Integrated Use of Imaging and Physiology in Left Main PCI: Updates and Impact Your Daily Practice

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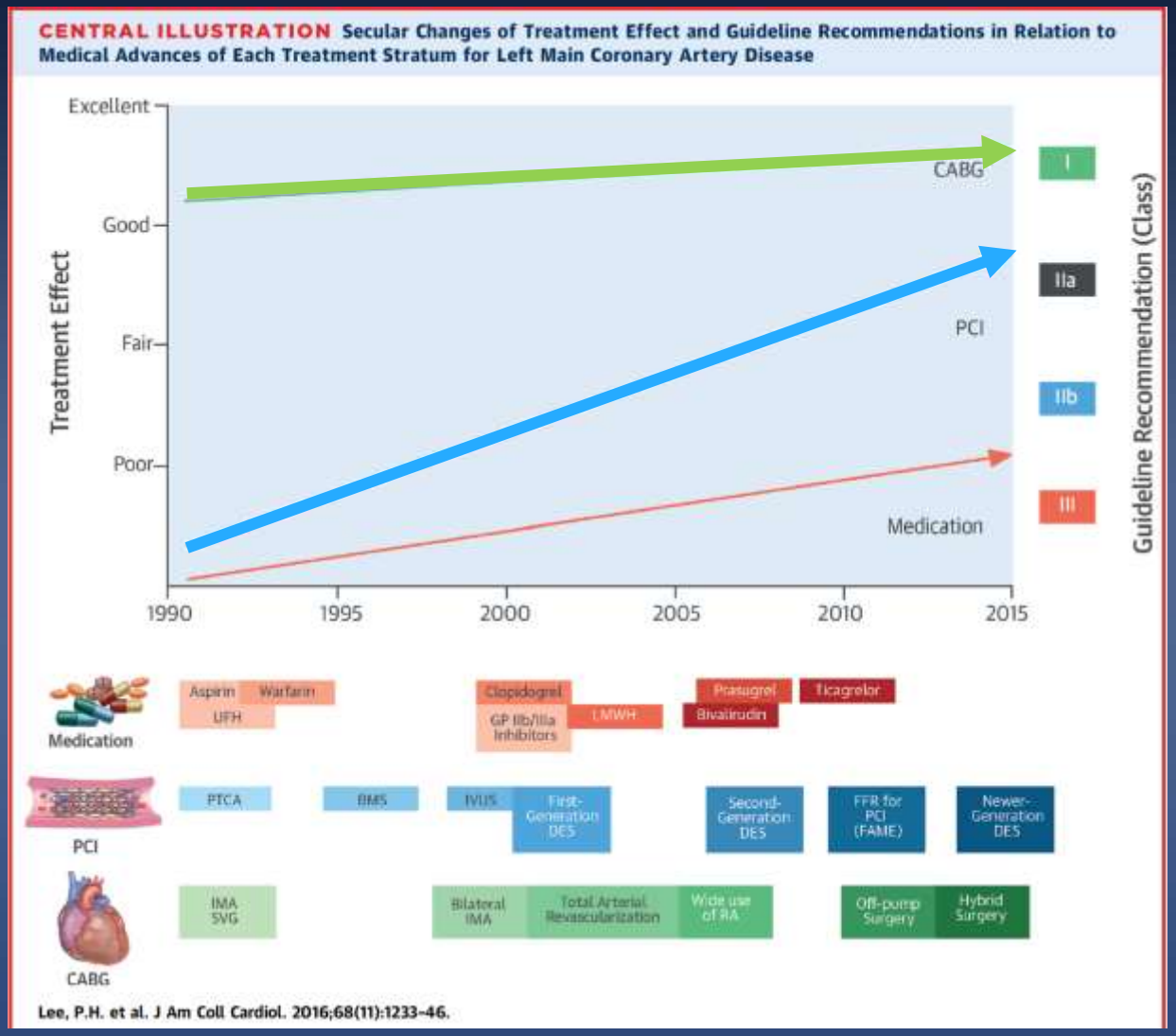
Left Main PCI: Narrowed Gap with CABG



PH Lee, DW Park, SJ Park et al, JACC. 2016;68:1233-46.

To Improve PCI Outcomes in Complex CAD

PCI procedure and equipment

- Thin-strut durable and bioabsorbable polymer-based DES
- Improved PCI guide wires, delivery systems and adjunct devices
- Expert techniques and devices to recanalize CTOs, manage bifurcations, calcium, etc.
- Advanced hemodynamic support options: transaxial forward flow pumps, ECMO
- Transradial artery access
- Approaches to prevent contrast nephropathy
- Superior catheterization labs: Better imaging, reduced radiation exposure

PCI guidance (pre- and post-procedure)

- Physiologic lesion assessment (iFR, FFR)
- Intravascular imaging (IVUS, OCT, NIRS)
- Goal of complete revascularization (anatomic, ischemic)

Adjunctive pharmacotherapy

- Procedural anticoagulation: Bivalirudin
- Potent P2Y12 inhibitors: Oral (prasugrel, ticagrelor), intravenous (cangrelor)
- Appropriate DAPT duration after PCI: Abbreviated vs. extended
- Foundational role of GDMT: statins, PCSK9i, beta-blockers, ACEI/ARB, etc.

Patient selection and pre-procedural planning

- Use of risk scores: SS, SSII, NERS I and II, others
- PCI planning tools: CTA and CT-FFR

Stone GW et al. EHJ 2017;38:3135-38

What Is Contemporary State-of-the Art PCI?
Make PCI to be Equivalent to CABG

EDITORIAL

EuroIntervention 2019;15:e219-e221 published online e-edition June 2019

Contemporary state-of-the-art PCI with functional and imaging concepts: forethoughts on the FAME 3 trial

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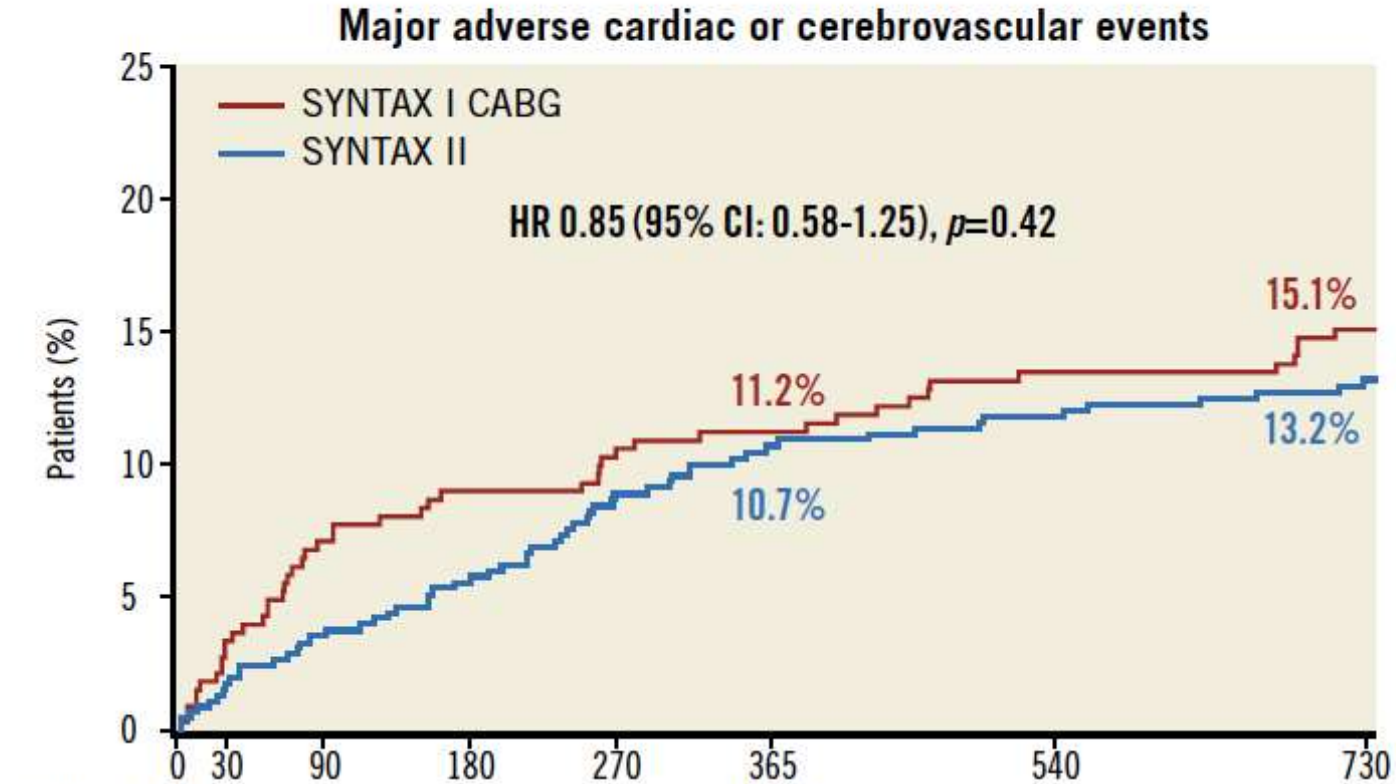
Division of Cardiology, Asan Medical Center, University of Ulsan College of Medicine, Seoul, South Korea

