Imaging-guided PSP
Optimizing PCI For Complex Lesions

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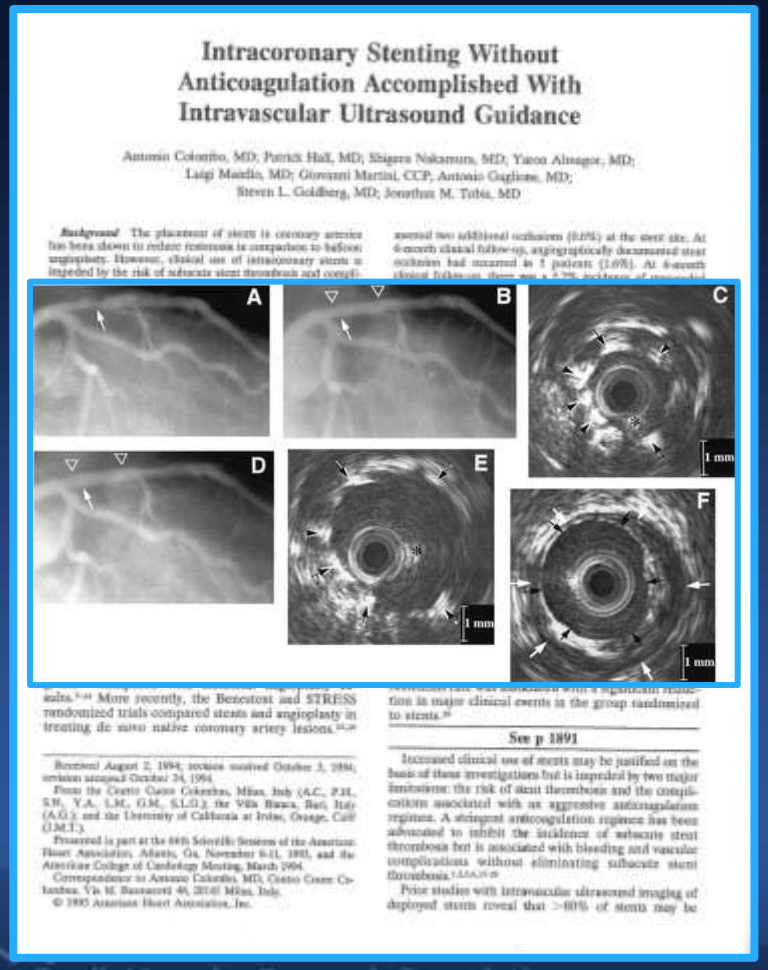
Intracoronary stenting without anticoagulation accomplished with *IVUS* guidance

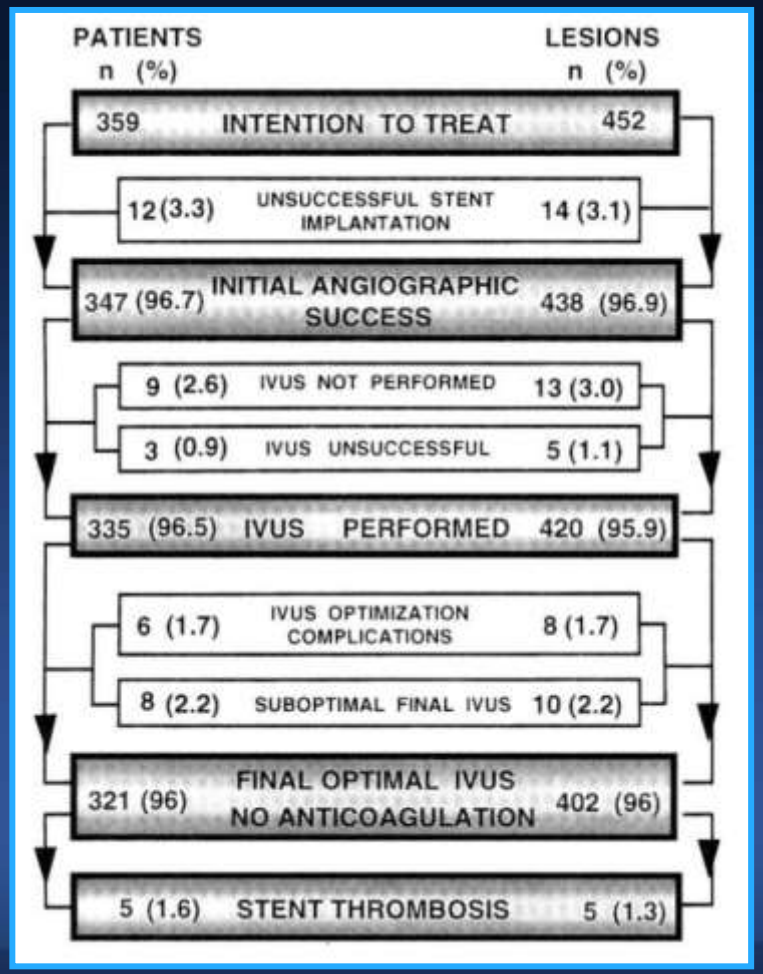
Antonio Colombo et al. Circulation. *1995 (25 years ago)*;91:1676–1688



Intracoronary Stenting Without Anticoagulation Accomplished With Intravascular Ultrasound Guidance

Antonio Colombo, MD; Patrick Hall, MD; Shigeru Nakamura, MD; Yaron Almagor, MD; Luigi Maiello, MD; Giovanni Martini, CCP; Antonio Gaglione, MD; Steven L. Goldberg, MD; Jonathan M. Tobis, MD

