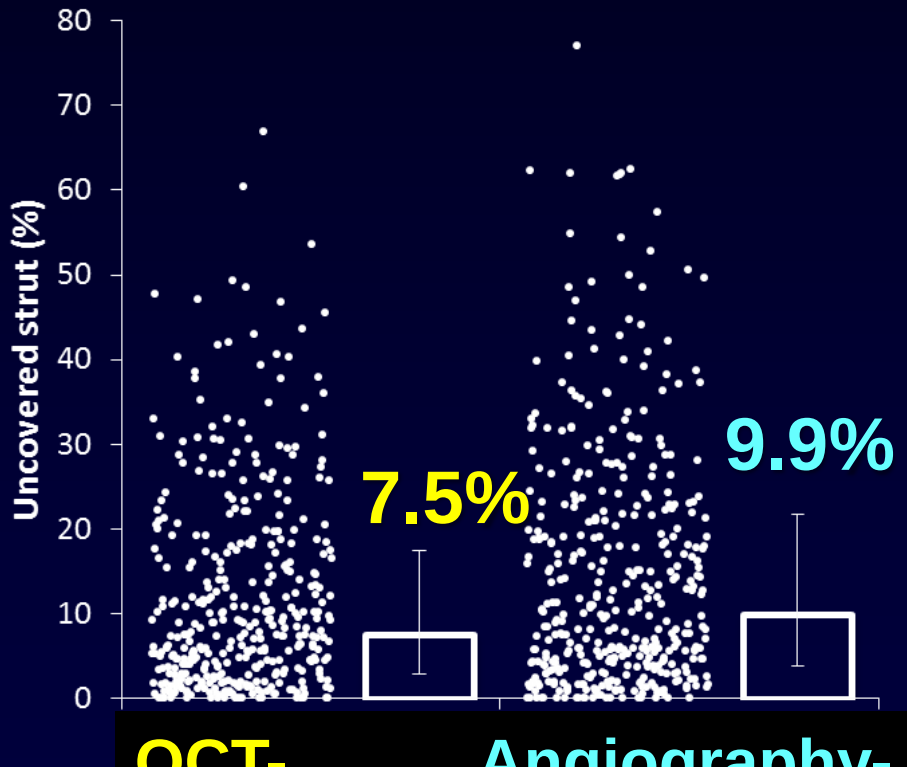
Median percentage of uncovered strut: 8.9% in EES and 8.2% in BES



OCT vs. Angiography

Mean difference of 2.8%
95% confidence interval, 0.8–4.8
p=0.009

7.5% in OCT guidance and 9.9% in angiography guidance



Lee SY, Kim JS, Hong MK (corresponding author), et al. Presented at ESC Late Breaking Science 2017

Secondary Outcome

	3-month DAPT (n=320)	12-month DAPT (n=459)	Difference (95% CI)	p
Cardiac death	0	0		-
MI	1 (0.3%)	0	0.3% (-0.3–0.9)	0.4108
Definite or probable ST	1 (0.3%)	0	0.3% (-0.3–0.9)	0.4108
Bleeding	1 (0.3%)	3 (0.7%)	-0.3% (-1.3–0.6)	0.5138
Major	0	1		
Minor	1	2		
Target-vessel revascularization	2 (0.6%)	2 (0.4%)	0.2% (-0.9–1.2)	0.7175
A composite of cardiac death, MI, definite/probable ST, and major bleeding	1 (0.3%)	1 (0.2%)	0.1% (-0.7–0.8)	0.7967

Lee SY, Kim JS, Hong MK (corresponding author), et al. Presented at ESC Late Breaking Science 2017

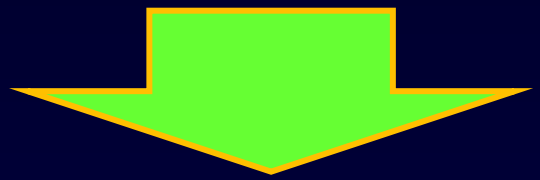
Imaging-guided PCI: Why NOT?

Barriers to implementing an intravascular imaging (1)

- **Cost with limited reimbursement**
- **Expertise**
  - ✓ Lack of standardization
  - ✓ Not understanding the image and how to use the information
  - ✓ Too much information – don't know what is/is not important

Barriers to implementing an intravascular imaging (2)

- Need to convince interventional cardiologists of the limitations of relying on coronary angiography alone



Like all medical imaging, IVUS and OCT require an understanding of what is important, what to ignore, and a knowledge of artifacts, limitations, and confounders.

Summary (1)

1. IVUS or OCT is recommended in selected patients to optimize stent implantation.

2. Many evidences demonstrating the usefulness of coronary imaging have been accumulated since the prior guidelines were released.

Summary (2)

3. Coronary imaging influenced the physicians' procedural strategies.

4. The barriers to implementing an intravascular imaging is still cost, expertise and physicians' need.

Dreams will come true