DES vs. BRS: Is Newer Better?

Outcomes of the ABSORB BVS in Very Small and Not Very Small Coronary Arteries:

The ABSORB III Randomized Trial

Gregg W. Stone

Columbia University Medical Center
NewYork-Presbyterian Hospital
Cardiovascular Research Foundation

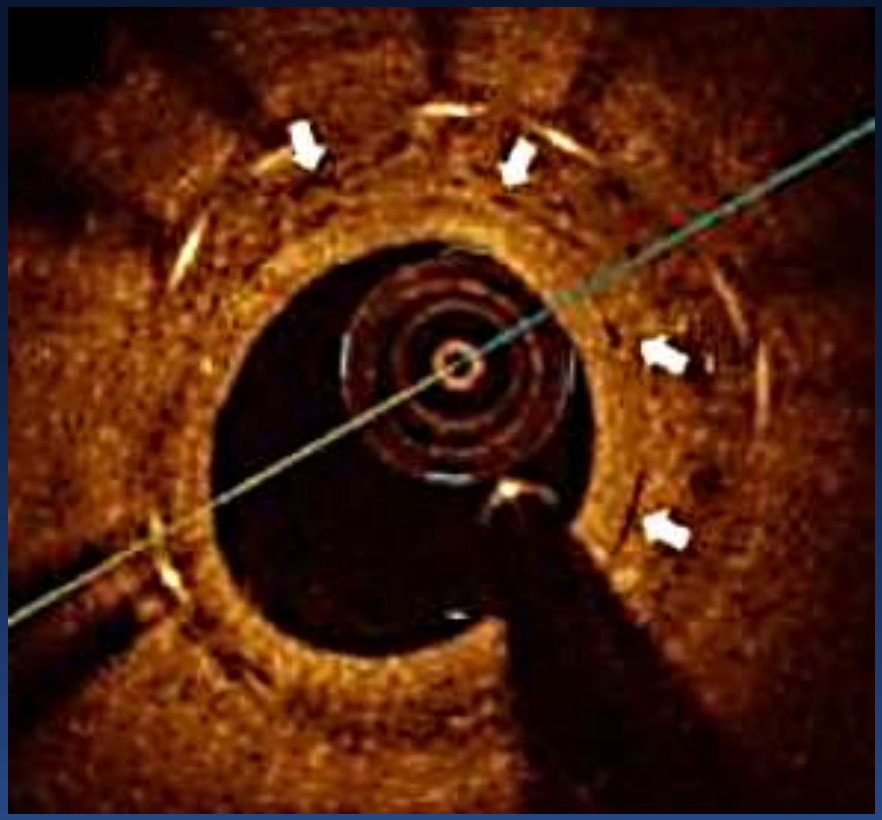
Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

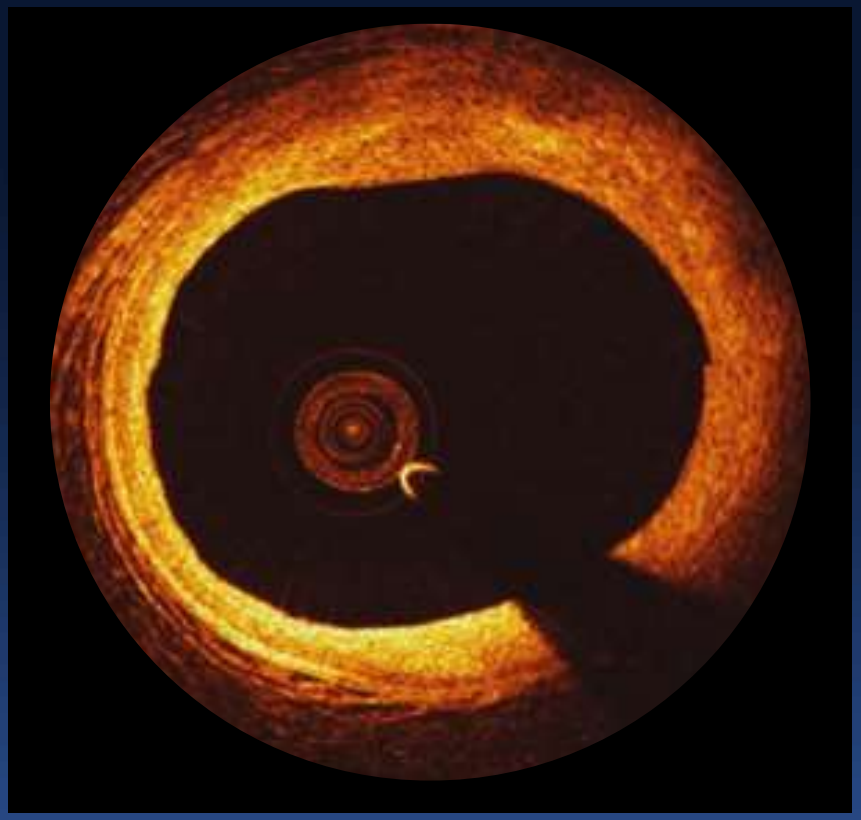
Affiliation/Financial Relationship	Company
• ABSORB clinical trial program study chairman (uncompensated)	• Abbott Vascular
• Consultant	• Reva Corp.

Metallic DES vs. Absorb BVS

Representative Human images at 5 Years



Metallic DES[1]