See p 1891

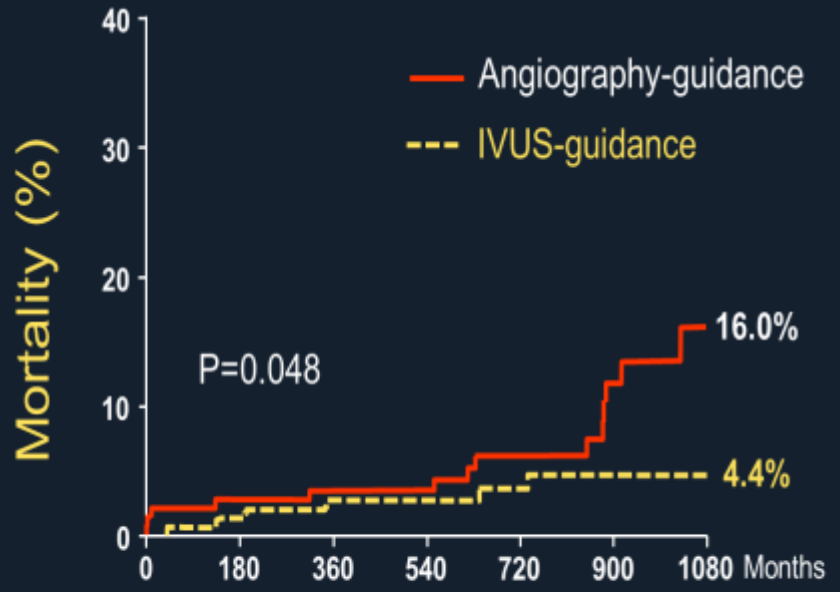


Stent Thrombosis

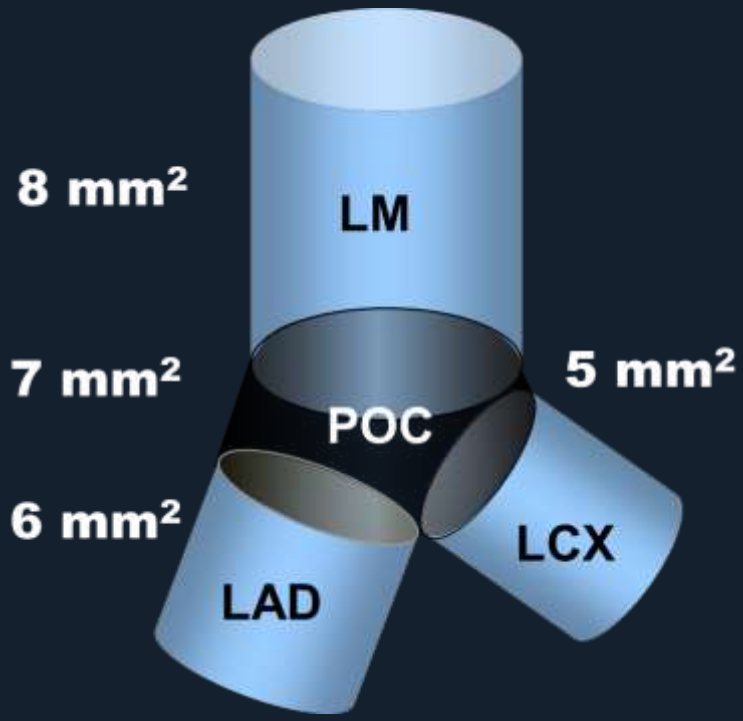
3-4%

1.6% at 6 months

IVUS Guided LM PCI



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

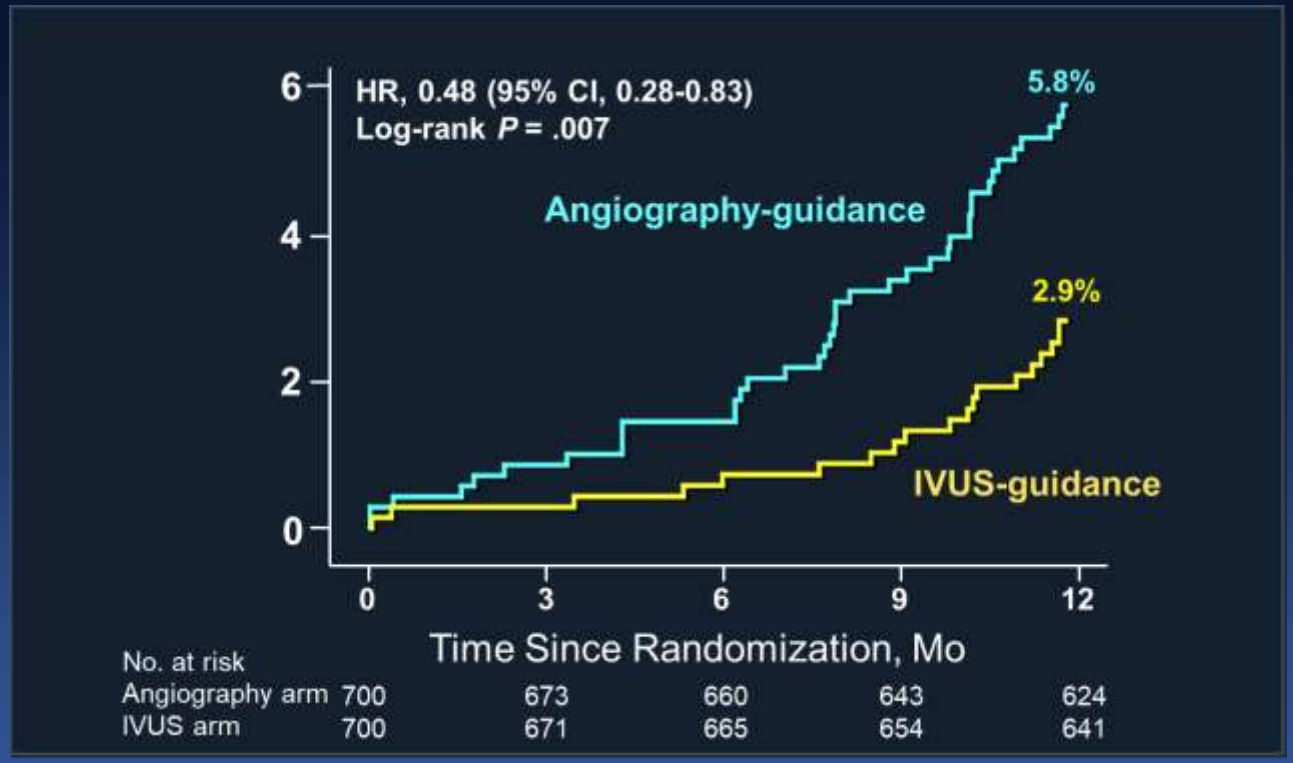


Park SJ et al, Circ Cardiovasc Interv. 2009;2(3):167-77.

