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Comparison of an everolimus-eluting bioresorbable scaffold with an everolimus-eluting metallic stent in routine PCI: three-year clinical outcomes from the AIDA trial

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A list of the study collaborators can be found in the Appendix.

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Introduction

We conducted the AIDA trial comparing the Absorb™ bioresorbable vascular scaffold (BVS; Abbott Vascular, Santa Clara, CA, USA) with the XIENCE everolimus-eluting stent (EES; Abbott Vascular) in daily practice to assess the complete safety and efficacy of the Absorb throughout the scaffold bioresorption period. Preclinical studies have shown that scaffold bioresorption takes 36 months[1]. Clinical studies have demonstrated that this period of scaffold bioresorption is associated with higher rates of device thrombosis[2]. Therefore, we herein report the complete three-year clinical outcomes of the Absorb in comparison with the XIENCE.

Methods

The study design, study population and endpoint definitions have been reported in detail previously[3,4]. All major adverse events were adjudicated by an independent clinical events committee. Time-to-event curves were constructed using the Kaplan-Meier method, and compared by log-rank test. Hazard ratios were determined using Cox regression.

Results

Baseline patient, lesion and procedural characteristics have been described previously[4,5]. Clinical status at three-year follow-up was known in 97.7% of patients.

Target vessel failure, cardiac death and target vessel revascularisation continued to accrue at similar rates up to three years in both arms **(Figure 1A, Figure 1B)**. The incidence of target vessel myocardial infarction (TV-MI) was significantly higher in the Absorb arm compared to the XIENCE arm **(Table 1, Figure 1C)**. At three years, 30 patients had definite scaffold thrombosis and five patients had definite stent thrombosis **(Table 2, Figure 1D)**. No case of additional stent thrombosis was noted between two and three years, against four cases of additional scaffold thrombosis. Of note, only one very late definite scaffold thrombosis (VLST) occurred in a patient on dual antiplatelet therapy (DAPT); the other patients with VLST were on single antiplatelet therapy **(Supplementary Table 1)**.

Discussion

AIDA is the largest randomised trial comparing the Absorb BVS to the XIENCE EES in daily practice. At three years, significantly

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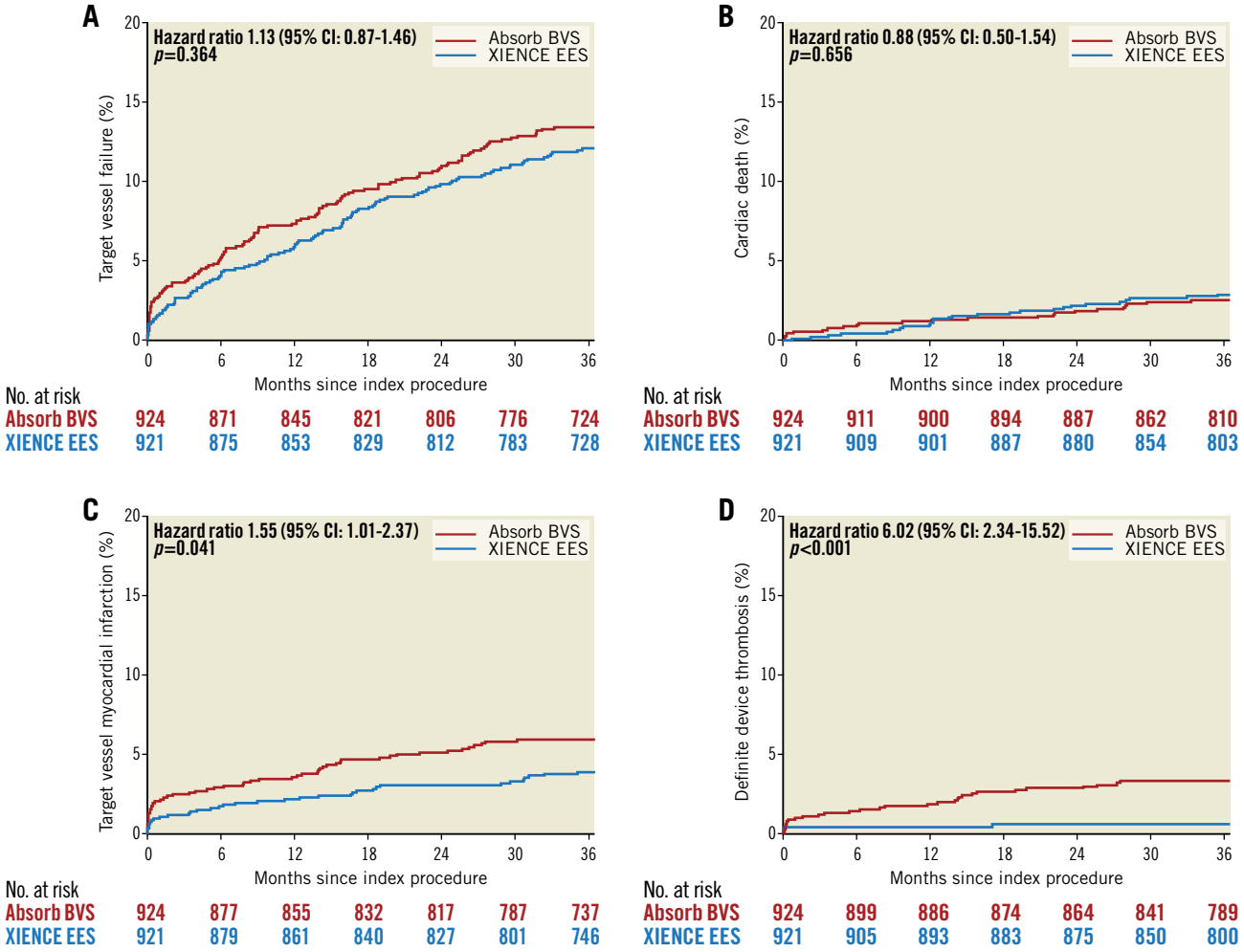