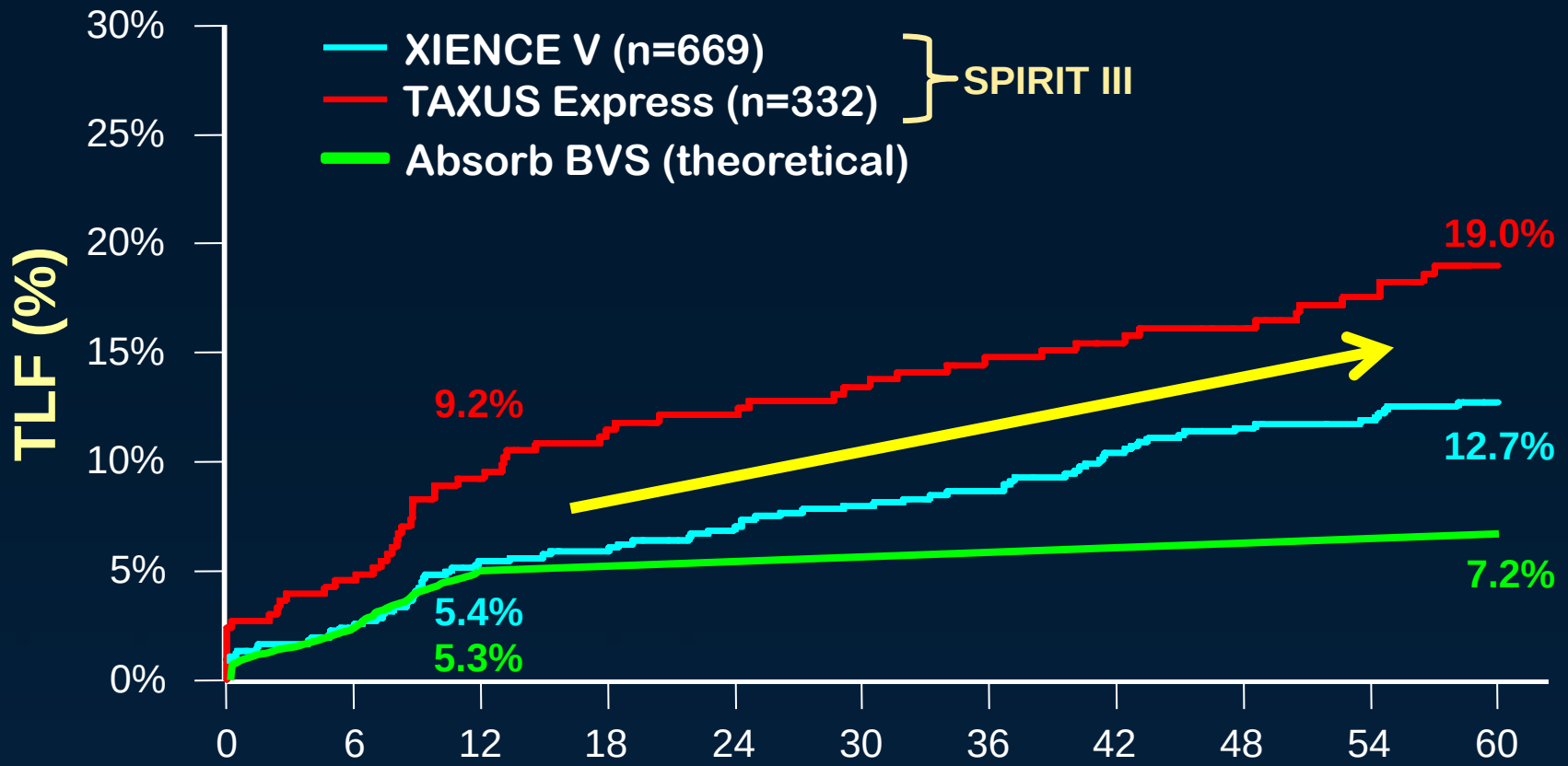


Absorb-Treated Artery[2]

[1]Atherosclerosis 2014;237:23e29

[2] Images courtesy of S Windecker, ABSORB Cohort B 5 Yrs

From TAXUS to XIENCE to ABSORB



Number at risk

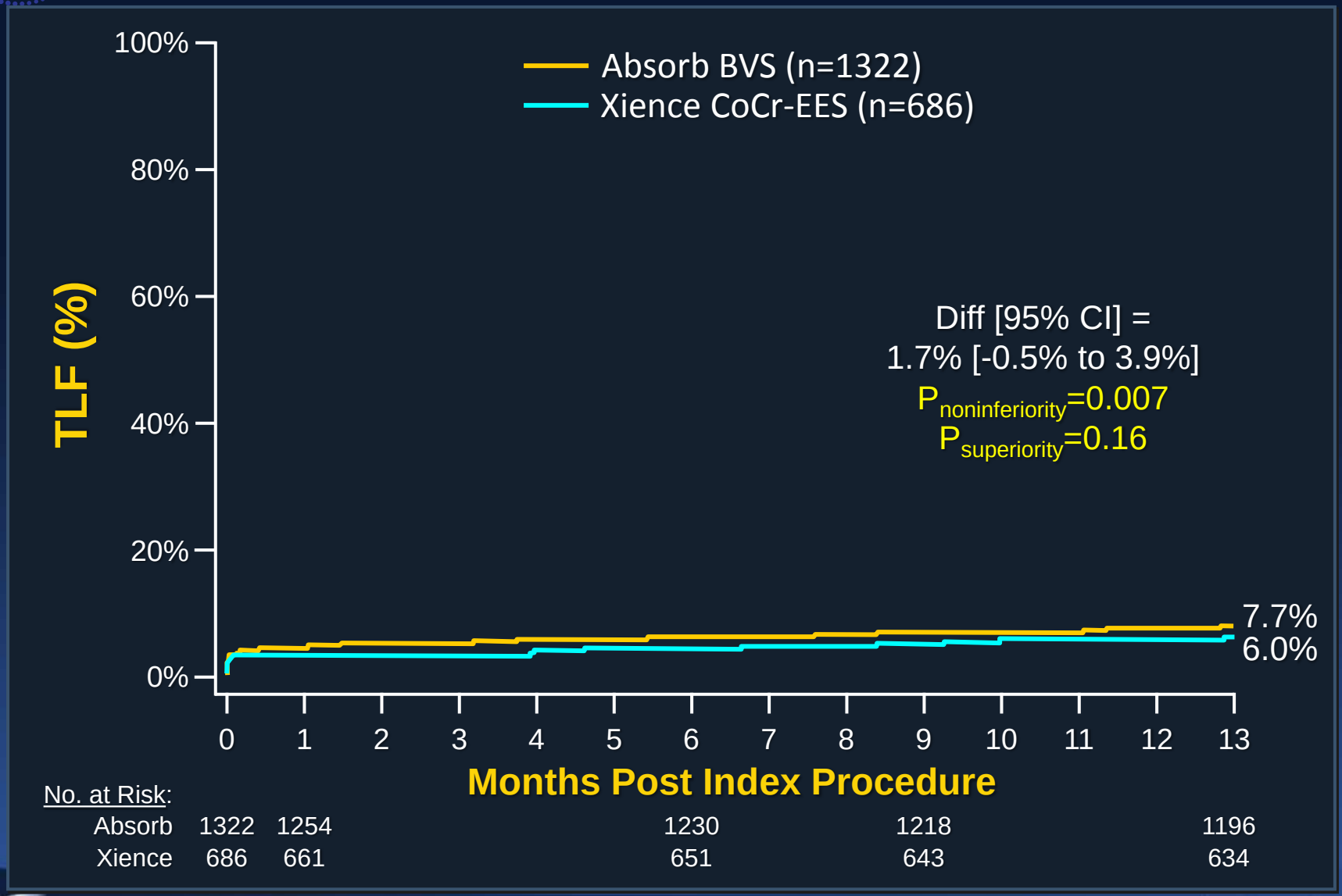
XIENCE V	669	646	616	601	582	571	565	548	537	529	521
TAXUS	332	310	288	274	269	262	255	248	243	231	223

TLF = cardiac death, target vessel MI, or ischemic-driven TLR

Spirit III: Gada H et al. J Am Coll Cardiol Intv 2013;6:1263–6

Cardiovascular Research Foundation
A Passion for Innovation
Columbia University Medical Center
NewYork-Presbyterian

Target Lesion Failure (1° EP)



Ellis SG et al. N Engl J Med. 2015;373:1905-15

Device Thrombosis to 1 Year

	Absorb (N=1322)	Xience (N=686)	p-value
Device Thrombosis (def*/prob)	1.54%	0.74%	0.13
- Early (0 to 30 days)	1.06%	0.73%	0.46
- Late (> 30 to 1 year)	0.46%	0.00%	0.10
- Definite* (1 year)	1.38%	0.74%	0.21
- Probable (1 year)	0.15%	0.00%	0.55

*One “definite ST” in the Absorb arm by ITT was in a pt that was treated with Xience

Ellis SG et al. N Engl J Med. 2015;373:1905-15

1-Year Device Thrombosis

Subgroup	Absorb (N=1322)	Xience (N=686)	RR (95% CI)	Relative Risk (95% CI)	p-value (interaction)
Age ≥64 years	1.8%	0.6%		3.22 (0.73-14.32)	0.38
Age <64 years	1.2%	0.9%		1.33 (0.36-4.99)	
Female	1.6%	2.0%		0.79 (0.23-2.78)	0.07
Male	1.5%	0.2%		7.21 (0.95-54.63)	
Diabetes	3.2%	1.4%		2.34 (0.67-8,13)	0.79
No diabetes	0.8%	0.4%		1.79 (0.37-8.56)	
Unstable angina/recent MI	1.0%	0.6%		1.88 (0.21-16.74)	0.91
Stable CAD	1.7%	0.8%		2.16 (0.73-6.42)	
Single TL/TV treated	1.6%	0.8%		2.09 (0.79-5.55)	n/a
Dual TL/TV treated	0.0%	0.0%		-	
Clopidogrel	1.8%	0.7%		2.69 (0.78-9.24)	0.33
Prasugrel or ticagrelor	0.8%	0.9%		0.96 (0.18-5.20)	
ACC/AHA class A or B1	0.8%	0.6%		1.36 (0.14-12.98)	0.67
ACC/AHA class B2 or C	1.9%	0.8%		2.32 (0.79-6.87)	
Lesion length <11.75 mm	1.4%	0.9%		1.58 (0.43-5.78)	0.56
Lesion length ≥11.75 mm	1.7%	0.6%		2.82 (0.63-12.67)	
RVD <2.63 mm	2.3%	0.9%		2.65 (0.77-9.07)	0.48
RVD ≥2.63 mm	0.8%	0.6%		1.28 (0.25-6.54)	

