

Contemporary Bifurcation PCI: How Advance Over Time?

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Coronary bifurcation lesion

- Approximately 15–20% of all coronary lesion
- One of the most challenging therapeutic procedures.
- Outcomes for bifurcation lesions have steadily improved since last decades
- Controversies about best treatment strategy in bifurcation lesions

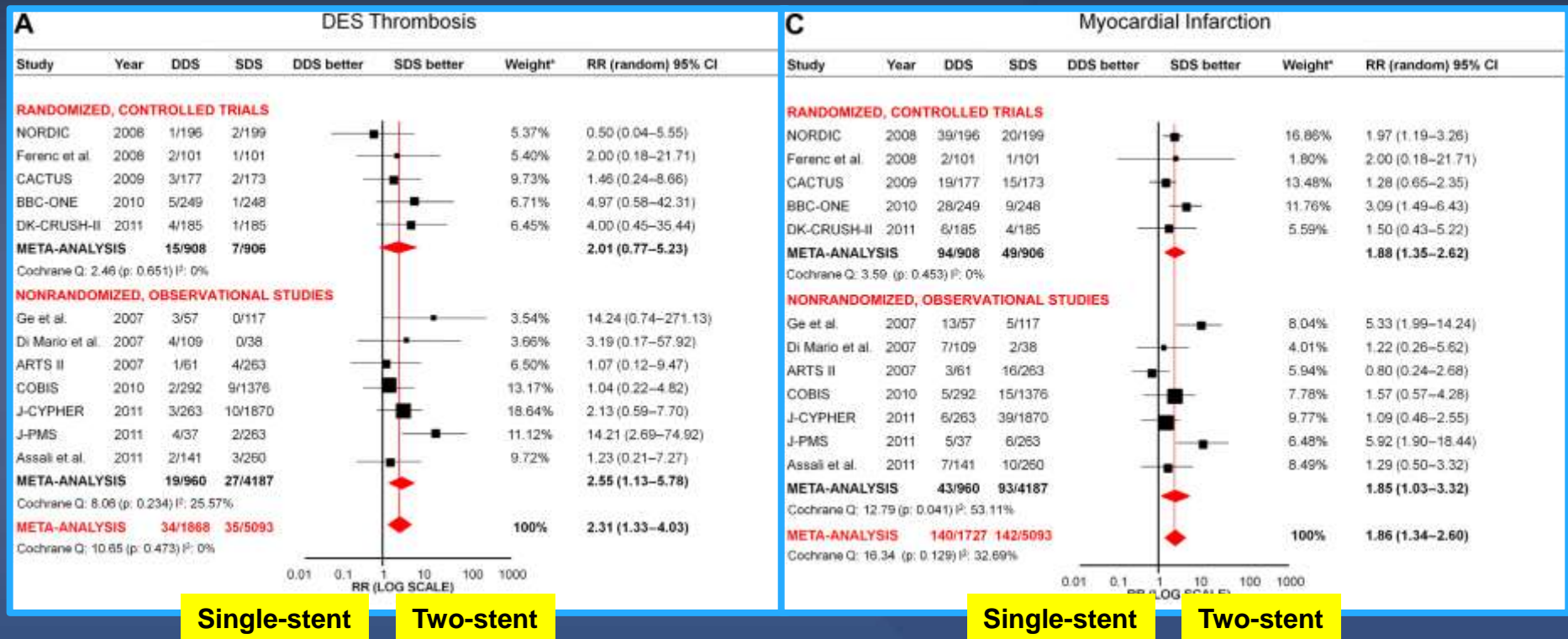
Bifurcation PCI

What We Know?

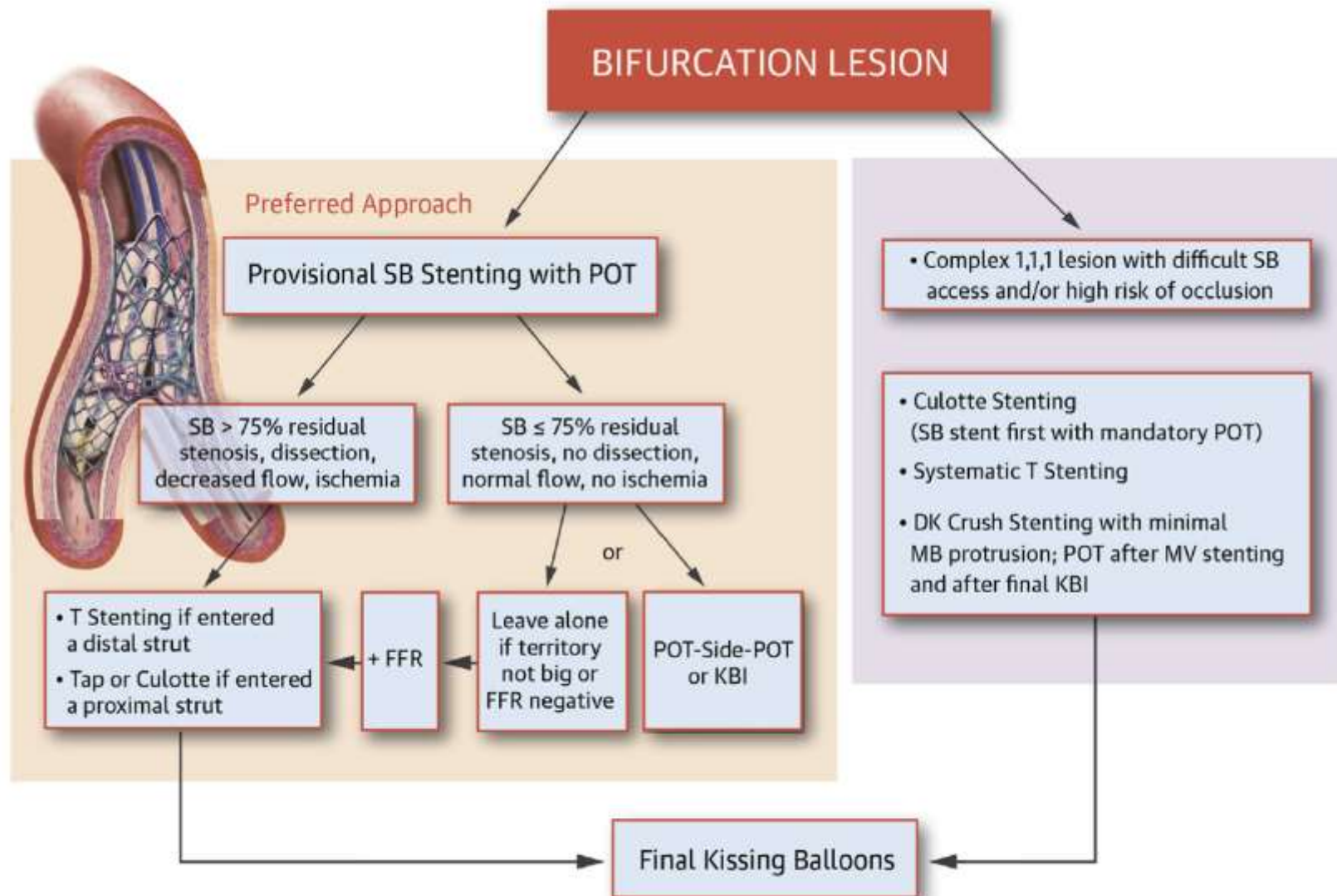
- 1. Single stent strategy with provisional stenting of SB**
- 2. Two-stents strategy**

Meta-Analysis of 12 Major Studies, 6961 Patients (5 RCTs and 7 observational studies)

