Imaging-guided PSP Optimizing PCI For Complex Lesions

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Intracoronary stenting without anticoagulation accomplished with *IVUS* guidance

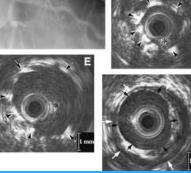
Antonio Colombo et al. Circulation. 1995 (25 years ago);91:1676–1688

Intracoronary Stenting Without Anticoagulation Accomplished With Intravascular Ultrasound Guidance

Autonin Colonito, MD, Partick Hal, MD; Shigera Nakamura, MD; Yatoo Alinagor, MD; Laigi Maidia, MD; Giovarni Martini, CCP, Antonio Gagliana, MD; Birven L. Goldberg, MD; Jonethus M. Tobia, MD

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sizes.¹⁵⁴⁴ More recently, the Benesteas and STRESS randomized trials compared steam and angioplasty in treating de novo native coronary artery lesions.^{16,29}

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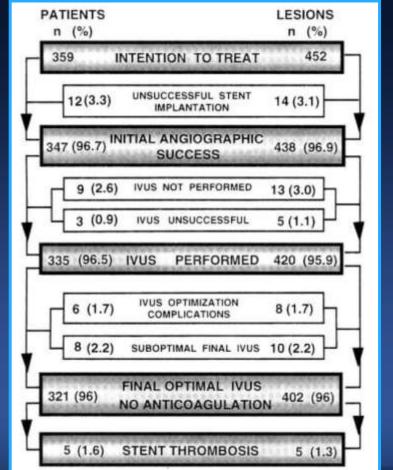
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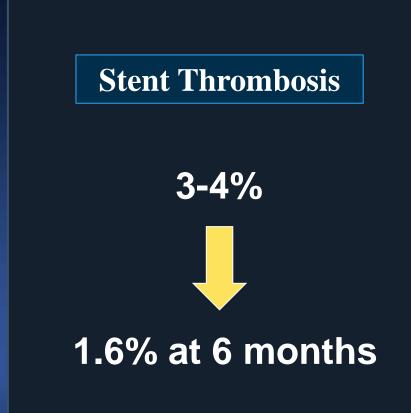
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See p 1891

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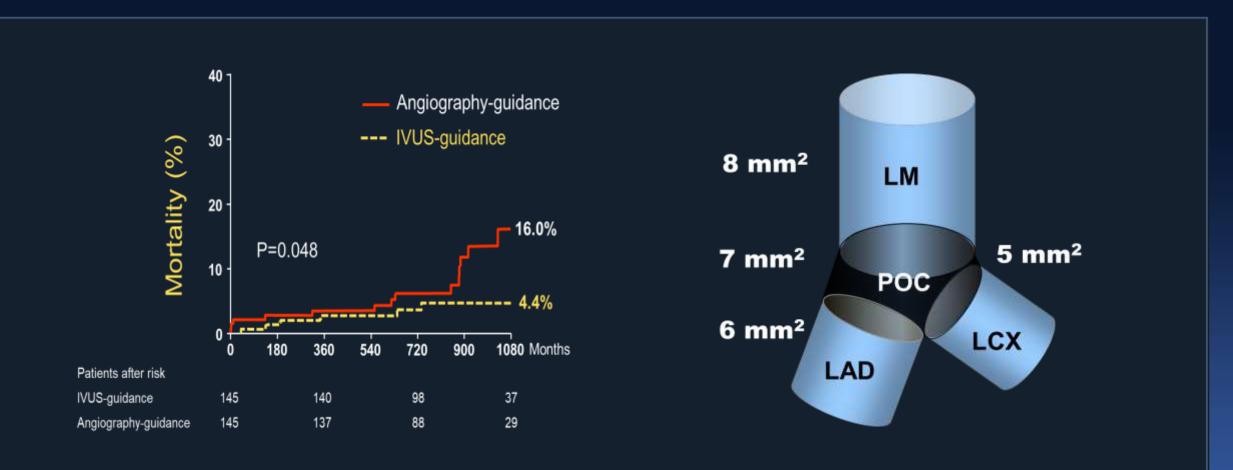
Prior studies with intravancular ultravenued imaging of hiployed storm reveal that >60% of stema may be