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

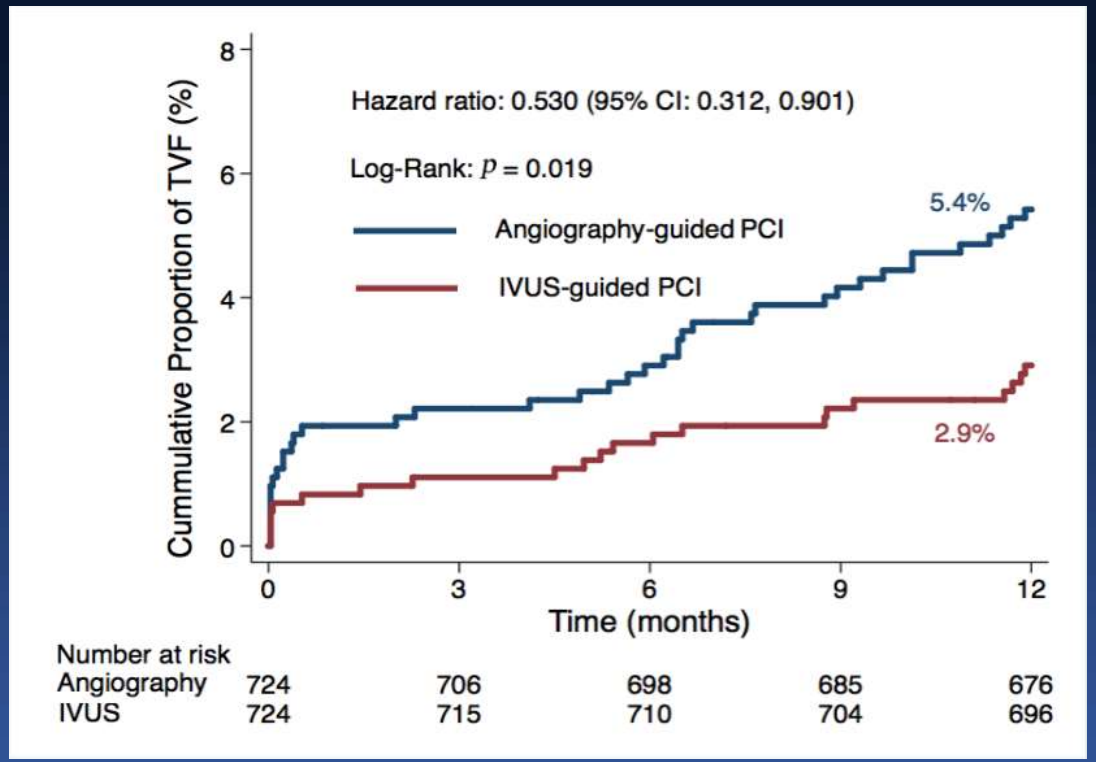
Randomized Trials

IVUS-XPL RCT



Hong SJ et al, *JAMA 2015*;314:2155-63

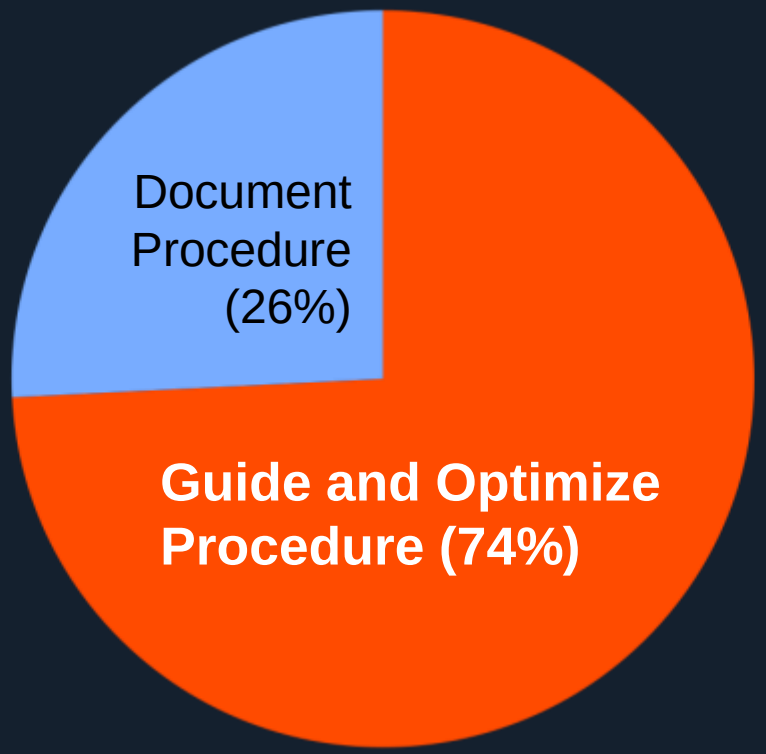
ULTIMATE RCT

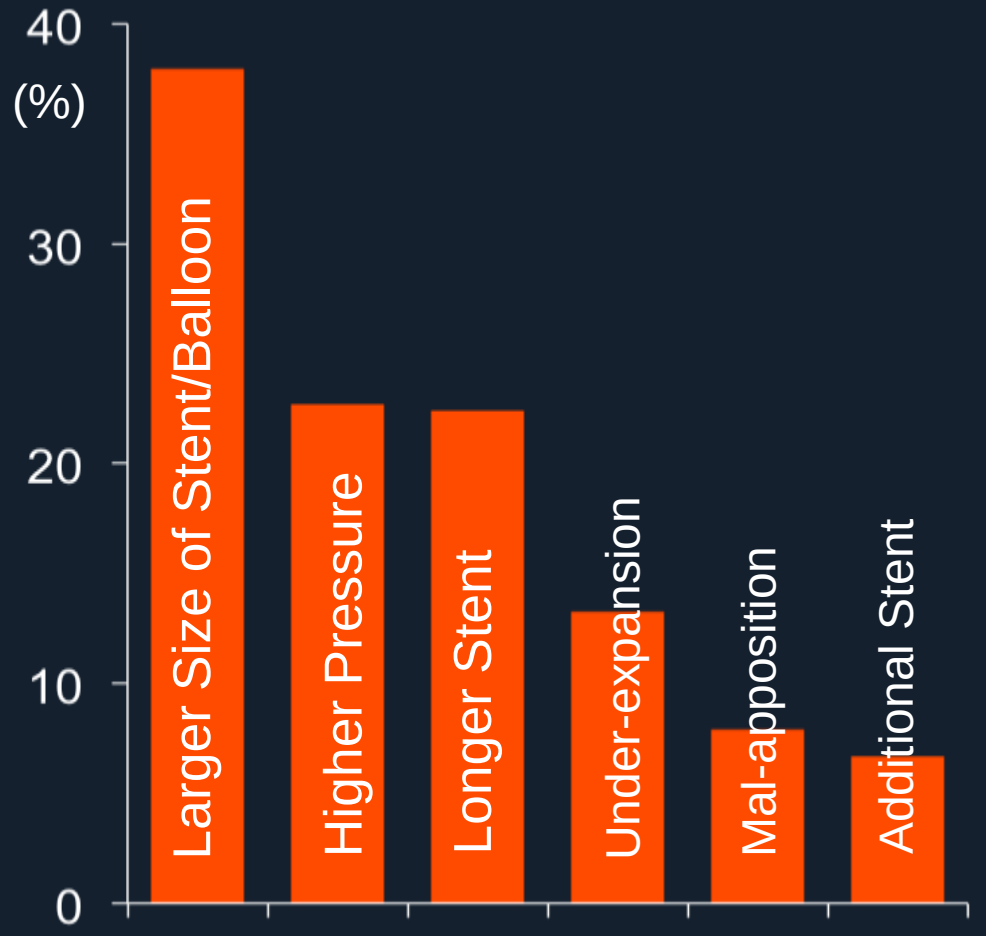


JACC. 2018 Sep 17. pii: S0735-1097(18)38433-X.