DW Park, SJ Park, Eurointervention 2019;15:e219-e221

State-of-the Art PCI in the Contemporary PCI Setting



Serruys P.W. Et al. Eurointervention 2019;15:e244-e252

State-of-the Art Left Main PCI in the Contemporary PCI Setting

CORONARY INTERVENTIONS
CLINICAL RESEARCH

EuroIntervention 2019;15:e244-e252 published

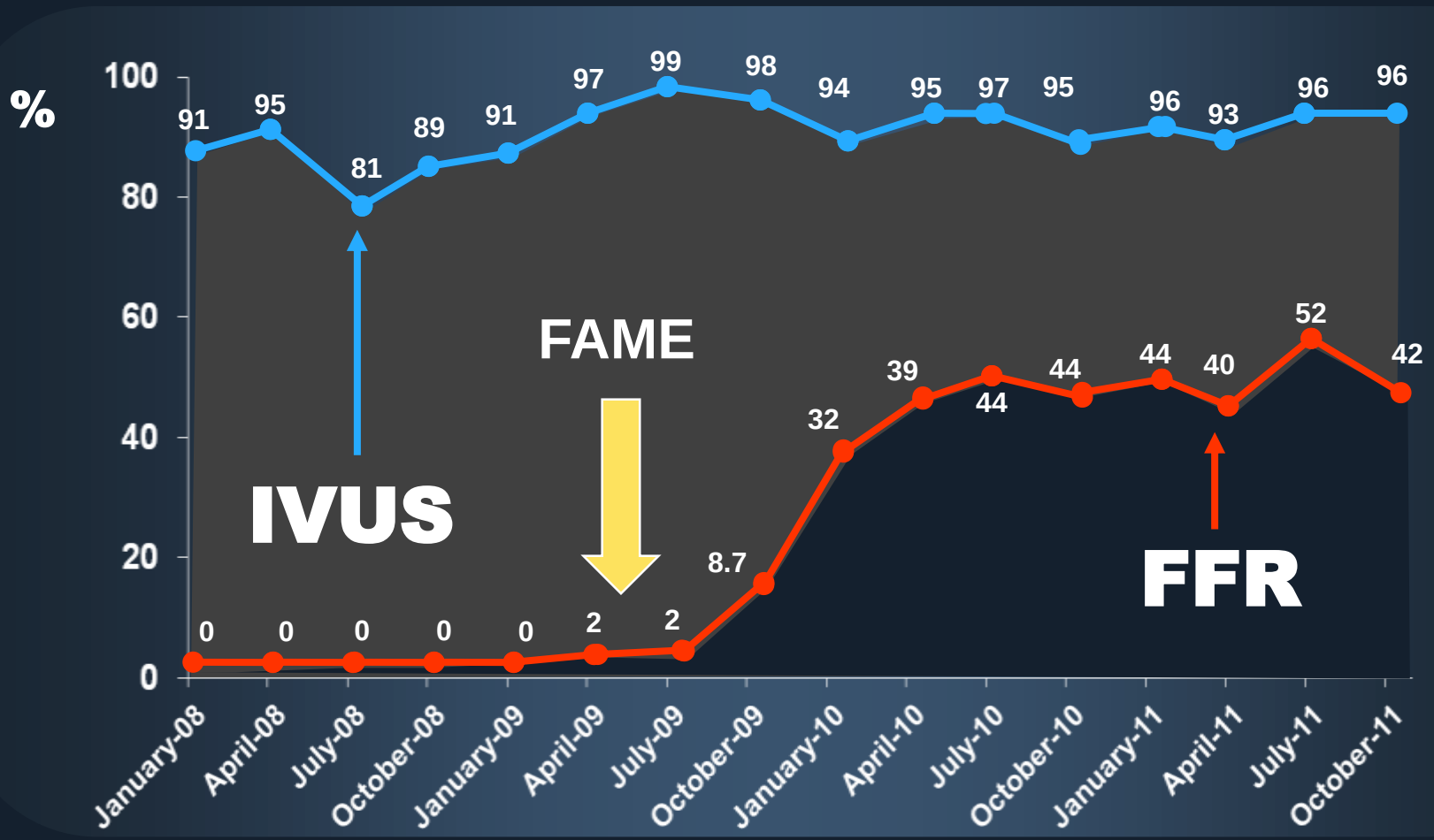
Clinical outcomes of state-of-the-art percutaneous coronary revascularisation in patients with three-vessel disease: two-year follow-up of the SYNTAX II study

Patrick W. Serruys[1,2*], MD, PhD; Norihiro Kogame[1], MD; Yuki Katagiri[1], MD; Rodrigo Modolo[1], MD; Pawel E. Buszman[4,5], MD, PhD; Andres Iniguez[6], MD, PhD; Javier Goicolea[7], MD, PhD; David Hildick-Smith[8], MD; Andrzej Ochala[3], MD, PhD; Dariusz Dudek[9], MD, PhD; Jan J. Piek[3], MD, PhD; Joanna J. Wykrzykowska[3], MD, PhD; Javier Escaned[10], MD, PhD; Adrian P. Banning[11], MBBS, MD; Vasim Farooq[12], MBChB, PhD; Yoshinobu Onuma[2], MD, PhD

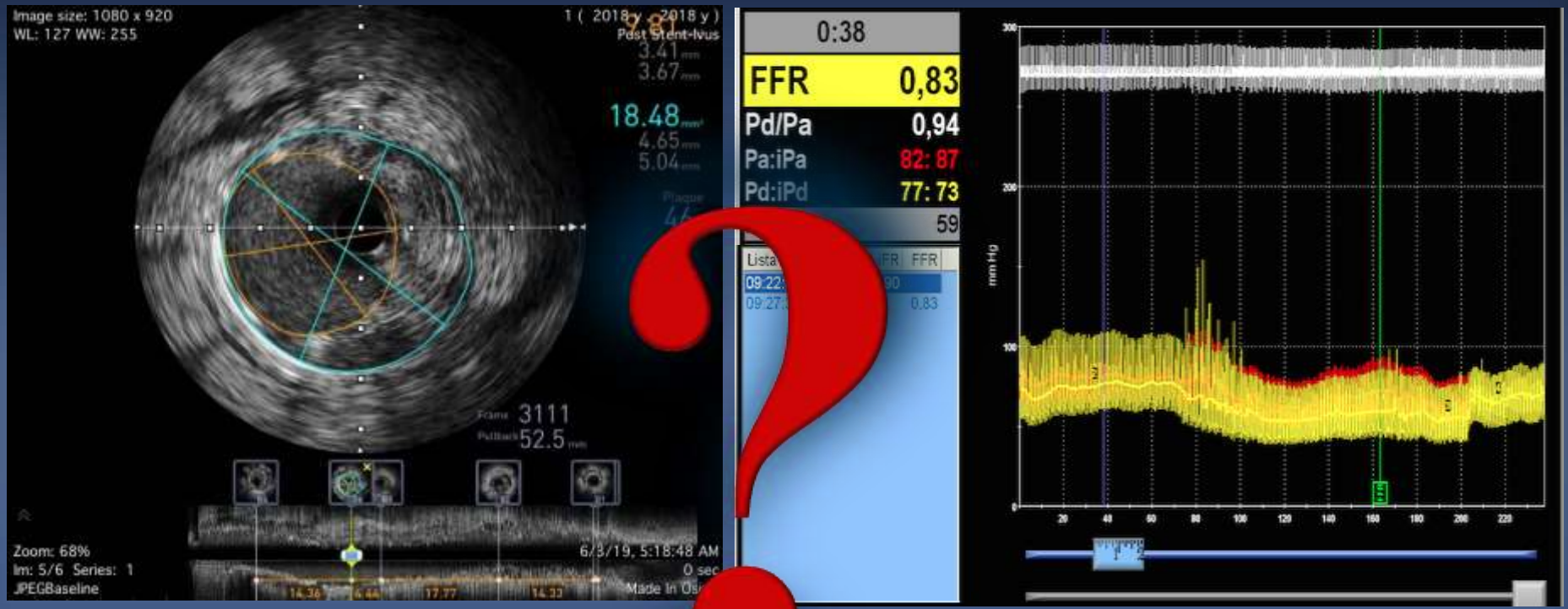
1. Heart-team discussion
2. **Functional-guided approach (FFR/iFR)**
3. **IVUS-guided PCI optimization**
4. Contemporary PCI/CTO techniques
5. GDMT (guideline-directed medical therapy)

Serruys P.W. Et al. Eurointervention 2019;15:e244-e252

Imaging and Physiology Use in AMC for PCI for LM and 3VD



Imaging and Physiology Concept
How To Impact on Your Daily Practice?

