TCT 2014 13 Sep 2014 - 17 Sep 2014 , Washington, DC - U.S.A
Plenary Session XII : Late-Breaking clinical Trials #2

ABSORB II : A Prospective, Randomized Trial of an Everolimus-Eluting Bioresorbable Scaffold Versus an Everolimus-Eluting Metallic Stent in Patients with Coronary Artery Disease

Patrick W. Serruys
Imperial College, London, UK
Erasmus University MC, Rotterdam, the Netherlands

ICPS, Bernard Chevalier
Massy, France
on behalf of the ABSORB II Investigators

Room: Level 3, Ballroom 11:00- 11:12, Sep 14st, 2014

In Partnership with the ACC
tct2014
Columbia University Medical Center
NewYork-Presbyterian

Disclosures

- Patrick W. Serruys is a member of the Advisory Board of Abbott Vascular
- Bernard Chevalier is a consultant for Abbott Vascular

Background

1. The polymeric bioresorbable scaffold should have mechanical properties sufficient to prevent acute recoil and late constrictive remodeling.

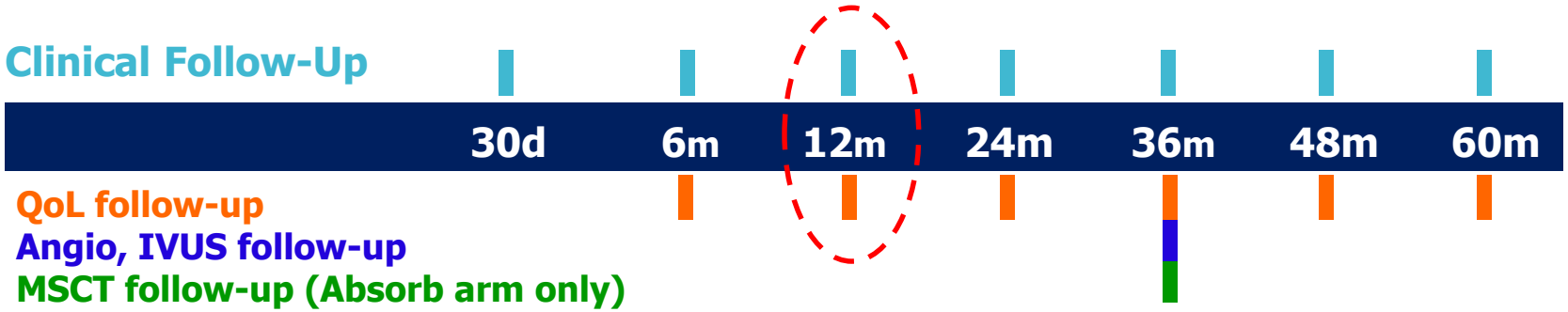
2. Following CE mark approval widespread dissemination of the Absorb™ bioresorbable scaffold has, until now, occurred without randomized comparison with its metallic counterpart (Xience™ stent).

3. Considering the rapid adoption of this novel treatment, the Steering Committee and Sponsor of the Trial decided to report the secondary clinical endpoints at 1 year in order to provide the medical community with the first randomized data on the device.

ABSORB II Study Design

501 subjects

Randomized 2:1 Absorb BVS:XIENCE / 46 sites (Europe and New Zealand)

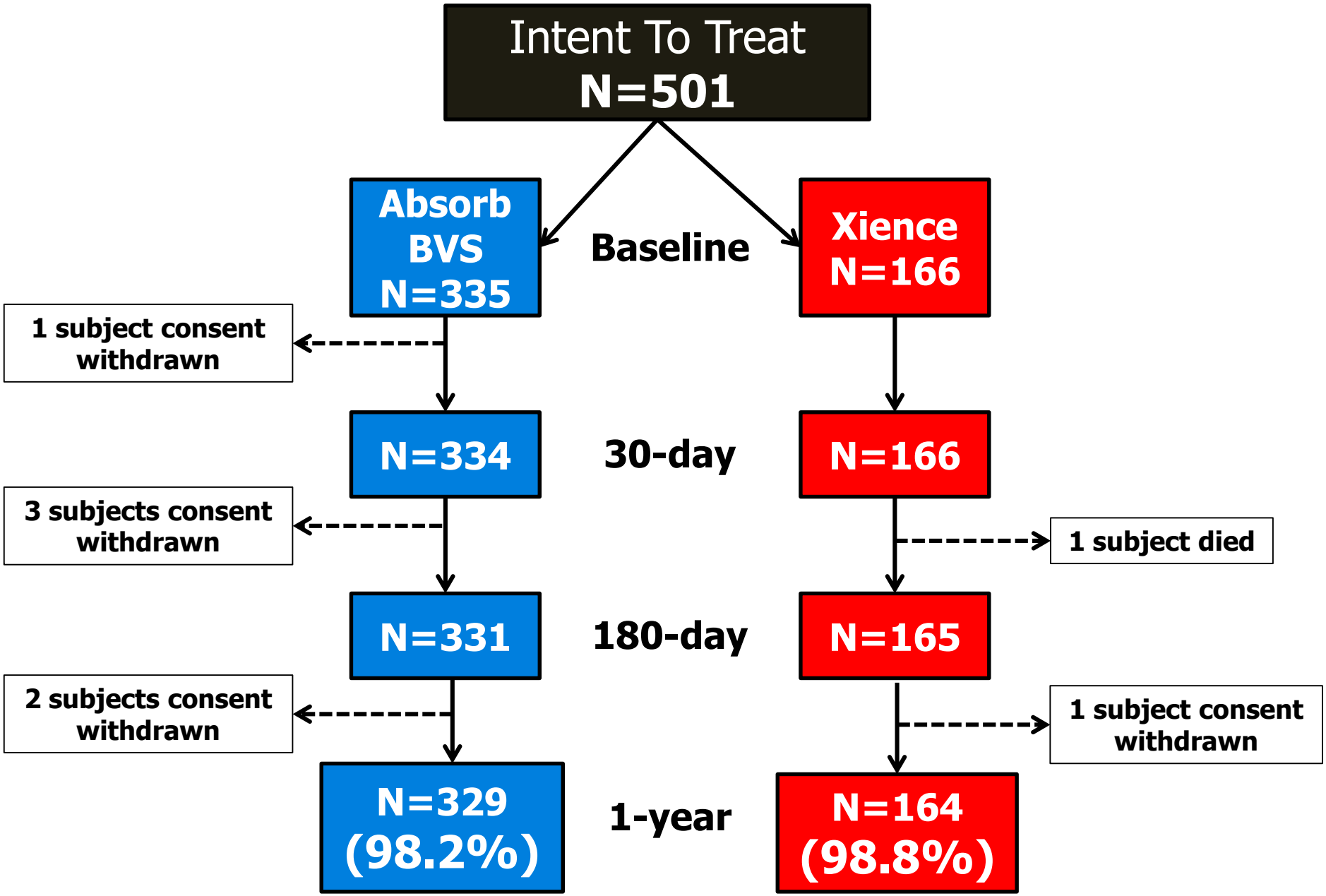


Study Objective	**Randomized against XIENCE control. First Patient In: 28-Nov-2011**
Co-primary Endpoints	**Vasomotion assessed by change in Mean Lumen Diameter between pre- and post-nitrate at 3 years (superiority)** **Minimum Lumen Diameter (MLD) at 3 years post nitrate minus MLD post procedure post nitrate (non-inferiority, reflex to superiority)**
Treatment	**Up to 2 *de novo* lesions in different epicardial vessels** **Planned overlapping allowed in lesions ≤ 48 mm**
Device Sizes	**Device diameters: 2.5, 3.0, 3.5 mm** **Device lengths: 12 (3.5 mm diameter only), 18, 28 mm**

ABSORB II Study Organisation

• Principal Investigator:	Patrick W. Serruys – Rotterdam, NL
• Co-Principal Investigator:	Bernard Chevalier – Massy, FR
• Steering Committee:	Michael Haude – Neuss, DE Angel Cequier – Barcelona, ES Dariusz Dudek – Krakow, PL
• Clinical Event Committee (CEC):	Eugene McFadden – Cork, IE Scot Garg – Blackburn, UK Claude Hanet – Yvoir, BE Giampaolo Niccoli – Roma, IT Benno Rensing – Nieuwegein, NL
• Data Safety Monitoring Board (DSMB):	Jan Tijssen – Amsterdam, NL Gert Richardt – Bad Segeberg, DE Philip Urban – Geneva, CH Keith Fox – Edinburgh, UK Marcus Wiemer – Bad Oeynhausen, DE
• Imaging Core Laboratory:	Cardialysis – Rotterdam, NL
• Blood Sample Central Laboratory:	ICON – Dublin, IE
• Sponsor:	Abbott Vascular – Santa Clara, USA

ABSORB II 1-Year Patient Flowchart



Characteristics of Patients at Baseline

		Absorb 335 pts	Xience 166 pts	95% CI
Age (year) mean ±SD		**61.5 ± 10.0**	**60.9 ± 10.0**	N.S.
Male	**%**	**75.5**	**79.5**	N.S.
Current Tobacco Use	**%**	**23.6**	**21.7**	N.S.
Hypertension	**%**	**69.0**	**71.7**	N.S.
Dyslipidemia	**%**	**75.2**	**80.1**	N.S.
All Diabetes Mellitus	**%**	**23.9**	**24.1**	**N.S.**
Diabetes Mellitus Insulin Dependent	**%**	**6.6**	**8.4**	**N.S.**
Family History of Premature CAD	**%**	**36.6**	**41.3**	N.S.
Prior Intervention in Target Vessel	**%**	**11.7**	**8.9**	N.S.
Prior MI	**%**	**28.0**	**28.9**	N.S.