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IVUS Guided LM PCI



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



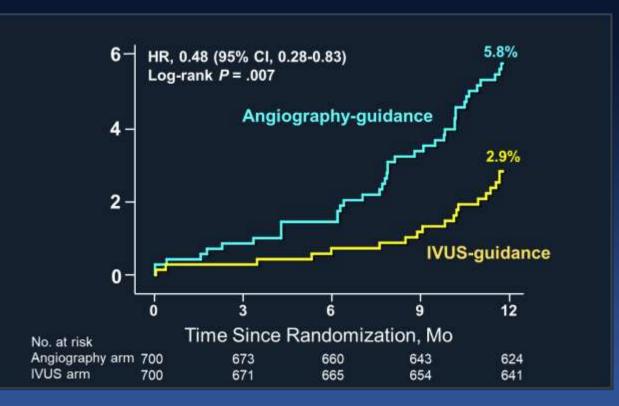


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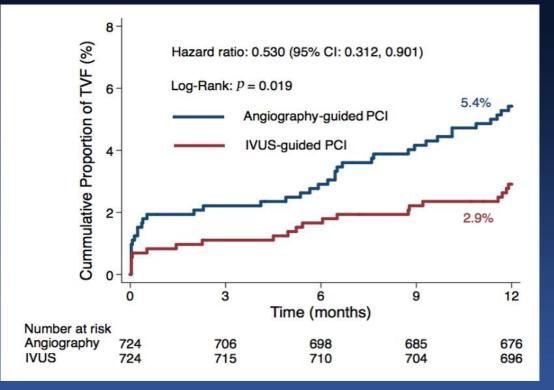
Randomized Trials

IVUS-XPL RCT

ULTIMATE RCT



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

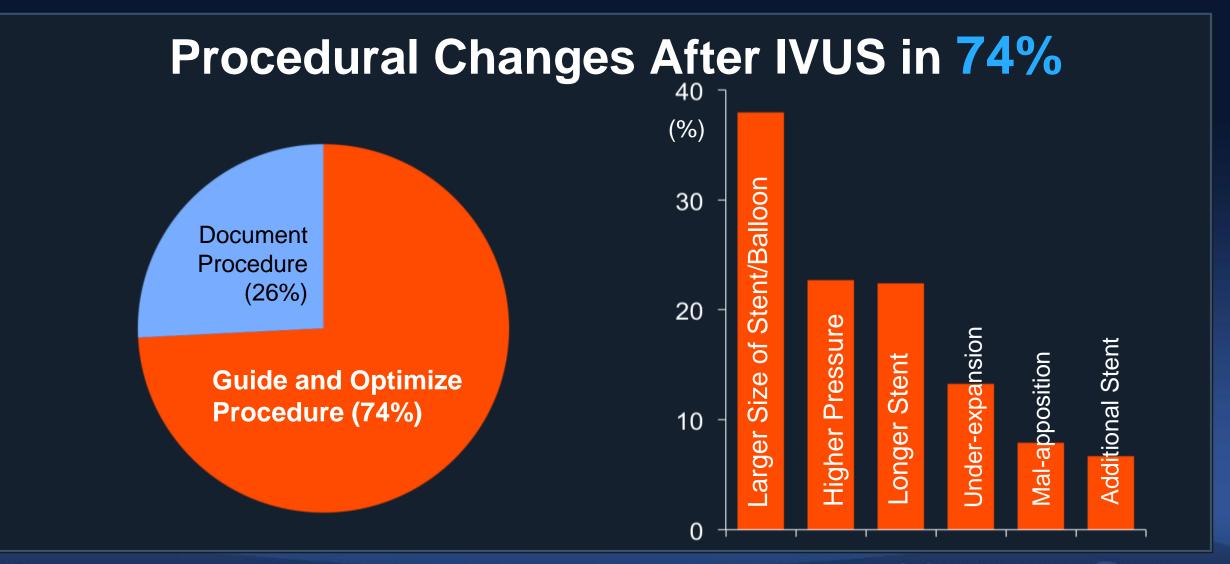


JACC. 2018 Sep 17. pii: S0735-1097(18)38433-X.