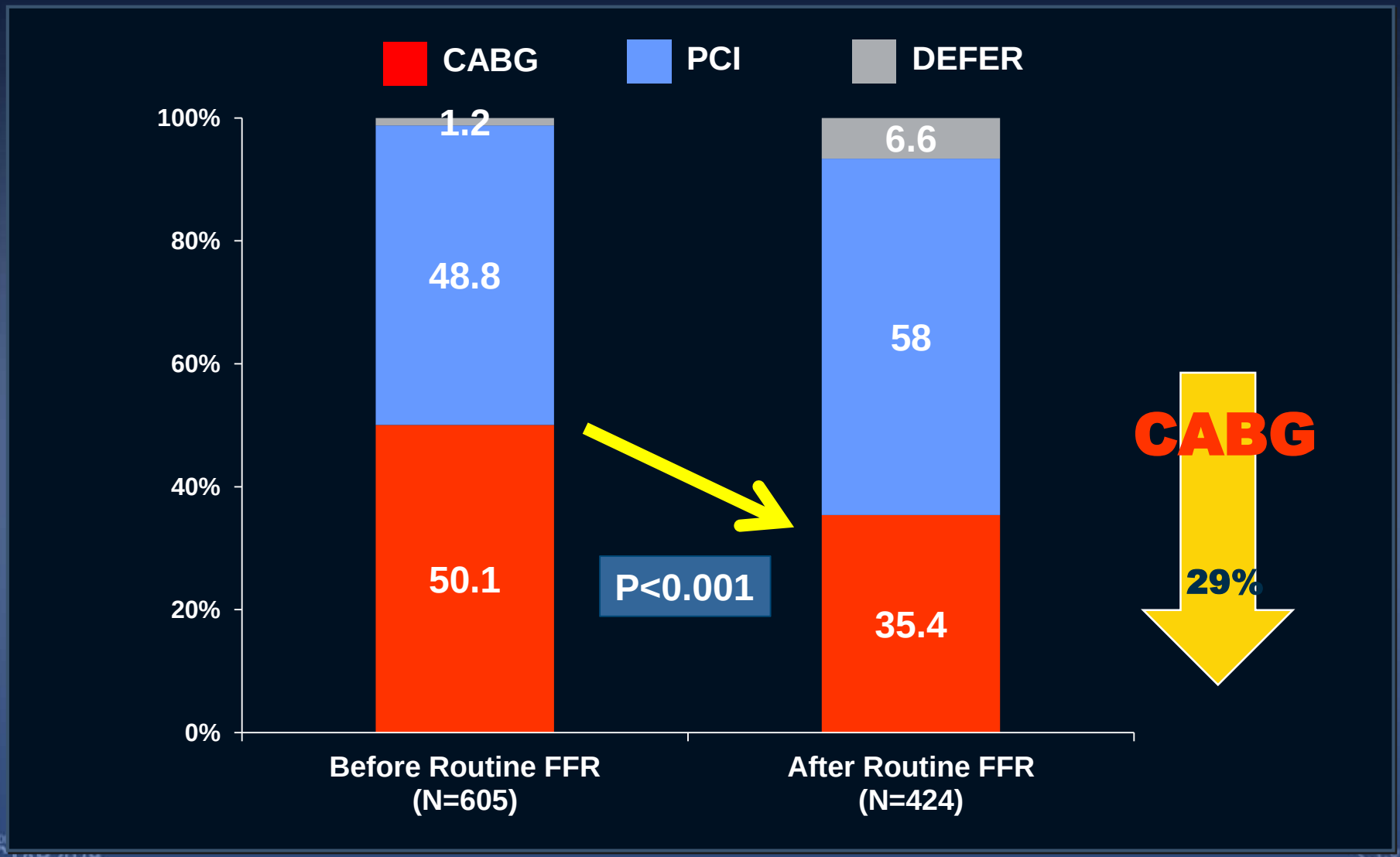


Anatomy

Physiology

Impact on Your Practice

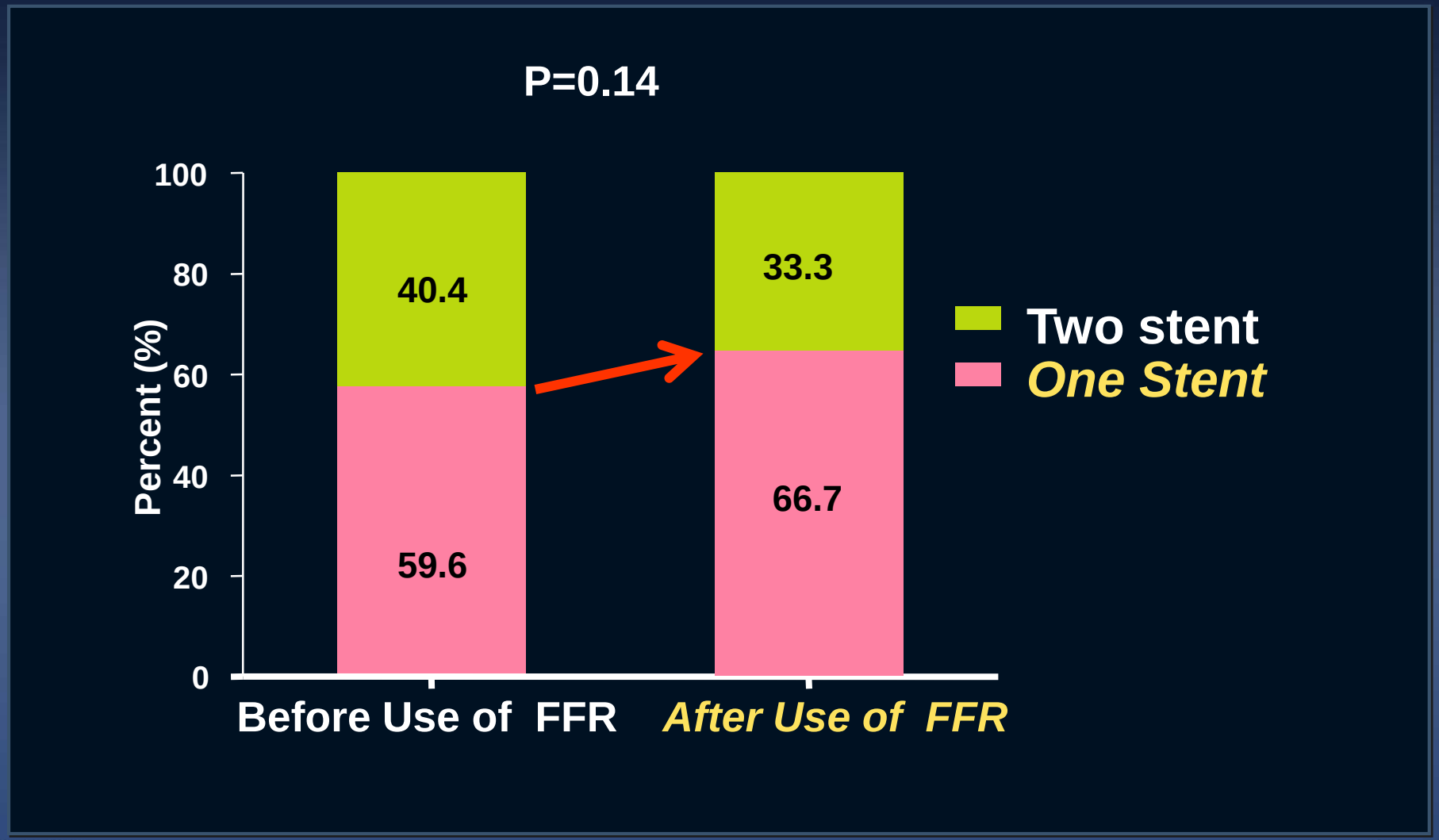
When You Use FFR, Less CABG



Ahn JM Park SJ et al. Am J Cardiol. 2015;116:1163-71.