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		Absorb 335 pts	Xience 166 pts	95% CI
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Male	%	75.5	79.5	N.S.
Current Tobacco Use	%	23.6	21.7	N.S.
Hypertension	%	69.0	71.7	N.S.
Dyslipidemia	%	75.2	80.1	N.S.
All Diabetes Mellitus	%	23.9	24.1	N.S.
Diabetes Mellitus Insulin Dependent	%	6.6	8.4	N.S.
Family History of Premature CAD	%	36.6	41.3	N.S.
Prior Intervention in Target Vessel	%	11.7	8.9	N.S.
Prior MI	%	28.0	28.9	N.S.
Stable Angina	%	63.9	64.5	N.S.
Unstable Angina	%	20.3	22.3	N.S.
Silent Ischemia	%	12.5	11.4	N.S.
Recent MI with normalized cardiac enzyme	%	3.3	1.8	N.S.

Characteristics of Lesions at Baseline

		Absorb 335 pts 364 lesions	Xience 166 pts 182 lesions	95% CI
Single Vessel Disease	**%**	**83.0**	**84.9**	**N.S.**
Target Vessel				
Left Anterior Descending Artery	%	**44.8**	**46.2**	N.S.
Left Circumflex Artery	%	**29.1**	**23.1**	N.S.
Right Coronary Artery	%	**26.1**	**30.8**	N.S.
Two or More Lesion Treated	**%**	**8.7**	**9.6**	N.S.
Calcification (Moderate or Severe)	**%**	**12.7**	**15.5**	N.S.
ACC/AHA Lesion Class				
A	%	**1.4**	**0.6**	N.S.
B1	**%**	**53.2**	**50.0**	**N.S.**
B2	**%**	**43.8**	**48.3**	**N.S.**
C	%	**1.7**	**1.1**	N.S.

Procedural Assessment Pre and Post Procedure

		Absorb 364 Lesions	Xience 182 Lesions	*p* value
Procedural Details Per Lesion				
Balloon dilatation prior to device implantation	%	**100**	**98.9**	**0.11**
Planned overlap with the same type of device	%	**15.4**	**11.0**	**0.16**
Unplanned/bailout implantation "same"	%	**3.8**	**6.0**	**0.25**

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Unplanned/bailout implantation "same"	%	**3.8**		**6.0**	**0.25**
Nominal size of study device	mm	**3.01**		**3.05**	**0.10**
Balloon dilatation after device implantation	%	**60.7**		**58.8**	**0.67**
Nominal diameter of last balloon used	mm	**3.08**	<	**3.16**	**0.02**
Maximum last balloon pressure used	atm	**14.23**	<	**15.03**	**0.01**
Acute recoil post device implantation	mm	**0.19**		**0.19**	**0.85**

Procedural Assessment Pre and Post Procedure

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Acute recoil post device implantation	mm	**0.19**		**0.19**	**0.85**
Acute Clinical Device Success	%	**99.2**		**100**	**0.55**
Acute Clinical Procedural Success	%	**96.1**		**98.8**	**0.16**

Angiography Assessment Pre and Post Procedure

		Absorb 364 Lesions		Xience 182 Lesions	*p* value
Lesion length obstruction	mm	13.8 ± 6.5		13.8 ± 6.6	1.00
Total device length	mm	21.1 ± 8.8		20.9 ± 7.4	0.74
Pre-procedure RVD	mm	2.59 ± 0.4		2.63 ± 0.4	0.36
Post- procedure RVD	mm	2.64 ± 0.4	<	2.80 ± 0.3	<0.001

Angiography Assessment Pre and Post Procedure

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Lesion length obstruction	mm	13.8 ± 6.5		13.8 ± 6.6	1.00
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Pre-procedure RVD	mm	2.59 ± 0.4		2.63 ± 0.4	0.36
Post- procedure RVD	mm	2.64 ± 0.4	<	2.80 ± 0.3	<0.001
Pre-procedure MLD	mm	1.07 ± 0.3		1.05 ± 0.3	0.44
Post-procedure in-device MLD	mm	2.22 ± 0.3	<	2.50 ± 0.3	<0.001

Angiography Assessment Pre and Post Procedure

		Absorb 364 Lesions		Xience 182 Lesions	*p* value
Lesion length obstruction	mm	13.8 ± 6.5		13.8 ± 6.6	1.00
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Pre-procedure RVD	mm	2.59 ± 0.4		2.63 ± 0.4	0.36
Post- procedure RVD	mm	2.64 ± 0.4	<	2.80 ± 0.3	<0.001
Pre-procedure MLD	mm	1.07 ± 0.3		1.05 ± 0.3	0.44
Post-procedure in-device MLD	mm	2.22 ± 0.3	<	2.50 ± 0.3	<0.001
Acute gain in-device	mm	1.15 ± 0.4	<	1.46 ± 0.4	<0.001
Pre-procedure %DS	%	59 ± 11		60 ± 12	0.30
Post-procedure in-device DS	%	16 ± 7	>	10 ± 5	<0.001

Angiography Assessment Pre and Post Procedure

		Absorb 364 Lesions		Xience 182 Lesions	*p* value
Lesion length obstruction	mm	13.8 ± 6.5		13.8 ± 6.6	1.00
Total device length	mm	21.1 ± 8.8		20.9 ± 7.4	0.74
Pre-procedure RVD	mm	2.59 ± 0.4		2.63 ± 0.4	0.36
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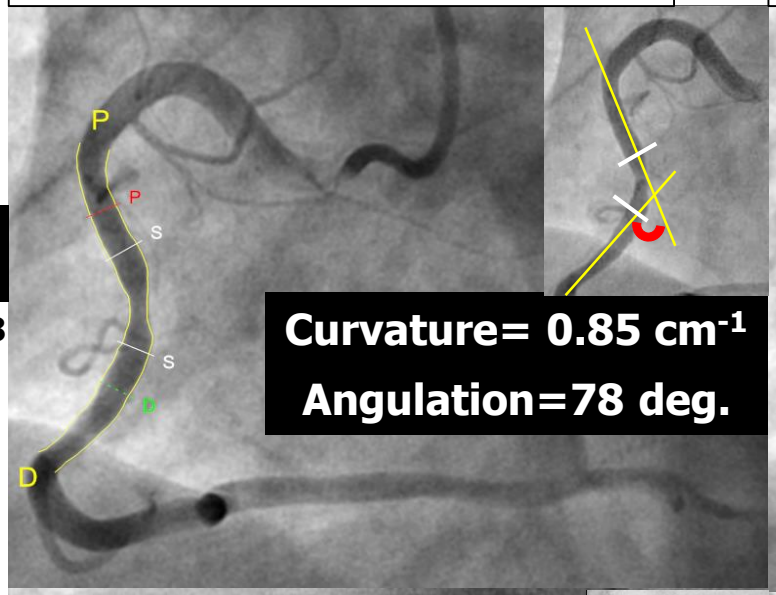
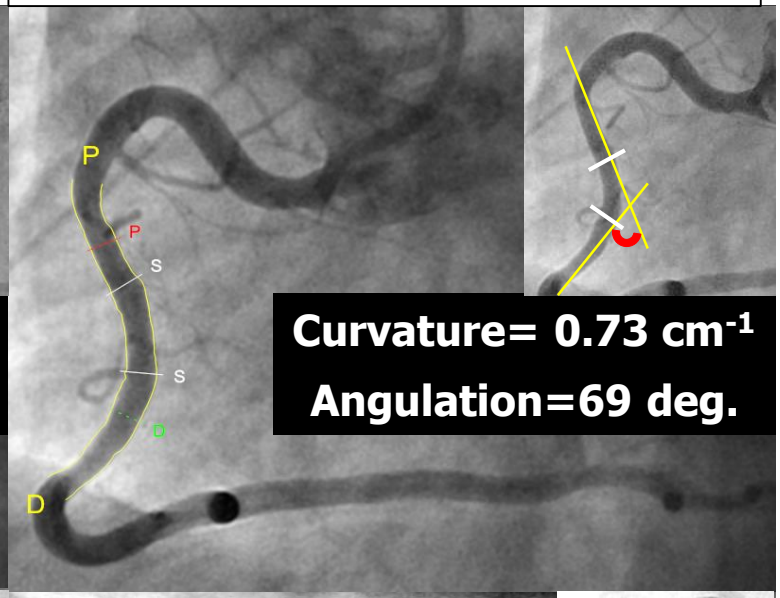
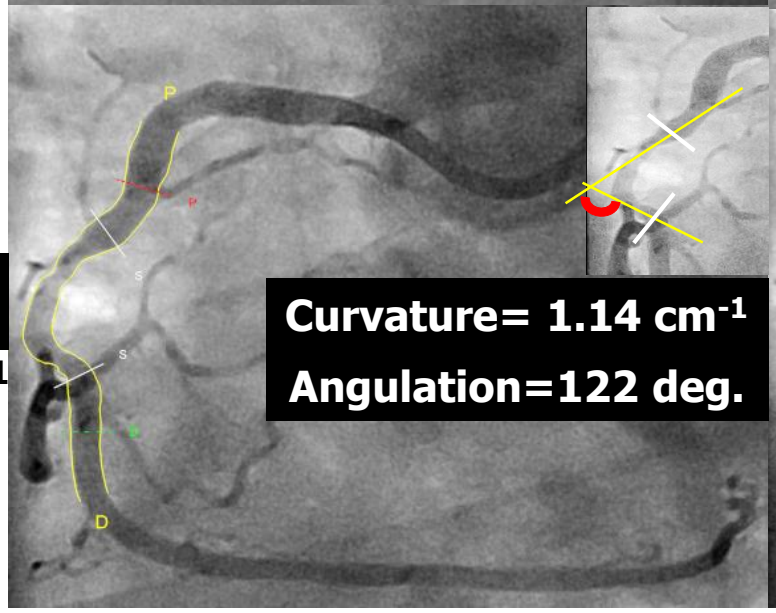
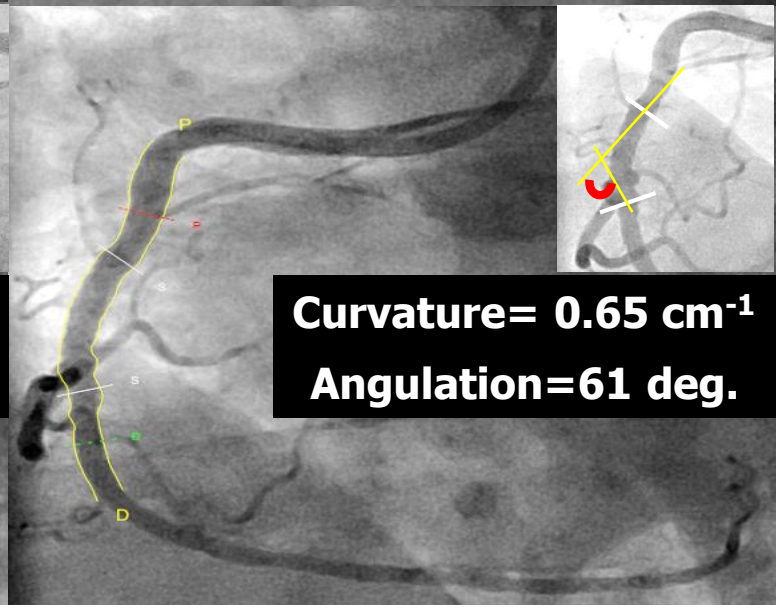
Acute gain in-device	mm	1.15 ± 0.4	<	1.46 ± 0.4	<0.001
Pre-procedure %DS	%	59 ± 11		60 ± 12	0.30
Post-procedure in-device DS	%	16 ± 7	>	10 ± 5	<0.001
Post-procedural curvature	cm^{-1}	0.29 ± 0.2	>	0.24 ± 0.2	0.02

