True Distal Left Main Bifurcation PCI (Medina 1,1,1, or 1,0,1): Contemporary Strategy – Provisional vs. Complex Stenting

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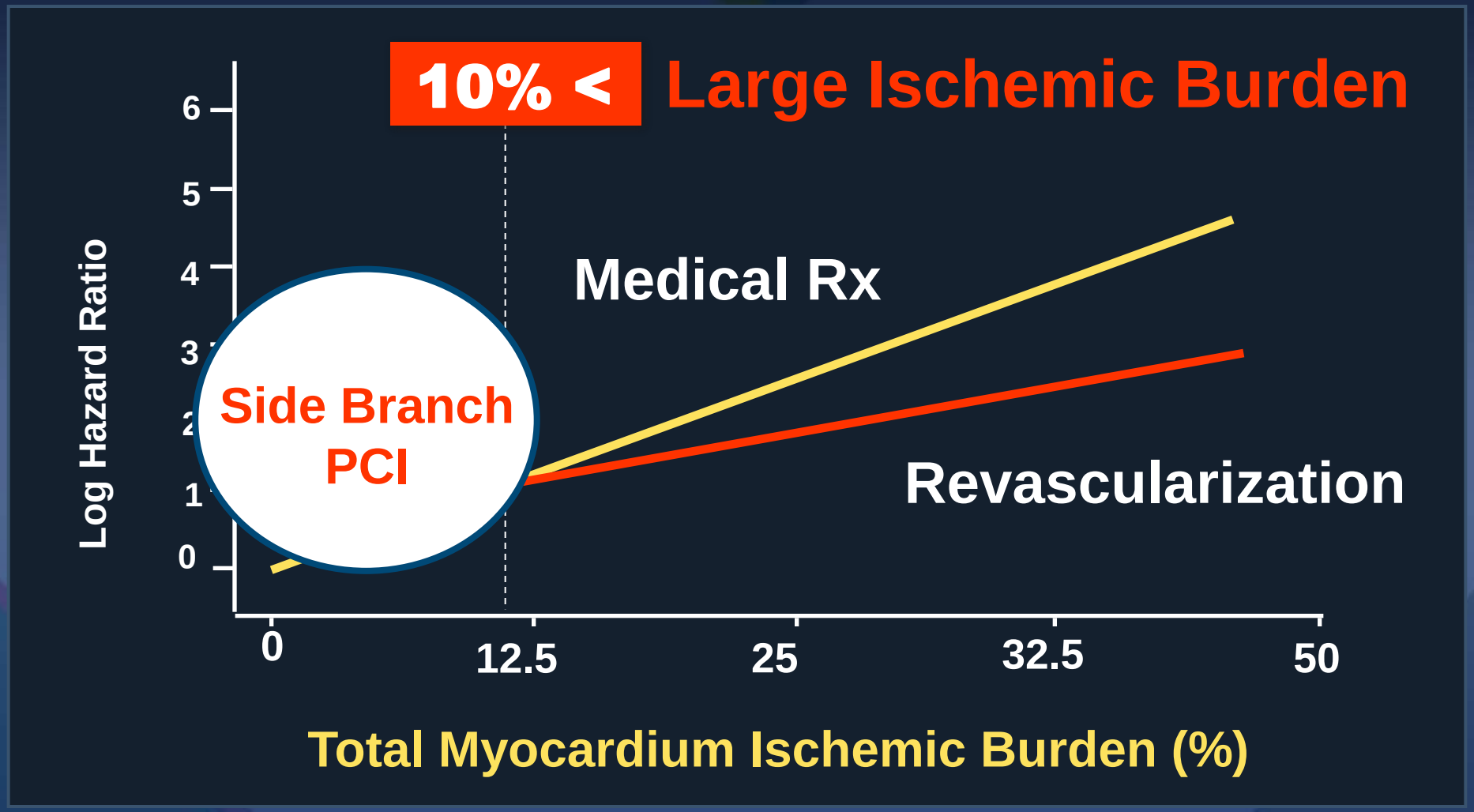
Asan Medical Center

Disclosure

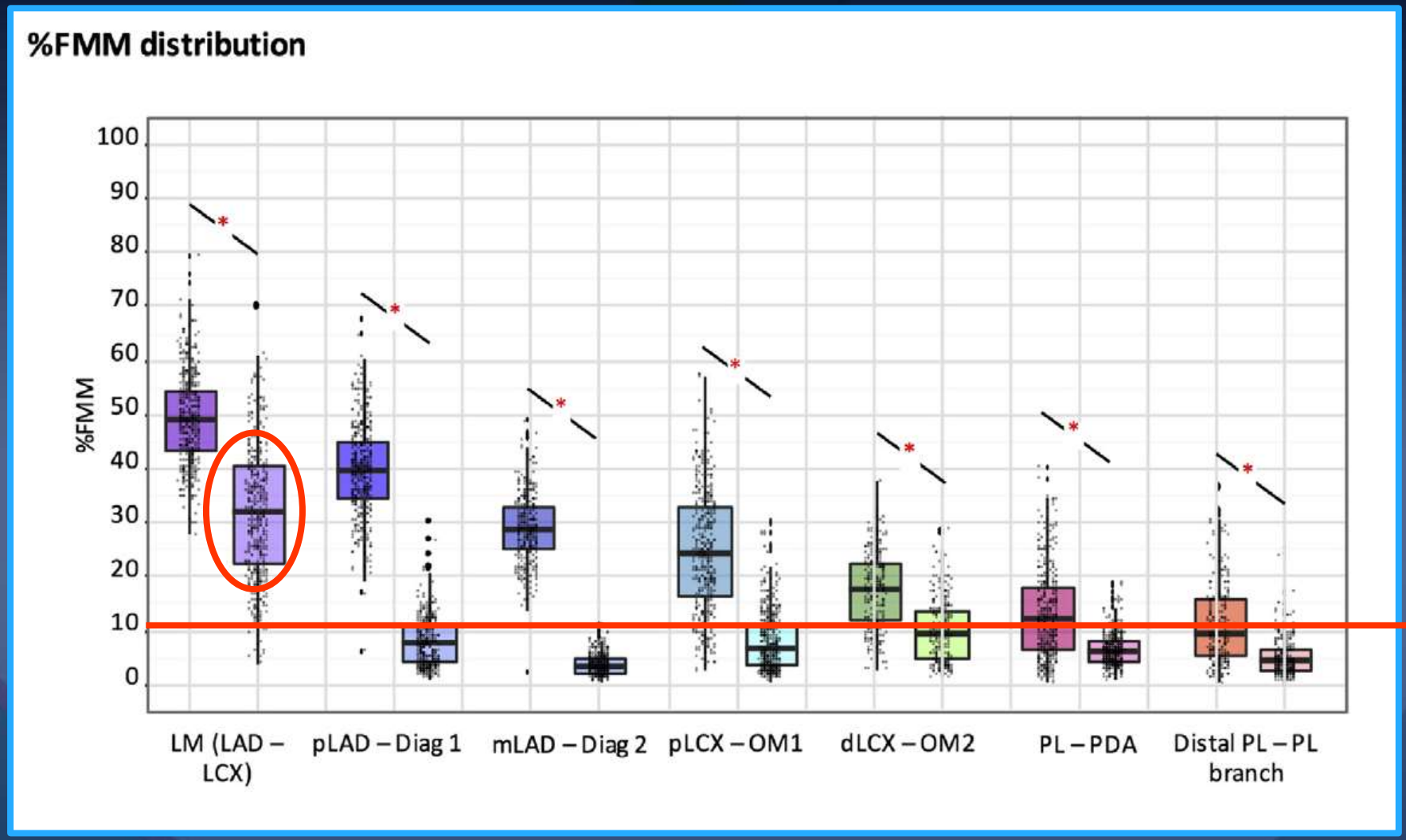
- I have noting to disclose

Survival Benefit *of Revascularization*



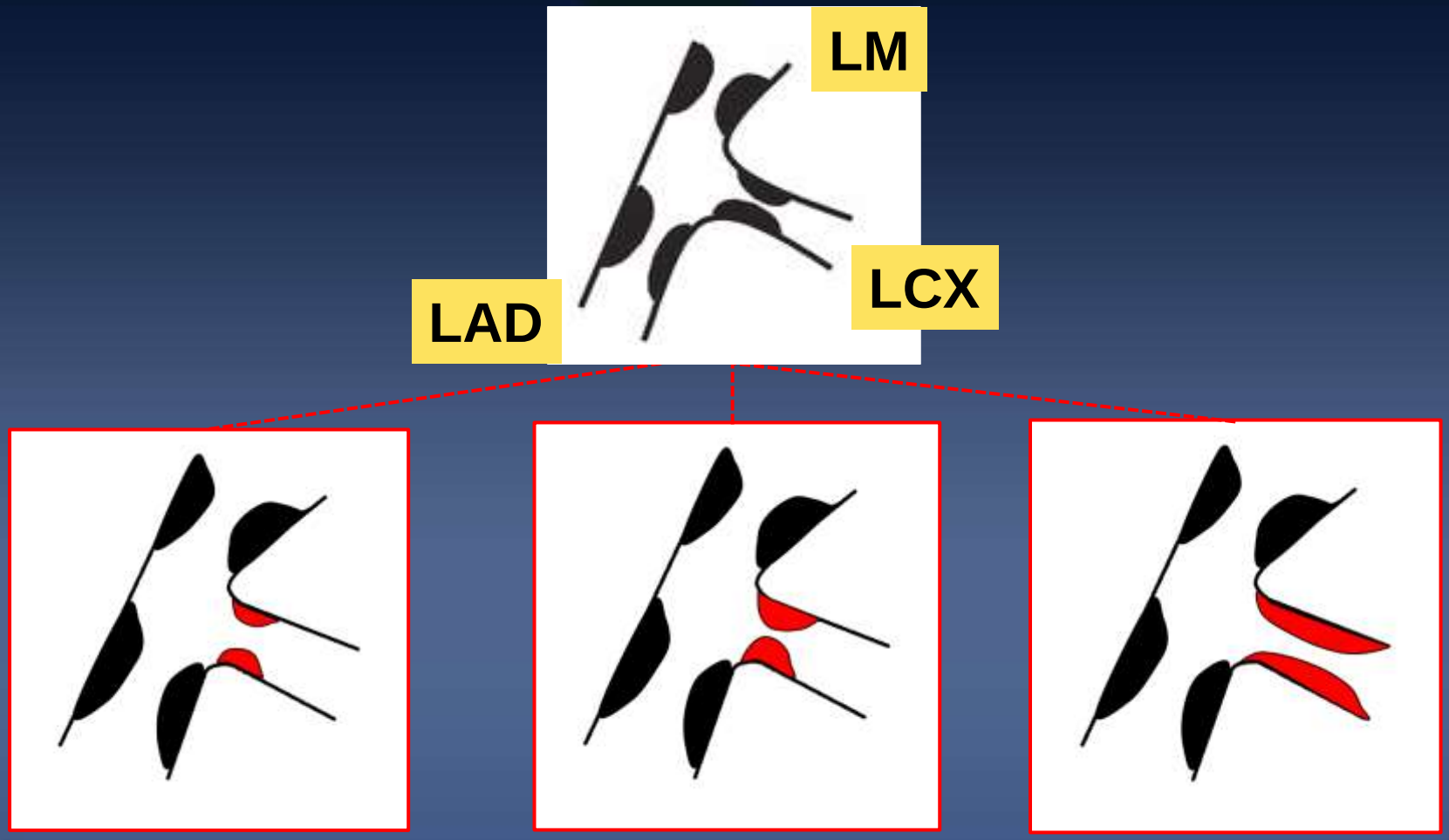
Hachamovitch R, Circulation. 2003;107:2900-2906