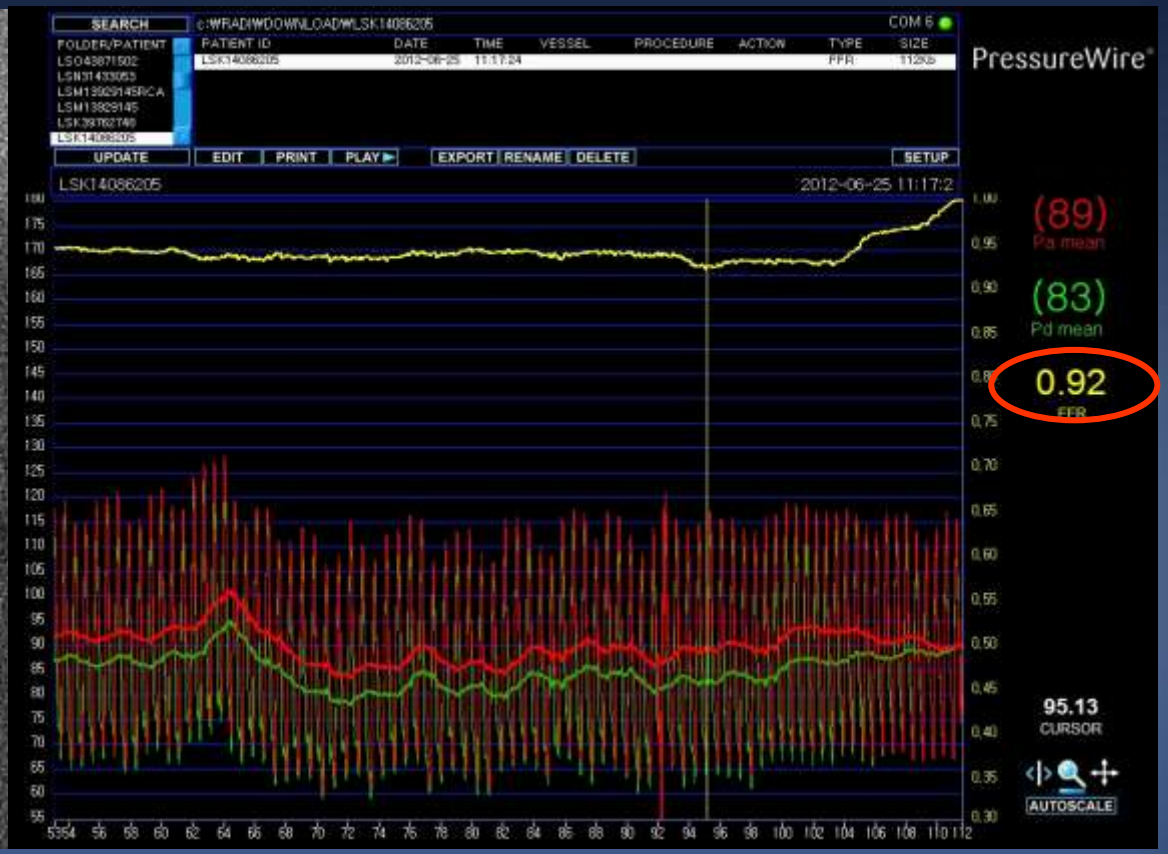
Impact on Your Practice

When You Use FFR, More Simple Approach



Ahn JM Park SJ et al. Am J Cardiol. 2015;116:1163-71.

Do You Want to Do Something?
Consider FFR, First !



Just Defer !

In the Era of ISCHEMIA

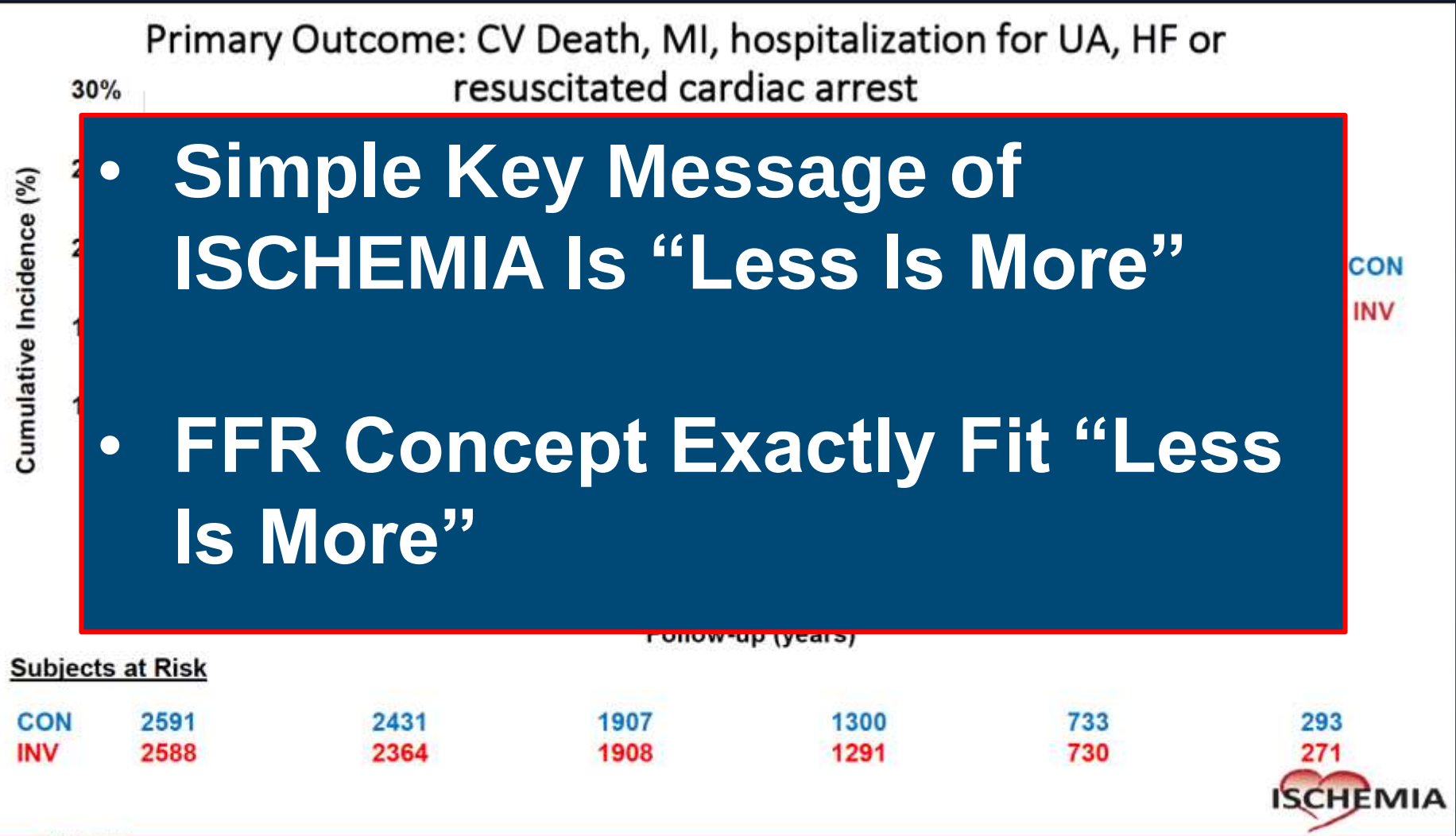
International Study Of Comparative Health Effectiveness With Medical And Invasive Approaches (ISCHEMIA):

Primary Report of Clinical Outcomes

Funded by the National Heart, Lung and Blood Institute

Judith S. Hochman, MD
NYU School of Medicine
On behalf of the ISCHEMIA Research Group

In the Era of ISCHEMIA



- **Simple Key Message of ISCHEMIA Is "Less Is More"**
- **FFR Concept Exactly Fit "Less Is More"**

Dear FAME 3 Investigators,

We are closing in on the end of the calendar year. We are also closing in on the end of FAME 3 enrolment! We have less than 20 patients left to enroll. However, with the holidays approaching, we are writing to ask for one final push in order to finish enrolment on time. The protocol and our agreement with the FDA stipulate that we will end enrolment on December 31st, 2019. It is critical that we include our 1500th before then. Please do all you can to include one or two more patients in the next couple of weeks. Thank you for all of your efforts. We are almost there!!

Best regards,

Bill Fearon
Frederik Zimmermann
and the FAME 3 Steering Committee

IVUS Impact on Your Practice

Editorial

Intravascular Ultrasound–Guided Percutaneous Coronary Intervention for Left Main Disease

Does Procedural Fine-Tuning Make a Relevant Clinical Benefit?