Provisional Single-Stenting is better than Double-Stenting



CENTRAL ILLUSTRATION Simplified Approach to Treatment of Bifurcation Lesions



* Imaging encouraged in all bifurcation stenting, especially with LM stenting

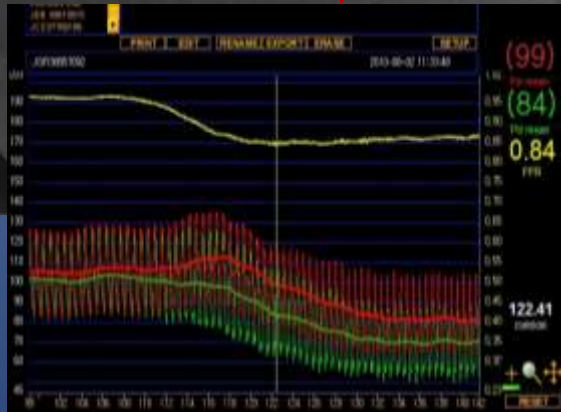
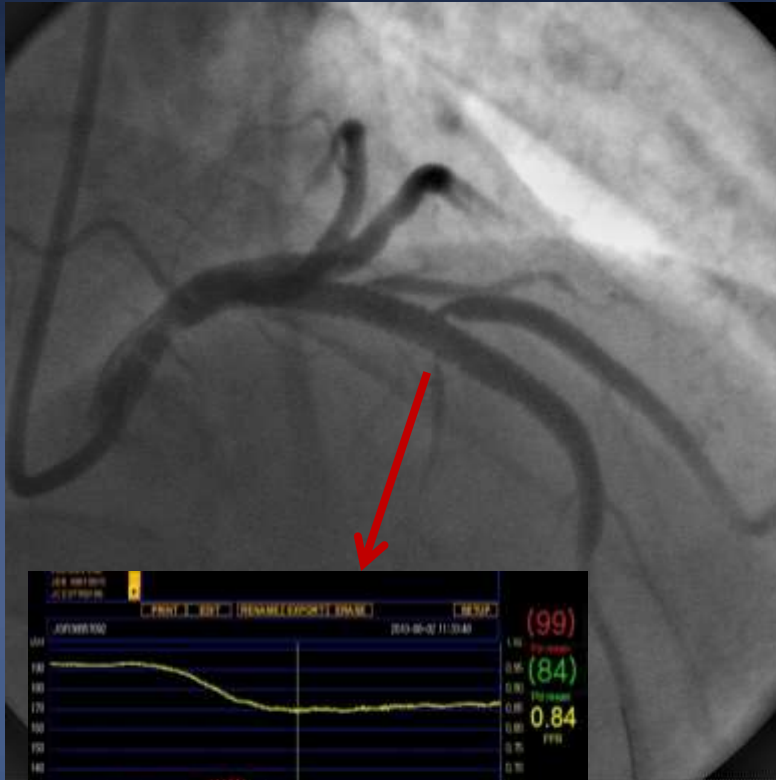
What Really Matters in Bifurcation PCI; *Techniques or Concept?*

**There has been conceptual changes for
bifurcation PCI !!**

- **Functional Concept**
- **Imaging Concept**

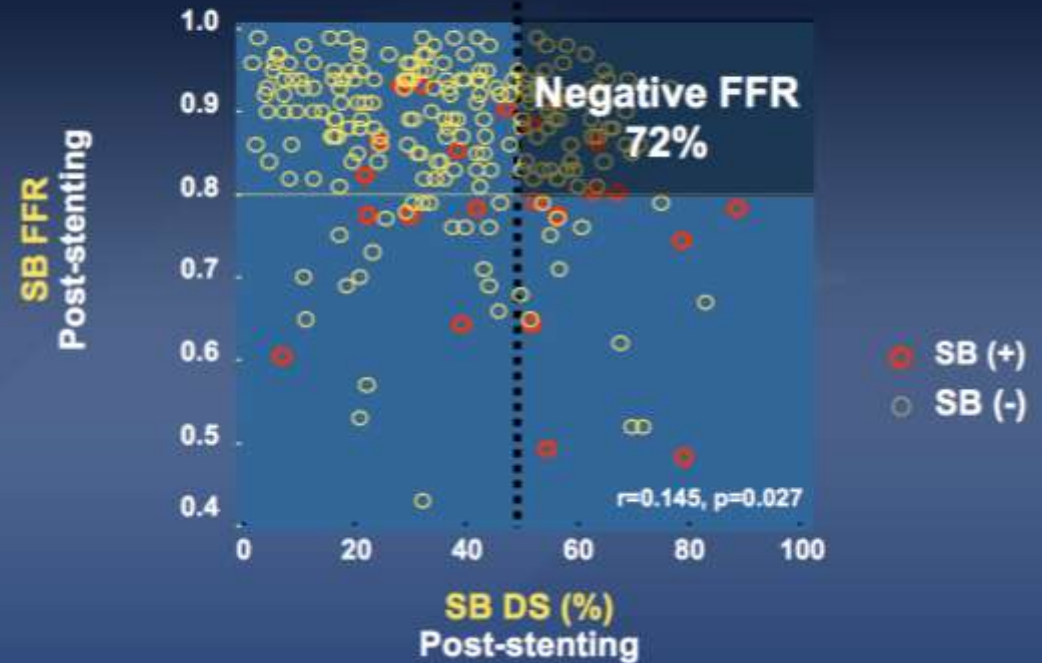
Functional Concept of Bifurcation PCI

To Treat or Not To Treat ?



FFR 0.84

Side Branch FFR After Main Vessel Stenting (n=232)