CT-FFR: Myocardial Mass >10%



Kim H.Y. et al. J Am Coll Cardiol Intv 2017;10:571–81

Ture Distal LM Bifurcation Lesion



Focal moderate lesion in LCX

Focal severe lesion in LCX

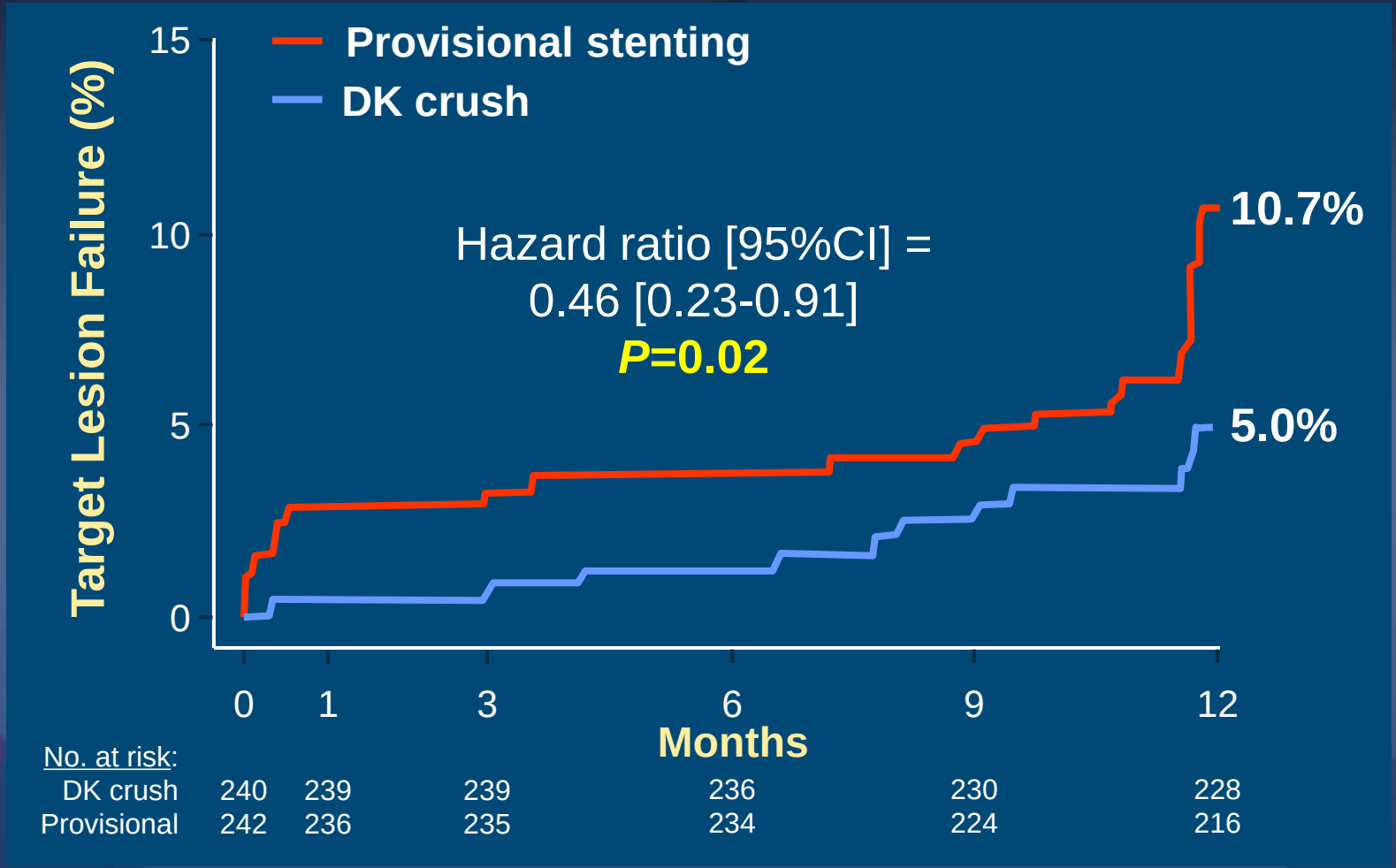
Diffuse lesion in LCX

"Anatomic Diversity of Distal Left Main Disease"

Anatomic Diversity of Distal LM Bifurcation PCI

- The approach is usually dictated by the SB (LCX):
  - True vs. Non-true
  - Size of SB (LCX)
  - Angle from MB (LAD)
  - Extent and distribution of SB (LCX) disease
  - How important the LCX (SB) is for that patient and for that specific anatomy

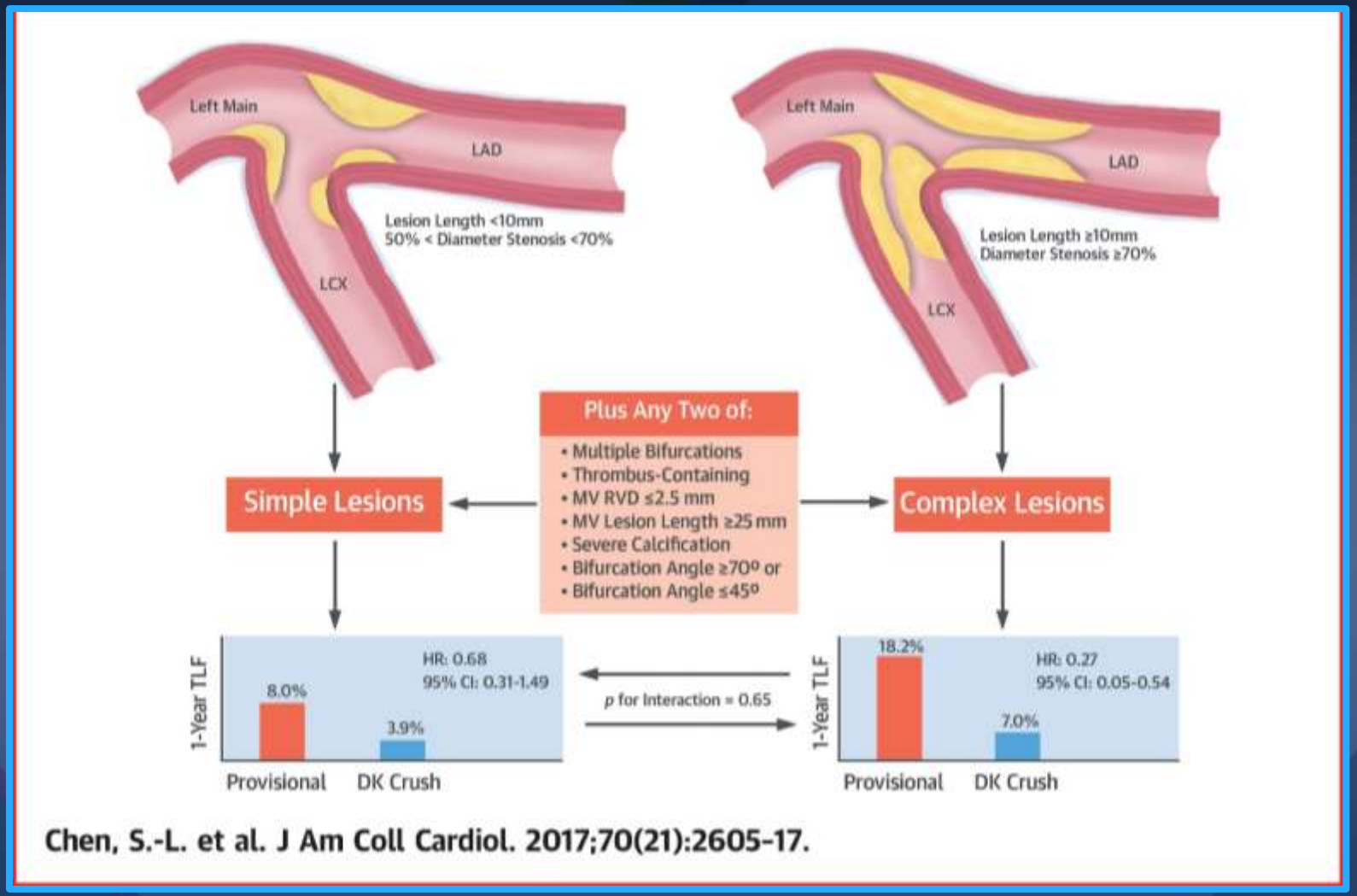
DKCRUSH V – DK Crush vs. Provisional Stenting in Distal LM True Bifurcations: TLF at 12-month



Chen, S.-L et al, JACC 2017; 70(21):2605-17

Better Strategy for Distal LM bifurcation?