Duk-Woo Park, MD, PhD; Seung-Jung Park, MD, PhD

Owing to the large area of jeopardized myocardium, left main coronary artery (LMCA) disease was associated with high morbidity and mortality and, thus, coronary artery bypass grafting has been the standard revascularization approach. However, over the several decades, there was a considerable evaluation in the field of percutaneous coronary intervention (PCI). Remarkable advancements in stent devices, technical refinement, and adjunctive medical therapy has led to improved PCI outcomes for unprotected LMCA disease.[1] Especially, with a widespread use of drug-eluting

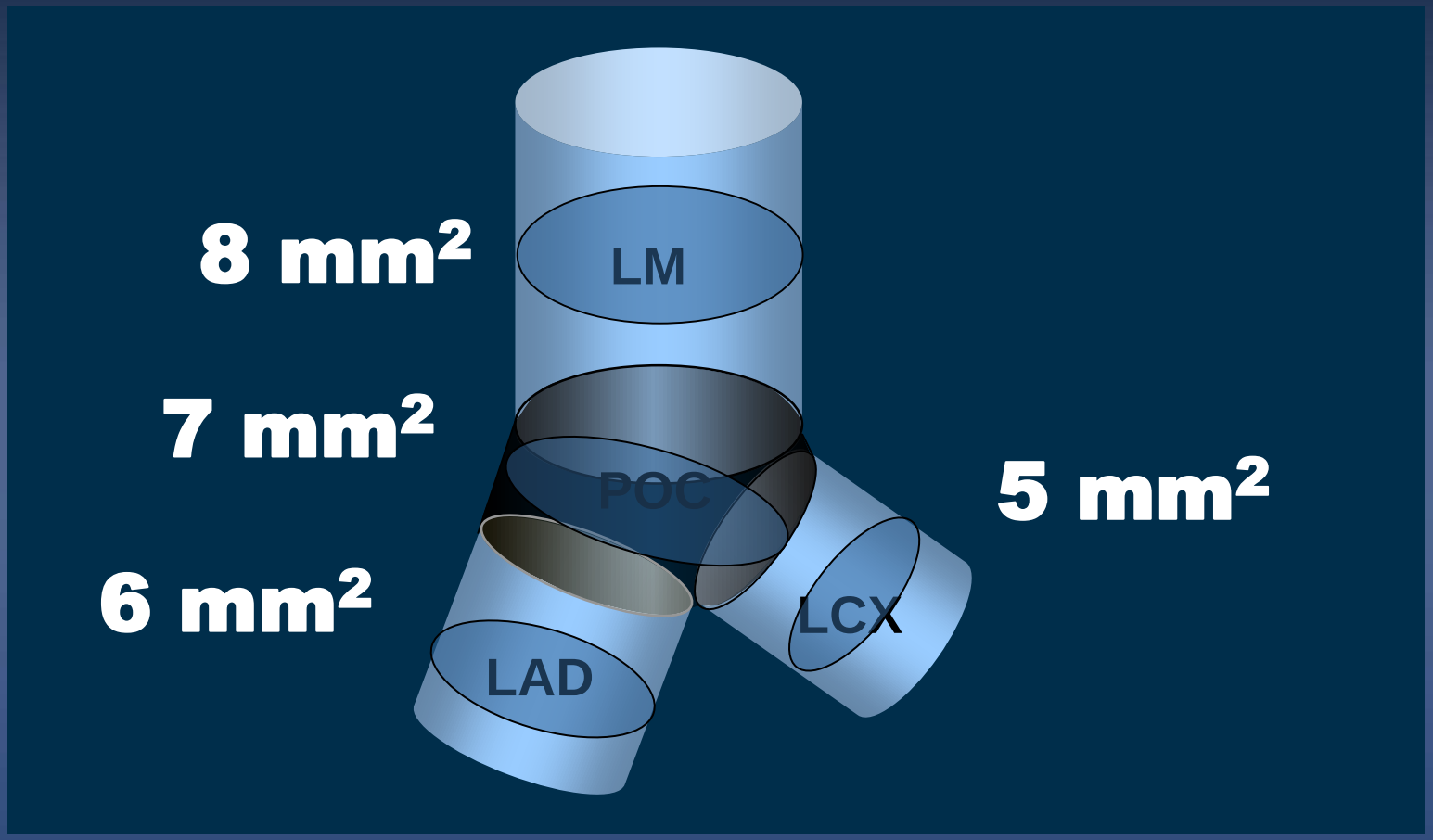
in >70%, which was almost like the real-world practice.[1] For LMCA PCI, how does IVUS guidance make stenting procedure to be more optimal? First, IVUS provides more reliable information than angiography on lesion characteristics regarding lumen size, plaque characterization, and disease distribution.[8] Such precise imaging of LMCA lesion using pre-PCI IVUS may inform optimal stent sizing, length, and positioning. Second, especially for distal LMCA bifurcation lesions, IVUS may be helpful to decide stenting strategy. Selection of a provisional or complex stenting should be based on disease

Park DW, Park SJ. Circ Cardiovasc Interv. 2017;10:e005293

IVUS "Rule of Thumb" for Distal LM-PCI

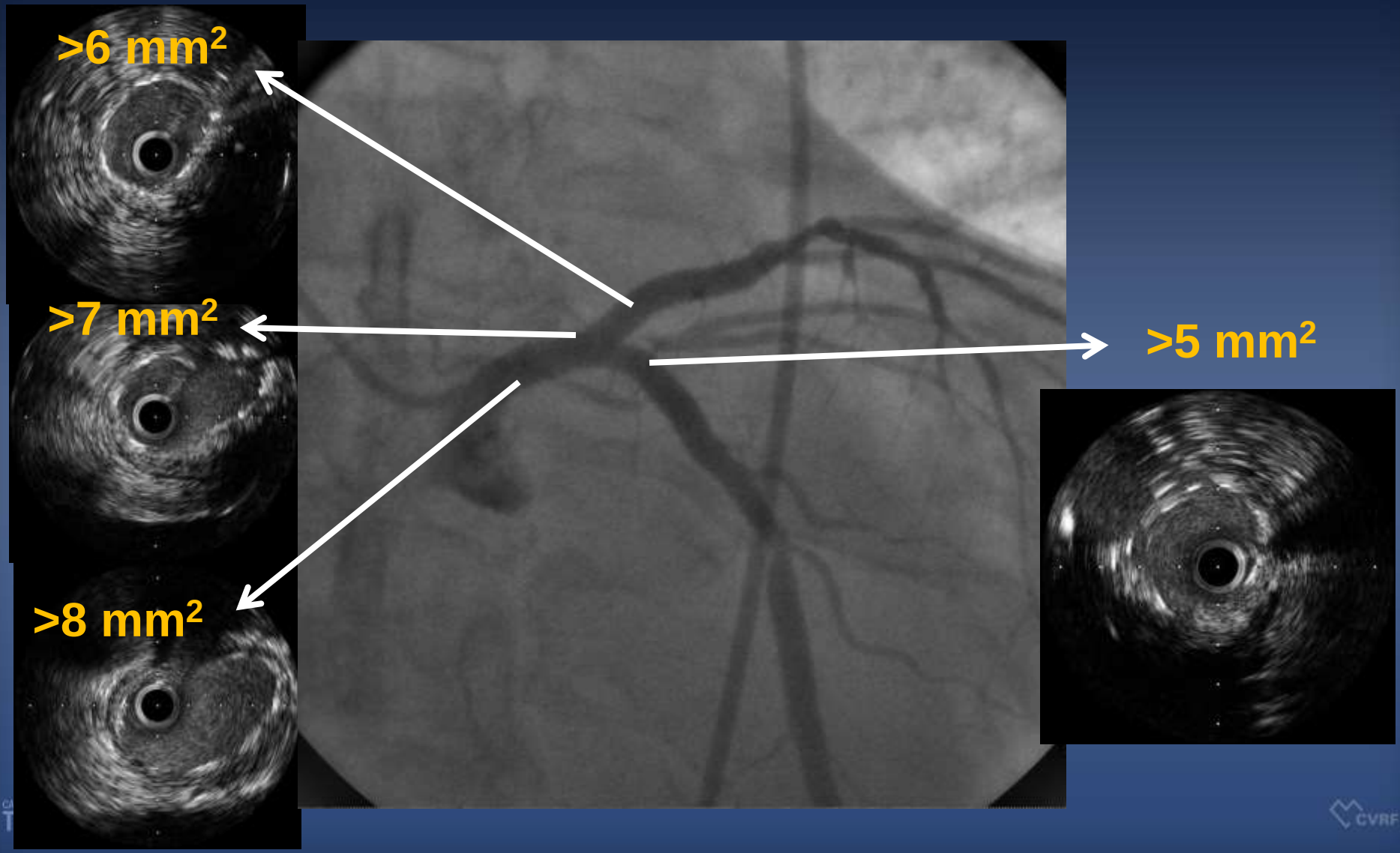
Stent CSA – 2 Stent PCI (Rule of 5,6,7,8 mm^2)