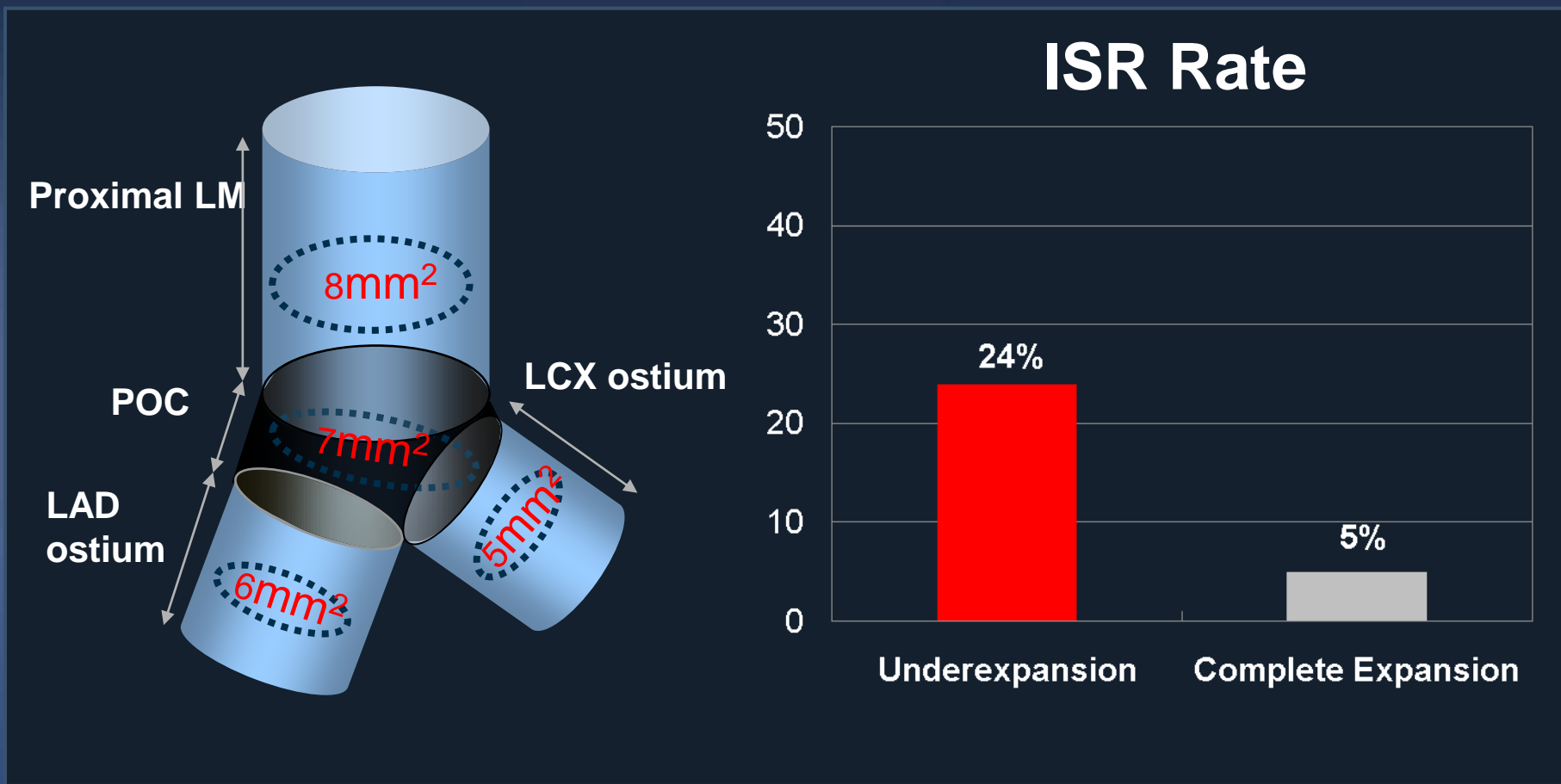


Ahn JM et al, JACC Cardiovasc Interv. 2011 Feb;5(2):155-61

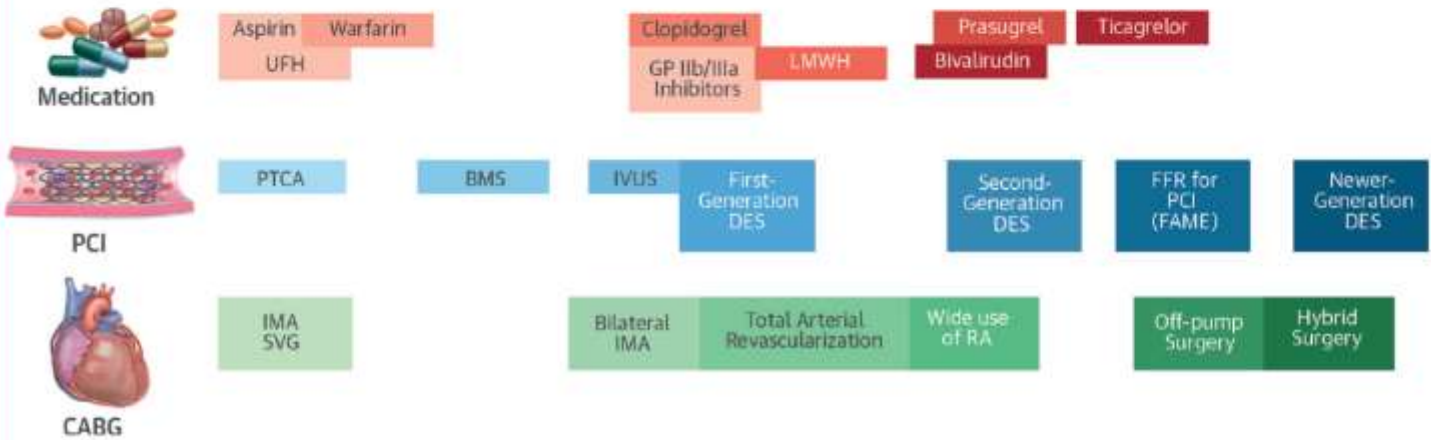
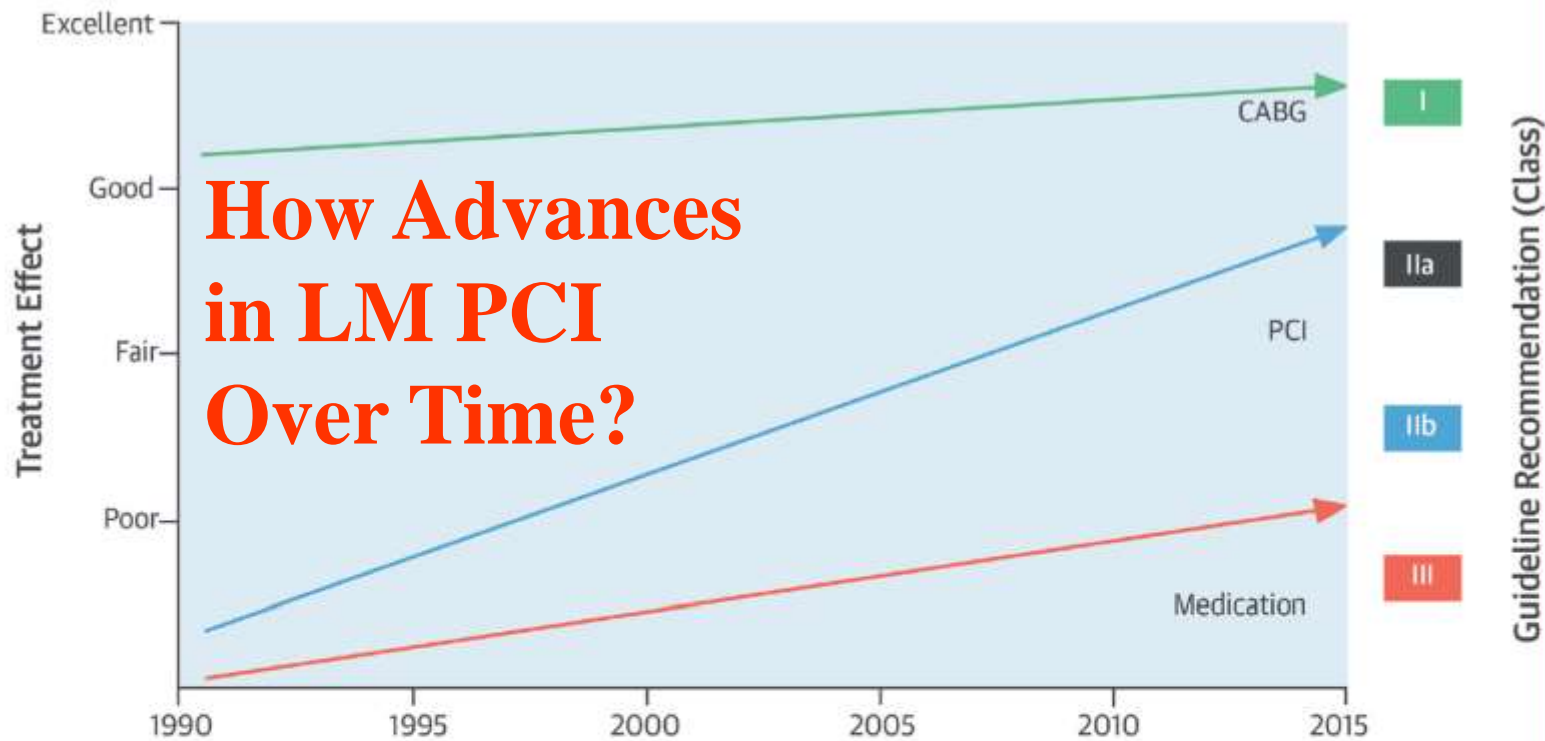
Imaging Concept of Bifurcation PCI