CardioVascular Research Foundation

ADAPT DES Study



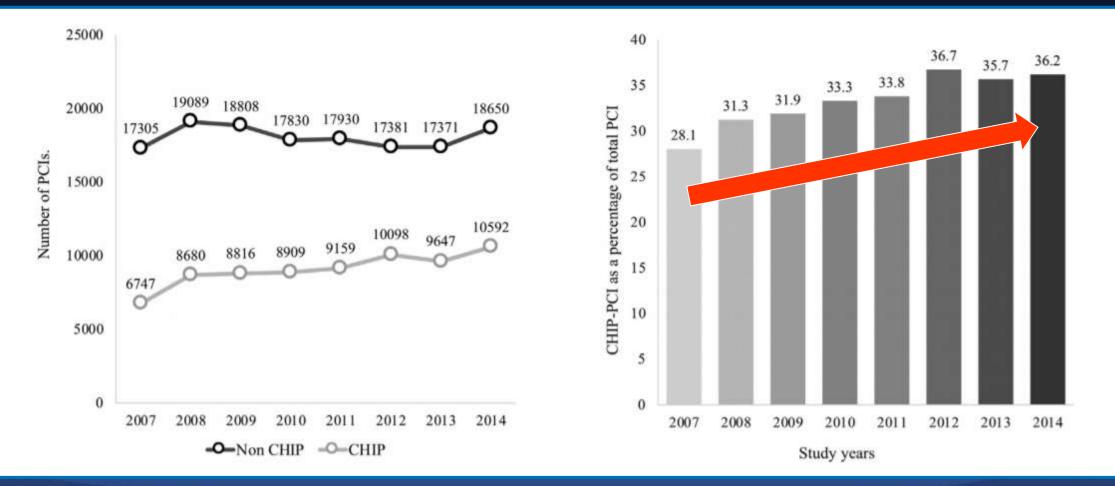
Witzenbichler et al. Circulation 2014;129:463-70



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Complex PCI Is Increasing

BCIS dataset between 2007-2014

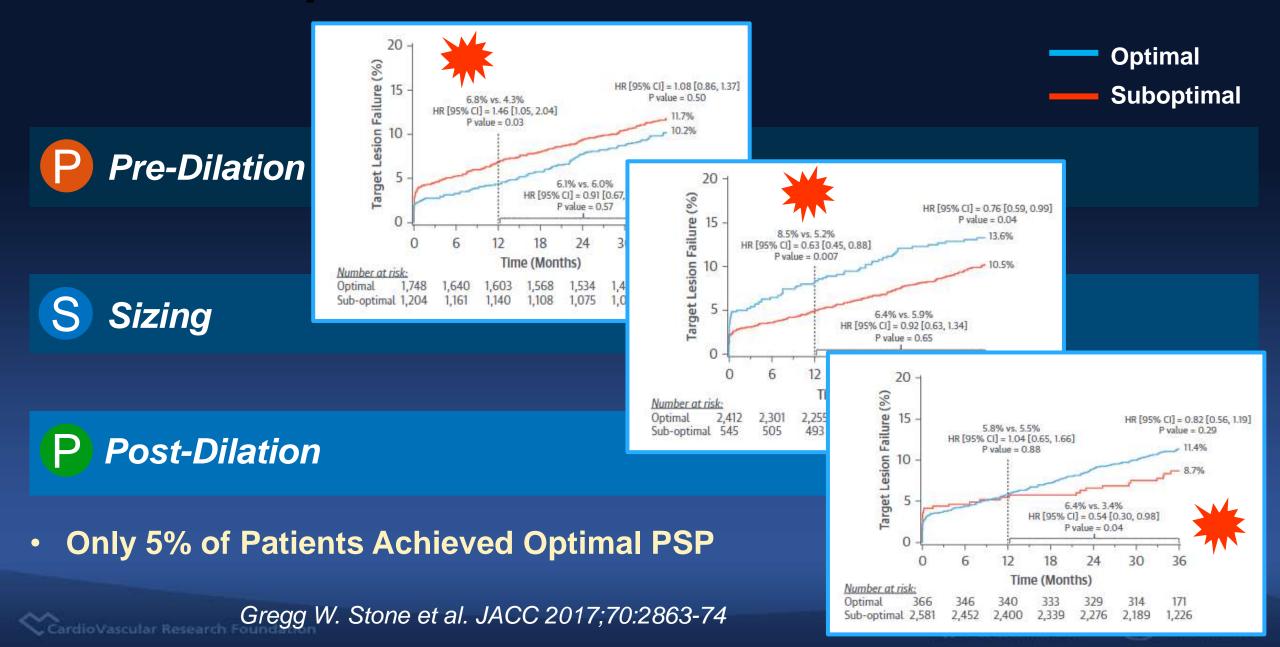


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AHJ 2020 Apr;222:15-25



BRS Experience From the ABSORB Trials



Objective

• We evaluated the 3-year outcomes of intracoronary

imaging-guided PSP (*iPSP*) in patients with complex

coronary artery lesions underwent PCI with DES.