Conformability (Curvature, Angulation) in Absorb BVS and Xience

	Pre device implantation	Post device implantation
Absorb Case:103257-1018		
Xience Case:100353-1011		

IVUS Assessment Pre and Post Procedure

		Absorb 364 Lesions		Xience 182 Lesions	*p* value
Pre-procedure vessel area	mm^2	11.5 ± 3.4	<	12.3 ± 3.4	0.02
Post-procedure vessel area	mm^2	13.2 ± 3.6	<	14.3 ± 3.6	0.001

IVUS Assessment Pre and Post Procedure

		Absorb 364 Lesions		Xience 182 Lesions	*p* value
Pre-procedure vessel area	mm^2	11.5 ± 3.4	<	12.3 ± 3.4	0.02
Post-procedure vessel area	mm^2	13.2 ± 3.6	<	14.3 ± 3.6	0.001
Pre-procedure plaque area / media	mm^2	6.7 ± 2.5	<	7.3 ± 2.7	0.01
Post-procedure plaque area / media	mm^2	7.1 ± 2.5		7.4 ± 2.4	0.18

IVUS Assessment Pre and Post Procedure

		Absorb 364 Lesions		Xience 182 Lesions	*p* value
Pre-procedure vessel area	mm^2	11.5 ± 3.4	<	12.3 ± 3.4	0.02
Post-procedure vessel area	mm^2	13.2 ± 3.6	<	14.3 ± 3.6	0.001
Pre-procedure plaque area / media	mm^2	6.7 ± 2.5	<	7.3 ± 2.7	0.01
Post-procedure plaque area / media	mm^2	7.1 ± 2.5		7.4 ± 2.4	0.18
Pre-procedure mean lumen area	mm^2	4.8 ± 1.4		5.0 ± 1.5	0.17
Post-procedure mean lumen area	mm^2	6.1 ± 1.4	<	6.9 ± 1.6	<0.001

IVUS Assessment Pre and Post Procedure

		Absorb 364 Lesions		Xience 182 Lesions	*p* value
Pre-procedure vessel area	mm^2	11.5 ± 3.4	<	12.3 ± 3.4	0.02
Post-procedure vessel area	mm^2	13.2 ± 3.6	<	14.3 ± 3.6	0.001
Pre-procedure plaque area / media	mm^2	6.7 ± 2.5	<	7.3 ± 2.7	0.01
Post-procedure plaque area / media	mm^2	7.1 ± 2.5		7.4 ± 2.4	0.18
Pre-procedure mean lumen area	mm^2	4.8 ± 1.4		5.0 ± 1.5	0.17
Post-procedure mean lumen area	mm^2	6.1 ± 1.4	<	6.9 ± 1.6	<0.001
Pre-procedure minimal lumen area	mm^2	2.0 ± 0.7		2.1 ± 0.8	0.20
Post-procedure minimal lumen area	mm^2	4.9 ± 1.4	<	5.7 ± 1.5	<0.001