Rule of Thumb - Effective Stent Area
(Rule of 5,6,7,8 mm²)

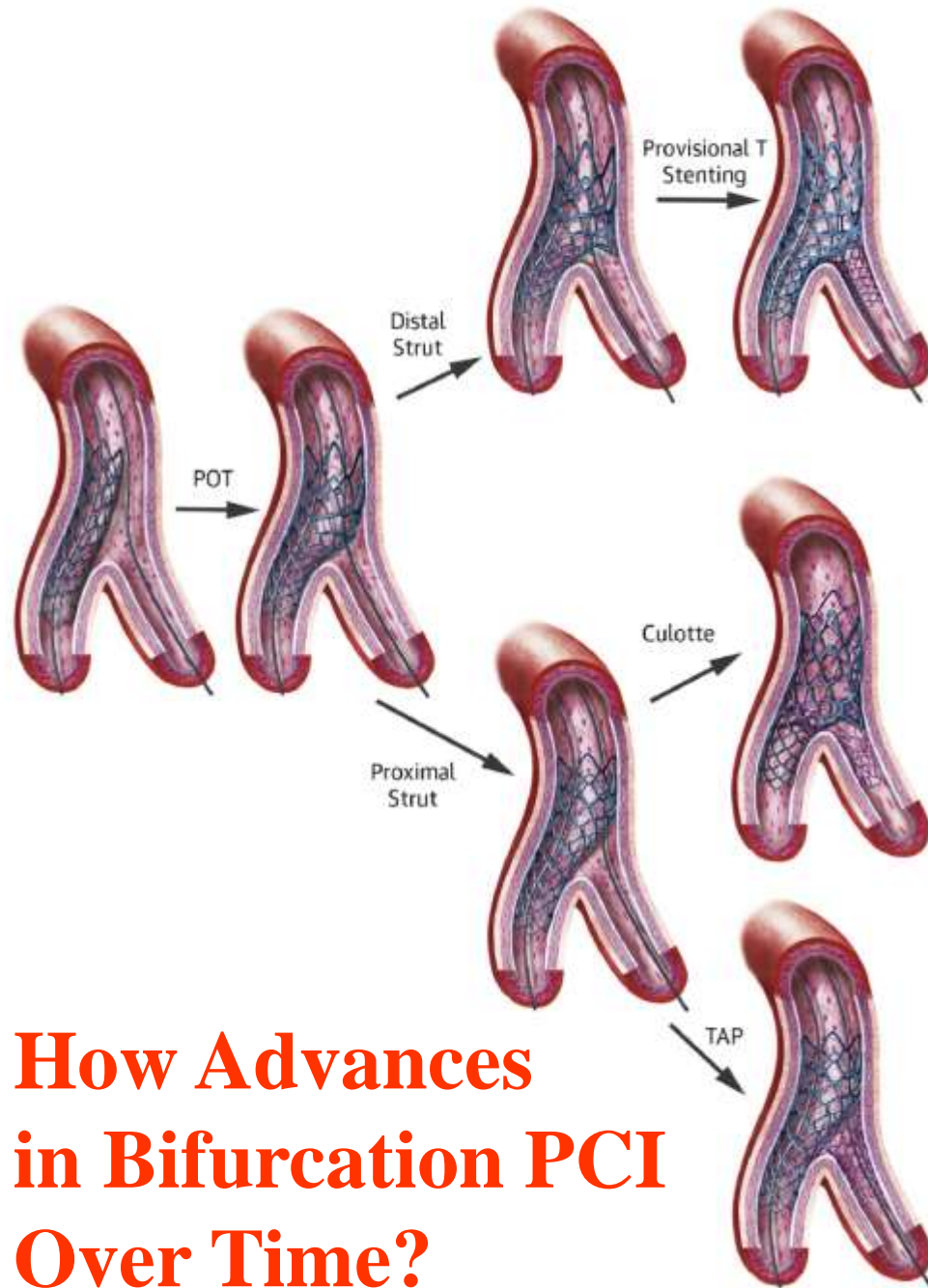
Restenosis Rate < 5% and TLR < 2%



CENTRAL ILLUSTRATION Secular Changes of Treatment Effect and Guideline Recommendations in Relation to Medical Advances of Each Treatment Stratum for Left Main Coronary Artery Disease



Lee, P.H. et al. J Am Coll Cardiol. 2016;68(11):1233-46.



How Advances in Bifurcation PCI Over Time?

Study Population

Study Inclusion Criteria

- Patients with LM and non-LM coronary bifurcation lesions treated with PCI were included from **IRIS-DES** and **IRIS-MAIN** registries

Primary Outcome

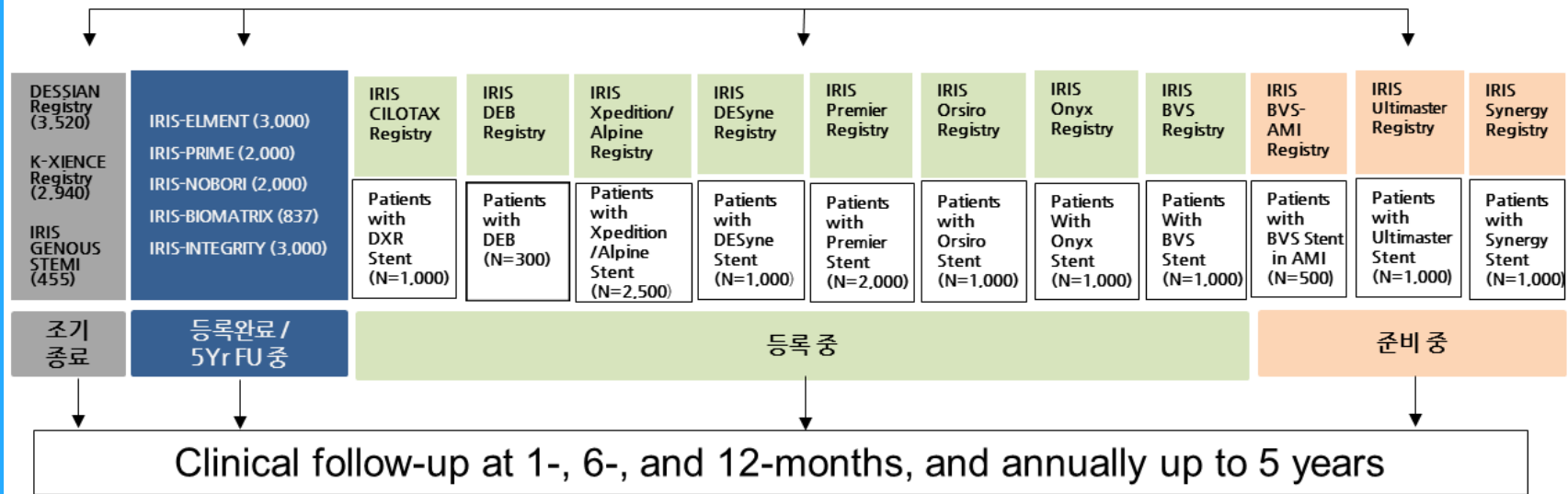
- **Target-vessel failure: a composite of cardiac death, target-vessel MI, clinical driven TVR**

Evaluation of Effectiveness and Safety of the First, Second, and New Drug-Eluting Stents in Routine Clinical Practice;