DKCRUSH-V Trial



Chen, S.-L. et al. J Am Coll Cardiol. 2017;70(21):2605-17.

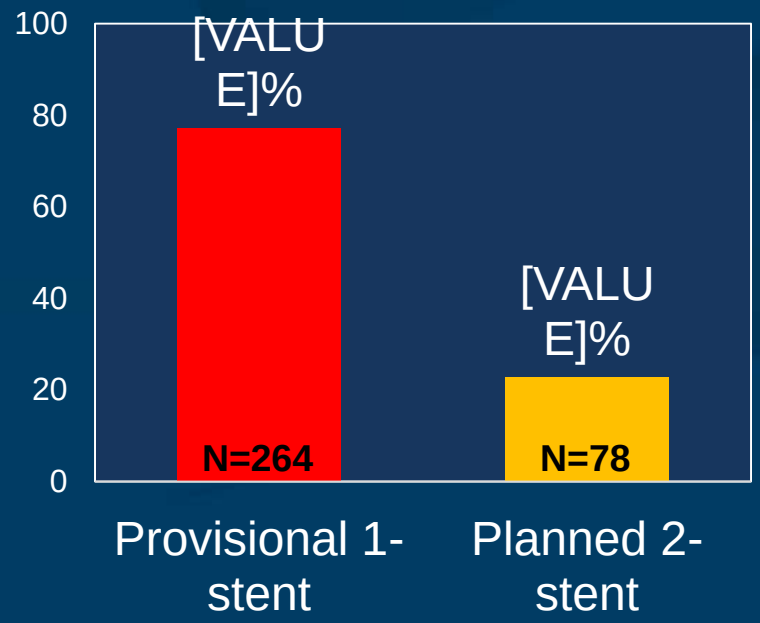
Chen, S.-L et al, JACC 2017; 70(21):2605-17

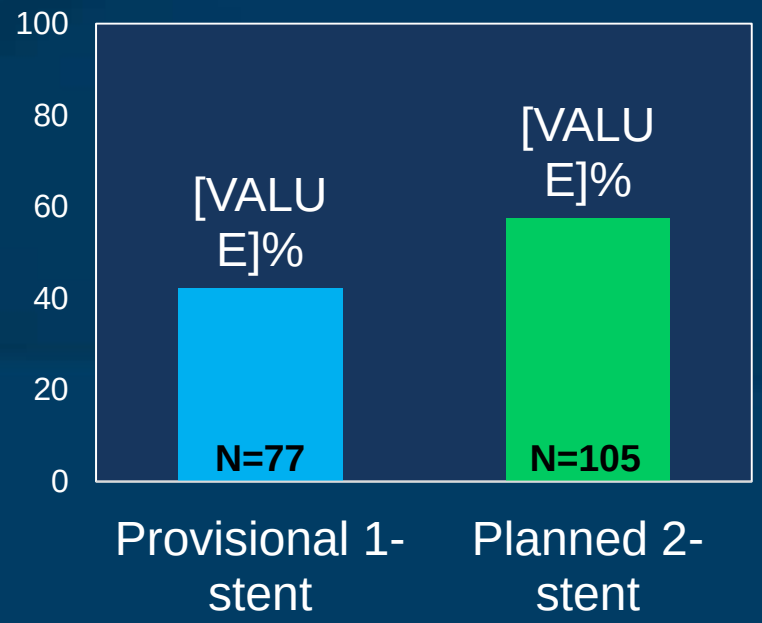
Provisional 1-Stent vs. Planned 2-Stents For LM Distal Bifurcation Disease (n=529)

Site-assessed distal LM bifurcation disease with QCA
N=524

0 or 1 side branches with DS ≥50% by QCA
N=342 (65.3%)

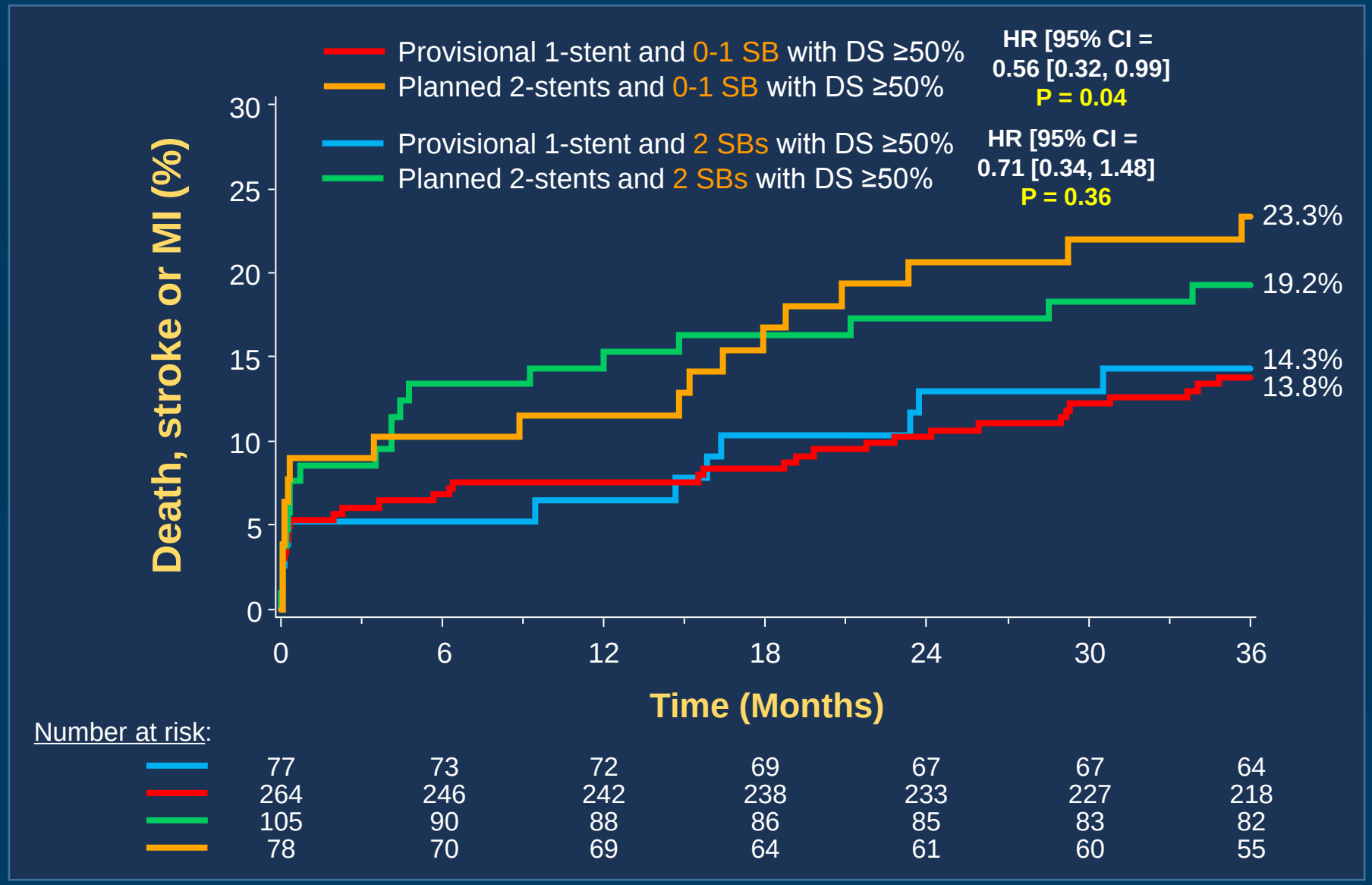
2 side branches with DS ≥50% by QCA
N=182 (34.7%)