IVUS Assessment Pre and Post Procedure

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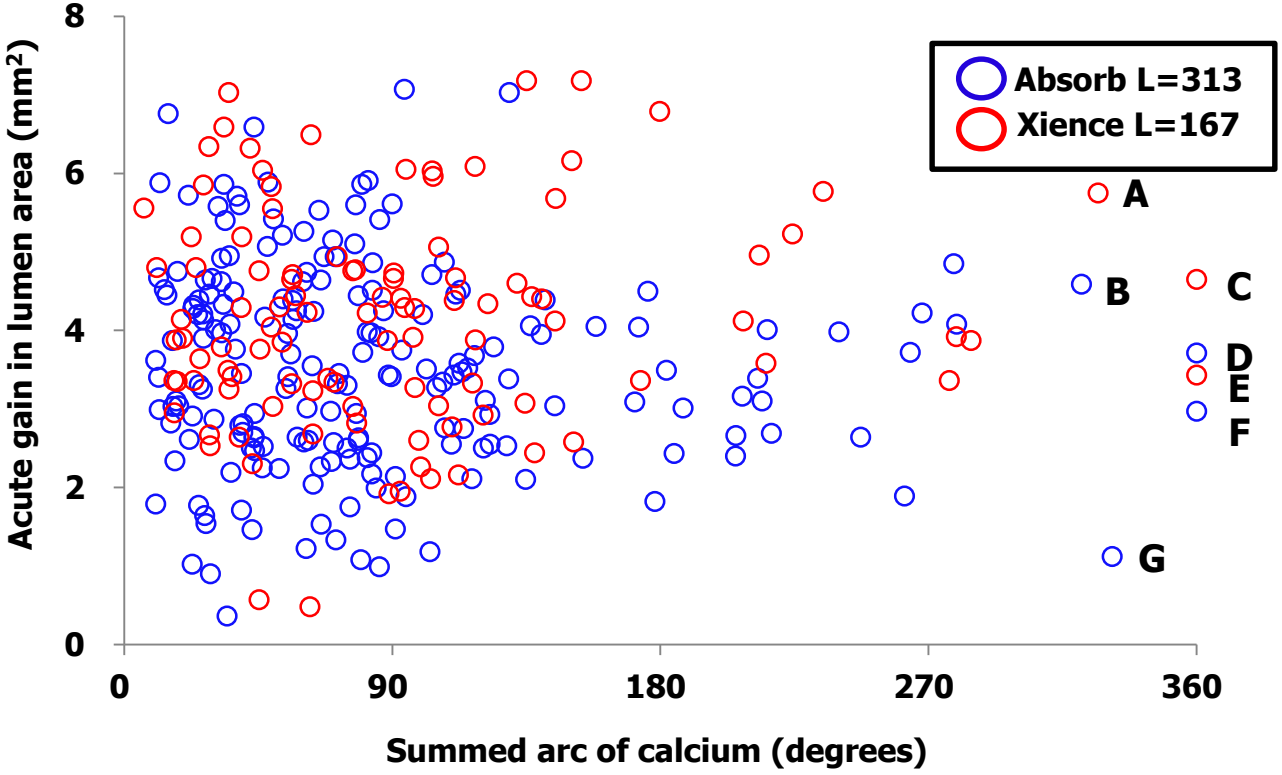
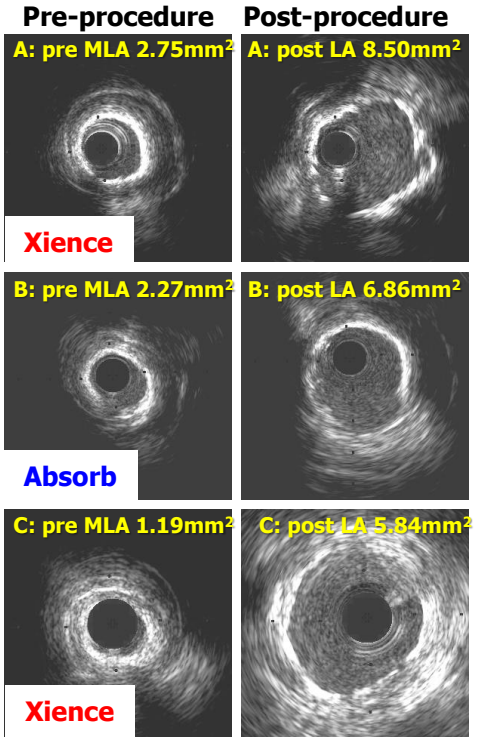
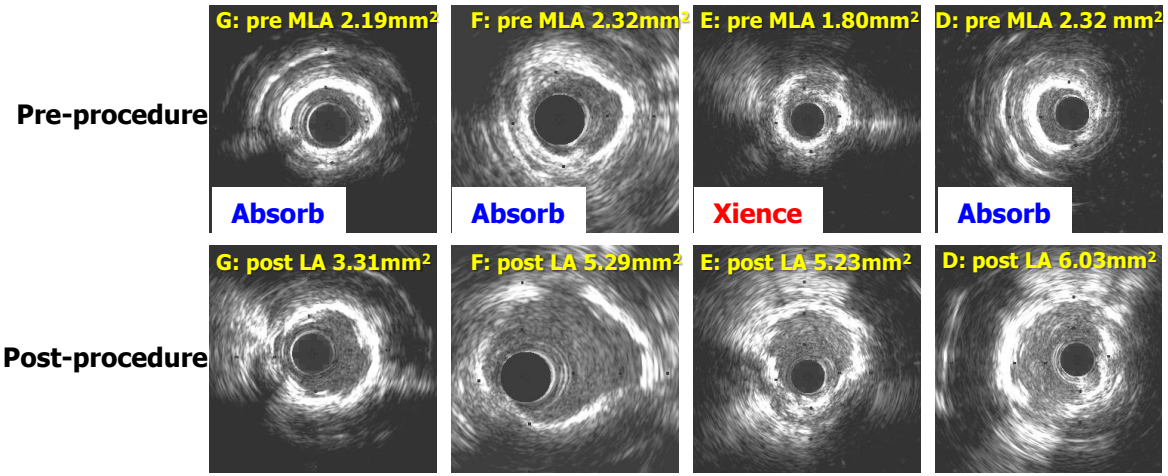
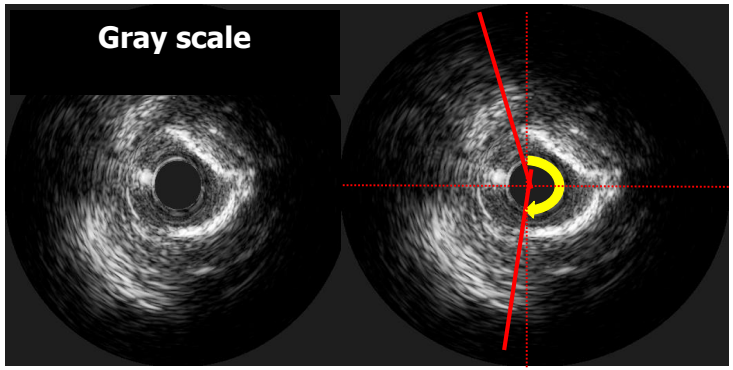
Pre-procedure vessel area	mm^2	11.5 ± 3.4	<	12.3 ± 3.4	0.02
Post-procedure vessel area	mm^2	13.2 ± 3.6	<	14.3 ± 3.6	0.001
Pre-procedure plaque area / media	mm^2	6.7 ± 2.5	<	7.3 ± 2.7	0.01
Post-procedure plaque area / media	mm^2	7.1 ± 2.5		7.4 ± 2.4	0.18
Pre-procedure mean lumen area	mm^2	4.8 ± 1.4		5.0 ± 1.5	0.17
Post-procedure mean lumen area	mm^2	6.1 ± 1.4	<	6.9 ± 1.6	<0.001
Pre-procedure minimal lumen area	mm^2	2.0 ± 0.7		2.1 ± 0.8	0.20
Post-procedure minimal lumen area	mm^2	4.9 ± 1.4	<	5.7 ± 1.5	<0.001
Acute gain in minimal lumen area	mm^2	2.9 ± 1.3	<	3.6 ± 1.3	<0.001

In both arms acute gain was not affected by the circumferential distribution of calcium









Arc of calcium:
207.8° (3 quadrant)

Clinical Outcomes

Cumulative incidence in percentage	Absorb 335 pts	Xience 166 pts	*p* value
Composite of cardiac death, target vessel MI and clinically indicated target lesion revascularization (TLF, DoCE)	**4.8 %**	**3.0 %**	**0.35**
Cardiac death	0 %	0 %	1.00
Target vessel MI	4.2 %	1.2 %	0.07
Clinically indicated TLR	1.2 %	1.8 %	0.69
All TLR	1.2 %	1.8 %	0.69

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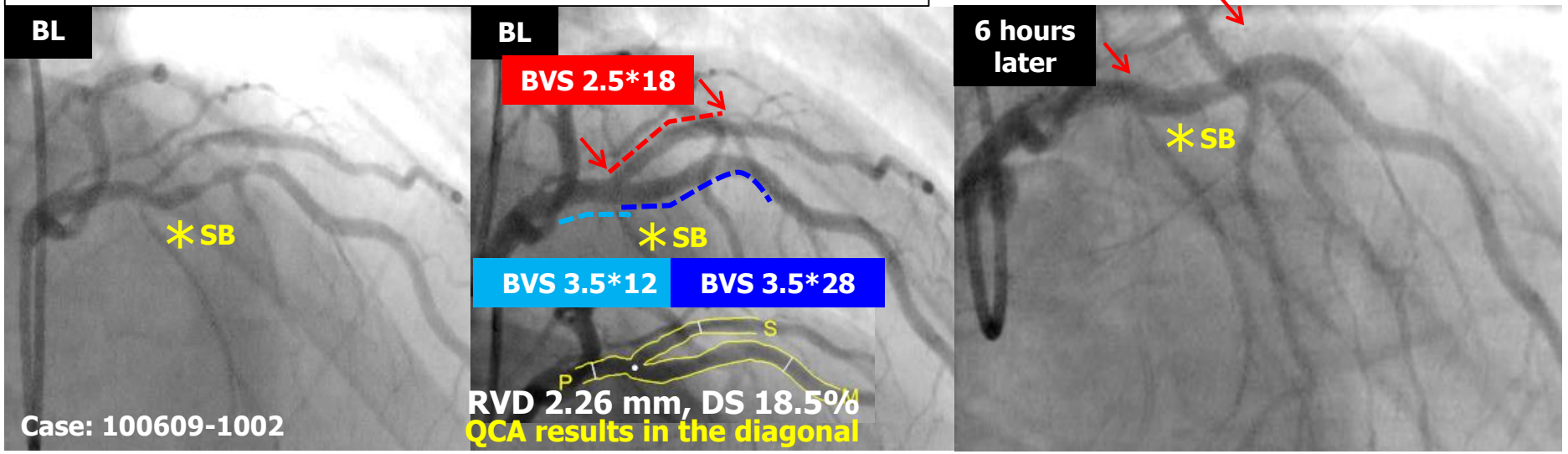
Cumulative incidence in percentage	Absorb 335 pts	Xience 166 pts	*p* value
Composite of cardiac death, target vessel MI and clinically indicated target lesion revascularization (TLF, DoCE)	**4.8 %**	**3.0 %**	**0.35**
Cardiac death	0 %	0 %	1.00
Target vessel MI	4.2 %	1.2 %	0.07
Clinically indicated TLR	1.2 %	1.8 %	0.69
All TLR	1.2 %	1.8 %	0.69
Composite of all death, all MI and all revascularization (PoCE)	**7.3 %**	**9.1 %**	**0.47**
All death	0 %	0.6 %	0.33
All MI	4.5 %	1.2 %	0.06
All revascularization	3.6 %	7.3 %	0.08