IRIS-DES Registry

Consecutive PCI patients receiving New DES without a mixture of other DES

Prospective Enrollment



***Primary end point: Composite of Death, MI, and TVR at 12-months**

IRIS-MAIN Registry

A GLOBAL, MULTICENTER, PROSPECTIVE, REAL WORLD OBSERVATIONAL STUDY
FOR UNPROTECTED LEFT MAIN DISEASE

All patients with LMCA disease: More than total 5,000 patients

PCI with any DES

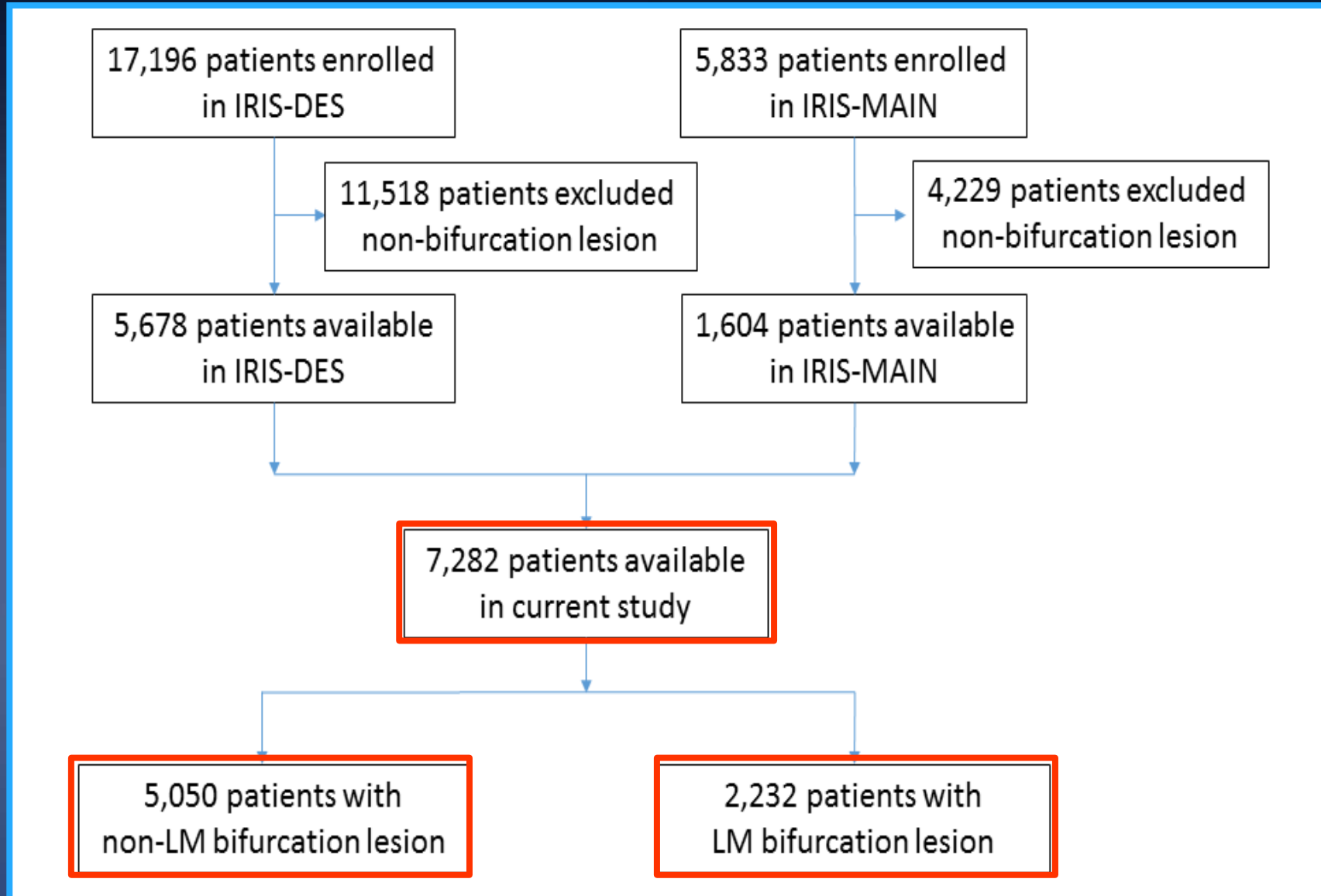
CABG

Medication
Treatment

Clinical follow-up at 1-, 6-, 12-months, and up to 10 years

***Primary end point:** Composite of Death, MI, stroke and TVR at 2Year

Flow Diagram of Study Population



Baseline characteristics

Characteristic	Non-LM Bifurcations (N = 5050)			LM Bifurcations (N = 2232)		
	1 st -generation DES (N=929)	2 nd -generation DES (N=4121)	P	1 st -generation DES (N=451)	2 nd -generation DES (N=1781)	P
Age, years	62.9 ± 10.5	63.6 ± 10.7	0.050	62.6 ± 10.5	64.9 ± 10.2	<0.001
Male sex	636 (68.5)	2935 (71.2)	0.100	355 (78.7)	1390 (78.0%)	0.810
BMI, kg/m ²	24.7 ± 2.9	24.7 ± 3.1	0.630	24.6 ± 2.7	24.4 ± 3.1	0.300
HTN	564 (60.7)	2523 (61.2)	0.800	265 (58.8)	1149 (64.5)	0.030
DM	306 (32.9)	1315 (31.9)	0.570	178 (39.5)	643 (36.1)	0.200
Requiring insulin	56 (6.0)	165 (4.0)	0.010	24 (5.3)	103 (5.8)	0.790
Current smoking	254 (27.3)	1219 (29.6)	0.190	125 (27.7)	436 (24.5)	0.180
Hyperlipidemia	402 (43.3)	1837 (44.6)	0.490	55 (53.4)	299 (57.2)	0.550
Previous MI	54 (5.8)	178 (4.3)	0.060	40 (8.9)	125 (7.0)	0.220
Previous PCI	130 (14.0)	353 (8.6)	<0.001	94 (20.8)	301 (16.9)	0.060
Previous stroke	74 (8.0)	293 (7.1)	0.400	34 (7.5)	142 (8.0)	0.840
Previous CHF	22 (2.4)	94 (2.3)	0.970	8 (1.8)	50 (2.8)	0.290

Baseline characteristics

Characteristic	Non-LM Bifurcations (N = 5050)			LM Bifurcations (N = 2232)		
	1 st -generation DES (N=929)	2 nd -generation DES (N=4121)	P	1 st -generation DES (N=451)	2 nd -generation DES (N=1781)	P
Atrial fibrillation	36 (3.9)	125 (3.0)	0.220	12 (2.7)	46 (2.6)	>0.99
Family hx. of CAD	42 (4.5)	296 (7.2)	0.004	47 (10.4)	161 (9.1)	0.420
Chronic lung disease	22 (2.4)	99 (2.4)	>0.99	11 (2.4)	48 (2.7)	0.890
Chronic renal failure	35 (3.8)	143 (3.5)	0.730	11 (2.4)	81 (4.5)	0.060
Peripheral v. disease	7 (0.8)	106 (2.6)	0.001	9 (2.0)	75 (4.2)	0.040
Clinical presentation			<0.001			0.009
Stable angina	459 (49.4)	1715 (41.6)		243 (53.9)	820 (46.0)	
Unstable angina	283 (30.5)	1335 (32.4)		147 (32.6)	654 (36.7)	
MI	187 (20.1)	1071 (26.0)		61 (13.5)	307 (17.2)	
Ejection fraction						
Mean, %	58.6 ± 9.5	58.5 ± 9.9	0.910	60.4 ± 8.6	58.8 ± 10.3	0.002