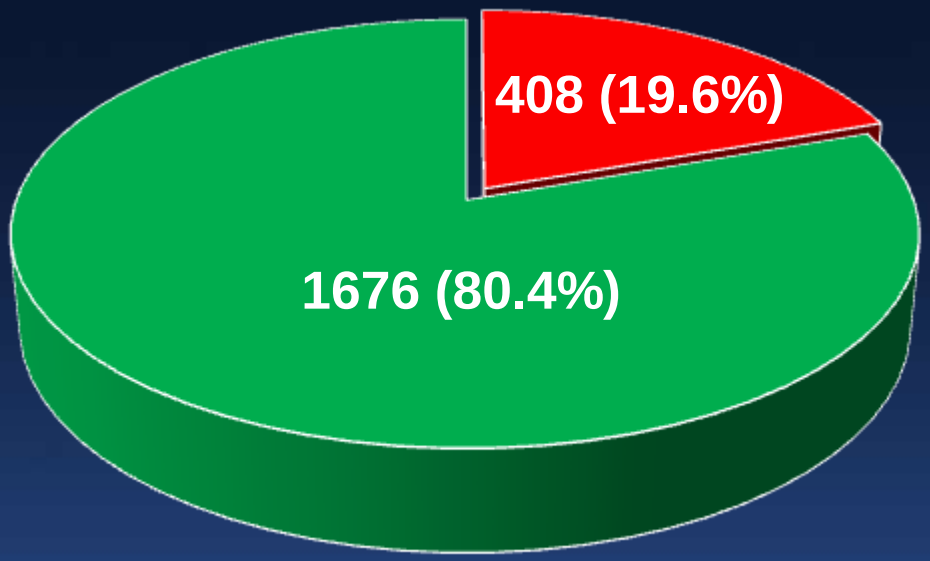
Ellis SG et al. N Engl J Med. 2015;373:1905-15

ABSORB III Analysis In Very Small Vessels

- Additional subgroup analyses were conducted to explore the differences in device thrombosis rates between Absorb and Xience
- Given the thicker struts of Absorb, a biologically relevant analysis was to examine outcomes in very small vessels
- We therefore performed detailed analyses according to reference vessel diameter (RVD) by QCA
- Note: QCA under-estimates visually assessed vessel diameter; 2.5 mm diameter by visual assessment (smallest RVD intended for Absorb) is ~2.25 mm by QCA

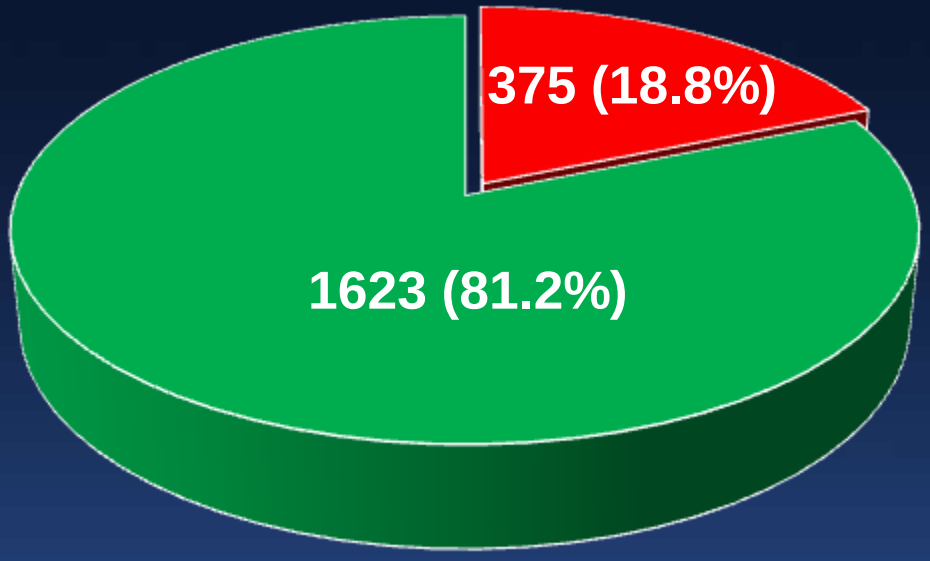
Patients and Lesions with QCA RVD <2.25 mm

Lesions (n=2084)



- QCA RVD <2.25 mm (median 2.09 [1.97, 2.19])
- QCA RVD ≥2.25 mm (median 2.74 [2.49, 3.03])

Patients (n=1998)



- 1 or 2 lesions with QCA RVD <2.25 mm
- All lesions with QCA RVD ≥2.25 mm

Device Thrombosis by Vessel Size

Any QCA RVD <2.25 mm vs. all RVD ≥2.25 mm

Any QCA RVD <2.25 mm

1-year results Absorb vs. Xience

4.6% vs. 1.5% respectively

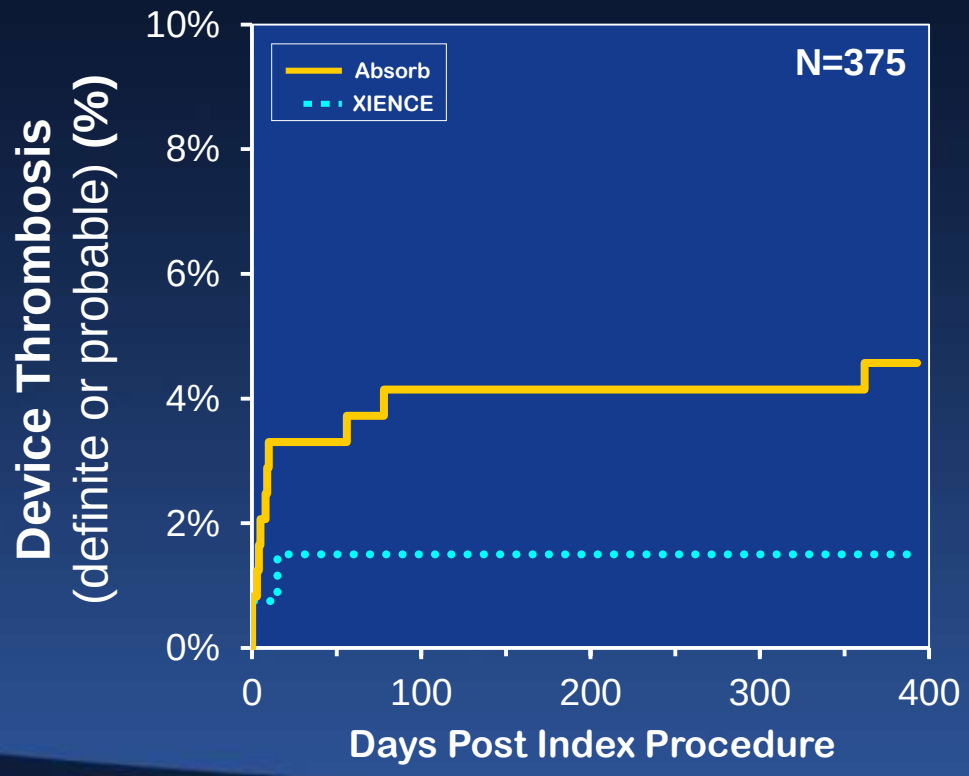
Diff [95%CI] = 3.1 [-0.3, 6.4]