Definite scaffold/stent thrombosis

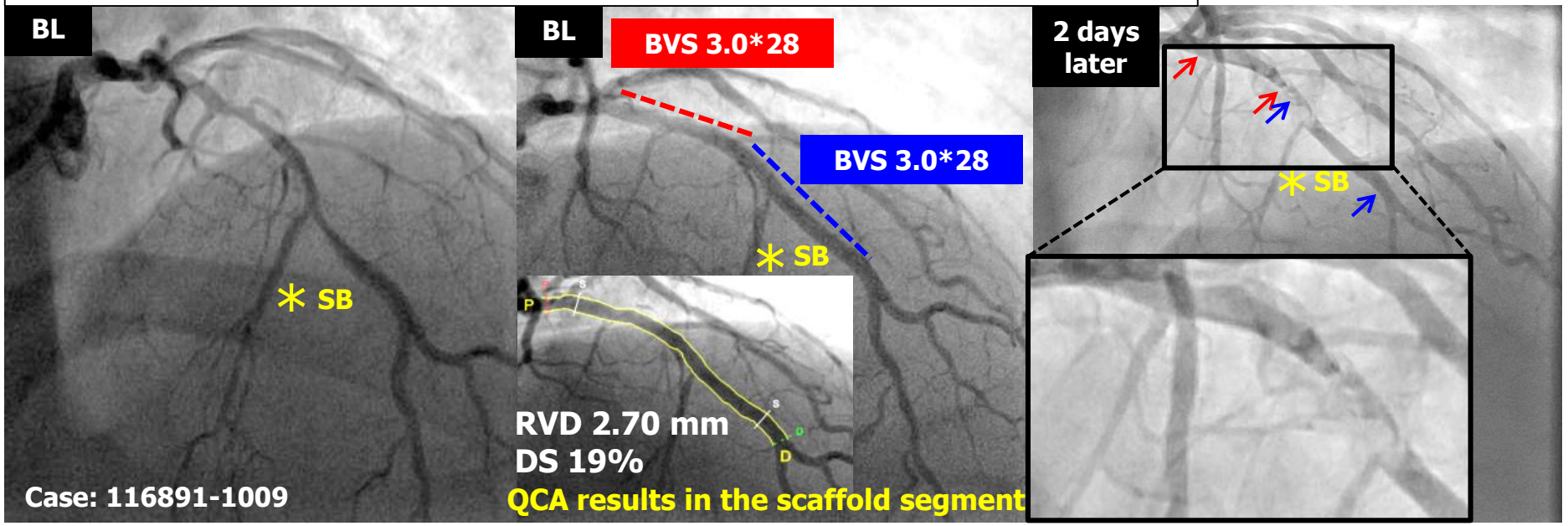
Cumulative incidence in percentage	Absorb 335 pts	Xience 166 pts	*p* value
Definite scaffold/stent thrombosis			
Acute (0-1 day)	0.3 (1pt)	0.0	NS
Sub-acute (2–30 days)	0.3 (1pt)	0.0	NS
Late (31–365 days)	0.0	0.0	NS
Probable scaffold/stent thrombosis			
Acute (0-1 day)	0.0	0.0	NS
Sub-acute (2–30 days)	0.0	0.0	NS
Late (31–365 days)	0.3 (1pt)	0.0	NS

Definite scaffold/stent thrombosis

Acute scaffold thrombosis at bifurcated lesion



Subacute scaffold thrombosis involving overlapping scaffolds



Cardiac Biomarker Rise <48 Hours After the Index Procedure and Per Protocol Peri-procedural MI

	Troponin 485/501 (96.8%)			CKMB 487/501 (97.2%)			CK 476/501 (95.0%)		
	Absorb (n=325)	Xience (n=160)	P value	Absorb (n=324)	Xience (n=163)	P value	Absorb (n=315)	Xience (n=161)	P value
Mean ratio vs. ULN	13.4±30.6	9.1±21.0	0.12	1.3±2.0	1.1±1.6	0.22	0.7±0.6	0.6±0.6	0.36

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Mean ratio vs. ULN	13.4±30.6	9.1±21.0	0.12	1.3±2.0	1.1±1.6	0.22	0.7±0.6	0.6±0.6	0.36
	%	%	P value	%	%	P value	%	%	P value
>1×ULN	62.8	61.9	0.85						
>2×ULN (~WHO)	48.6	45.6	0.54						
>3×ULN	38.2	36.9	0.79						
>5×ULN (TUD)	29.8	25.6	0.33						
>10×ULN (SCAI)	19.1	15.0	0.27						

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>2×ULN (~WHO)	48.6	45.6	0.54	13.3	9.8	0.27			
>3×ULN	38.2	36.9	0.79	7.1	6.1	0.69			
>5×ULN (TUD)	29.8	25.6	0.33	4.9	2.5	0.19			
>10×ULN (SCAI)	19.1	15.0	0.27	0.6	0.6	1.00			

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>2×ULN (~WHO)	48.6	45.6	0.54	13.3	9.8	0.27	5.1	1.9	0.09
>3×ULN	38.2	36.9	0.79	7.1	6.1	0.69	1.3	1.9	0.69
>5×ULN (TUD)	29.8	25.6	0.33	4.9	2.5	0.19	0	0.6	0.34
>10×ULN (SCAI)	19.1	15.0	0.27	0.6	0.6	1.00	0	0	1.00

Per Protocol PMI (WHO): elevation of total creatine kinase (CK) to >2 x normal along with elevated CKMB without clinical symptoms and ECG change

Per Protocol PMI: Absorb 3.9% (13/335) vs. Xience 1.2% (2/166) p=0.16

Results of Medication and Exercise Testing

	6 months			12 months		
	Absorb 335 pts	Xience 166 pts	p value	Absorb 335 pts	Xience 166 pts	p value
Anti-angina Medication %						
Beta blocker	**71.0**	**67.9**	0.48	**70.5**	**65.9**	0.29
Calcium channel blocker	**20.8**	**21.2**	0.92	**23.7**	**23.2**	0.89
Nitrate	**17.8**	**26.7**	**0.02**	**19.5**	**26.2**	**0.09**
Dual antiplatelet therapy	**97.3**	**97.0**	1.00	**82.8**	**83.1**	0.87

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Exercise Test Performed	%	**91.9**	**94.6**	0.28	**86.0**	**85.5**	0.9
Maximal HR	beats/min	**132**	**132**	0.93	**133**	**135**	0.38
Maximal workload	METS	**9.02**	**9.05**	0.95	**9.32**	**9.41**	0.83
Exercise duration	min	**8.10**	**8.53**	0.22	**8.55**	**8.99**	0.26
≥0.1mV ST depression or chest pain	%	**18.2**	**20.4**	0.57	**15.0**	**15.5**	0.9

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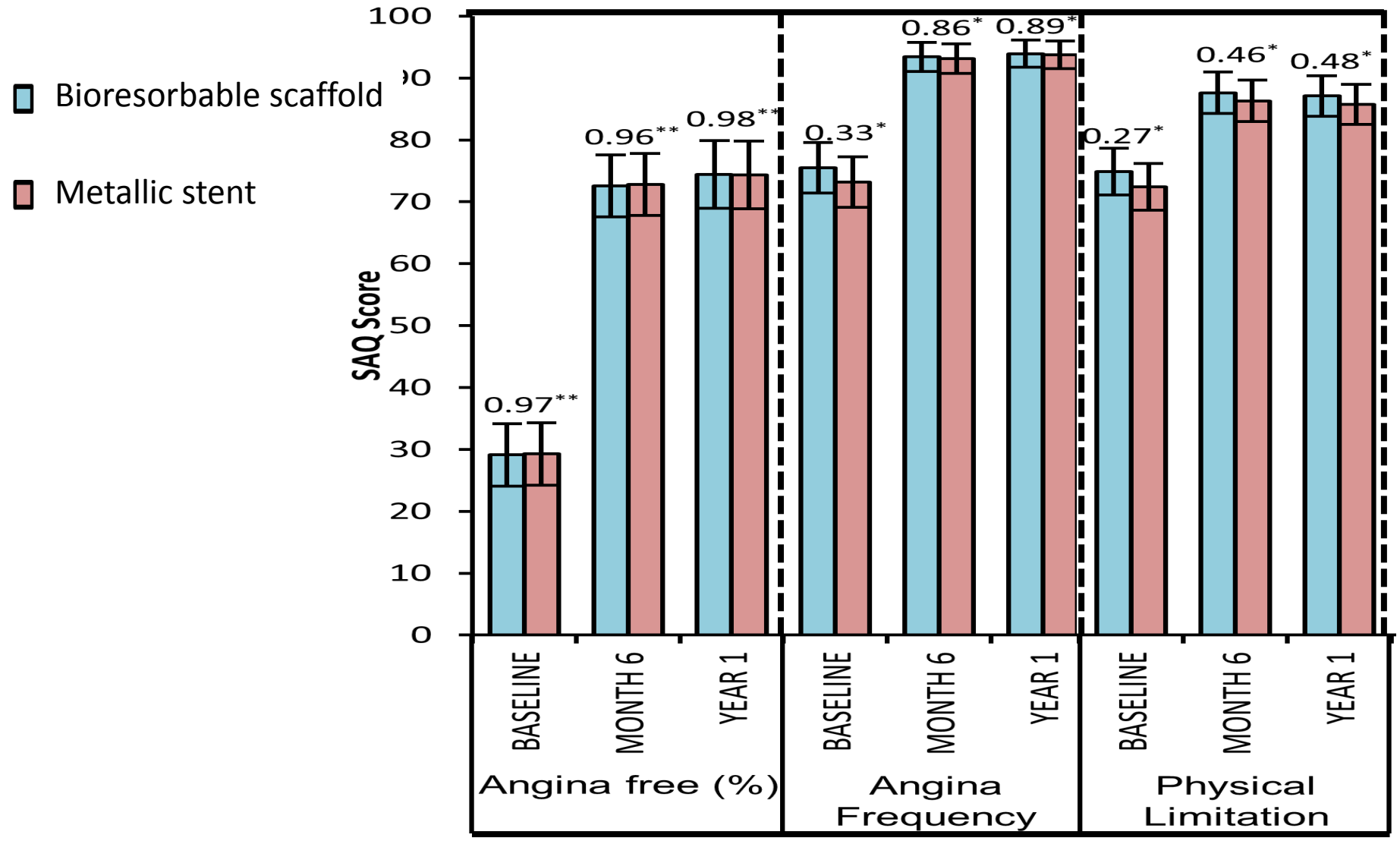
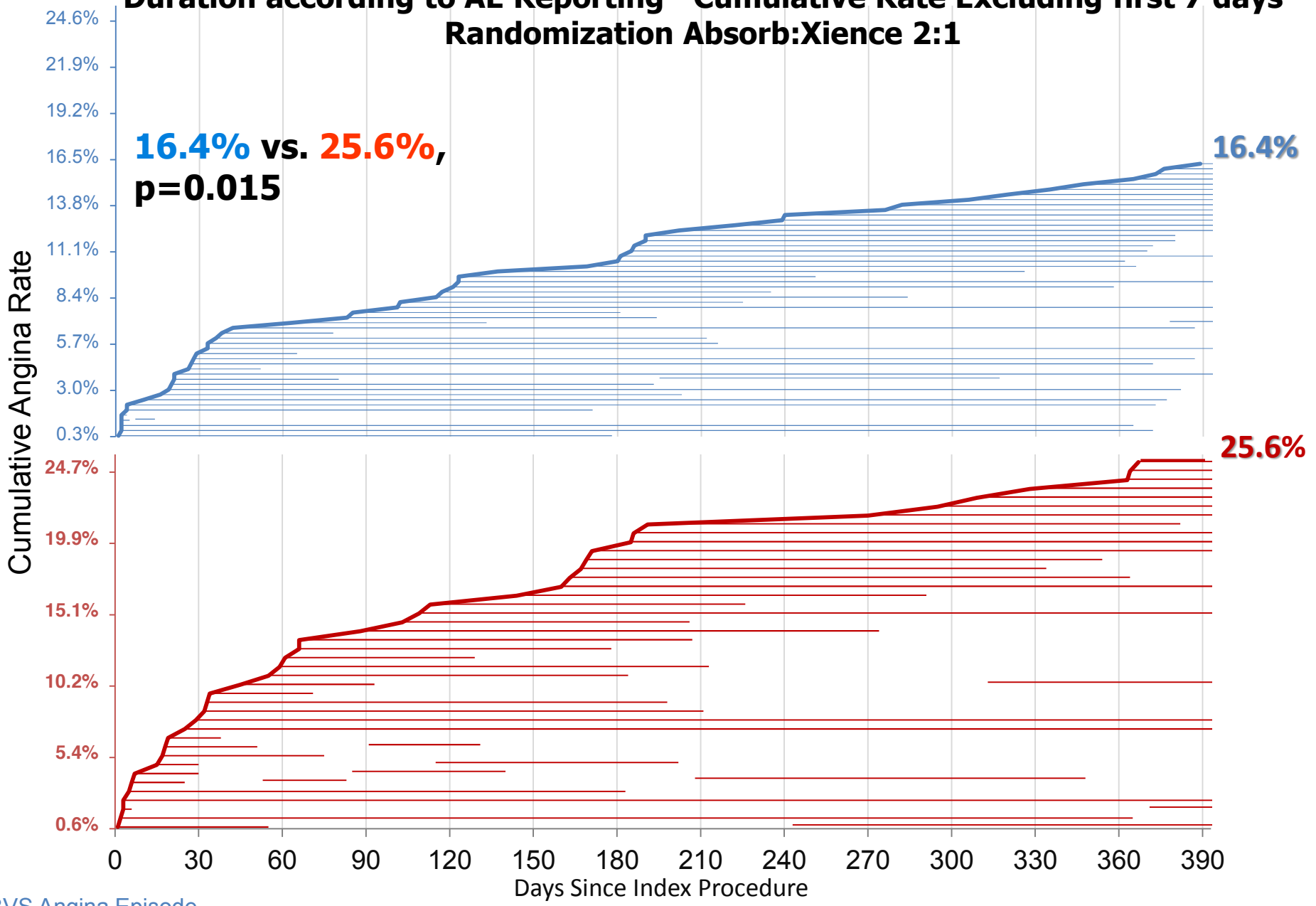
≥0.1mV ST depression or chest pain	%	**18.2**	**20.4**	0.57	**15.0**	**15.5**	0.9
Terminated due to >0.2 mV ST depression	%	**4.3**	**17.2**	**0.05**	**4.9**	**5.9**	1.0