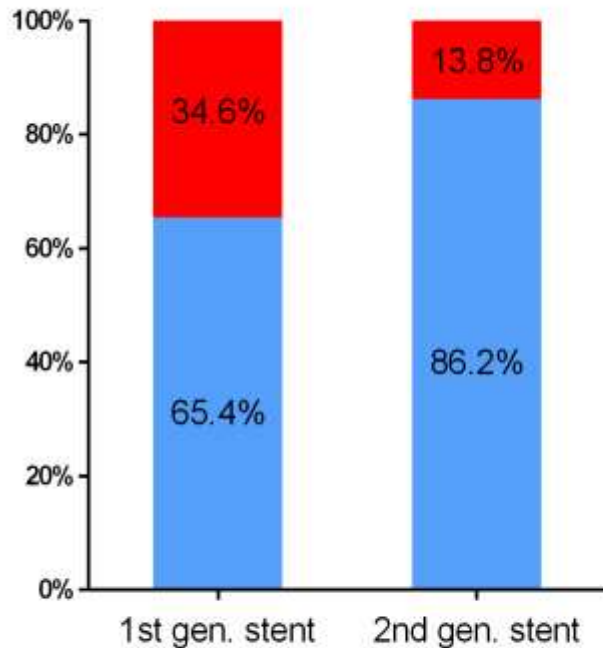
Angiographic characteristics

Characteristic	Non-LM Bifurcations (N = 5050)			LM Bifurcations (N = 2232)		
	1 st -generation DES (N=929)	2 nd -generation DES (N=4121)	P	1 st -generation DES (N=451)	2 nd -generation DES (N=1781)	P
Bifurcation lesion			0.09			NA
LM	0	0		451 (100.0)	1781 (100.0)	
LAD	729 (78.5)	3099 (75.2)		0	0	
LCX	152 (16.4)	796 (19.3)		0	0	
RCA	48 (5.2)	226 (5.5)		0	0	
Disease extent			0.01			0.11
1-VD	585 (63.0)	2808 (68.1)		0	0	
2-VD	290 (31.2)	1113 (27.0)		334 (74.1)	1383 (77.7)	
3-VD	54 (5.8)	200 (4.9)		117 (25.9)	398 (22.3)	
Stenting strategy			<0.001			<0.001
Simple-crossover	624 (67.2)	3755 (91.1)		278 (61.6)	1335 (75.0)	
2-stent strategy	305 (32.8)	366 (8.9)		173 (38.4)	446 (25.0)	