ADAPT DES Study

Procedural Changes After IVUS in 74%

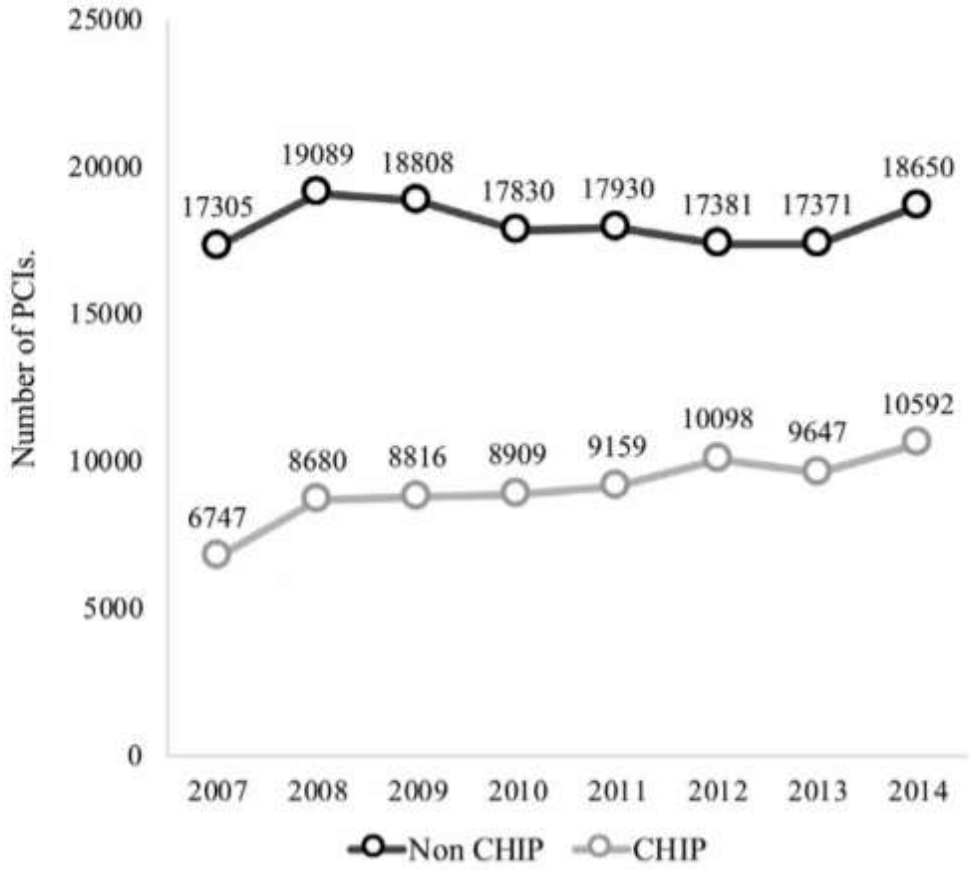


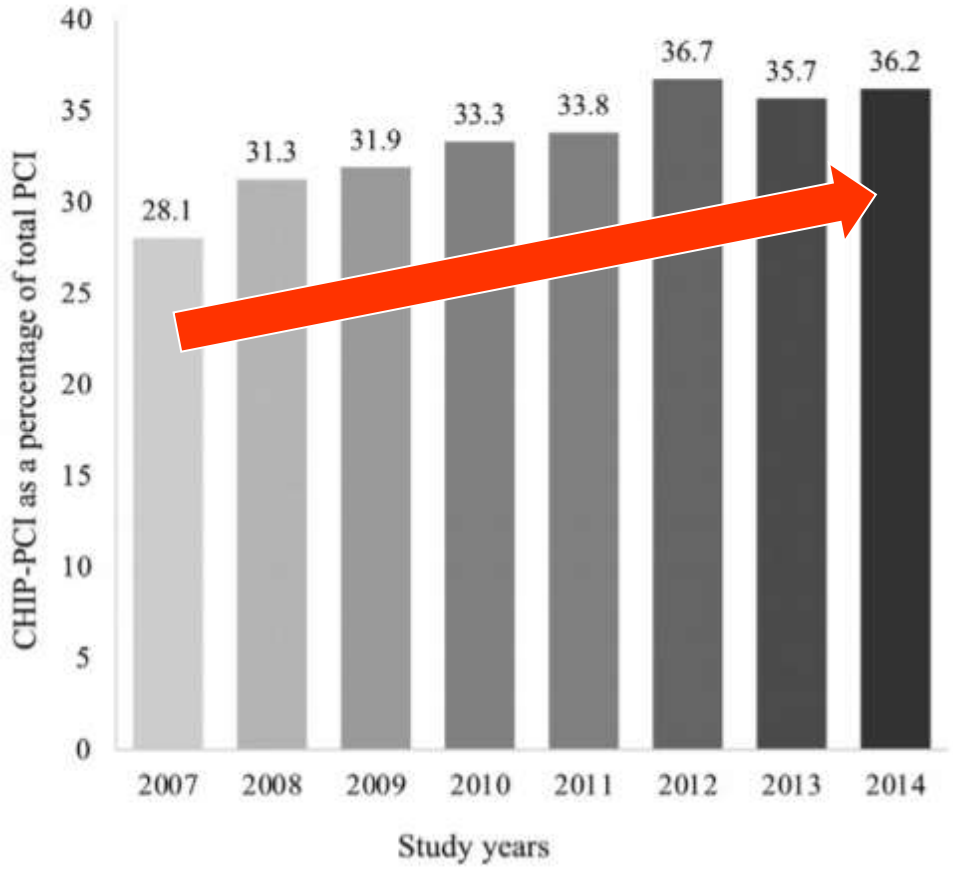


Witzenbichler et al. Circulation 2014;129:463-70

Complex PCI Is Increasing

BCIS dataset between 2007-2014





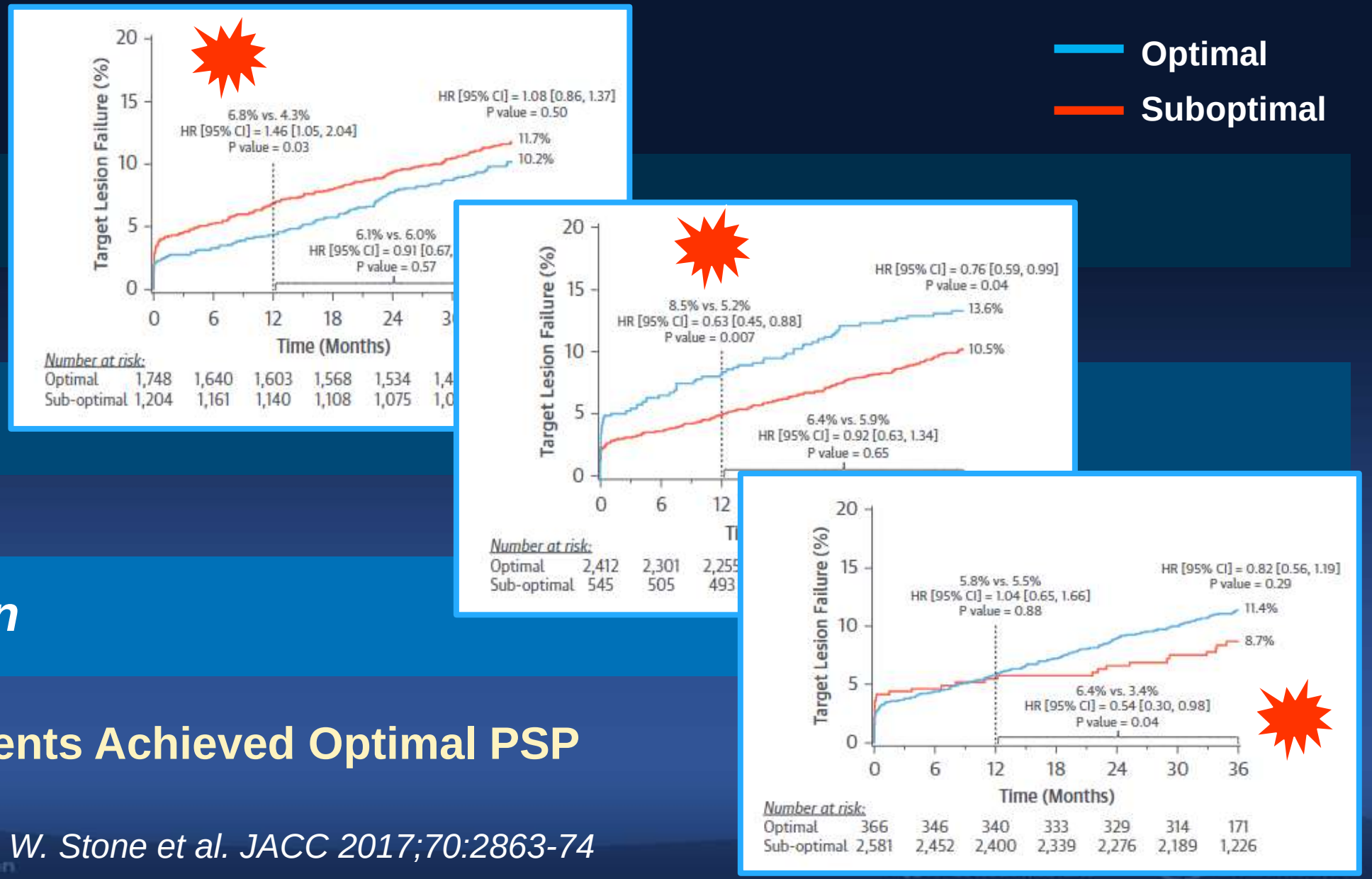
AHJ 2020 Apr;222:15-25

BRS Experience From the ABSORB Trials

P ***Pre-Dilation***

S ***Sizing***

P ***Post-Dilation***



- **Only 5% of Patients Achieved Optimal PSP**

Gregg W. Stone et al. JACC 2017;70:2863-74

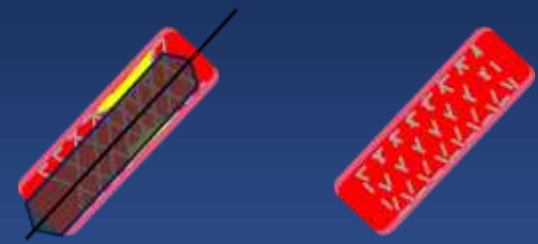
Objective

- We evaluated the 3-year outcomes of intracoronary imaging-guided PSP (***iPSP***) in patients with complex coronary artery lesions underwent PCI with DES.

Park HB, Ahn JM, Park SJ et al. JACC: Cardiovascular Interventions Volume 13, Issue 12, June 2020

Imaging Guided PSP

Under the Intracoronary Imaging Guidance

Inspection of lesion characteristic by IVUS	**Selection of stent size and length by IVUS**	**Surveillance of stent outcomes**