Restenosis Rate < 5% and TLR < 2%

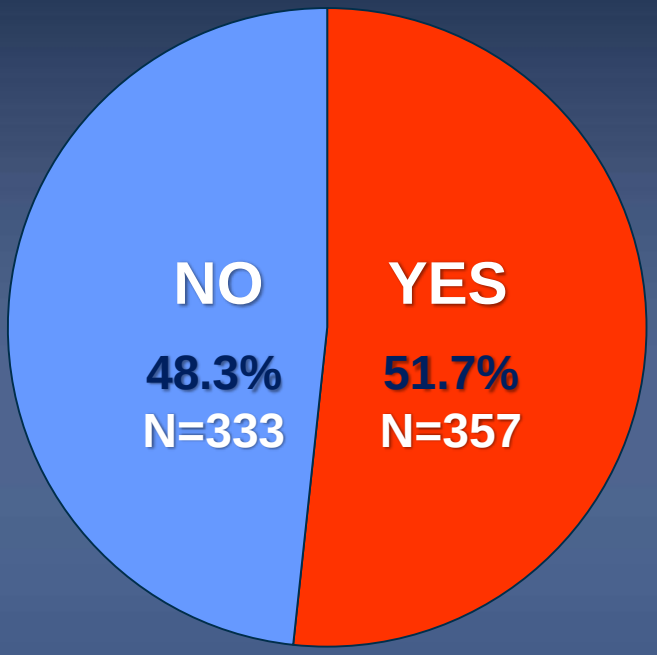


Kang et al. Circ Cardiovasc Interv 2011;4:1168-74

Immediate Post-Stent CSA Guarantee
Good Late Outcomes



IVUS Impact on Your Practice:
Change in stent optimization in EXCEL

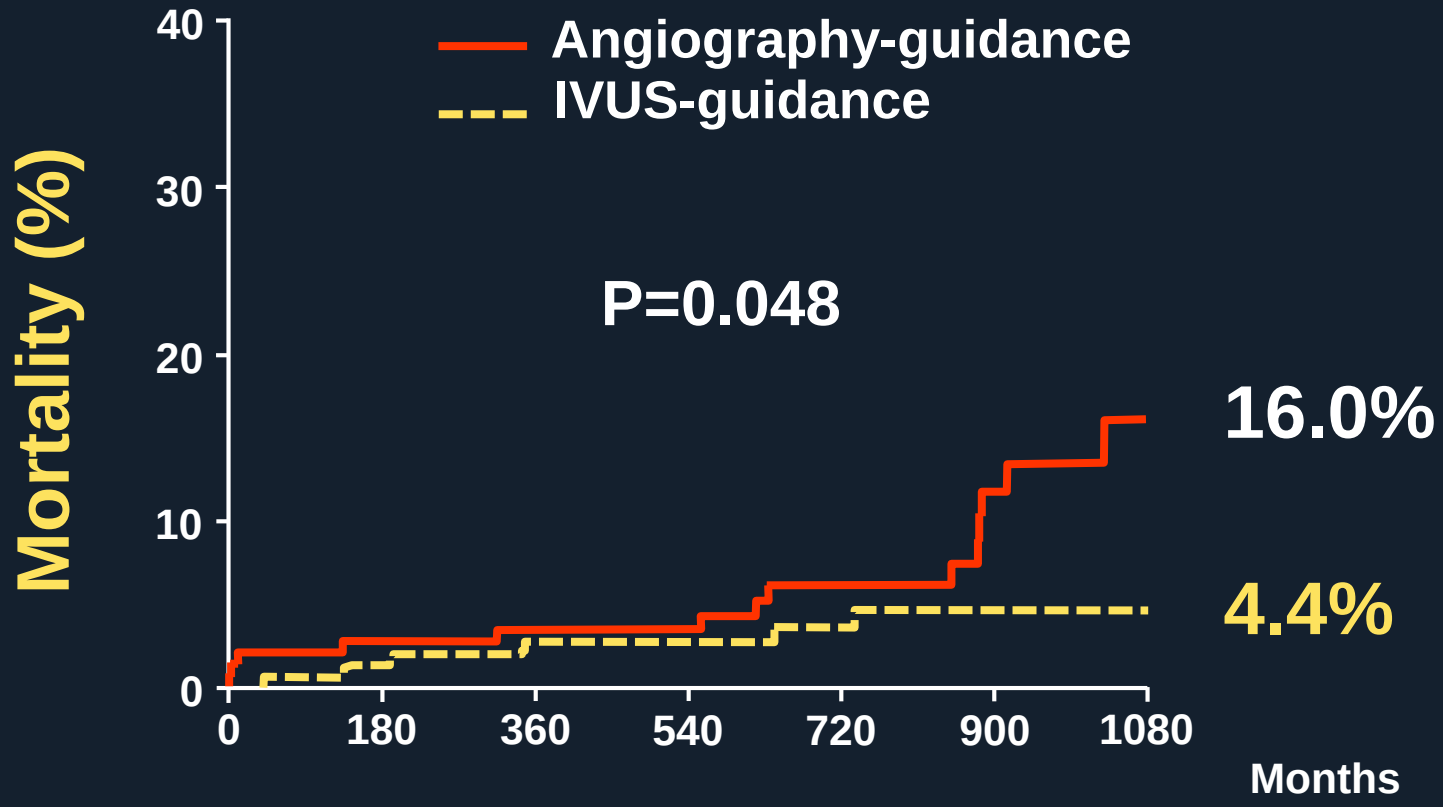


Any IVUS usage for LM lesion (n=690)

- Used larger balloon: 30% (107)
- Post-dilated: 29% (102)
- Used higher pressure: 17% (62)
- Treated stent under-expansion: 16% (57)
- Led to provisional 1 stent strategy rather than planned 2 stents: 11% (41)
- Led to planned 2 stent strategy rather than provisional 1 stent: 9% (33)

A, Maehara, TCT 2018

Why IVUS in LM Stenting ?
IVUS Guidance Saved Lives !

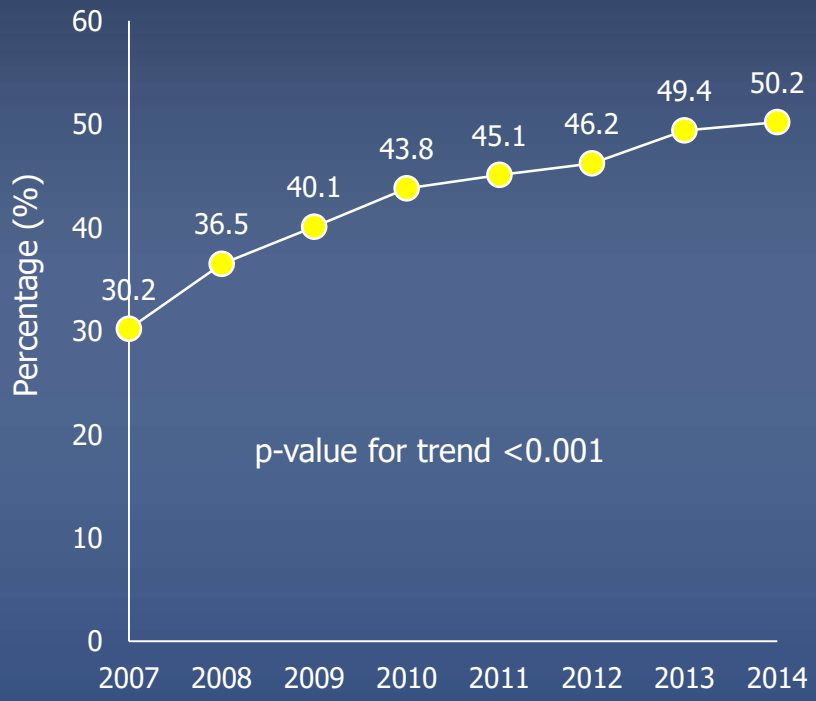


Patients after risk				
IVUS-guidance	145	140	98	37
Angiography-guidance	145	137	88	29

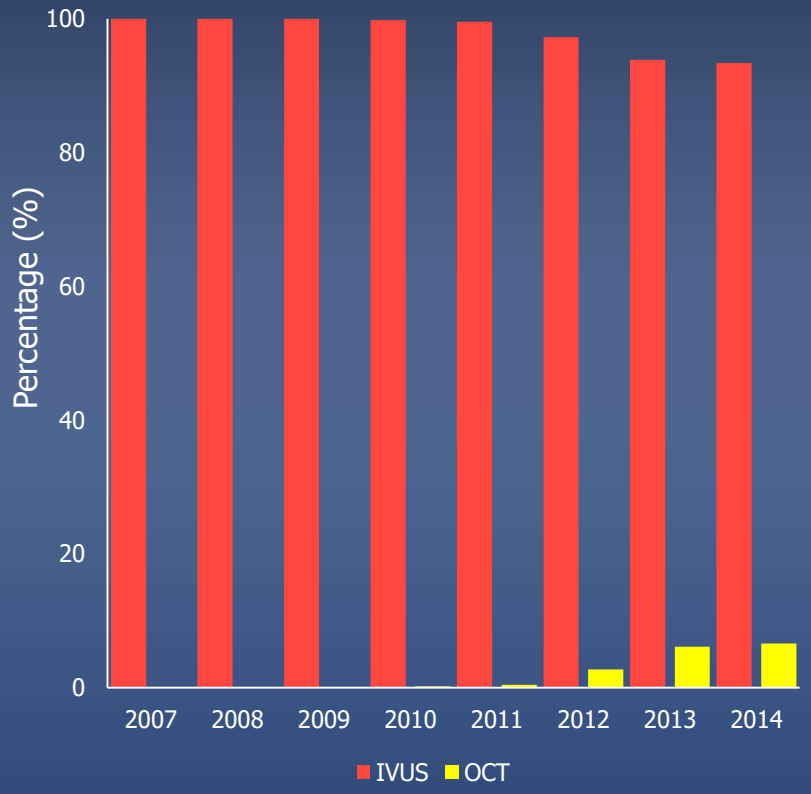
Park SJ et al, Circulation. Cardiovasc Interv. 2009;2(3):167-77.