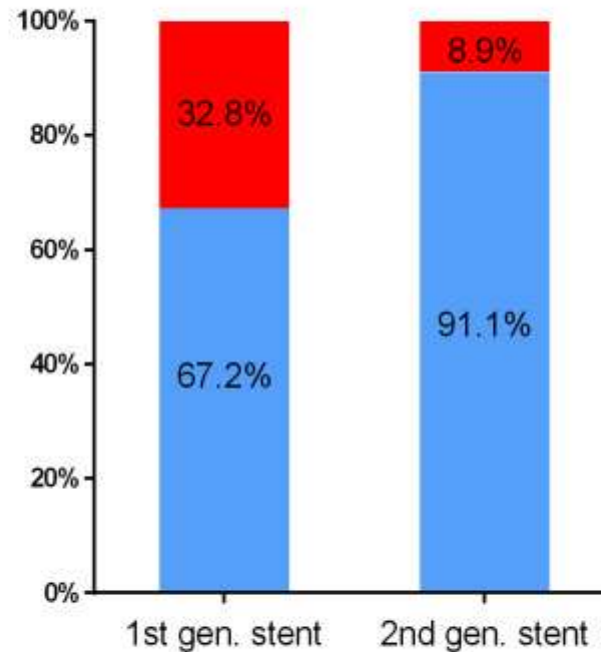
Simple vs. complex stent strategy

Over time from 1st-DES to 2nd-DES

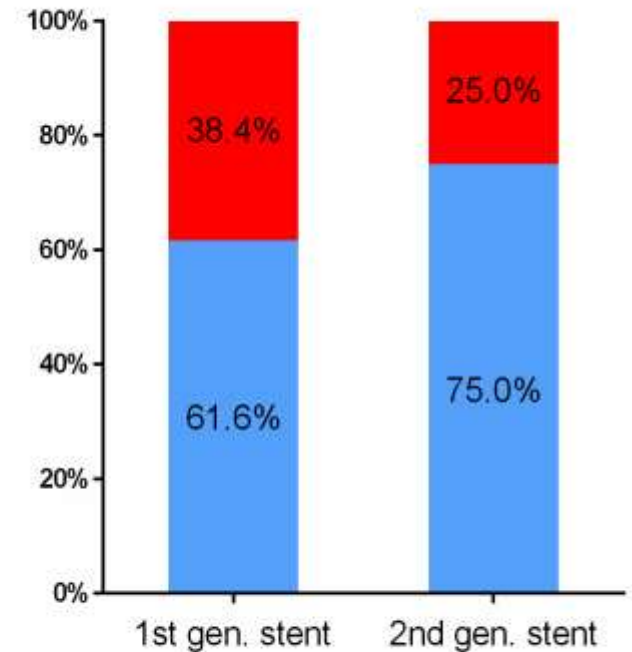
A All Bifurcations



B Non-LM Bifurcations



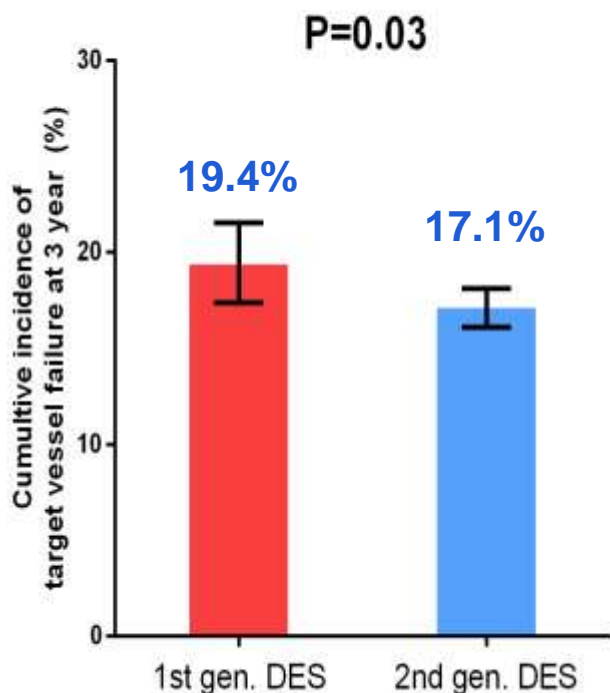
C LM Bifurcations



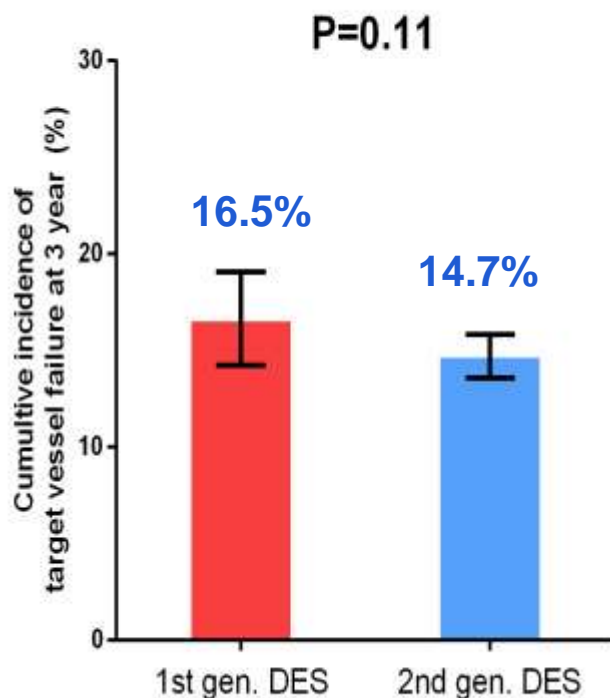
■ Two-stent strategy
■ Simple crossover

Primary Outcome (Target-Vessel Failure) Over time from 1st-DES to 2nd-DES

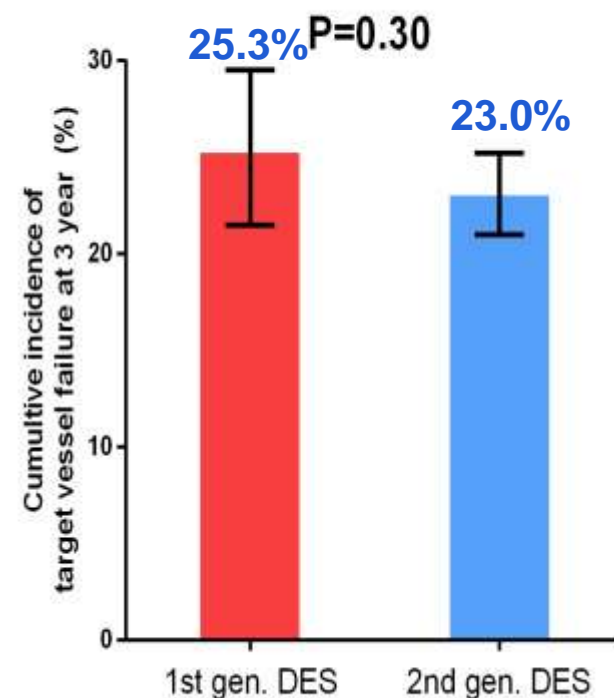
A All Bifurcations



B Non-LM Bifurcations



C LM Bifurcations



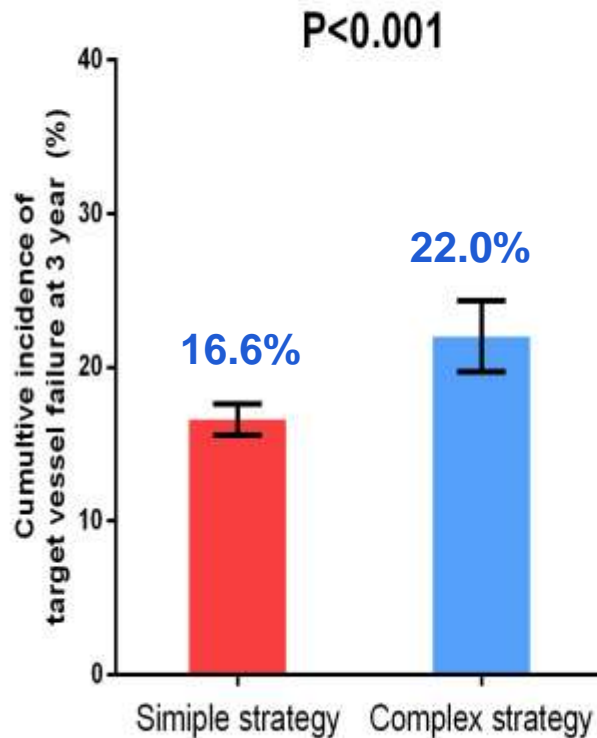
TVR: composite of cardiac death, target-vessel MI, clinical driven TVR

Clinical outcomes according to stent generation

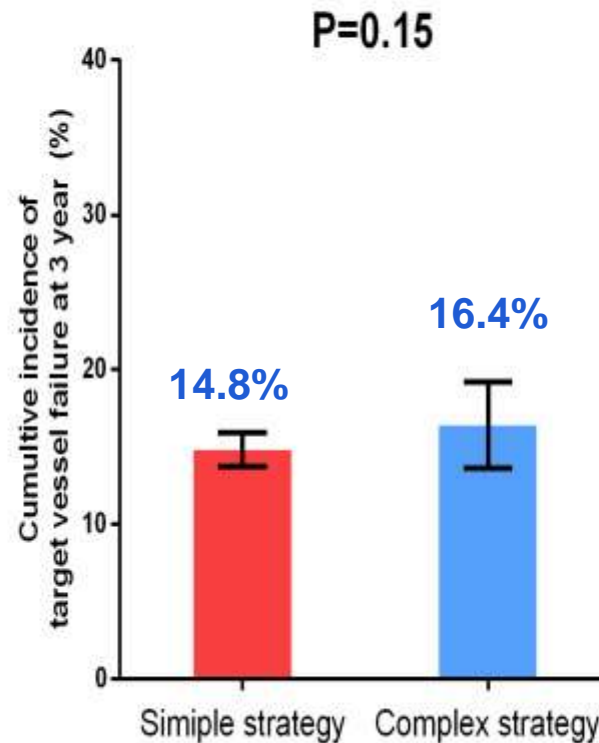
Characteristic	Non-LM Bifurcations (N = 5050)			LM Bifurcations (N = 2232)		
	1 st -generation DES (N=929)	2 nd -generation DES (N=4121)	P	1 st -generation DES (N=451)	2 nd -generation DES (N=1781)	P
Primary outcome						
Target-vessel failure	16.5 (14.1–18.9)	14.7 (13.5–15.8)	0.11	25.3 (21.2–29.3)	23.0 (19.3–26.7)	0.30
Secondary outcomes						
Death from any cause	5.4 (3.9–6.8)	4.6 (3.9–5.3)	0.37	4.7 (2.8–6.7)	7.9 (6.5–9.4)	0.02
Cardiac	3.7 (2.5–5.0)	3.3 (2.7–3.9)	0.55	3.4 (1.7–5.1)	6.1 (4.8–7.4)	0.03
Non-cardiac	1.7 (0.8–2.5)	1.4 (1.0–1.7)	0.46	1.4 (0.3–2.5)	2.0 (1.2–2.7)	0.38
MI	11.3 (9.3–13.3)	8.9 (8–9.8)	0.02	19.2 (15.5–22.8)	15.0 (13.3–16.7)	0.04
Any revascularization	8.1 (6.3–9.9)	9.3 (8.3–10.2)	0.32	13.7 (10.5–16.9)	9.6 (8.0–11.1)	0.02
Stent thrombosis	0.2 (-0.1–0.6)	0.4 (0.2–0.6)	0.53	0.7 (-0.1–1.4)	0.4 (0.1–0.6)	0.35