Calcification Plaque burden and configuration Opening of side branch	Stent landing zone configuration Lesion length Reference vessel size	Stent apposition Stent area Procedural complications
P Pre-dilation	S Stent Sizing	P Post-dilation
		
Lesion pre-modification for stent delivery and expansion: High pressure balloon Cutting or scoring balloon Rota-ablation	Full lesion coverage Adequate stent size	Complete stent apposition Sufficient stent area No geographic miss No procedural complications

Park HB, Ahn JM, Park SJ et al. JACC: Cardiovascular Interventions Volume 13, Issue 12, June 2020

Methods

- From IRIS-DES Registry (NCT01186133) Between 2008 and 2017.
- A total 9525 patients with single complex coronary lesions were enrolled in this analysis.
- Complex coronary lesions were included
    1. LMCA
    2. Bifurcation
    3. Diffuse lesion (>30mm)
    4. Severely calcified lesion
    5. In-stent restenosis
- Primary outcome was the composite of cardiac death, target vessel MI and target vessel revascularization

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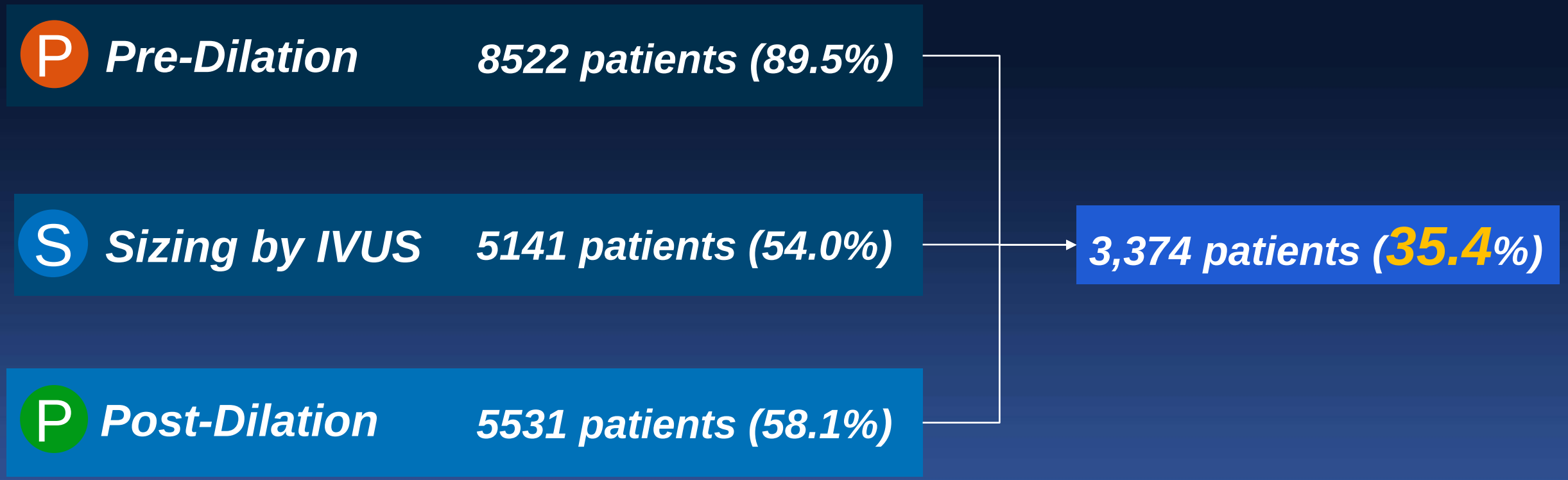
Imaging Guided PSP