Trends in imaging for uLMS PCI in England and Wales 2007-2014

Percentage of imaging use during uLMS-PCI

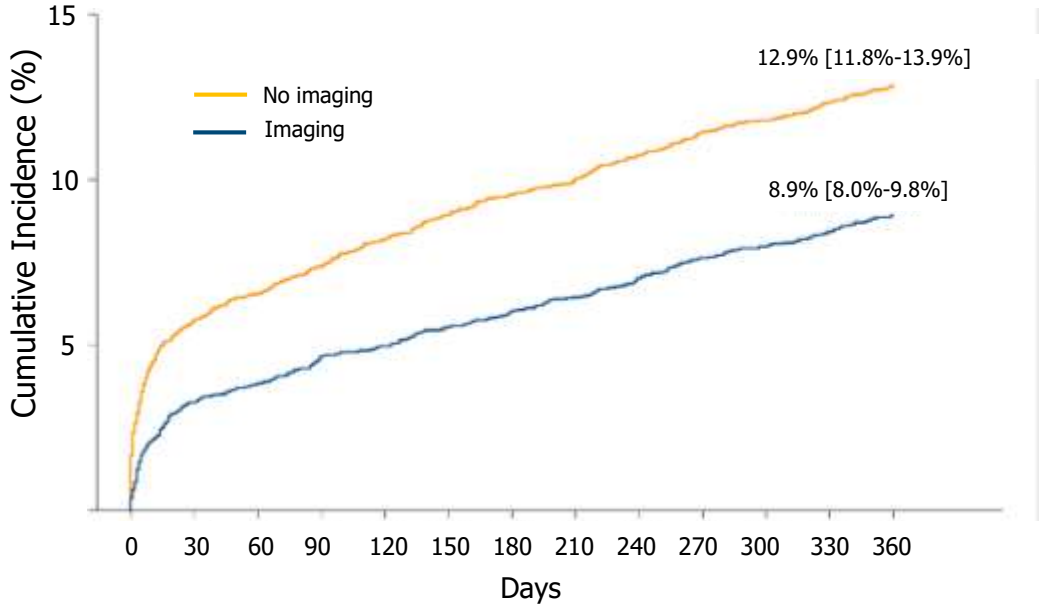


Temporal change in IVUS vs. OCT



Kinnaird et al. TCT2019

Survival by intravascular imaging use after uLMS-PCI in England and Wales 2007-2014



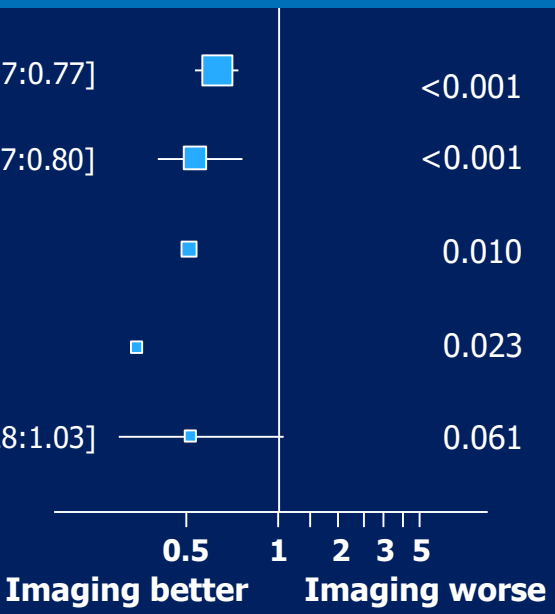
Kaplan-Meier curves of 12-month mortality categorised by intravascular imaging use

Kinnaird et al. TCT2019

All Registry Studies of IVUS-Guided Left Main PCI with DES

Totality of Studies of Imaging to Guide uLMS-PCI and Survival

Study	Count	Imaging N (%)	No Imaging N (%)	Odds ratio (95% CI)	p-value
Kinnaird et al	5056	335 (9.0%)	528 (12.9%)	0.66 [0.57:0.77]	<0.001
SCAAR	2468	37 (33.7%)	63 (56.6%)	0.54 [0.37:0.80]	<0.001
Hernandez et al	1010	37 (7.0%)	66 (13.0%)	0.55	0.010
Gao et al	582	5 (1.7%)	15 (5.2%)	0.32	0.023
Park et al	402	12 (6.0%)	27 (13.6%)	0.54 [0.28:1.03]	0.061



Kinnaird et al. TCT2019

Meta-analysis of IVUS-Guided DES

8 trials, 3276 randomized pts, only complex lesions

(3 studies 1st gen DES, 3 studies 2nd gen DES, 2 studies not stated)

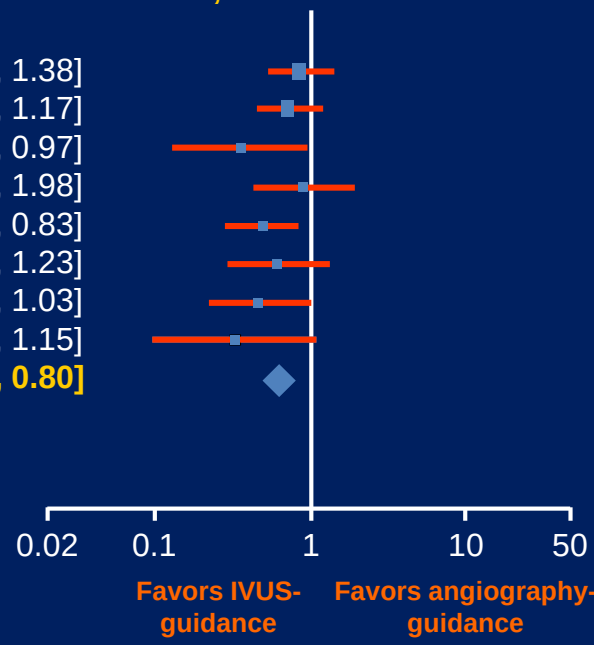
Mean FU 1.4 ± 0.5 years

MACE

Study or Subgroup	IVUS guided PCI Events	Total	Angiography guided PCI Events	Total	Weight	Risk Ratio M-H, Random 95% CI
MACE						
AIR-CTO, 2015	25	115	29	115	23.2%	0.86 [0.54, 1.38]
AVIO, 2013	24	142	33	142	22.9%	0.73 [0.45, 1.17]
CTO-IVUS, 2015	5	201	14	201	5.1%	0.36 [0.13, 0.97]
HOME DES IVUS, 2010	11	105	12	105	8.5%	0.92 [0.42, 1.98]
IVUS-XPL, 2015	19	700	39	700	17.6%	0.49 [0.28, 0.83]
RESET, 2013	12	269	20	274	10.5%	0.61 [0.30, 1.23]
Tan et al, 2015	8	61	17	62	8.8%	0.48 [0.22, 1.03]
Zhang et al, 2016	3	42	9	42	3.3%	0.33 [0.10, 1.15]
Subtotal (95%)		**1635**		**1641**	**100.0%**	**0.64 [0.51, 0.80]**
Total events	107		173			