Primary Outcome (Target-Vessel Failure) According to Stenting Strategy

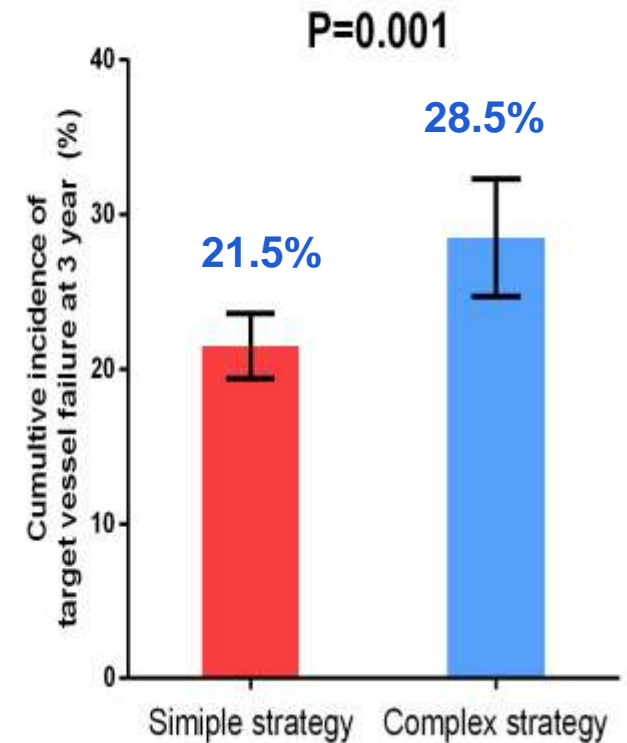
All Bifurcations



Non-LM Bifurcations



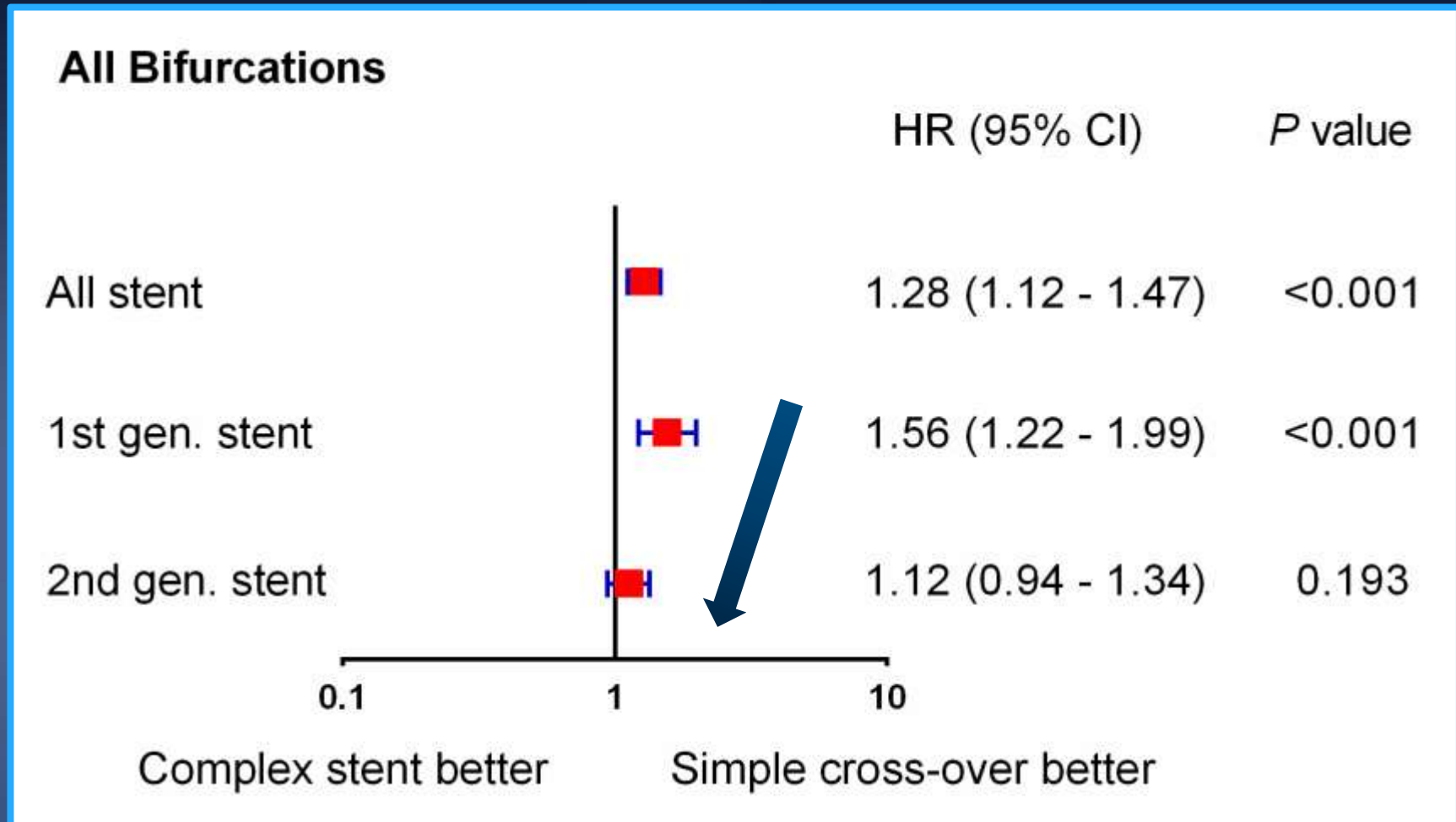
LM Bifurcations



Clinical outcomes according to stent strategy

Characteristic	Non-LM Bifurcations (N = 5050)			LM Bifurcations (N = 2232)		
	Simple Strategy (N=4379)	Complex strategy (N=671)	P	Simple Strategy (N=1613)	Complex strategy (N=619)	P
Primary outcome						
TVF	14.8 (13.7–15.9)	16.4 (13.6–19.2)	0.15	21.5 (19.4–23.6)	28.5 (24.7–32.3)	0.001
Secondary outcomes						
Death	5.0 (4.3–5.7)	3.7 (2.2–5.2)	0.17	7.2 (5.8–8.6)	6.7 (4.5–8.9)	0.53
Cardiac	3.6 (3–4.2)	2.3 (1.1–3.5)	0.10	5.5 (4.2–6.8)	5.0 (3.1–6.9)	0.54
Non-cardiac	1.4 (1.0–1.8)	1.4 (0.5–2.3)	0.98	1.9 (1.2–2.6)	1.8 (0.6–3.0)	0.85
MI	12.7 (10.2–15.2)	8.9 (8.0–9.8)	0.001	19.1 (16.0–22.2)	14.6 (12.9–16.3)	0.007
Any revascularization	9.0 (8.0–10.0)	9.2 (6.9–11.5)	0.79	9.2 (7.6–10.8)	14.0 (11.0–17.0)	0.004
Stent thrombosis	0.4 (0.2–0.6)	0.0 (0.0-0.0)	0.12	0.4 (0.1–0.7)	0.5 (-0.1–1.1)	0.79

Adjusted HR for Target-Vessel Failure According to stent strategy over time



**Multivariable Cox regression models are adjusted for age, sex, diabetes, previous MI, previous PCI, chronic renal failure, clinical presentation, ejection fraction, bifurcation location, disease extent, and use of intravascular ultrasound.

Adjusted HR for Target-Vessel Failure According to stent strategy over time

Non-LM Bifurcation



LM Bifurcation



**Multivariable Cox regression models are adjusted for age, sex, diabetes, previous MI, previous PCI, chronic renal failure, clinical presentation, ejection fraction, bifurcation location, disease extent, and use of intravascular ultrasound.

In Summary...

- Over the last decade, patients with bifurcation lesions, patient characteristics, stenting strategy, and PCI outcomes have substantially changed.
- Simple stenting strategy has been more frequently used and clinical outcomes have been improved from 1st generation DES to 2nd generation DES.

In Summary...

- Although simple strategy was associated with a lower rate of target-vessel failure, the treatment gap between 1st and 2nd gen-DES has progressively narrowed over time.
- This trend might be due to improved stent device, technique, clinical concept and increasing experience and expertise for bifurcation PCI.