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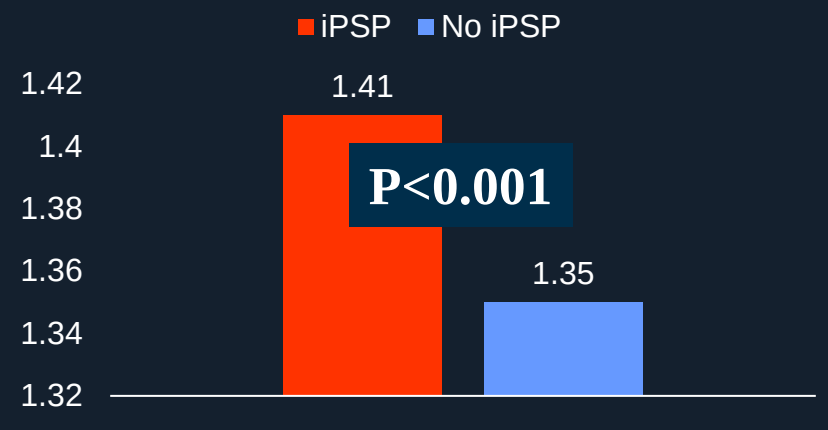
Baseline Characteristics

	iPSP (N=3374)	No iPSP (N=6151)	P value
Age, years	62.8 ± 10.5	64.3 ± 11.0	<0.001
Male sex, n (%)	2530 (75.0)	4286 (69.7)	<0.001
Body mass index, kg/m^2	24.8 ± 3.0	24.7 ± 3.3	0.03
Diabetes mellitus	1096 (32.5)	2067 (33.6)	0.27
Hypertension	2120 (62.8)	3731 (60.7)	0.04
Hyperlipidemia	2137 (63.3)	2838 (46.1)	<0.001
Current smoker	956 (28.3)	1734 (28.2)	0.88
Family history of CAD	285 (8.5)	313 (5.1)	<0.001
Previous MI	160 (4.7)	343 (5.6)	0.08
Previous Heart failure	69 (2.1)	134 (2.2)	0.67
Previous Stroke	215 (6.4)	415 (6.8)	0.48
Peripheral artery disease	72 (2.1)	114 (1.9)	0.35

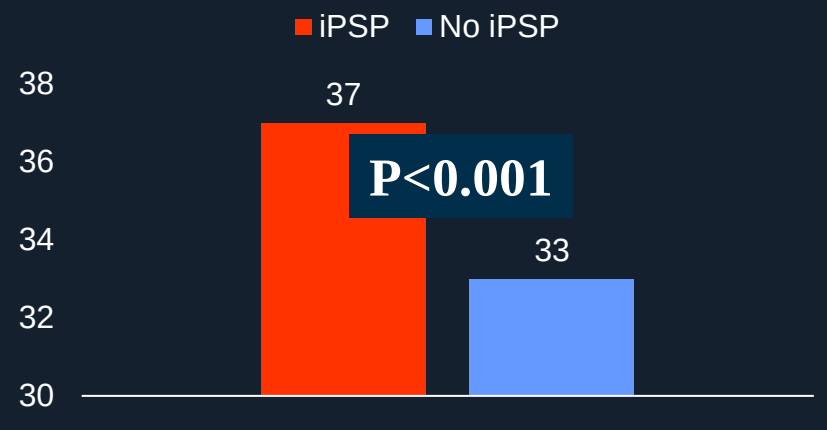
	iPSP (N=3374)	No iPSP (N=6151)	P value
Chronic lung disease	82 (2.4)	130 (2.1)	0.32
Chronic kidney disease	129 (3.8)	260 (4.2)	0.34
Atrial fibrillation	93 (2.8)	215 (3.7)	0.03
LV Ejection fraction, %	59.1 ± 8.9	57.8 ± 11.1	<0.001
Extent of disease			0.001
Single-vessel disease	2216 (65.7)	3862 (62.8)	
Two-vessel disease	793 (23.5)	1477 (24.0)	
Three-vessel disease	365 (10.8)	812 (13.2)	
LMCA lesion	193 (5.7)	261 (4.2)	0.001
Bifurcation lesion	2365 (70.7)	3462 (56.3)	<0.001
Long lesion	1923 (57.0)	3219 (52.3)	<0.001
Severe calcification	185 (5.5)	575 (9.4)	<0.001

Procedural Outcomes

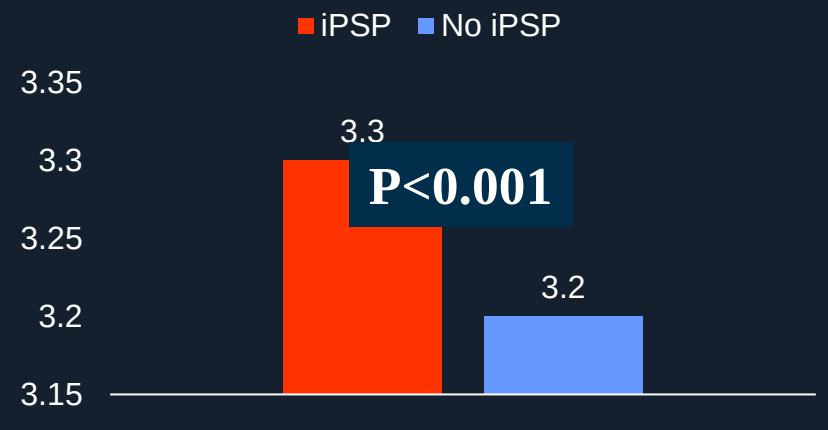
Stent Number



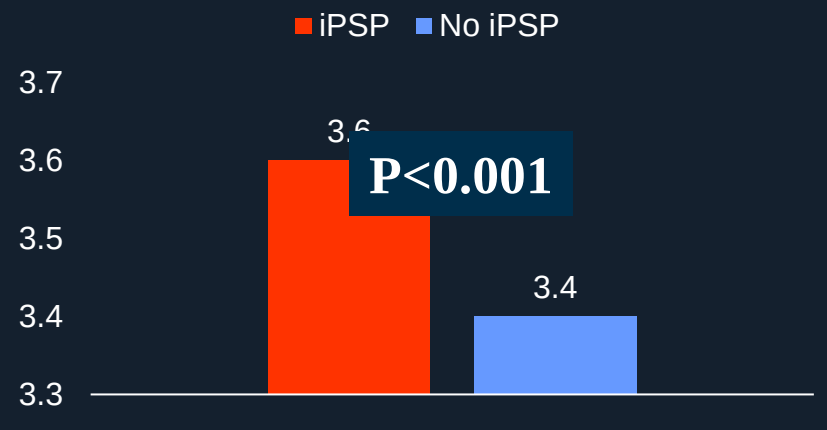
Stent Length (mm)



Stent Diameter (mm)