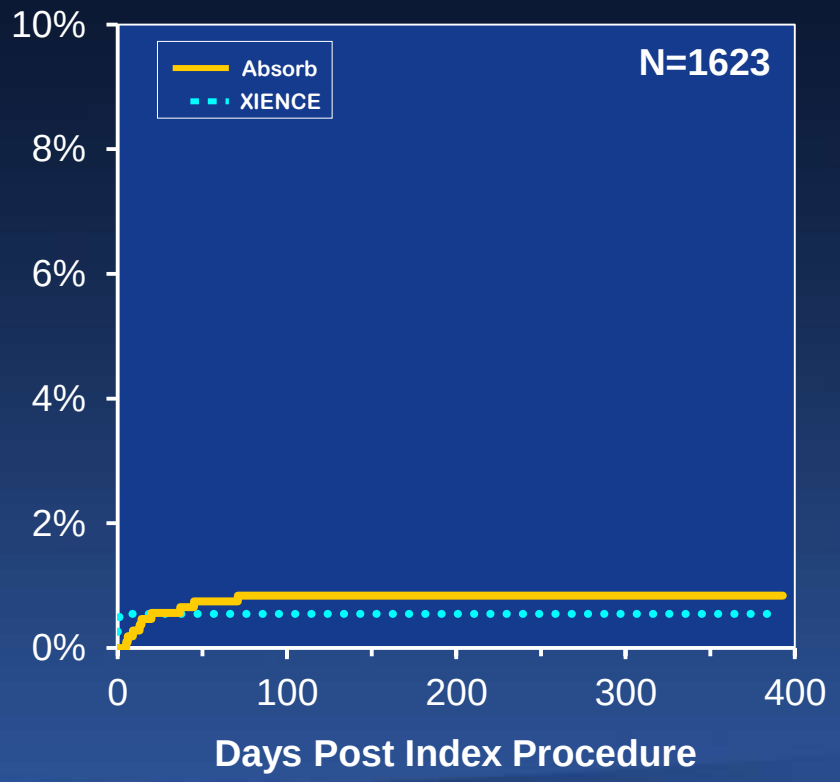
All QCA RVD ≥2.25 mm

1-year results Absorb vs. Xience

0.8% vs. 0.5% respectively

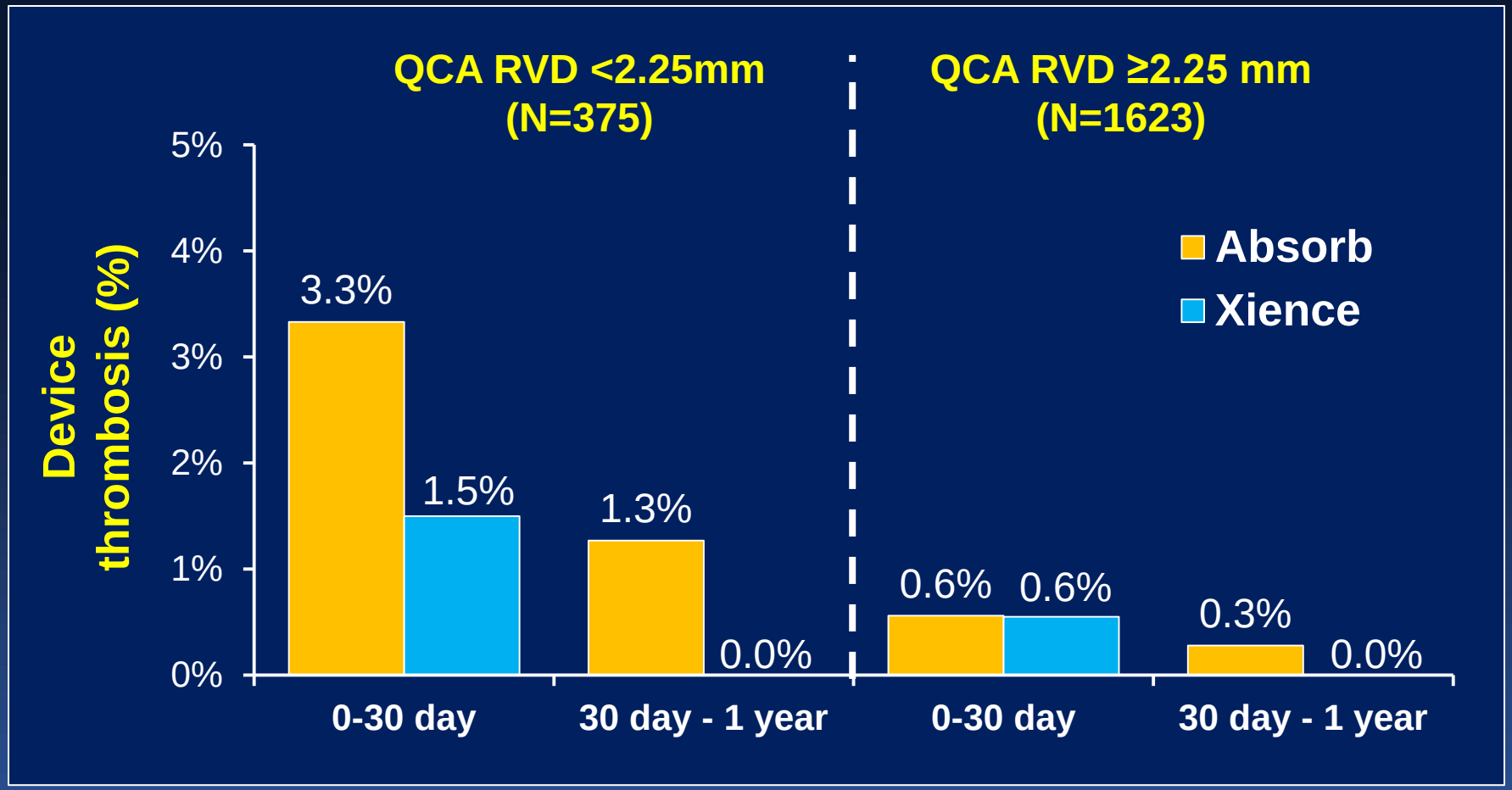
Diff [95%CI] = 0.3 [-0.5, 1.1]