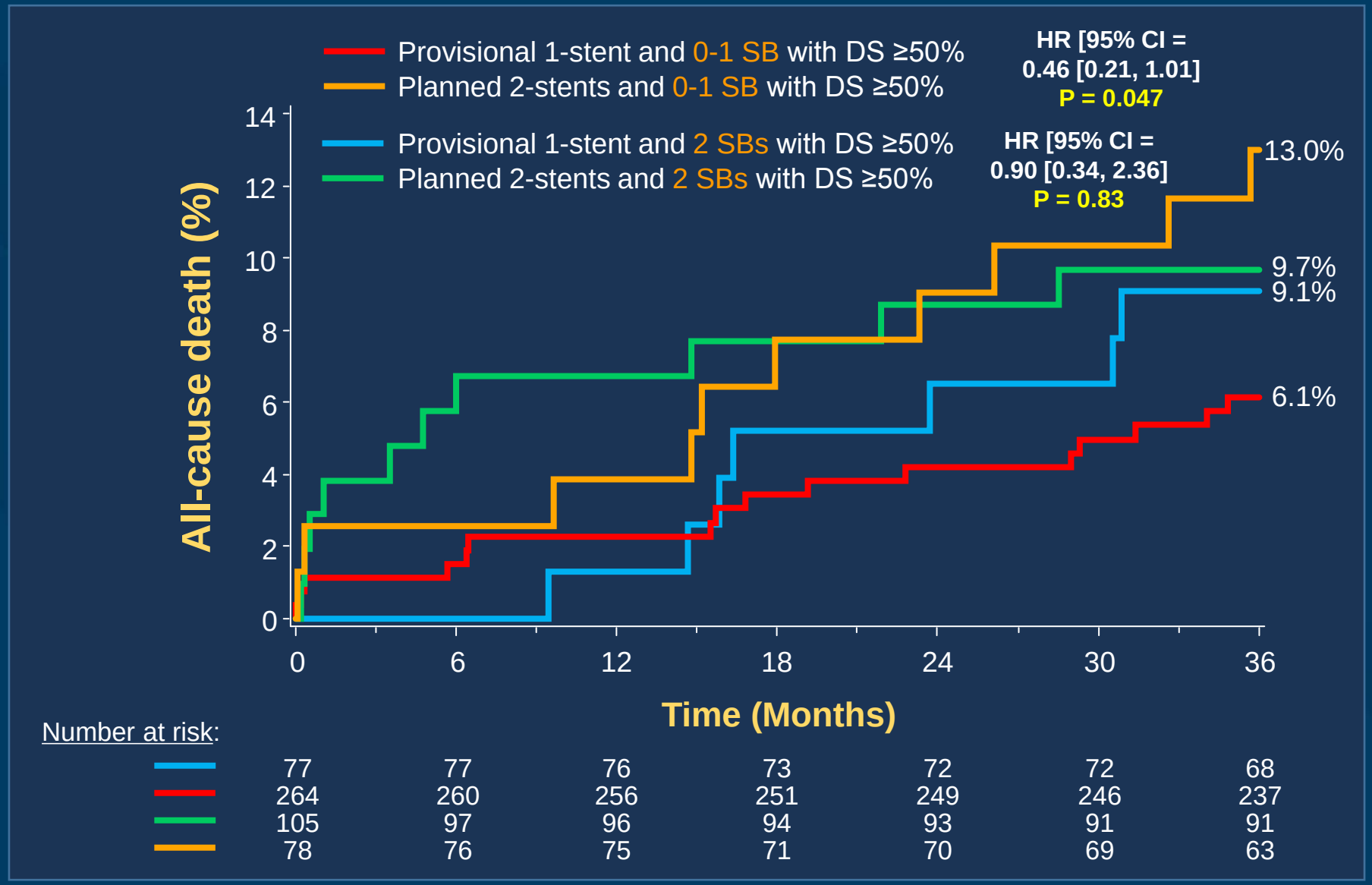
Kandzari DE et al. Submitted

Provisional 1-Stent vs. Planned 2-Stents For LM Distal Bifurcation Disease (n=529)



Kandzari DE et al. Submitted

Provisional 1-Stent vs. Planned 2-Stents For LM Distal Bifurcation Disease (n=529)



Kandzari DE et al. Submitted

Real-World Data Is Still Lacking…

Left Main Bifurcation PCI:

Merged Analysis using the Largest Real-World Left Main Database

Safety and Effectiveness of Second-Generation Drug-Eluting Stents in Patients With Left Main Coronary Artery Disease

Pil Hyung Lee, MD,[a] Osung Kwon, MD,[a] Jung-Min Ahn, MD,[a] Cheol Hyun Lee, MD,[a] Do-Yoon Kang, MD,[a] Jung-Bok Lee, PhD,[b] Soo-Jin Kang, MD, PhD,[a] Seung-Whan Lee, MD, PhD,[a] Young-Hak Kim, MD, PhD,[a] Cheol Whan Lee, MD, PhD,[a] Seong-Wook Park, MD, PhD,[a] Duk-Woo Park, MD, PhD,[a] Seung-Jung Park, MD, PhD[a]

ABSTRACT

BACKGROUND Limited data are available on the relative performances between different types of drug-eluting stents (DES) for obstructive left main coronary artery disease (LMCAD).

OBJECTIVES This study sought to compare effectiveness and safety profiles of various second-generation DES for LMCAD in real-world clinical practice.

METHODS Among 4,470 patients in 3, multicenter, prospective registries (IRIS-DES [Interventional Cardiology Research Incorporation Society-Drug-Eluting Stents] registry, the IRIS-MAIN [Interventional Cardiology Research Incorporation Society-Left MAIN Revascularization] registry, and the PRECOMBAT [PREmier of Randomized COMparison of Bypass Surgery versus AngioplasTy Using Drug-Eluting Stent in Patients with Left Main Coronary Artery Disease] study) treated between July 2007 and July 2015, the authors identified 2,692 patients with significant LMCAD who received second-generation DES; 1,254 with cobalt-chromium everolimus-eluting stents (CoCr-EES), 232 with biodegradable polymer biolimus-eluting stents (BP-BES), 616 with platinum-chromium EES (PtCr-EES), and 590 with Resolute zotarolimus-eluting stent (Re-ZES). The primary outcome was target-vessel failure.

RESULTS The observed 3-year rates of target-vessel failure were not significantly different for the different types of DES (16.7% for the CoCr-EES, 13.2% for the BP-BES, 18.7% for the PtCr-EES, and 14.7% for the Re-ZES; $p = 0.15$). In multiple treatment propensity score analysis, the adjusted hazard ratios (HRs) for target-vessel failure were similar in between-group comparisons of the different DES, except for the PtCr-EES versus the BP-BES (reference; HR: 1.60; 95% confidence interval: 1.01 to 2.54; $p = 0.046$). There were no significant differences in risk of composite of all-cause death, any myocardial infarction, or any revascularization and its individual components according to the different types of DES. Although the 3-year incidence of stent thrombosis was considerably low (≤1.0%) for all types of DES, between-group differences were observed, generally favoring the EES platforms.

CONCLUSIONS In this pooled analysis of 3 prospective registries involving unrestricted use of various second-generation DES for LMCAD, we found no significant between-group differences in 3-year risk of target-vessel failure, except for a higher risk of primary outcome with PtCr-EES compared to BP-BES. (Evaluation of the First, Second, and New Drug-Eluting Stents in Routine Clinical Practice [IRIS-DES]; NCT01186133) (J Am Coll Cardiol 2018;71:832–41)

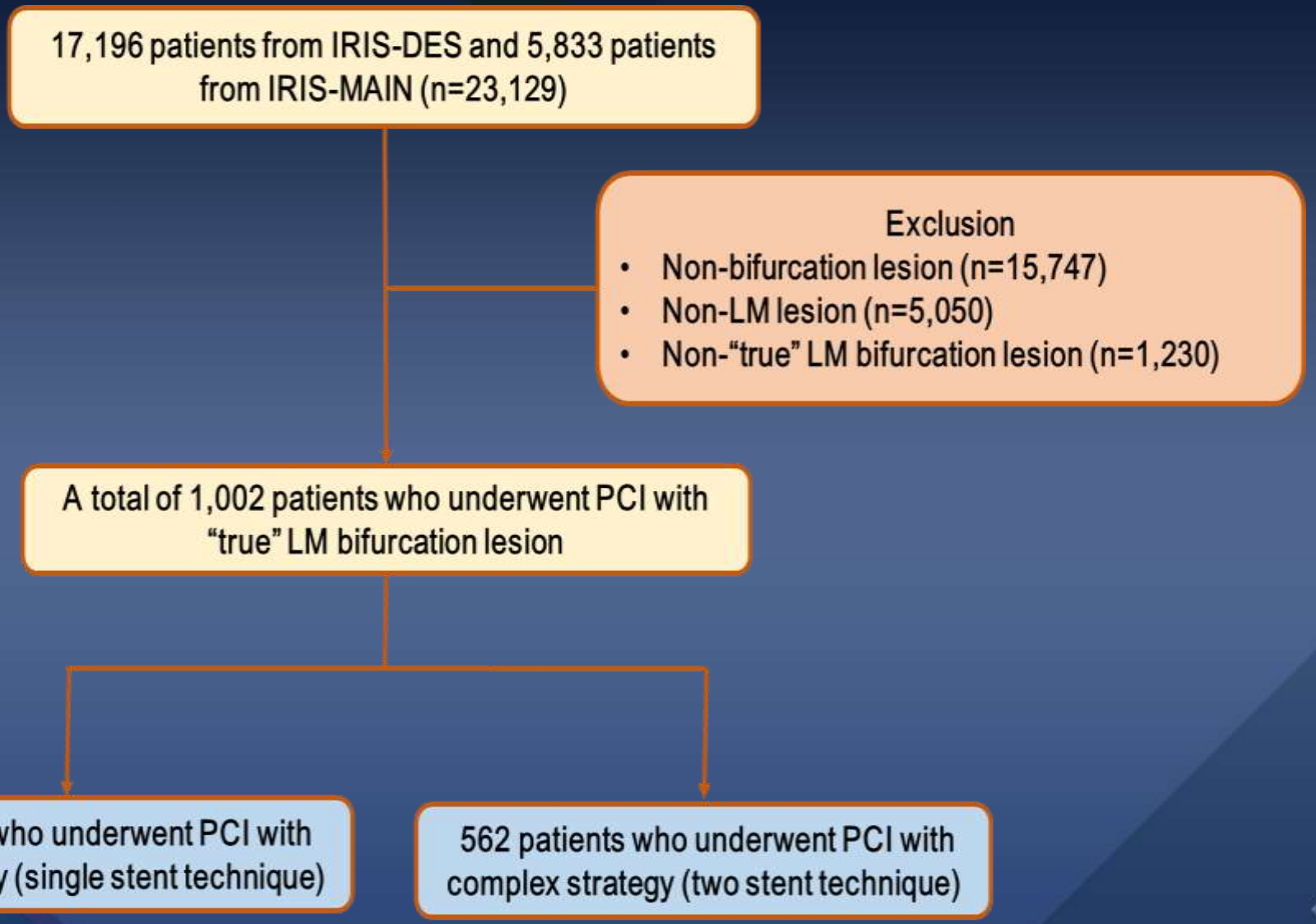
J Am Coll Cardiol 2018;71:832–41.

Population and Inclusion Criteria

- The study population were pooled from two large-scaled, independent, multicenter, observational studies of the IRIS-MAIN and IRIS-DES registry.