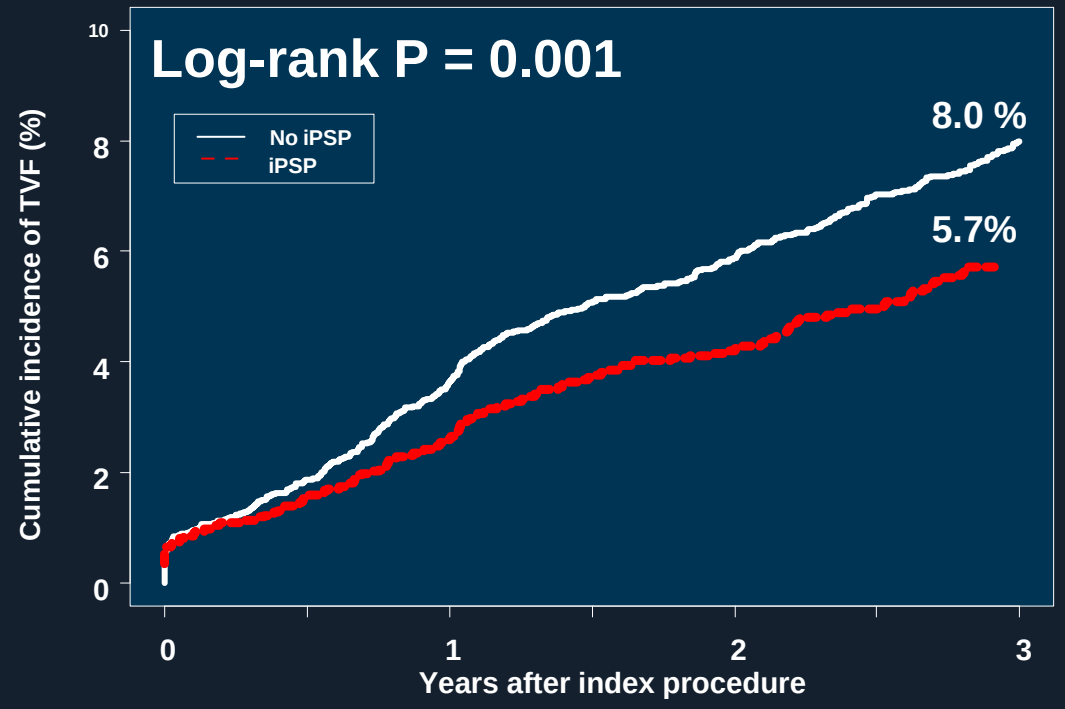


Final Balloon Size (mm)



Unadjusted Kaplan-Meier Curves

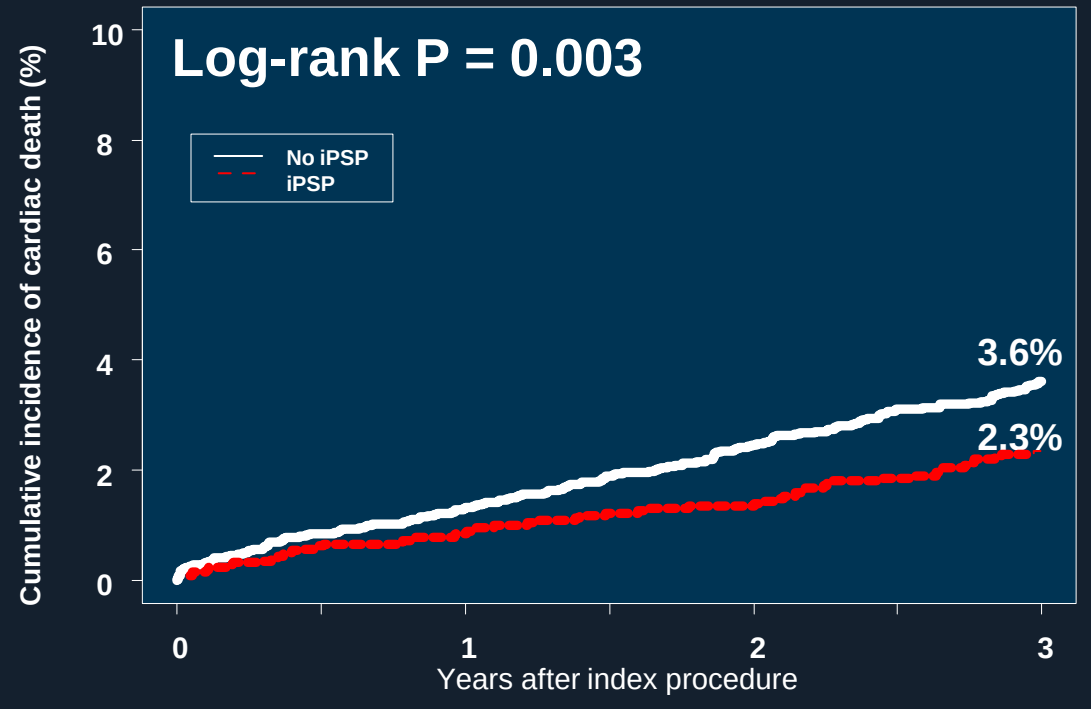
Primary Outcome



No. of at risk

No iPSP	6151	4928	3993	3324
iPSP	3374	2733	2147	1897

Cardiac Death



No. of at risk

No iPSP	6151	5039	4140	3538
iPSP	3374	2886	2206	1794

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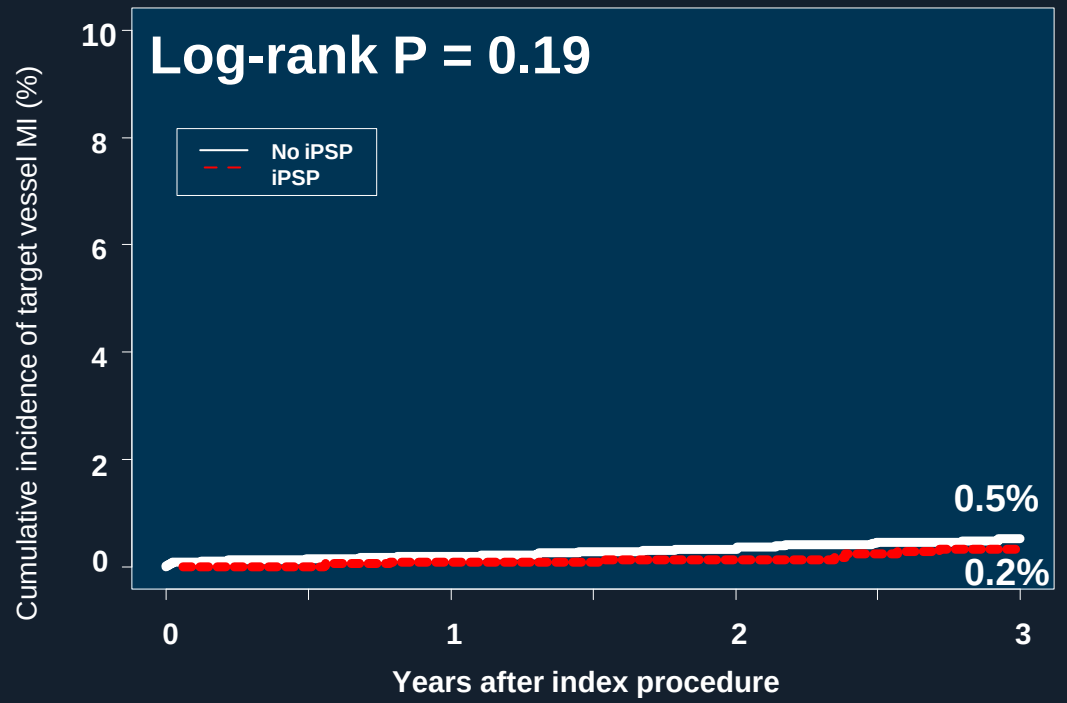
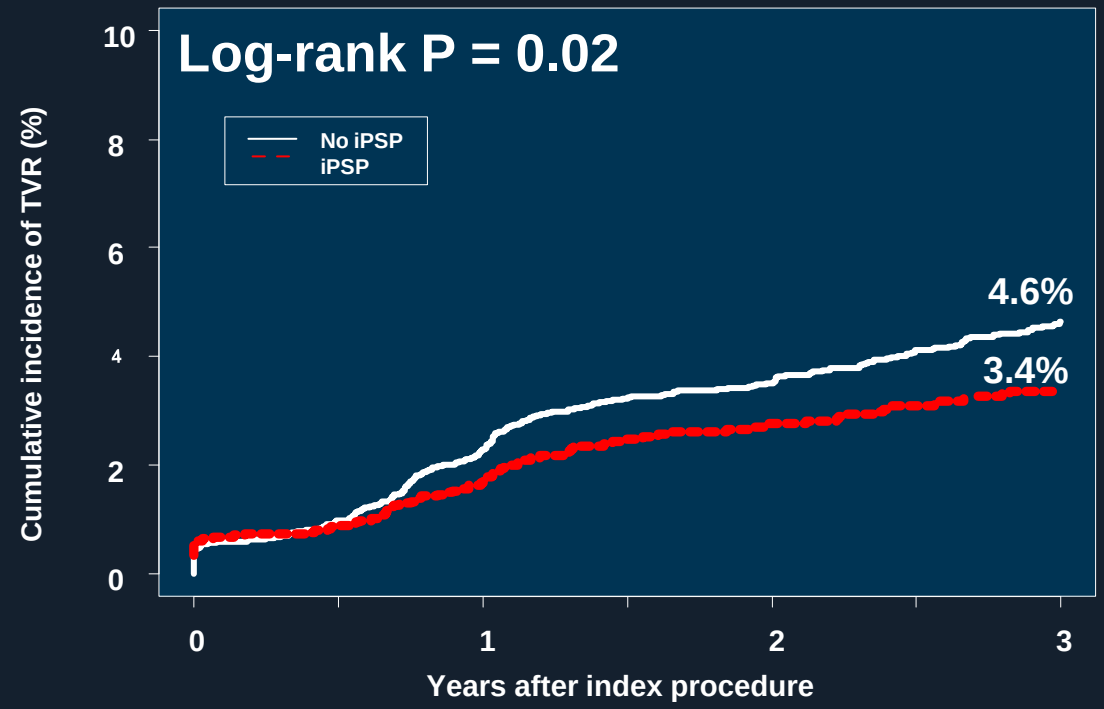
Unadjusted Kaplan-Meier Curves