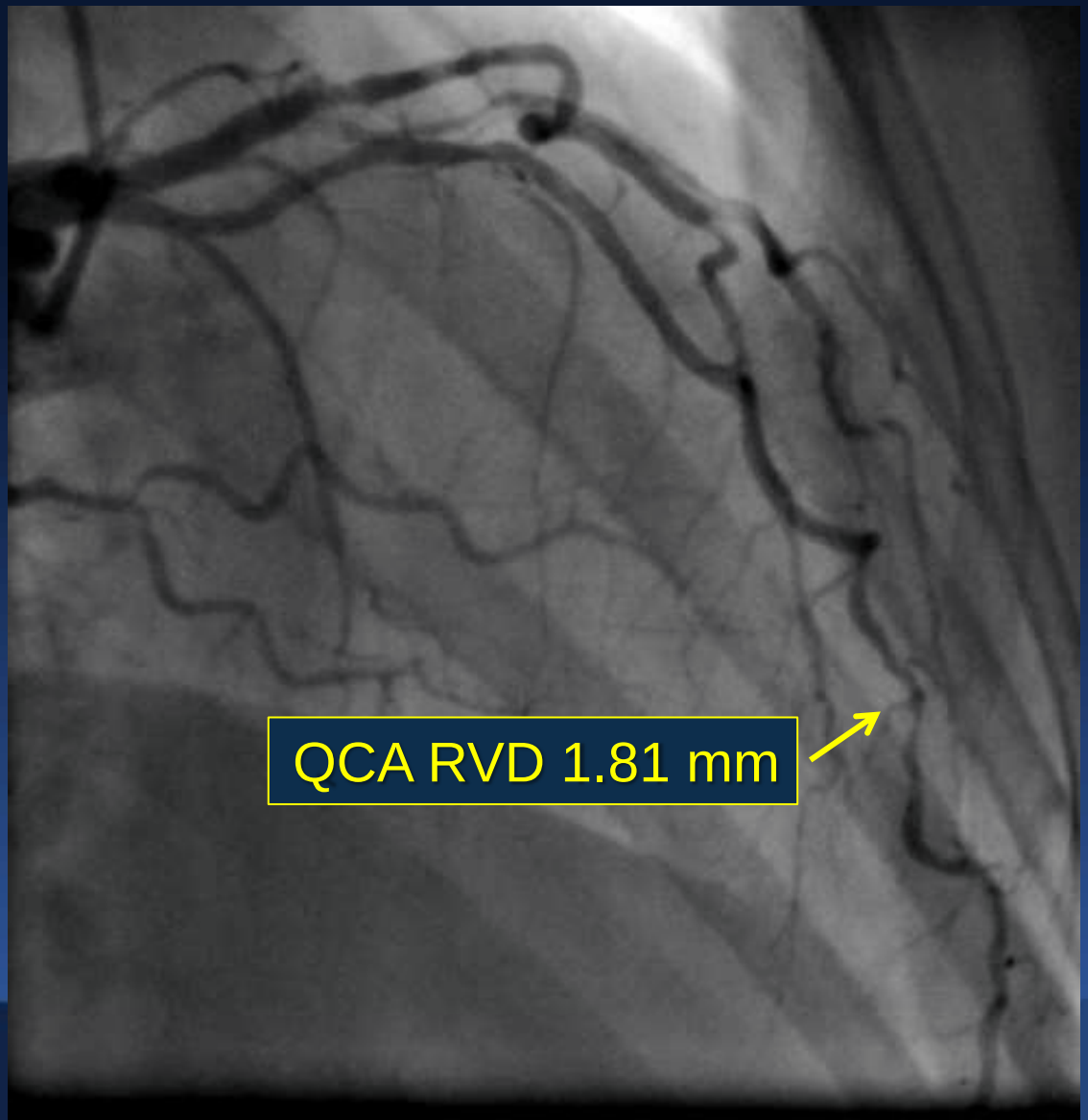
Additive interaction P-value = 0.11

Device Thrombosis by Timing and Vessel Size

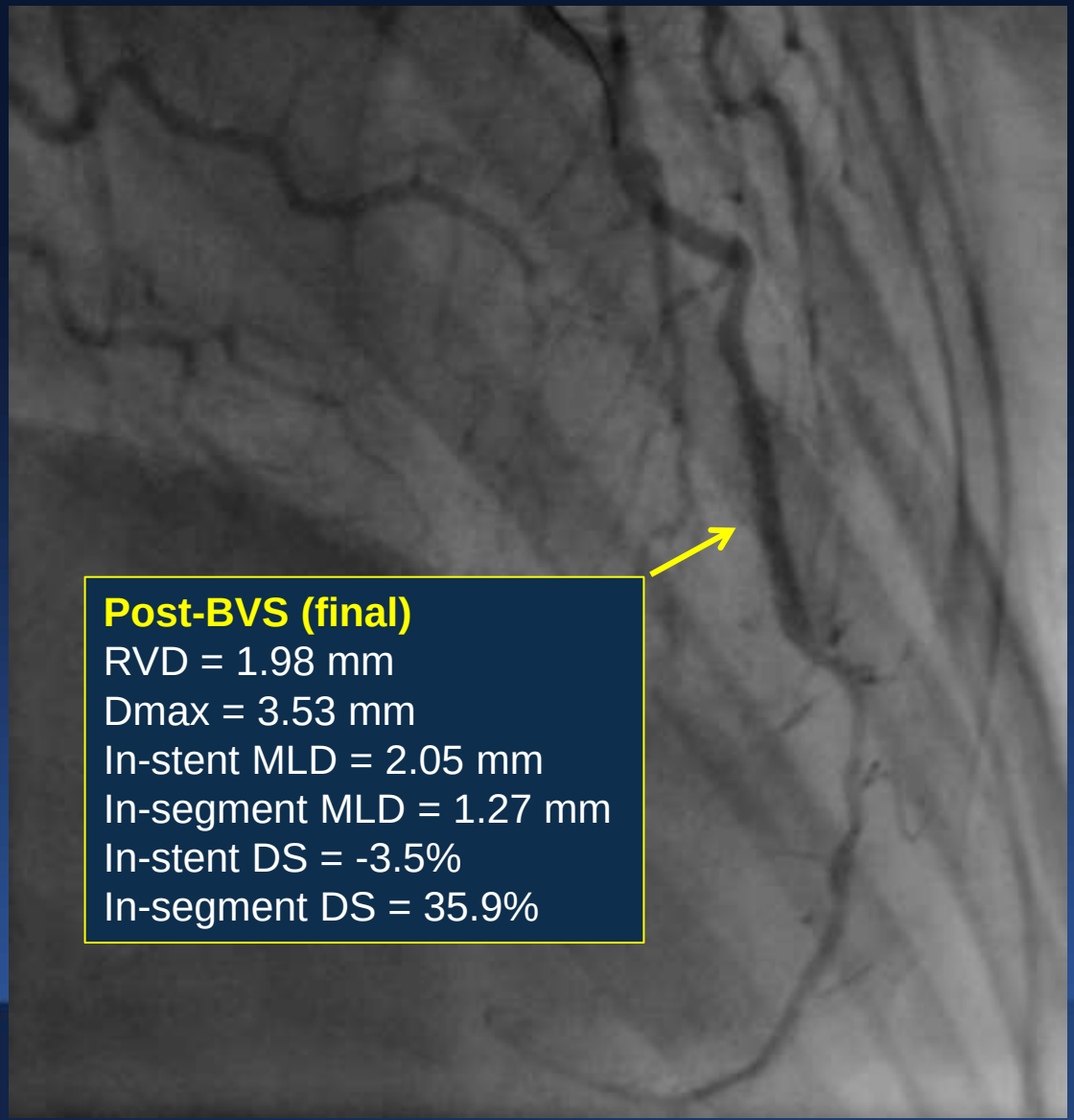


All P=NS

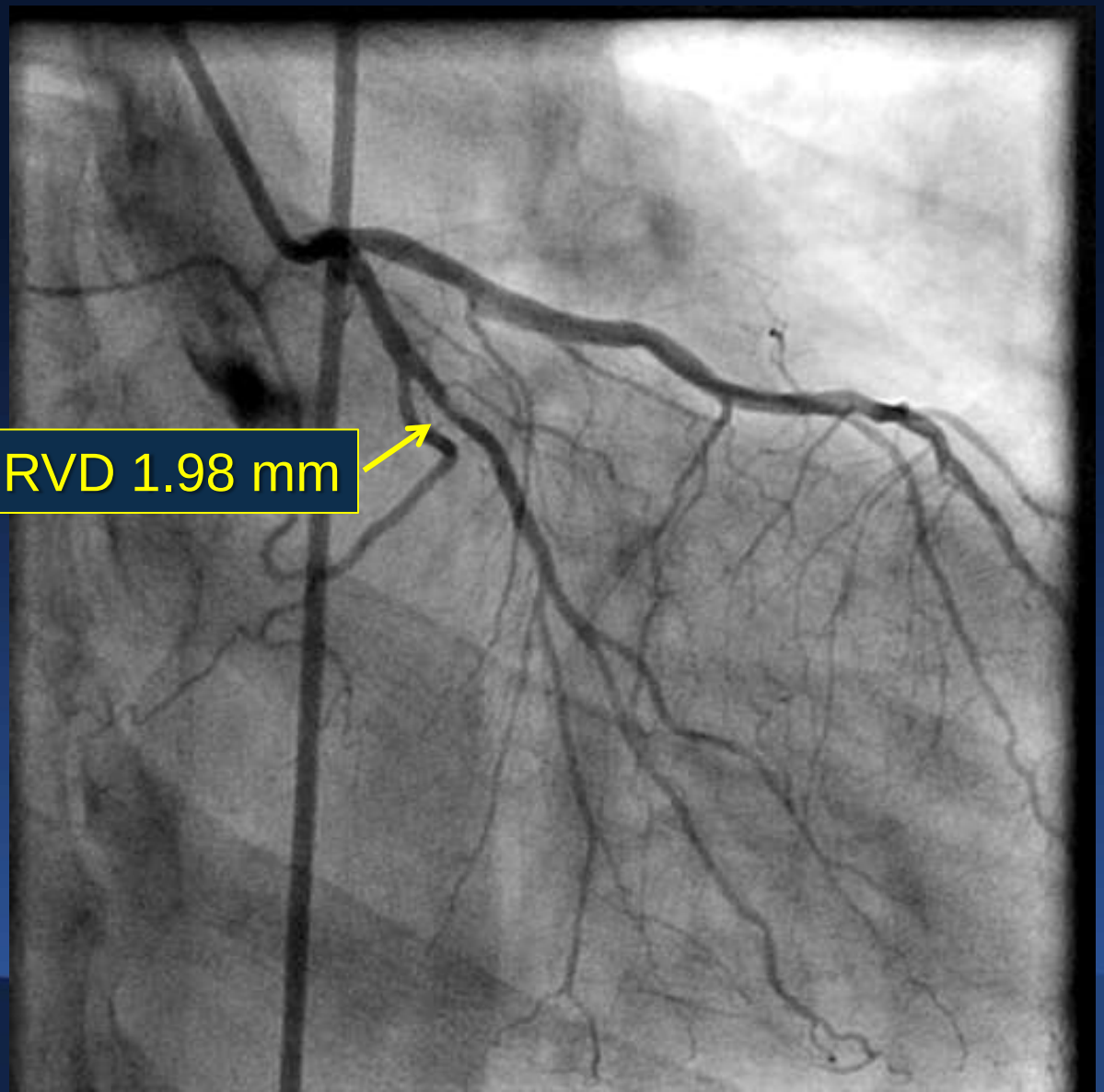
Example 1: Very small vessel enrolled in ABSORB III



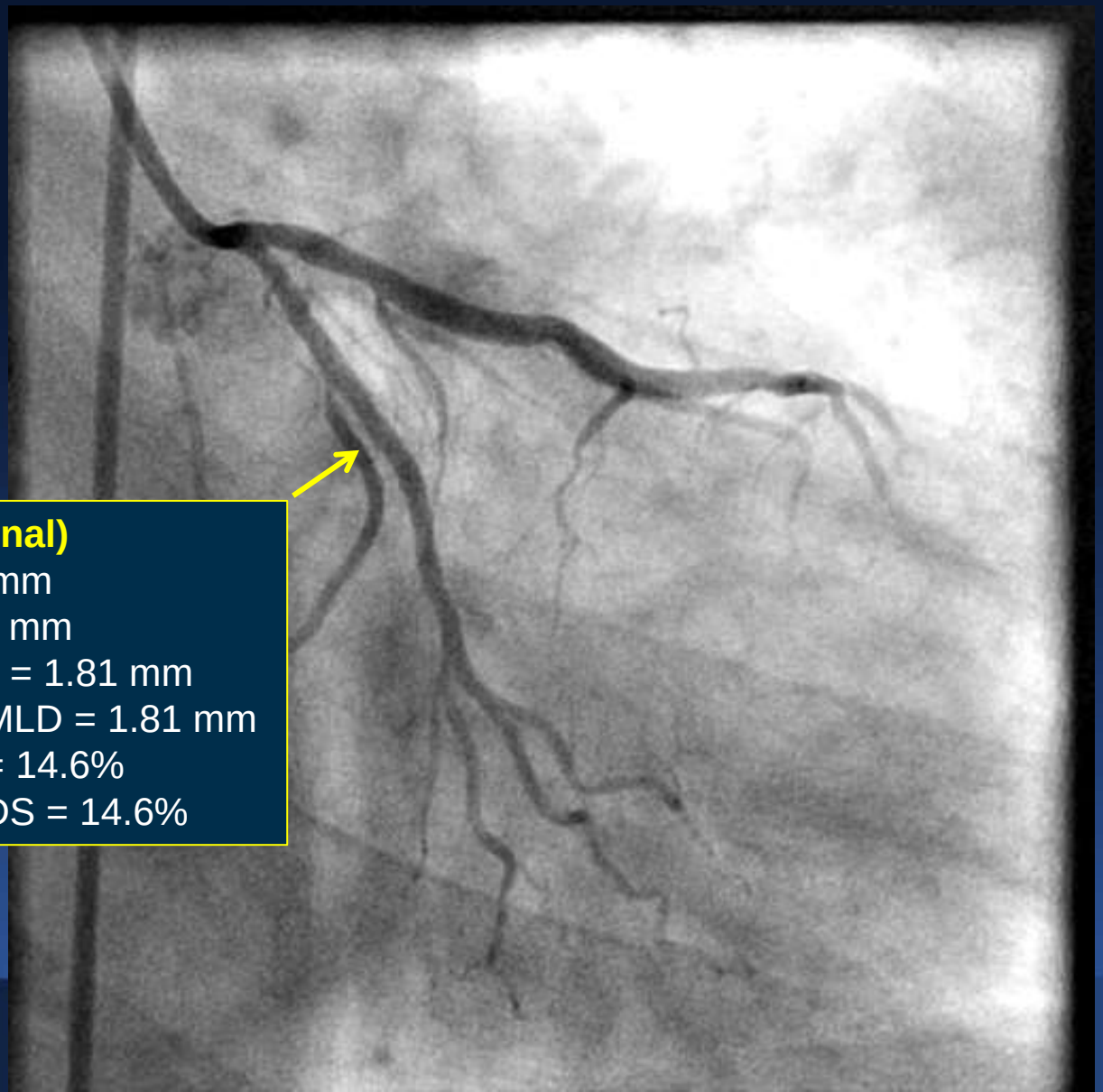