1. Distal LM bifurcation stenosis >50% with ischemic symptom or positive stress test
2. Medina type 1,1,1 or 0,1,1
3. LAD and LCX diameter both > 2.5mm

Study Population



Study Endpoints

Primary Endpoint

- Target-vessel failure
  : a composite of cardiac death, target-vessel MI, or clinically-indicated target-vessel revascularization [TVR]

Secondary Endpoints

- death (cardiac or non-cardiac), MI (Q-waver or Non-Q-wave), repeat revascularization (TVR or non-TVR), and stent thrombosis.

Baseline Clinical Characteristics

Characteristic	Unadjusted Data			IPTW-Adjusted		
	1-stent (*n* = 440)	2-stent (*n* = 562)	*P*	1-stent (*n* = 440)	2-stent (*n* = 562)	*P*
Age, year	64.4 ± 10.5	64.4 ± 9.8	0.97	64.5 ± 10.6	64.6 ± 9.9	0.93
Male sex, n (%)	340 (77.3)	438 (77.9)	0.86	339 (77.1)	434 (77.2)	0.96
Body mass index, kg/m^2	24.2 ± 3.0	24.7 ± 2.9	0.01	24.5 ± 3.1	24.5 ± 2.9	0.88
Hypertension	280 (63.6)	361 (64.2)	0.89	281 (64.0)	361 (64.1)	0.96
Diabetes mellitus	172 (39.1)	198 (35.2)	0.23	163 (37.0)	209 (37.1)	0.96
Current smoking	123 (28.0)	135 (24.0)	0.18	112 (25.4)	144 (25.5)	0.95
Hyperlipidemia	64 (14.5)	53 (9.4)	0.02	52 (11.9)	67 (11.8)	0.98
Previous MI	29 (6.6)	50 (8.9)	0.22	33 (7.6)	44 (7.8)	0.90
Previous PCI	77 (17.5)	121 (21.5)	0.13	87 (19.8)	111 (19.7)	0.97
Previous stroke	35 (8.0)	42 (7.5)	0.86	33 (7.4)	43 (7.6)	0.91
Previous heart failure	17 (3.9)	10 (1.8)	0.07	12 (2.6)	14 (2.5)	0.93

Baseline Clinical Characteristics

Characteristic	Unadjusted Data			IPTW-Adjusted		
	1-stent (*n* = 440)	2-stent (*n* = 562)	*P*	1-stent (*n* = 440)	2-stent (*n* = 562)	*P*
Chronic renal failure	11 (2.5)	20 (3.6)	0.43	19 (4.3)	25 (4.5)	0.85
Clinical presentation			0.06			0.47
Stable angina	206 (46.8)	274 (48.8)		219 (49.8)	268 (47.7)	
Unstable angina	145 (33.0)	206 (36.7)		142 (32.3)	202 (35.9)	
MI	89 (20.2)	82 (14.6)		79 (18.0)	92 (16.4)	
EF Mean, %	58.8 ± 10.5	59.6 ± 9.8	0.28	59.3 ±10.2	59.2 ± 10.1	0.94
Discharge medications						
Aspirin	427 (97.0)	557 (99.1)	0.03	432 (98.2)	552 (98.2)	0.99
ADP receptor antagonist	420 (95.5)	542 (96.4)	0.52	422 (96.0)	540 (96.0)	0.99
β-blocker	248 (56.4)	312 (55.5)	0.83	245 (55.6)	313 (55.6)	0.99
Calcium channel blocker	212 (48.2)	268 (47.7)	0.92	209 (47.6)	268 (47.7)	0.98
ACE inhibitor or ARB	204 (46.4)	254 (45.2)	0.76	197 (44.9)	252 (44.8)	0.97
Statin	167 (38.0)	221 (39.3)	0.70	170 (38.7)	217 (38.6)	0.97

Angiographic and Procedural Characteristics

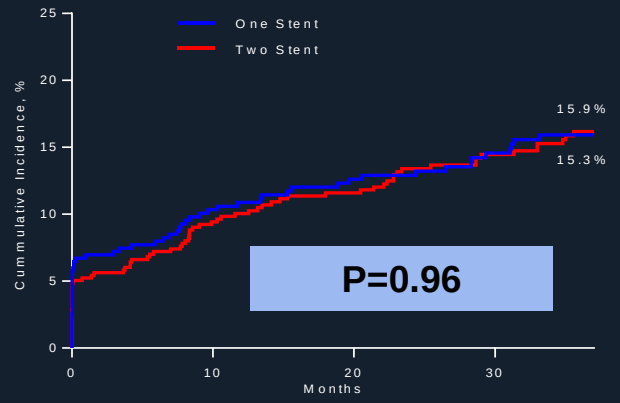
Characteristic	Unadjusted Data			IPTW-Adjusted		
	1-stent (*n* = 440)	2-stent (*n* = 562)	*P*	1-stent (*n* = 440)	2-stent (*n* = 562)	*P*
Disease extent			0.46			0.98
2-vessel disease	327 (74.3)	430 (76.5)		333 (75.8)	426 (75.7)	
3-vessel disease	113 (25.7)	132 (23.5)		107 (24.2)	136 (24.3)	
Medina			0.99			0.79
1.1.1	412 (93.6)	525 (93.4)		411 (93.6)	524 (93.1)	
0.1.1	28 (6.4)	37 (6.6)		29 (6.4)	42 (6.9)	
Use of IVUS	323 (73.4)	432 (76.9)	0.23	329 (74.8)	422 (75.0)	0.95

Angiographic and Procedural Characteristics

Characteristic	Unadjusted Data			IPTW-Adjusted		
	1-stent (*n* = 440)	2-stent (*n* = 562)	*P*	1-stent (*n* = 440)	2-stent (*n* = 562)	*P*
DES type			0.47			0.93
1st-generation						
SES	94 (21.4)	151 (26.9)		107 (24.4)	139 (24.7)	
PES	5 (1.1)	5 (0.9)		5 (1.2)	4 (0.8)	
2nd-generation						
CoCr-EES	118 (26.8)	147 (26.2)		112 (25.4)	151 (26.9)	
PtCr-EES	82 (18.6)	105 (18.7)		80 (18.1)	107 (19.0)	
PC-ZES	73 (16.6)	81 (14.4)		70 (15.8)	83 (14.8)	
Re-ZES	28 (6.4)	21 (3.7)		27 (6.0)	25 (4.4)	
BES	32 (7.3)	36 (6.4)		30 (6.9)	37 (6.7)	
Others	8 (1.8)	16 (2.8)		10 (2.1)	15 (2.7)	

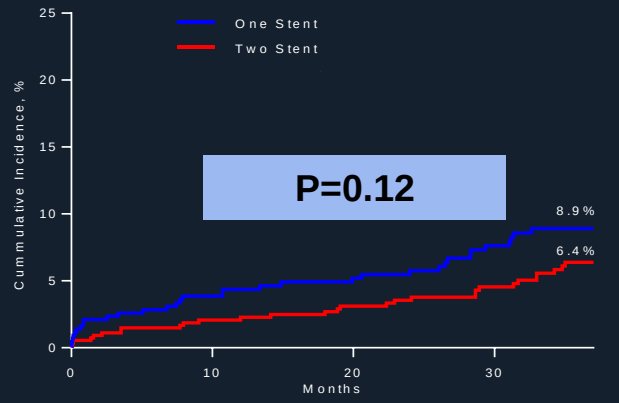
Unadjusted 3-Year Event Rate of Clinical Outcome

TVF



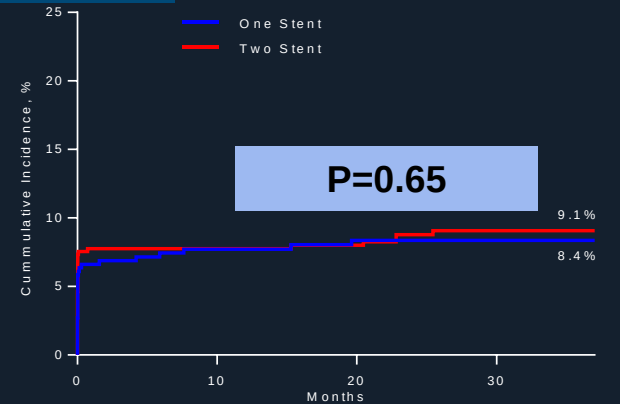
No. at Risk					
One Stent	440	336	301	255	219
Two Stetn	562	445	397	320	266

Death



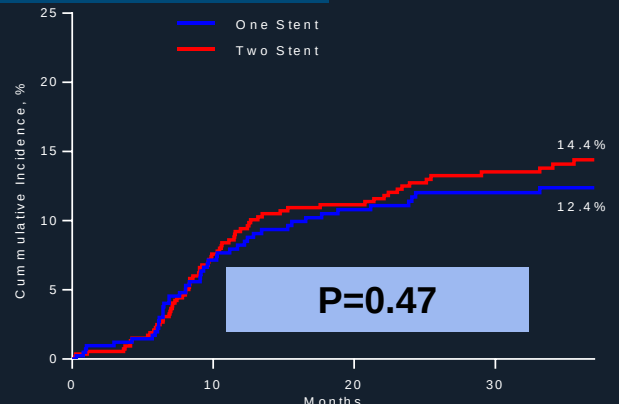
No. at Risk					
One Stent	440	376	345	295	258
Two Stetn	562	503	454	376	318