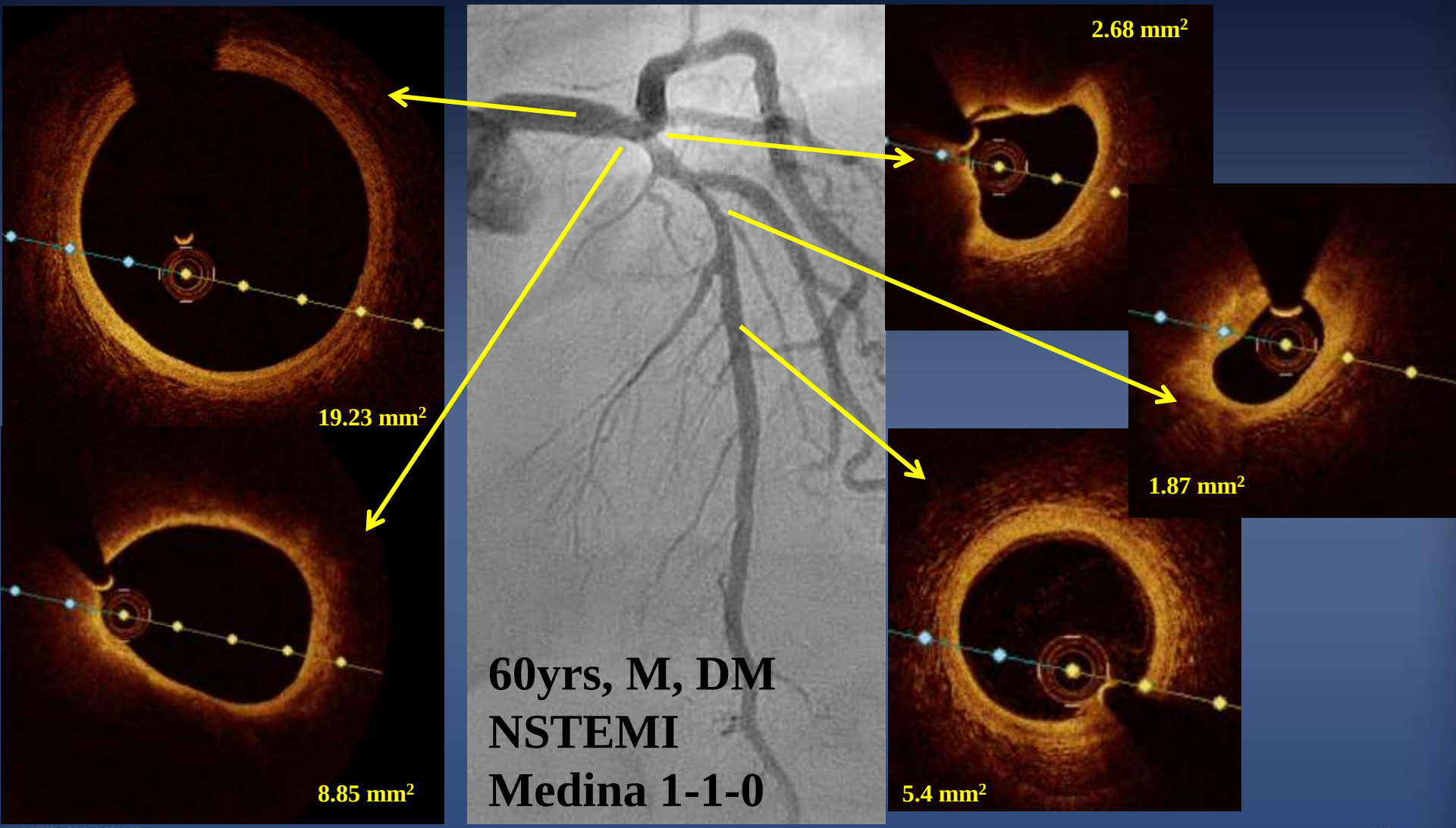
Heterogeneity: Tau²=0.00; Chi²=6.67, df=7 (P=0.46); I²=0%

Test for overall effect: Z=3.88, P=0.0001



Bavishi C and Stone GW. AHJ 2017;185:26-34

OCT-Guided LM PCI



OCT-Guided LM PCI: Co-Registration

LM Crossover
DES: 3.5*28
POT: NC 20 atm

ILUMIEN IV: OPTIMAL PCI

2,524-3,400 pts with high-risk clinical or angiographic features undergoing PCI at 125 centers in the US, Canada, Western Europe, and Asia-Pacific

HR clinical:
Diabetes
HR angio:
Troponin+ ACS culprit
Stent length ≥28 mm
2-stent bifurcation
Severe calcification
CTO
Diffuse/MF ISR

Randomize 1:1

OCT-guided* PCI
(modified ILUMIEN III protocol)

Angiography-guided PCI

Final OCT (blinded in angiography arm)

Follow-up: Minimum 1 year, maximum 2 years

Primary endpoints:

1) Minimal stent area (MSA) by OCT (powered for superiority)
2) Target vessel failure (event-driven, powered for superiority)

Principal investigators: Ziad Ali and Ulf Landmesser

Study chair: Gregg W. Stone

Sponsor: Abbott Vascular

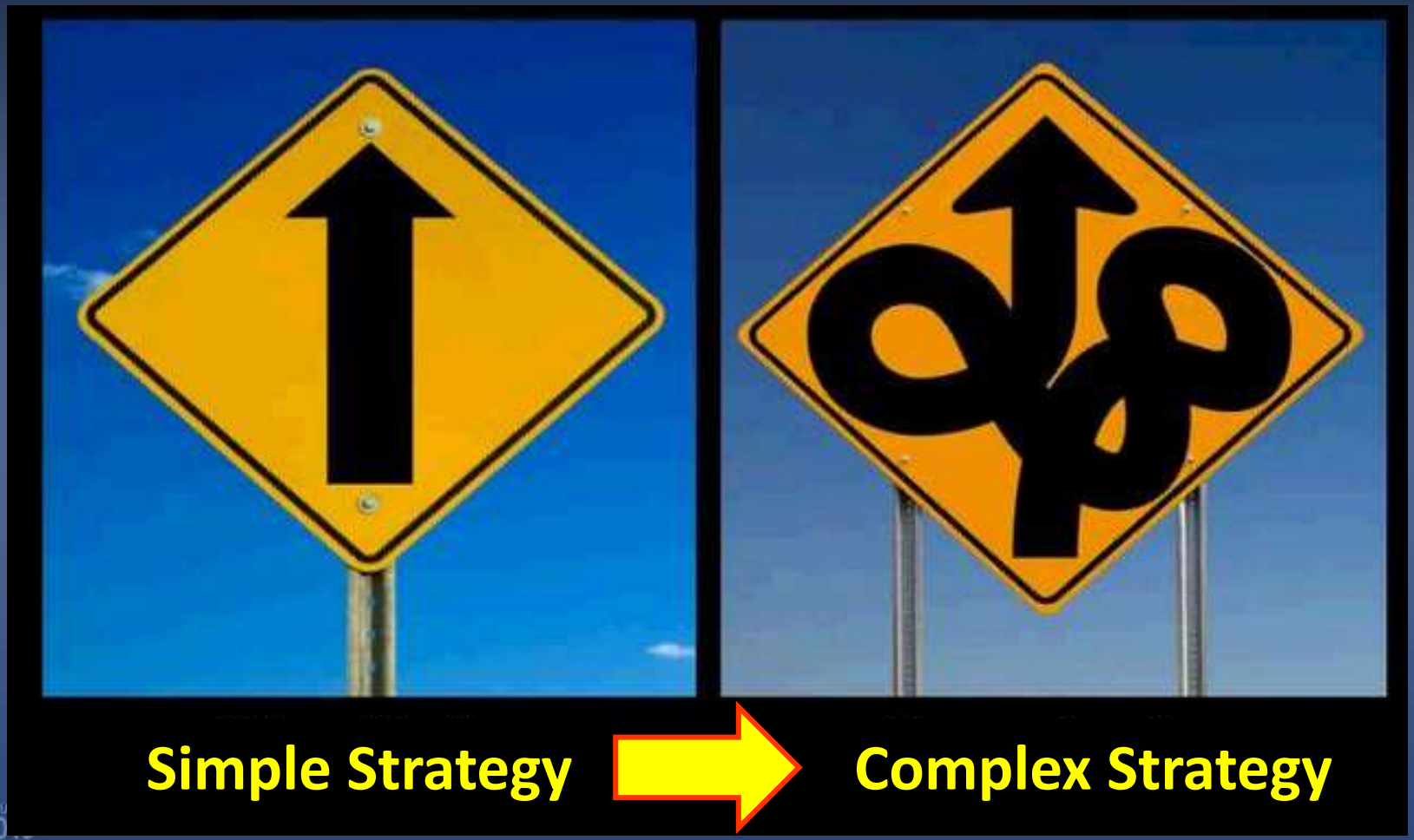
State-of-Art Left Main PCI
Summary

- For complex LM PCI, the physiology/imaging strategy was associated with improved clinical outcomes.
  - This strategy leads to significantly fewer lesions treated with PCI and simpler strategy, as well as better treated with IVUS optimization.

- Combined IVUS/OCT catheters are being commercialized in USA, Canada and Japan.
  - When/if these catheters are combined with physiology measures, only one device would be needed in this complex PCI procedures.

State-of-Art LM PCI 2019

If You Perform Bifurcation PCI With Angiographic Concept Alone



State-of-Art LM PCI 2019

If You Perform Bifurcation PCI With Imaging and Functional Concept