Example 1: Very small vessel enrolled in ABSORB III



Example 2: Very small vessel enrolled in ABSORB III



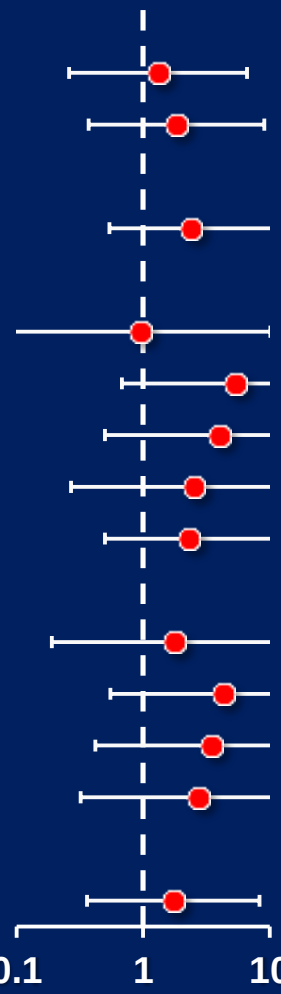
Example 2: Very small vessel enrolled in ABSORB III



Post-BVS (final)
RVD = 2.12 mm
Dmax = 2.44 mm
In-stent MLD = 1.81 mm
In-segment MLD = 1.81 mm
In-stent DS = 14.6%
In-segment DS = 14.6%