MI



No. at Risk					
One Stent	440	316	288	248	214
Two Stetn	562	412	369	298	246

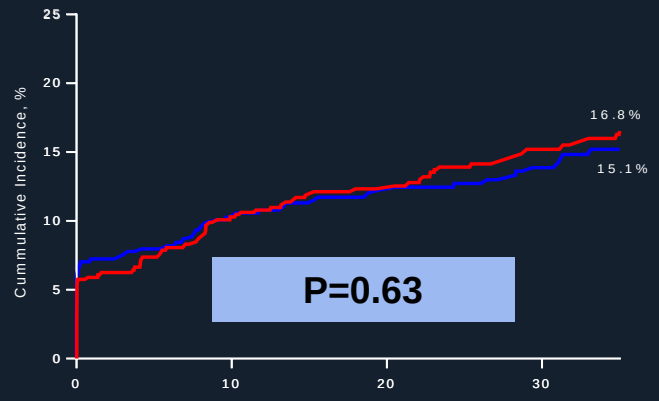
Revascularization



No. at Risk					
One Stent	440	351	308	257	221
Two Stetn	562	464	402	321	264

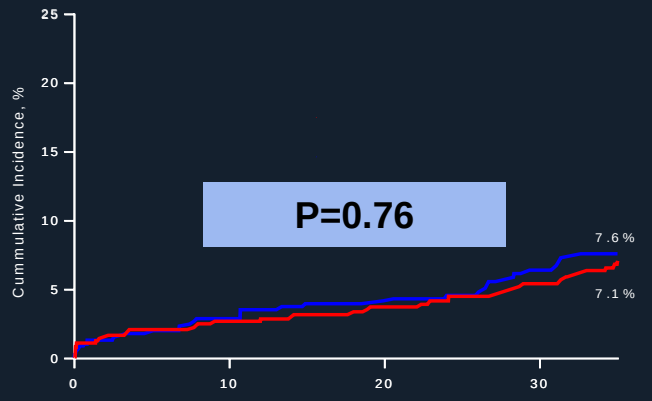
IPTW-Adjusted Outcomes

TVF



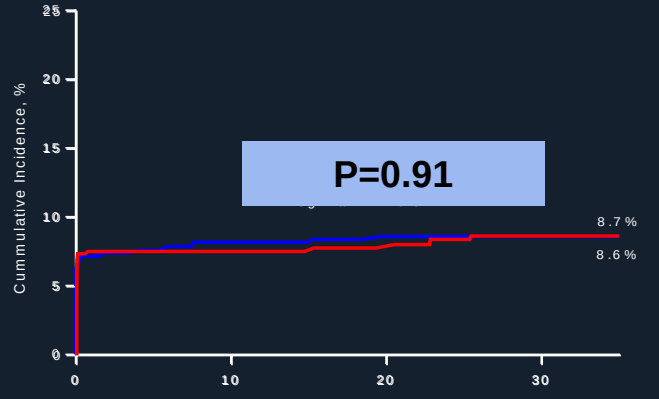
No. at Risk					
One Stent	440	395	386	379	373
Two Stent	562	504	493	476	467

Death



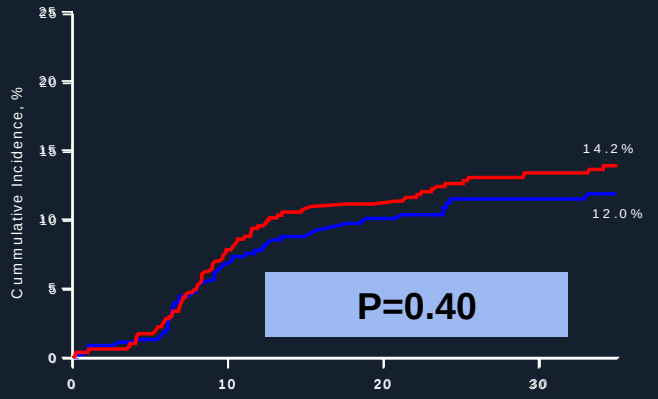
No. at Risk					
One Stent	440	427	422	412	407
Two Stent	562	547	541	531	522

MI



No. at Risk					
One Stent	440	404	402	402	402
Two Stent	562	519	518	513	513

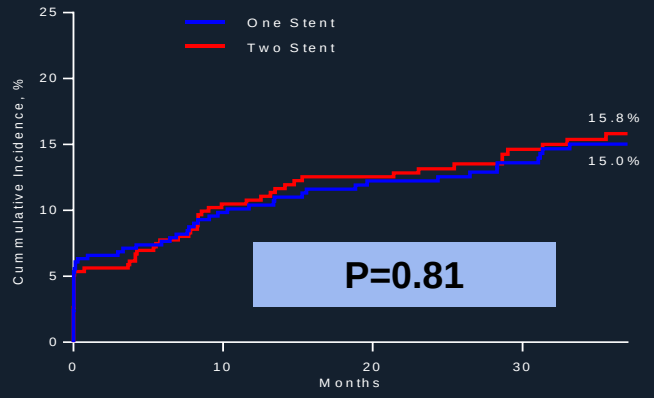
Revascularization



No. at Risk					
One Stent	440	410	395	389	387
Two Stent	562	518	500	487	482

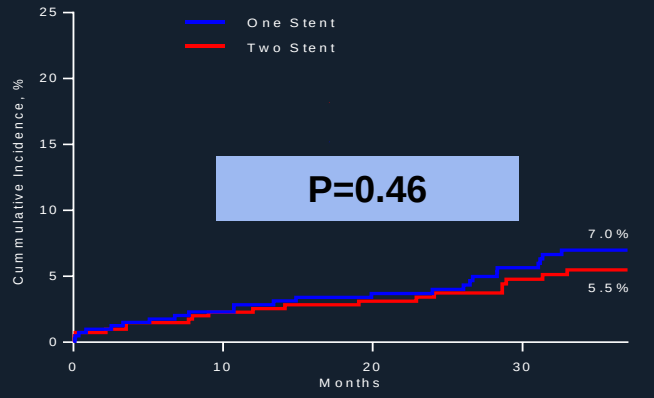
PS Matching-Adjusted Outcome

TVF



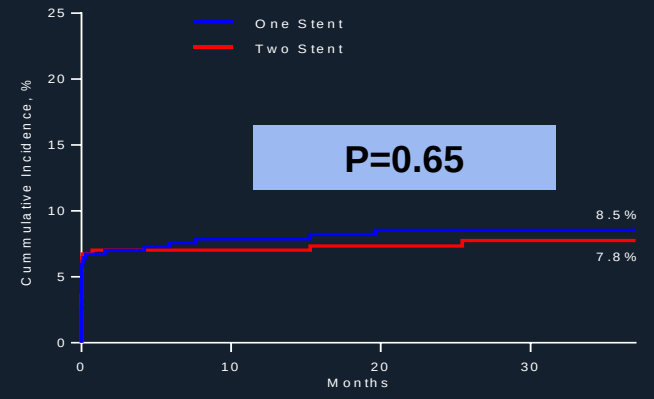
No. at Risk					
One Stent	417	323	289	246	211
Two Stetn	417	325	290	231	189

Death



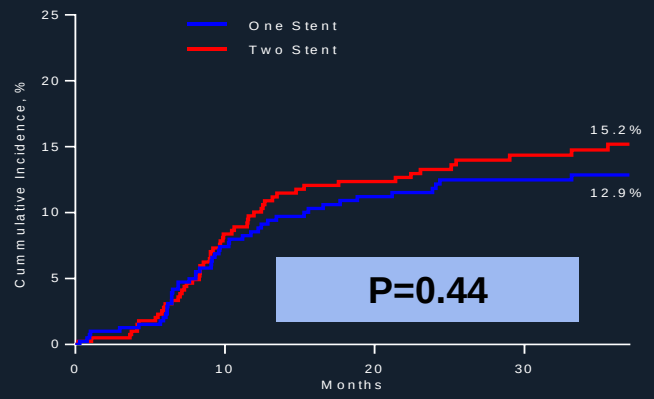
No. at Risk					
One Stent	417	363	332	286	250
Two Stetn	417	374	336	272	226

MI



No. at Risk					
One Stent	417	305	277	240	207
Two Stetn	417	311	279	224	182

Revascularization



No. at Risk					
One Stent	417	338	295	248	216
Two Stetn	417	342	293	230	189

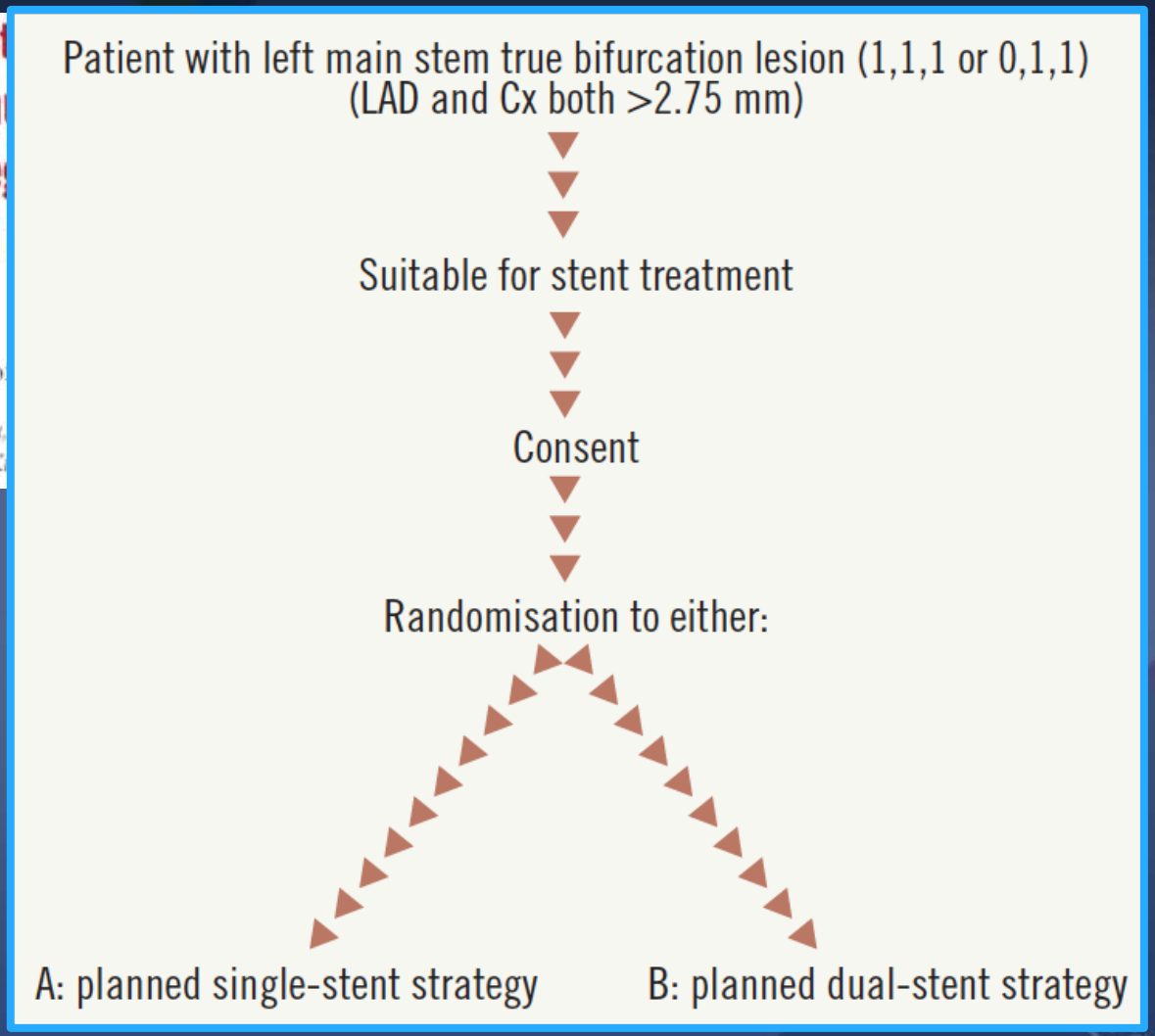
Better Strategy for Distal LM bifurcation?