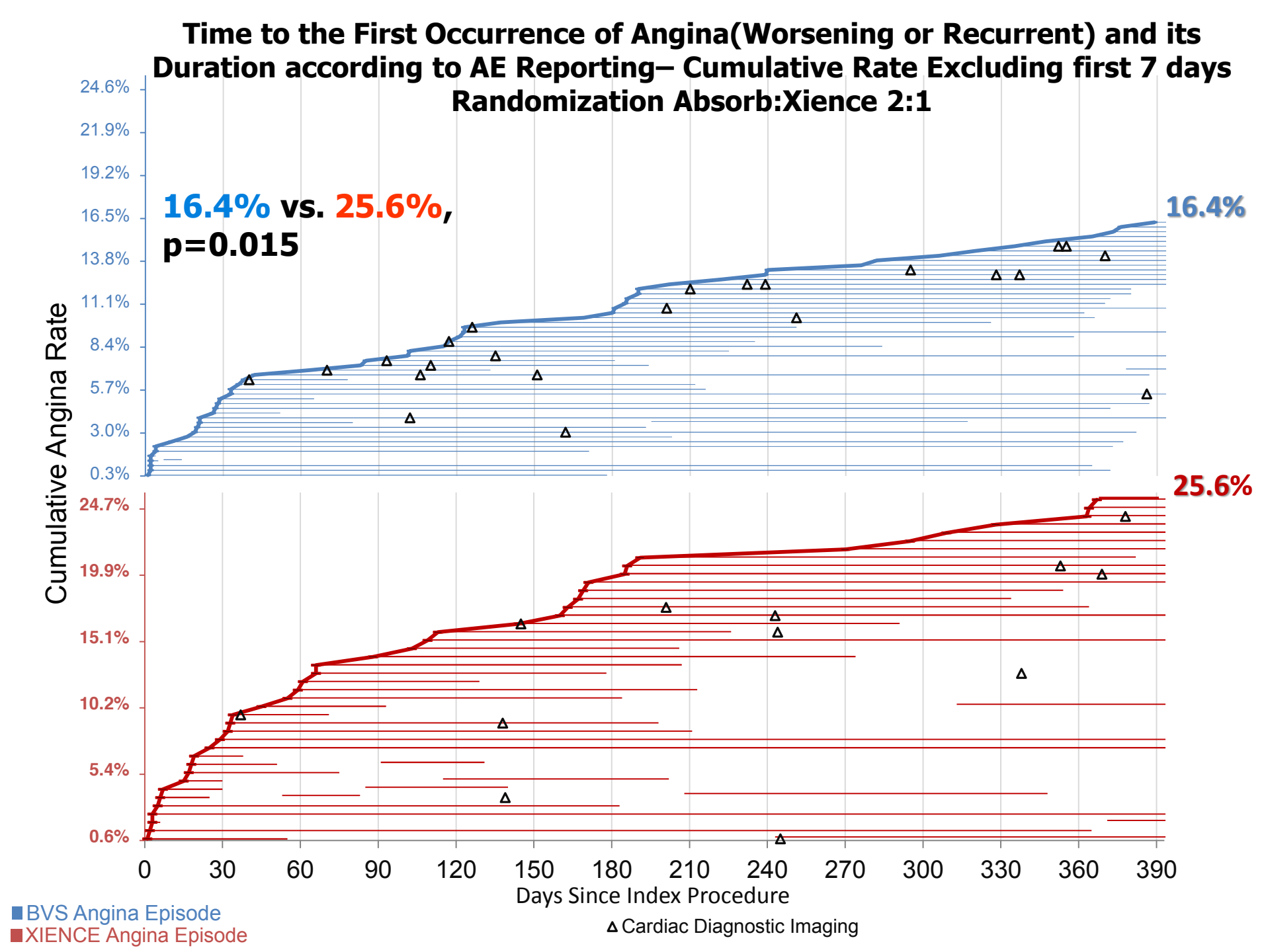
Seattle Angina Questionnaire (SAQ) Related to Angina Frequency and Physical Limitation and Freedom from Angina as Assessed with Angina-Frequency Scale of SAQ