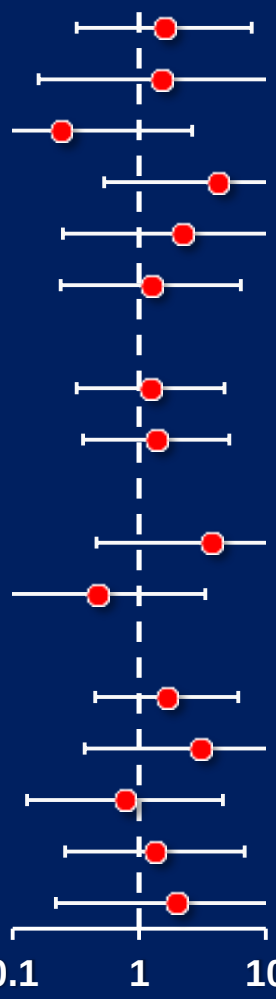
Device Thrombosis in RVD <2.25 mm Subgroup

Subgroup	Absorb N=242	Xience N=133	Relative Risk (95% CI)	p-value (interaction)
Age ≥65 years	5.1	0.0	n/a	n/a
Age <65 years	4.1	3.1	1.32 (0.26-6.63)	
Female	6.4	3.5	1.83 (0.37-9.08)	n/a
Male	3.8	0.0	n/a	
Diabetes	10.6	4.4	2.38 (0.54-10.56)	n/a
No diabetes	1.3	0.0	n/a	
Unstable angina/recent MI	3.1	3.2	0.95 (0.09-10.12)	0.28
Stable CAD	5.2	1.0	5.31 (0.68-41.28)	
Single lesion treated	4.1	1.0	3.98 (0.50-31.37)	0.77
Dual lesion treated	7.0	2.8	2.51 (0.27-23.11)	
Clopidogrel	5.2	2.2	2.30 (0.50-10.58)	n/a
Prasugrel or ticagrelor	2.5	0.0	n/a	
ACC/AHA class A or B1	3.2	1.8	1.77 (0.19-16.64)	0.57
ACC/AHA class B2 or C	5.5	1.3	4.30 (0.55-33.78)	
QCA lesion length <10.56 mm	5.3	1.5	3.45 (0.42-28.04)	0.88
QCA lesion length ≥10.56 mm	4.0	1.5	2.72 (0.32-22.81)	
QCA RVD <2.09 mm	3.8	0.0	n/a	n/a
QCA RVD ≥2.09 mm	5.7	3.3	1.73 (0.36-8.29)	



Device Thrombosis in RVD ≥2.25 mm Subgroup

Subgroup	Absorb N=1074	Xience N=549	Relative Risk (95% CI)	p-value (interaction)
Age ≥64 years	1.1	0.7	1.58 (0.32-7.76)	0.97
Age <64 years	0.6	0.4	1.49 (0.16-14.21)	
Female	0.3	1.4	0.24 (0.02-2.62)	0.08
Male	1.1	0.3	4.19 (0.53-33.35)	
Diabetes	1.3	0.6	2.18 (0.25-19.32)	0.69
No diabetes	0.7	0.5	1.24 (0.24-6.37)	
Unstable angina/recent MI	0.6	0.0	n/a	n/a
Stable CAD	0.9	0.8	1.23 (0.32-4.73)	
Single lesion treated	0.9	0.6	1.37 (0.36-5.14)	n/a
Dual lesion treated	0.6	0.0	n/a	
Clopidogrel	1.1	0.3	3.70 (0.46-29.97)	0.16
Prasugrel or ticagrelor	0.5	1.1	0.47 (0.07-3.34)	
ACC/AHA class A or B1	0.0	0.0	n/a	n/a
ACC/AHA class B2 or C	1.2	0.7	1.65 (0.45-6.06)	
QCA lesion length <11.95 mm	1.2	0.4	3.05 (0.37-25.22)	0.33
QCA lesion length ≥11.95 mm	0.6	0.7	0.77 (0.13-4.59)	
QCA RVD <2.74 mm	1.0	0.7	1.33 (0.26-6.83)	0.78
QCA RVD ≥2.74 mm	0.7	0.4	1.95 (0.22-17.37)	



TLF by Vessel Size

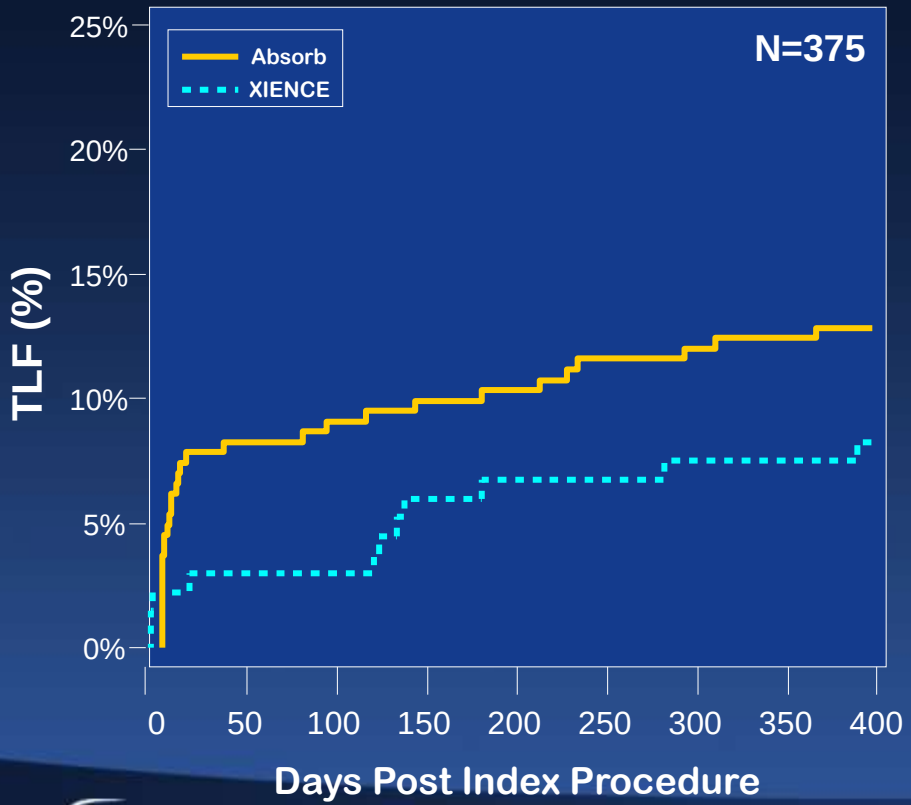
Any QCA RVD <2.25 mm vs. all RVD ≥2.25 mm

Any QCA RVD <2.25 mm

1-year results Absorb vs. Xience

12.9% vs. 8.3% respectively

Diff [95%CI] = 4.6 [-1.7, 10.9]