EBC-MAIN Trial

The European Bifurcation Club Left Main St
rationale and design of an international, m
randomised comparison of two stent strate
treatment of left main coronary bifurcation

Alaide Chieffo[1*], MD; David Hildick-Smith[2], MD; on behalf o

1. Interventional Cardiology Unit, San Raffaele Scientific Institute, Milan,
Brighton and Sussex University Hospitals NHS Trust, Brighton, United K



Chieffo A. al, Eurointervention 2016;12:47-52

2-Stent Bifurcation Techniques for Distal Left Main Disease

- DKCRUSH, Mini-crush (or step crush)
- T-stent, modified T-stent or TAP
- Culotte, Szabo Culotte
- V-stent
- Y-stent (SKS-simultaneous kissing stents)
- Etc…

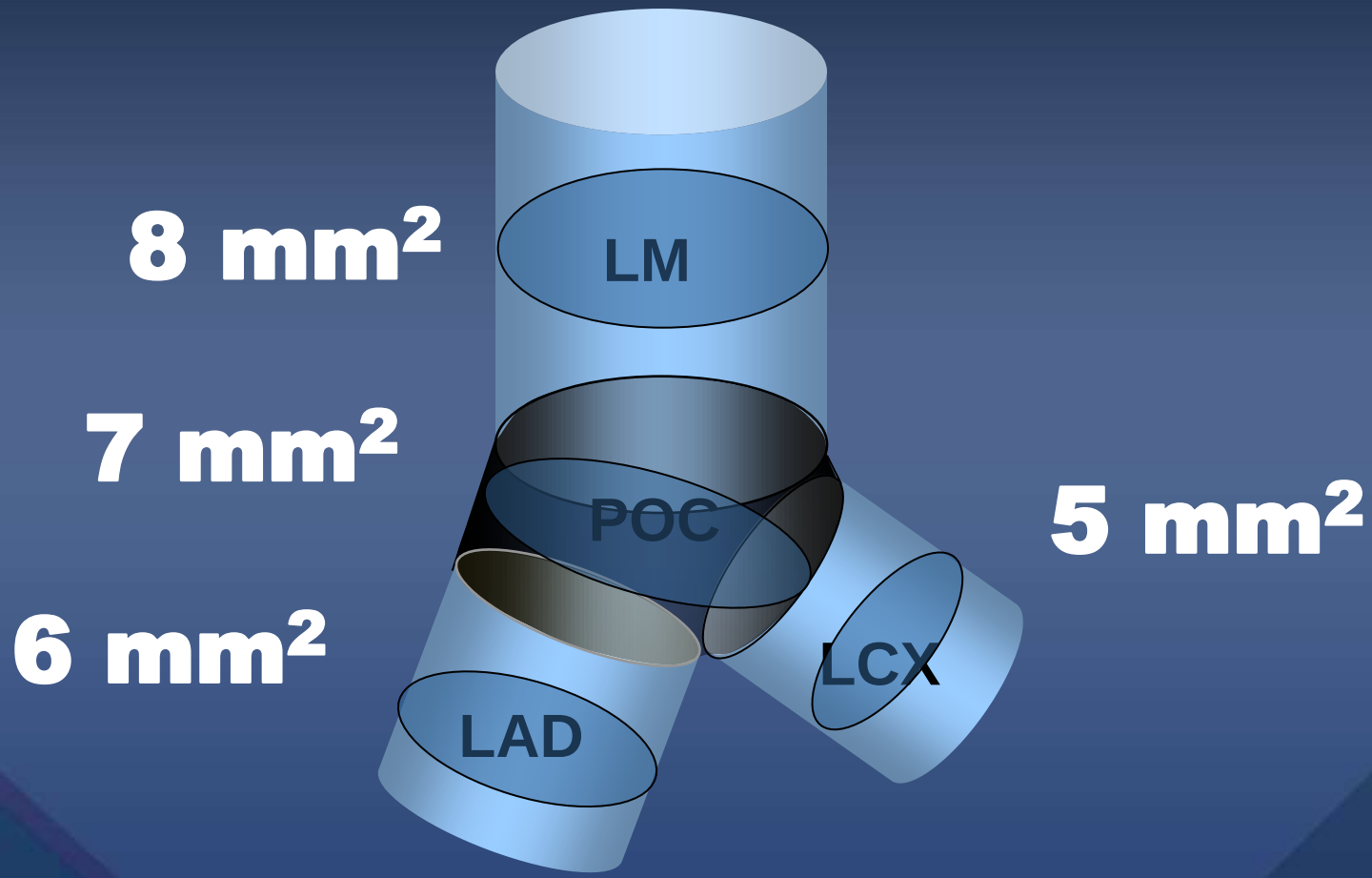
Any Different Outcomes ?
with Different 2 Stent Techniques

- Different Indications,
- Very Limited Data,
- Small Difference in Soft End Point (Late Loss, TLR, Branch Restenosis) without Any Hard Endpoint Difference (Death or MI).

IVUS Impact in LM Bifurcation PCI:

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

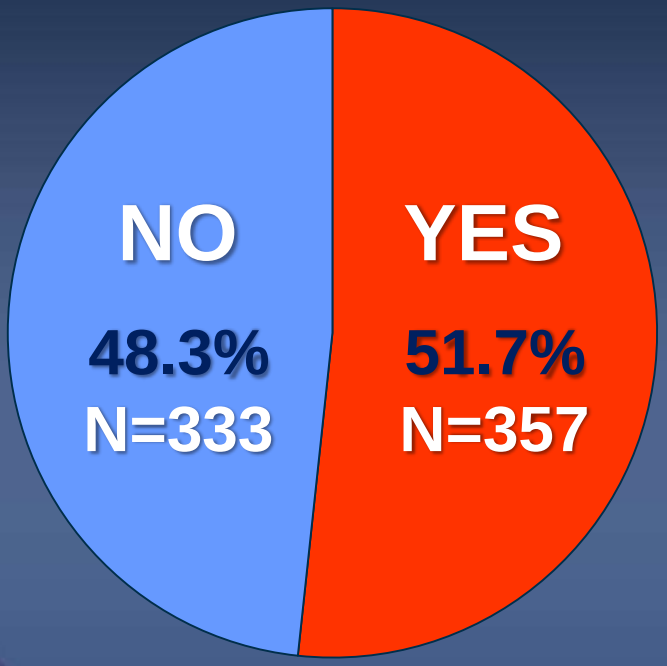
Restenosis Rate < 5% and TLR < 2%



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

IVUS-guided PCI in EXCEL Trial: 690/935 pts (74%)