Imaging Guided PSP

Under the Intracoronary Imaging Guidance

Inspection of lesion characteristic by IVUS

Calcification Plaque burden and configuration Opening of side branch

Pre-dilation

Selection of stent size and length by IVUS

Stent landing zone configuration Lesion length Reference vessel size

Stent Sizing

Surveillance of stent outcomes

Stent apposition Stent area Procedural complications

Post-dilation

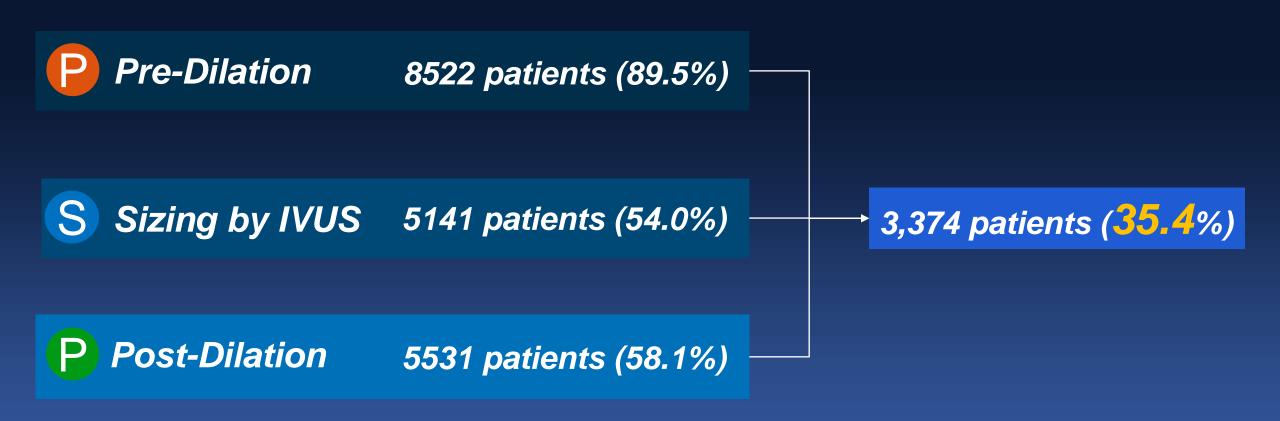
Lesion pre-modification for stent delivery and expansion:

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

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

Imaging Guided PSP



Baseline Characteristics

	iPSP	No iPSP	Duolue		iPSP	No iPSP	P value
	(N=3374)	(N=6151)	P value		(N=3374)	(N=6151)	P value
Age, years	62.8 ± 10.5	64.3 ± 11.0	<0.001	Chronic lung disease	82 (2.4)	130 (2.1)	0.32
Male sex, n (%)	2530 (75.0)	4286 (69.7)	<0.001	Chronic kidney disease	129 (3.8)	260 (4.2)	0.34
Body mass index, kg/m ²	24.8 ± 3.0	24.7 ± 3.3	0.03	Atrial fibrillation	93 (2.8)	215 (3.7)	0.03
Diabetes mellitus	1096 (32.5)	2067 (33.6)	0.27	LV Ejection fraction, %	59.1 ± 8.9	57.8 ± 11.1	<0.001
Hypertension	2120 (62.8)	3731 (60.7)	0.04	Extent of disease			0.001
Hyperlipidemia	2137 (63.3)	2838 (46.1)	<0.001	Single-vessel disease	2216 (65.7)	3862 (62.8)	
Current smoker	956 (28.3)	1734 (28.2)	0.88	Two-vessel disease	793 (23.5)	1477 (24.0)	
Family history of CAD	285 (8.5)	313 (5.1)	<0.001	Three-vessel disease	365 (10.8)	812 (13.2)	
Previous MI	160 (4.7)	343 (5.6)	0.08	LMCA lesion	193 (5.7)	261 (4.2)	0.001
Previous Heart failure	69 (2.1)	134 (2.2)	0.67	Bifurcation lesion	2365 (70.7)	3462 (56.3)	<0.001
Previous Stroke	215 (6.4)	415 (6.8)	0.48	Long lesion	1923 (57.0)	3219 (52.3)	<0.001
Peripheral artery disease	72 (2.1)	114 (1.9)	0.35	Severe calcification	185 (5.5)	575 (9.4)	<0.001