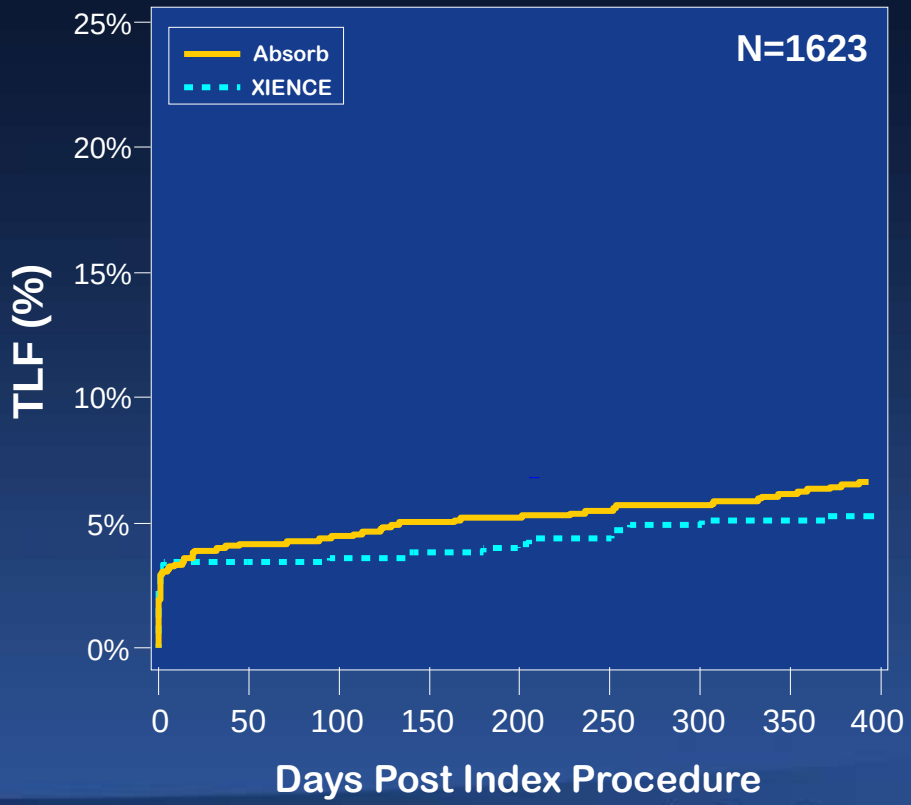


All QCA RVD ≥2.25 mm

1-year results Absorb vs. Xience

6.6% vs. 5.5% respectively

Diff [95%CI] = 1.2 [-1.3, 3.6]



Additive interaction P-value = 0.31

Clinical Outcomes in Patients with Lesions with QCA RVD <2.25 mm (not intended for Absorb BVS)

1-Year Event Rates	Absorb (N=242)	XIENCE (N=133)	Difference [95%CI]	P-value
TLF	12.9%	8.3%	**4.6%** [-2.4%, 10.6%]	0.18
- Cardiac death	0.8%	0.0%	**0.8%** [-2.0%, 3.0%]	0.54
- TV-MI	10.0%	4.5%	**5.5%** [-0.5%, 10.5%]	0.06
- ID-TLR	6.6%	6.8%	**-0.1%**[1] [-6.3%, 4.9%]	0.96
Stent thrombosis	4.6%	1.5%	**3.1%** [-1.2%, 6.8%]	0.15

1. Absorb = 6.64%; Xience = 6.77%

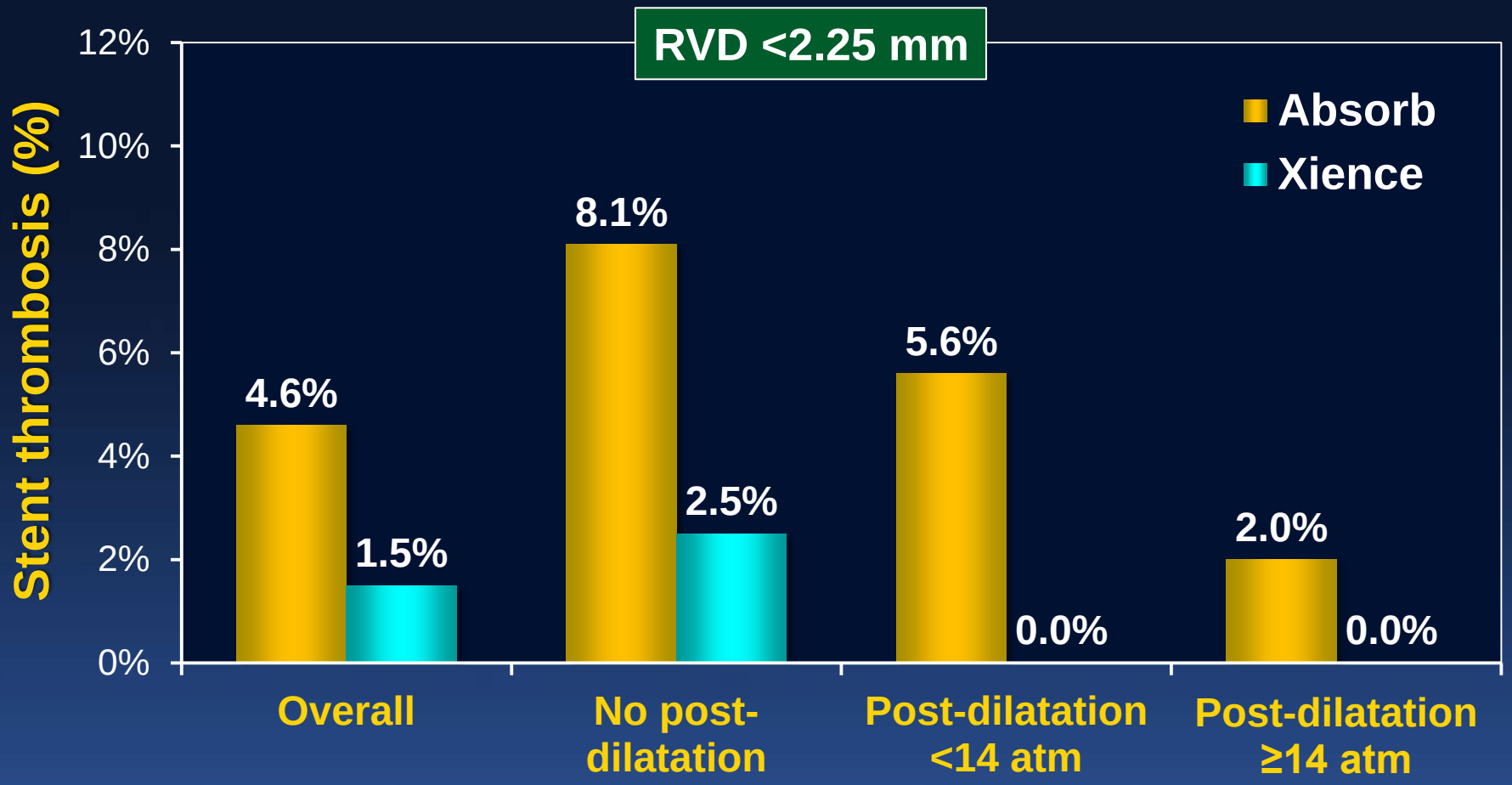
Clinical Outcomes in Patients with all Lesions with QCA RVD ≥2.25 mm (indicated for Absorb BVS)

1-Year Event Rates	Absorb (N=1074)	XIENCE (N=549)	Difference [95%CI]	P-value
TLF	6.7%	5.5%	**1.1%**[1] [-1.5%, 3.4%]	0.38
- Cardiac death	0.6%	0.2%	**0.4%** [-0.5%, 1.1%]	0.43
- TV-MI	5.2%	4.6%	**0.5%**[2] [-1.9%, 2.6%]	0.64
- ID-TLR	2.2%	1.5%	**0.8%**[3] [-0.8%, 2.1%]	0.29
Stent thrombosis	0.9%	0.6%	**0.3%** [-0.8%, 1.1%]	0.76

1. Absorb = 6.65%, Xience = 5.54%, difference = 1.12%
2. Absorb = 5.15%; Xience = 4.61%, difference = 0.54%
3. Absorb = 2.249%; Xience = 1.476%, difference = 0.773%

1-Year ST in Very Small Vessels

Impact of Post-Dilatation and Pressure



	Overall	No post-dilatation	Post-dilatation <14 atm	Post-dilatation ≥14 atm
Absorb:	11/238	6/74	3/54	2/101
Xience:	2/133	2/79	0/15	0/36

All P=NS

ABSORB III

Small Vessel Analysis Conclusions

- Compared to the thin strut XIENCE metallic DES, the thicker strut Absorb BVS results in similar 1-year outcomes in coronary arteries with QCA RVD ≥2.25 mm, but may have higher event rates in very small vessels
- These findings have important implications for device selection (and potentially technique) to optimize 1-year outcomes when selecting patients and lesions for Absorb BVS