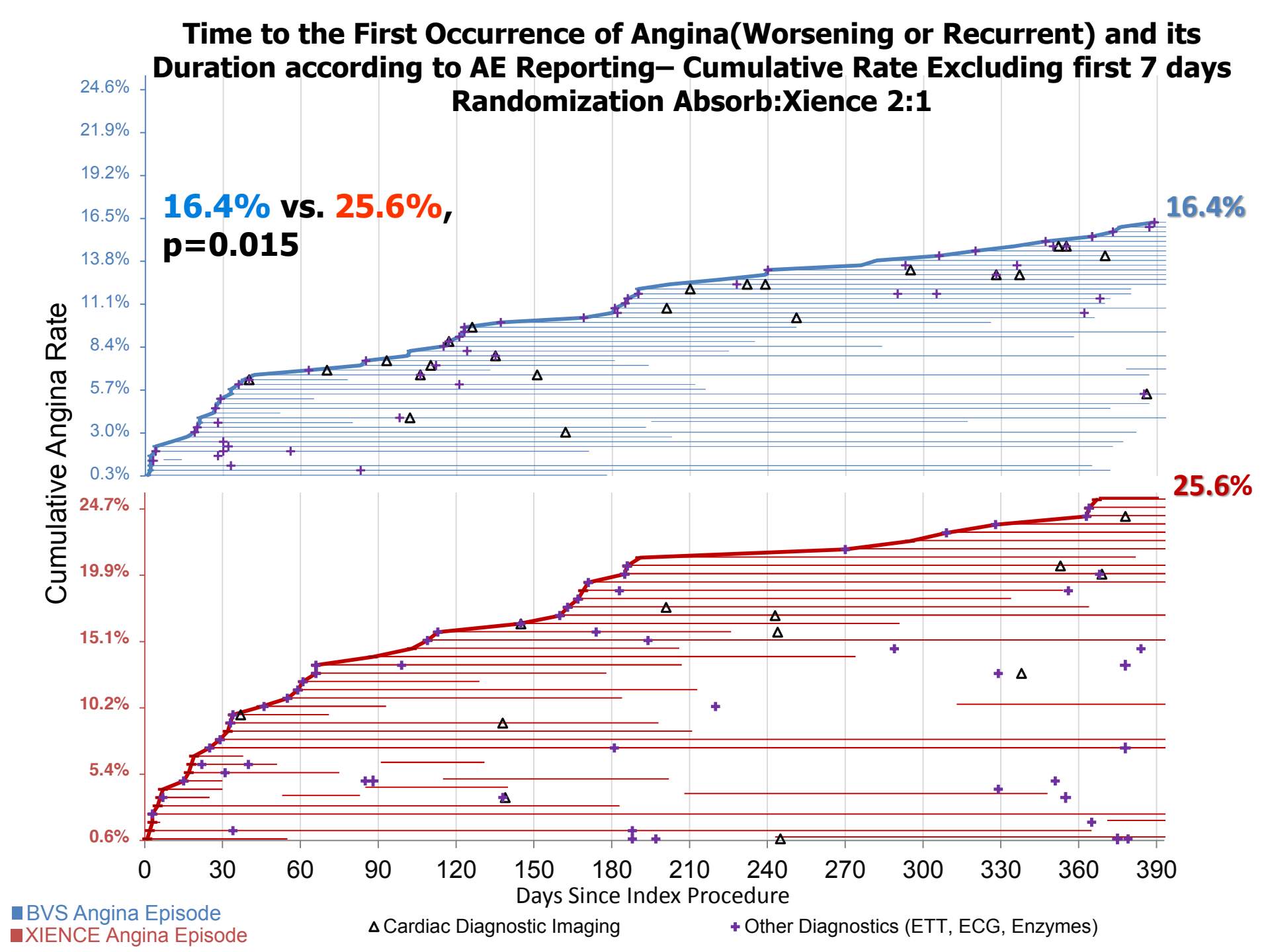


*p-value from post-hoc t-test **p-value from post-hoc chi-square test

Time to the First Occurrence of Angina(Worsening or Recurrent) and its Duration according to AE Reporting– Cumulative Rate Excluding first 7 days Randomization Absorb:Xience 2:1




Time to the First Occurrence of Angina(Worsening or Recurrent) and its Duration according to AE Reporting– Cumulative Rate Excluding first 7 days Randomization Absorb:Xience 2:1
16.4% vs. 25.6%, p=0.015
16.4%
25.6%
Cumulative Angina Rate
24.6%
21.9%
19.2%
16.5%
13.8%
11.1%
8.4%
5.7%
3.0%
0.3%
24.7%
19.9%
15.1%
10.2%
5.4%
0.6%
0
30
60
90
120
150
180
210
240
270
300
330
360
390
Days Since Index Procedure
BVS Angina Episode
XIENCE Angina Episode
Cardiac Diagnostic Imaging


Time to the First Occurrence of Angina(Worsening or Recurrent) and its Duration according to AE Reporting– Cumulative Rate Excluding first 7 days
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90
120
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180
210
240
270
300
330
360
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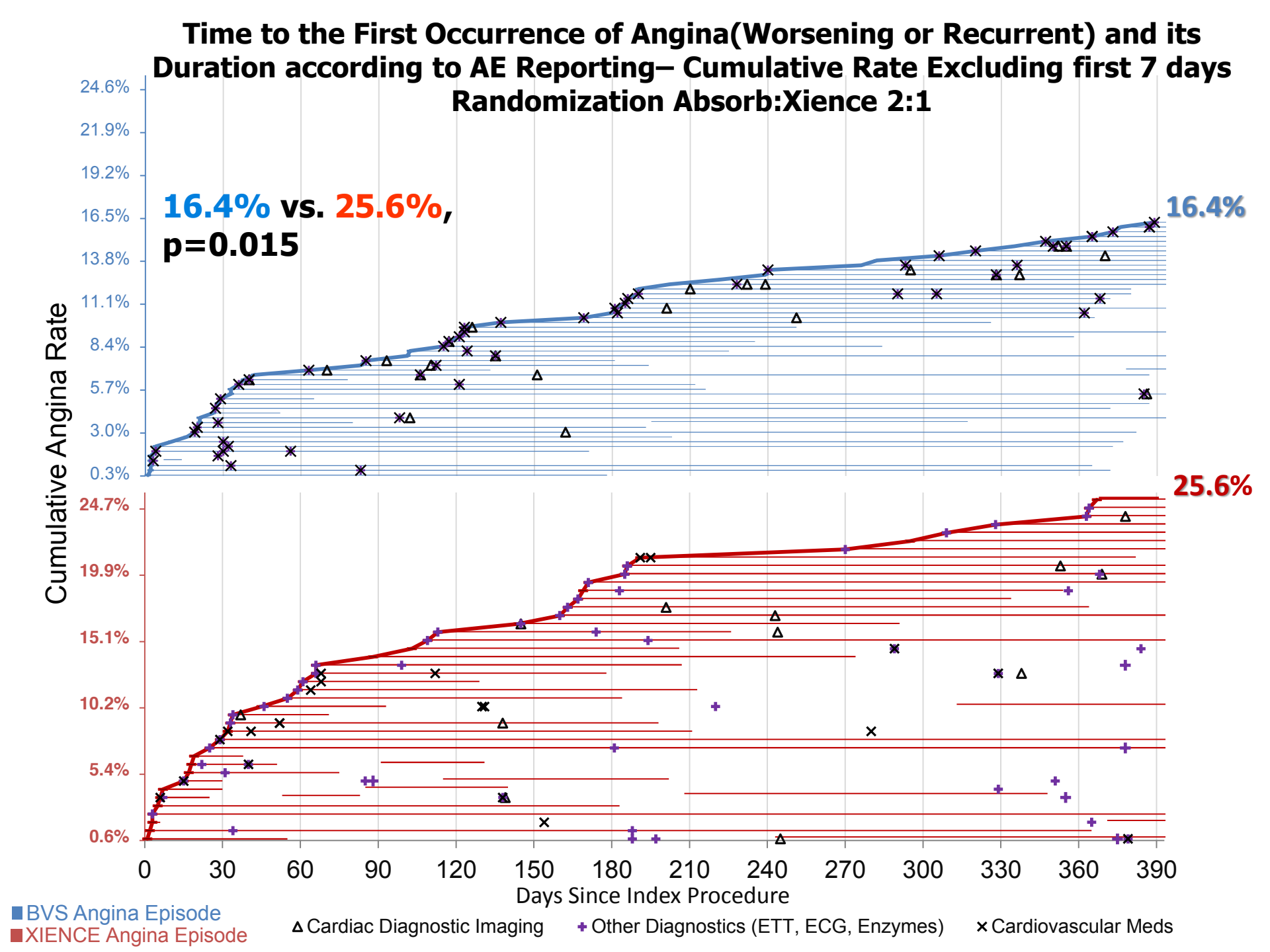
Days Since Index Procedure
BVS Angina Episode
XIENCE Angina Episode
Cardiac Diagnostic Imaging
Other Diagnostics (ETT, ECG, Enzymes)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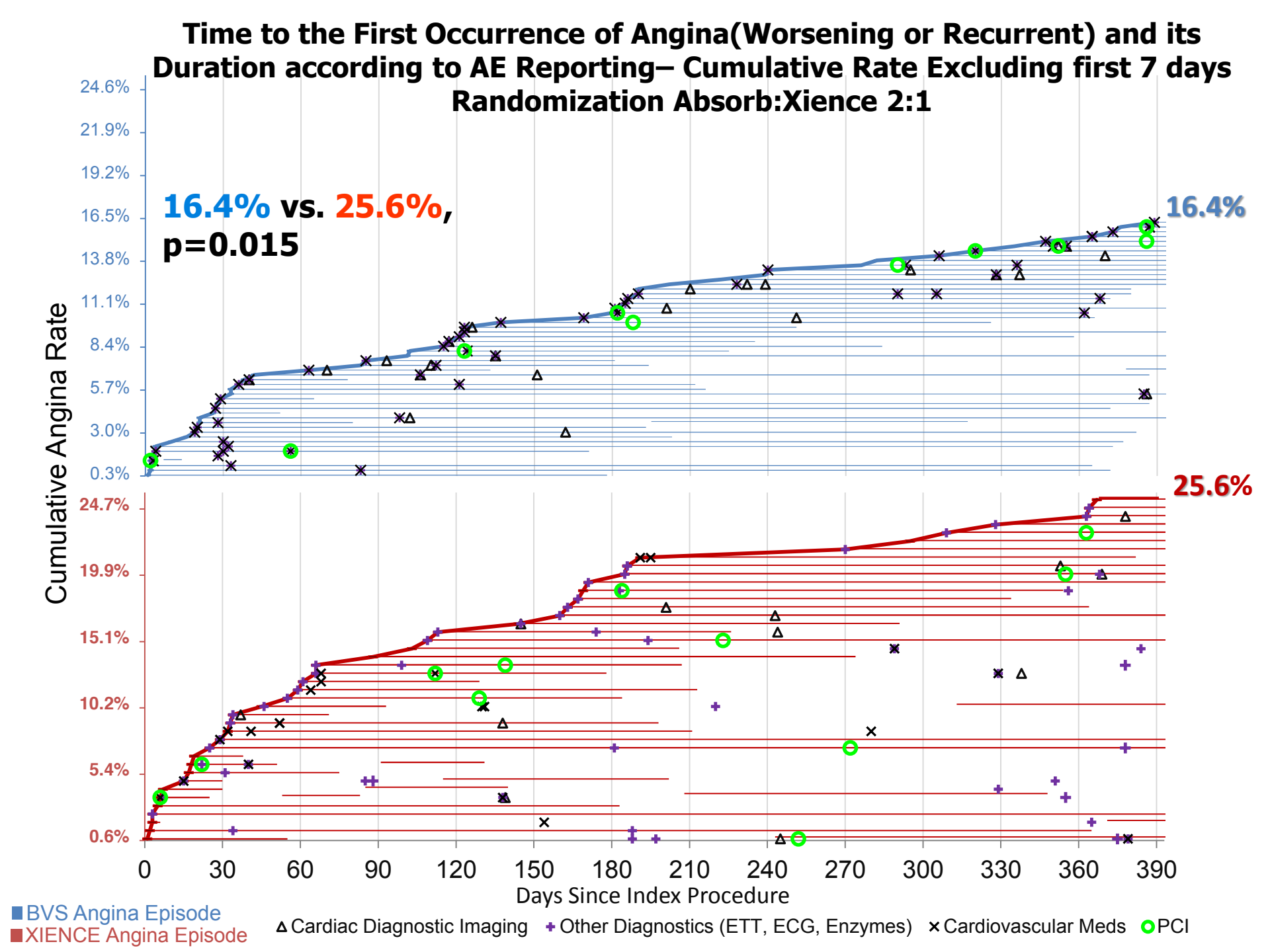
Days Since Index Procedure
BVS Angina Episode
XIENCE Angina Episode
Cardiac Diagnostic Imaging
Other Diagnostics (ETT, ECG, Enzymes)
Cardiovascular Meds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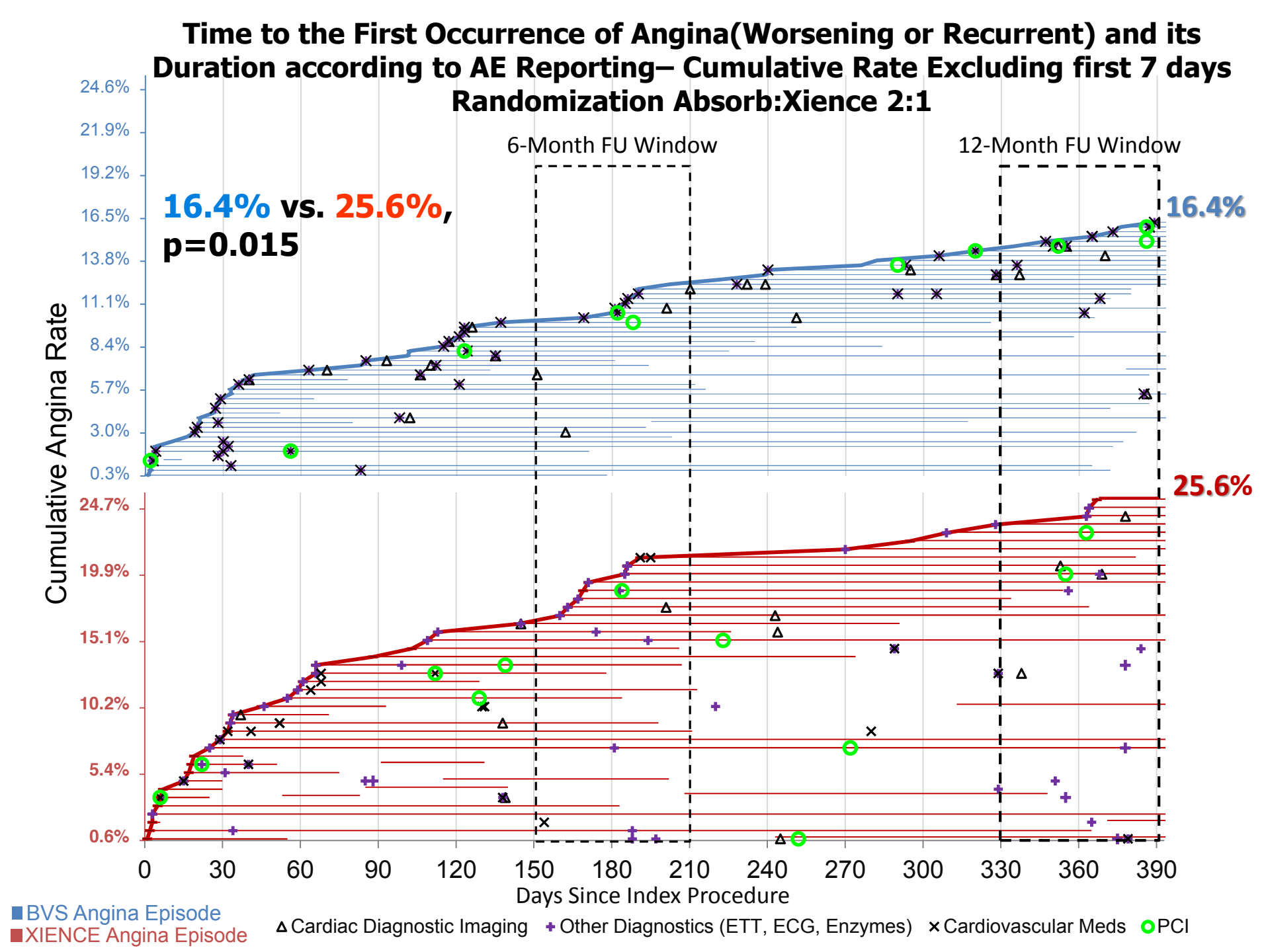
Days Since Index Procedure
BVS Angina Episode
XIENCE Angina Episode
Cardiac Diagnostic Imaging
Other Diagnostics (ETT, ECG, Enzymes)
Cardiovascular Meds
PCI