Target Vessel MI



No. of at risk				
No iPSP	6151	5633	4231	3682
iPSP	3374	3111	2273	2062

Target Vessel Revascularization



No. of at risk				
No iPSP	6151	4957	4018	3347
iPSP	3374	2736	2163	1921

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Clinical Outcomes At 3 Years

	Crude cumulative incidence (%)			Multivariate analysis		PS matching		IPTW	
	iPSP	No iPSP	P	HR (95% CI)	P	HR (95% CI)	P	HR (95% CI)	P
Primary outcome	5.7	8.0	0.001	0.74 (0.61-0.90)	0.003	0.71 (0.56-0.90)	0.005	0.71 (0.63-0.81)	<0.001
Cardiac death	2.3	3.6	0.003	0.73 (0.53-0.99)	0.047	0.78 (0.53-1.15)	0.20	0.62 (0.51-0.75)	0.003
Target vessel MI	0.2	0.5	0.19	0.68 (0.30-1.55)	0.36	0.78 (0.29-2.09)	0.62	0.65 (0.38-1.10)	0.10
TVR	3.4	4.6	0.02	0.73 (0.57-0.94)	0.02	0.68 (0.50-0.92)	0.01	0.74 (0.63-0.87)	<0.001

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Adjusted Hazard Ratios for Primary Outcomes According to Components of iPSP

	Univariate analysis		Multivariate analysis*	
	HR (95% CI)	P value	HR (95% CI)	P value
Pre-dilation	0.89 (0.69-1.15)	0.374	0.84 (0.64-1.11)	0.216
Stent-sizing	0.79 (0.67-0.93)	0.004	0.89 (0.74-1.07)	0.219
Post-dilation	0.79 (0.67-0.94)	0.006	0.80 (0.67-0.96)	0.016

* The multivariate analysis model included 18 clinical variables: age, sex, body mass index, hypertension, diabetes mellitus, prior history of MI, prior history of heart failure, prior history of stroke, hyperlipidemia, chronic kidney disease, peripheral artery disease, chronic lung disease, atrial fibrillation, acute coronary syndrome at presentation, left ventricular ejection fraction, disease extent of CAD (1-, 2-, or 3-vessel disease), involvement of LMCA, and angiographically severely calcified lesion. The primary outcome was defined as the composite of cardiac death, target vessel MI, or target vessel revascularization.

Procedures and Clinical Outcomes by iPSP Scenarios

Scenario	Pre-dilation	IVUS	Post-dilation	No. of patients (%)	Stent diameter (mm)	Post balloon size (mm)	Annualized event rate	Adjusted HR (95% CI)	P value
1	No	No	No	406 (4.3)	3.19 ± 0.46		3.94 %	Reference	
2	Yes	No	No	2130 (22.4)	3.06 ± 0.40		2.69 %	0.85 (0.57-1.26)	0.413
3	No	Yes	No	159 (1.7)	3.41 ± 0.45		2.03 %	0.71 (0.33-1.56)	0.394
4	**No**	**No**	**Yes**	129 (1.4)	3.04 ± 0.41	3.10 ± 0.81	3.04 %	0.81 (0.35-1.85)	0.613
					Δ +0.05 (P=0.550)				
5	Yes	Yes	No	1299 (13.6)	3.26 ± 0.85		2.90 %	0.91 (0.60-1.38)	0.663
6	**Yes**	**No**	**Yes**	1719 (18.0)	3.08 ± 0.38	3.12 ± 0.86	3.07 %	0.80 (0.53-1.21)	0.297
					Δ +0.04 (P=0.104)				
7	**No**	**Yes**	**Yes**	309 (3.2)	3.43 ± 0.41	3.79 ± 0.70	2.04%	0.72 (0.39-1.35)	0.306
					Δ +0.35 (P<0.001)				
8	**Yes**	**Yes**	**Yes**	3374 (35.4)	3.26 ± 0.39	3.58 ± 0.60	1.98%	0.63 (0.42-0.93)	0.022
					Δ +0.32 (P<0.001)				

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Summary

- This study showed that the so called iPSP strategy was significantly associated with a lower risk of cardiac death, target vessel MI, or TVR at 3 years in patients with complex coronary artery disease.
- In addition, iPSP was significantly associated with a lower risk of cardiac mortality and TVR, respectively.
- The clinical benefit of iPSP seems to be attributed to safe and effective post-dilation, with the larger final balloon size guided by intracoronary imaging.
- This study suggested that physicians should recognize the importance of iPSP strategy and more actively consider it for the treatment of complex coronary artery stenosis, even in the current era of second- and third-generation DES.
- Our findings should be further evaluated through randomized controlled trial such as ILUMIEN IV to confirm the effects of iPSP.