Procedural Outcomes

Stent Number



Stent Length (mm)



Stent Diameter (mm)



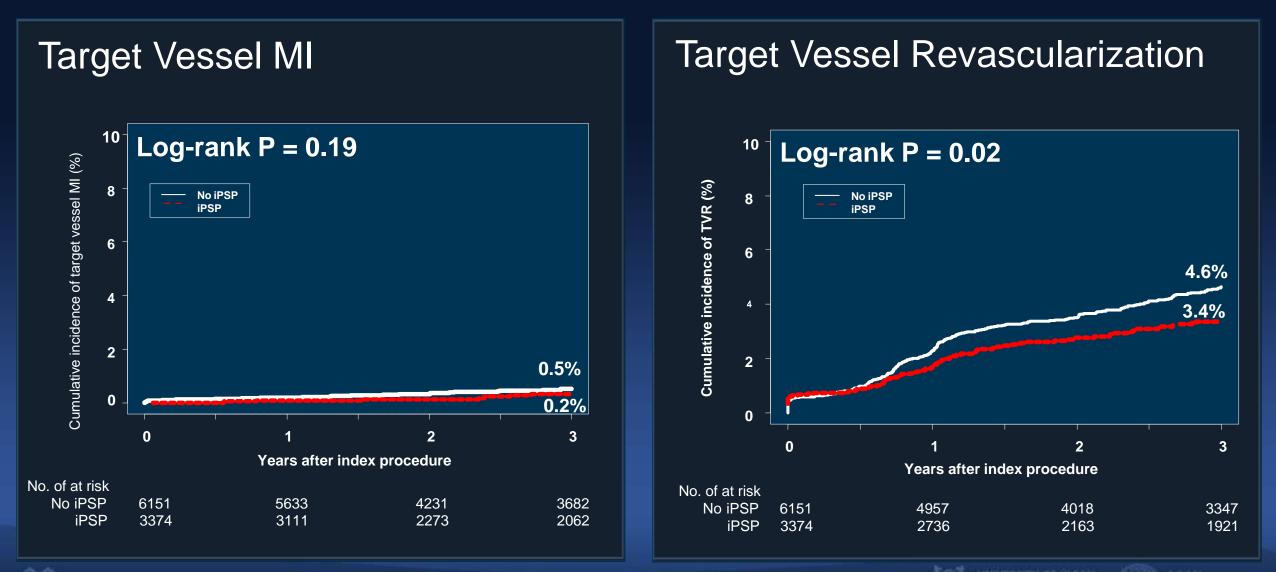
Final Balloon Size (mm)



Unadjusted Kaplan-Meier Curves

Cardiac Death Primary Outcome 10 10 Log-rank P = 0.001 Log-rank **P** = 0.003 Cumulative incidence of cardiac death (%) 8.0 % Cumulative incidence of TVF (%) No iPSP 8 8 No iPSP **iPSP iPSP** 5.7% 6 6 3.6% 4 4 2.3% 2 2 0 0 2 3 0 2 3 0 Years after index procedure Years after index procedure No. of at risk No. of at risk 3324 No iPSP 6151 4928 3993 No iPSP 3538 6151 5039 4140 iPSP 3374 2733 2147 1897 iPSP 3374 2886 2206 1794

Unadjusted Kaplan-Meier Curves



Clinical Outcomes At 3 Years

	Crude cumulative			Multivariate analysis		PS matching		IPTW	
	incidence (%)								
	iPSP	No iPSP	Р	HR (95% CI)	Р	HR (95% CI)	Р	HR (95% CI)	Р
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

Adjusted Hazard Ratios for Primary Outcomes According to Components of iPSP

	Univariate ana	alysis	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.

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Procedures and Clinical Outcomes by iPSP Scenarios

Scenario Pre-dilation IVUS Post-dilation		Post-dilation	No. of patients	Stent diameter	Post balloon size	Annualized	Adjusted HR (95% CI)	P value				
		(%)	(mm)	(mm)	event rate	, , ,						
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)											

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 postdilation, 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 thirdgeneration DES.
- Our findings should be further evaluated through randomized controlled trial such as ILUMIEN IV to confirm the effects of iPSP.