Time to the First Occurrence of Angina(Worsening or Recurrent) and its Duration according to AE Reporting– Cumulative Rate Excluding first 7 days Randomization Absorb:Xience 2:1
6-Month FU Window
12-Month FU Window
16.4% vs. 25.6%, p=0.015
16.4%
25.6%
Cumulative Angina Rate
24.6%
21.9%
19.2%
16.5%
13.8%
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Other Diagnostics (ETT, ECG, Enzymes)
Cardiovascular Meds
PCI

Summary-1

- The device success rates in this population with B1/B2 lesions were comparable between the two arms (device success: Absorb 99% vs Xience 100%).

- Acute gain by angiography and IVUS was significantly lower in the Absorb arm than in the Xience arm, (QCA, Absorb 1.15 ± 0.4 mm vs Xience 1.46 ± 0.4 mm, $p<0.001$; IVUS, Absorb 2.9 ± 1.3 mm^2, Xience 3.6 ± 1.3 mm^2, $p <0.001$)

- This difference in acute gain is not related to the acute recoil measured immediately after device implantation (0.19 mm for both), but could be attributed to the difference in pressure and nominal size of the balloon used during the post-implantation dilatation performed in a similar proportion (~60%) of patients in each arm.

- Two definite scaffold thromboses were documented, one acutely within 24 hours after the procedure and the second case sub-acutely on day 2. The rate of definite scaffold thrombosis was 0.6% in the Absorb arm and 0% in the Xience arm (p=1.0).

Summary-2

- Comprehensive analysis of three sets of myocardial biomarkers did not indicate substantial difference of myonecrosis despite differences in strut thickness and width of the two respective devices; however, the per protocol peri-procedural MI rates based on WHO definition were 3.9% in the Absorb arm and 1.2% in the Xience arm (p=0.16) respectively. Application of more contemporary enzyme thresholds for MI criteria such as SCAI (CKMB >10 x ULN; 0.6% vs 0.6%, p=1.0) or TUD (Troponin > 5 x ULN; 29.8 % vs. 25.6 %, p=0.33) did not reveal any difference between the two arms.

- Exercise performance and angina status as assessed by SAQ were comparable, however a difference in nitrate use was observed at 6 months (17.8% vs 26.7%, p=0.02) and 12 months (19.5% vs 26.2%, p=0.09) in favor of the Absorb arm.

Summary-3

- The difference in cumulative rates (21.8% in the Absorb arm vs 30.5% in the Xience arm, p=0.04, 16.4% vs 25.6%, p=0.015 if episodes during index hospitalisation were excluded) of angina according to AE reporting (recurrent or worsening angina) is a post-hoc, hypothesis generating observation that warrants further physiological and clinical investigation.

- At one year, DoCE (cardiac death, TV-MI and TLR, Absorb: 4.8% vs Xience: 3.0%, p=0.35), PoCE (all death, all MI and all revascularization, Absorb:7.3% vs Xience: 9.1%, p=0.47) and their components were similar between the two arms.

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A bioresorbable everolimus-eluting scaffold versus a metallic everolimus-eluting stent for ischaemic heart disease caused by de-novo native coronary artery lesions (ABSORB II): an interim 1-year analysis of clinical and procedural secondary outcomes from a randomised controlled trial

Patrick W Serruys, Bernard Chevalier, Dariusz Dudek, Angel Cequier, Didier Carrié, Andres Iniguez, Marcello Dominici, René J van der Schaaf, Michael Haude, Luc Wasungu, Susan Veldhof, Lei Peng, Peter Staehr, Maik J Grundeken, Yuki Ishibashi, Hector M Garcia-Garcia, Yoshinobu Onuma

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Thank you !