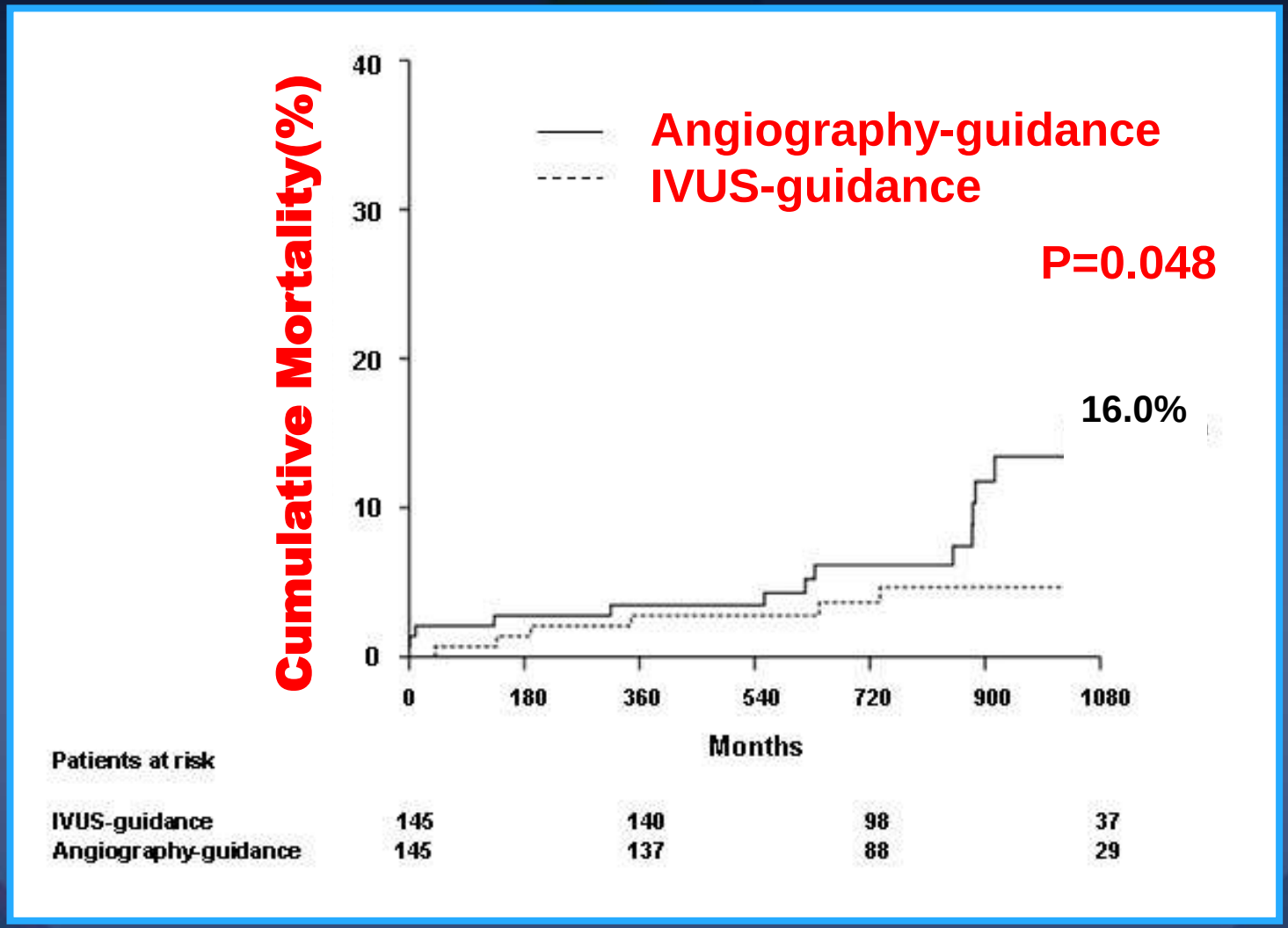
Change in LM stenting by IVUS



- 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)

Maehara A. TCT 2016

IVUS Guidance Saves Lives in Left Main PCI



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

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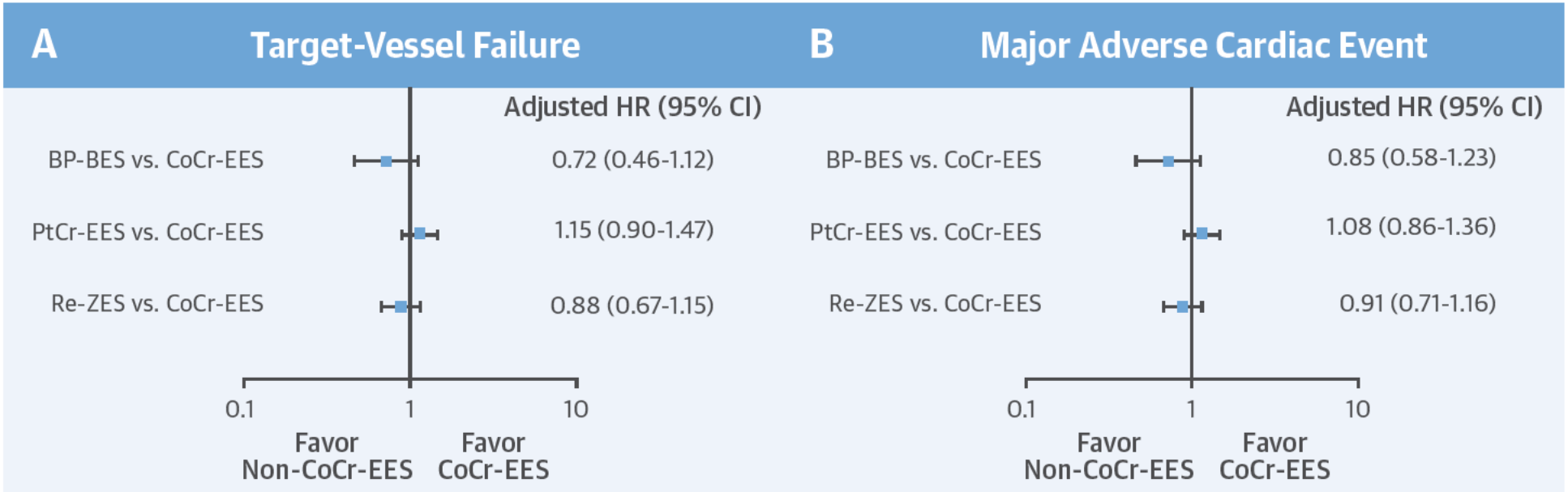
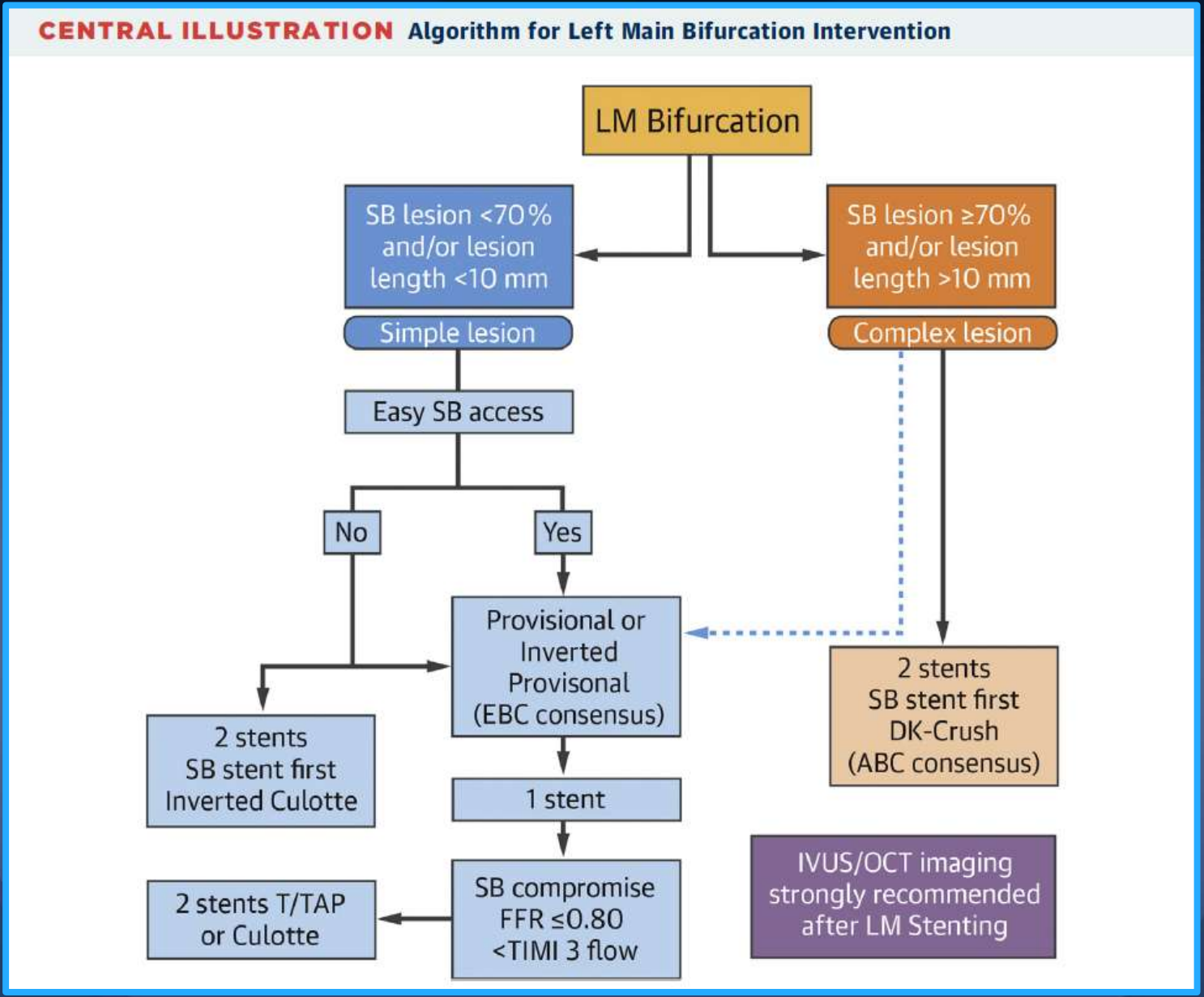
Safety and Effectiveness of Second-Generation Drug-Eluting Stents in Patients With Left Main Coronary Artery Disease

CENTRAL ILLUSTRATION **Comparison Between Outcomes of Different Types of Drug-Eluting Stents in the Propensity-Score Analyses: Adjusted HR**



Lee, P.H. et al. J Am Coll Cardiol. 2018;71(8):832–41.

Current PCI for Distal LM bifurcation



Rab, T. et al. J Am Coll Cardiol Intv. 2017;10(9):849–65.

Distal LM Bifurcation PCI
How To Do ?

- Provisional approach is recommended in most of distal LM disease.
- According to the status of SB (LCX) disease, either 1- or any 2-stent strategy is selected in the contemporary PCI with second-generation DES.
- Side branch strategy with functional concept (FFR-guided) can make a good clinical outcomes.
- Whatever you used 2-stent technique, imaging concept (IVUS optimization-effective stent area, 5.6.7.8 mm^2) can make a good clinical outcomes.