Figure 1. *Time-to-first event curves. A) Target vessel failure. B) Cardiac death. C) TV-MI. D) Definite device thrombosis up to three years.*

Table 1. Clinical outcomes up to 3 years.

	Absorb (n=924)	XIENCE (n=921)	Hazard ratio (95% CI)	*p*-value◊	Total number of events reported before data lock on 29 December 2018*	
					Absorb	XIENCE
All-cause death	44 (4.8%)	52 (5.7%)	0.84 (0.56-1.26)	0.397	54	68
Cardiac death	23 (2.5%)	26 (2.9%)	0.88 (0.50-1.54)	0.656	28	31
Cardiovascular death	28 (3.1%)	28 (3.1%)	0.99 (0.59-1.68)	0.986	33	36
All myocardial infarction	74 (8.2%)	49 (5.5%)	1.52 (1.06-2.19)	0.021	86	53
Target vessel myocardial infarction	54 (5.9%)	35 (3.9%)	1.55 (1.01-2.37)	0.041	61	39
Non-target vessel myocardial infarction	21 (2.4%)	14 (1.6%)	1.49 (0.76-2.93)	0.241	26	15
Any revascularisation	140 (15.5%)	120 (13.4%)	1.17 (0.92-1.49)	0.206	162	127
Target vessel revascularisation	90 (10.0%)	77 (8.6%)	1.17 (0.86-1.59)	0.304	105	79
Target lesion revascularisation	71 (7.9%)	52 (5.8%)	1.37 (0.96-1.96)	0.082	78	56
Composite endpoints						
Target vessel failure#	123 (13.5%)	110 (12.1%)	1.13 (0.87-1.46)	0.364	142	118
Target lesion failure¶	107 (11.7%)	92 (10.2%)	1.17 (0.89-1.55)	0.265	119	100
Patient-oriented composite endpoint‡	195 (21.3%)	177 (19.3%)	1.11 (0.91-1.36)	0.305	224	197

◊ *p*-values were calculated by the log-rank test. #Composite of cardiac death, target vessel myocardial infarction and target vessel revascularisation. ¶Composite of cardiac death, target vessel myocardial infarction and target lesion revascularisation. ‡Composite of death, myocardial infarction or any revascularisation. *No data sweep was performed, therefore no *p*-values or Kaplan-Meier estimates are given.

Table 2. Incidence of device thrombosis up to 3-year follow-up.

	Absorb (n=924)	XIENCE (n=921)	Hazard ratio (95% CI)	*p*-value◊	Total number of events reported before data lock on 29 December 2018*	
					Absorb	XIENCE
Definite	30 (3.3%)	5 (0.5%)	6.02 (2.34-15.52)	<0.001	33	8
Probable	4 (0.4%)	3 (0.3%)	1.33 (0.30-5.93)	0.709	5	4
Possible	8 (0.9%)	15 (1.7%)	0.53 (0.22-1.25)	0.140	10	16
Definite/probable	34 (3.7%)	8 (0.9%)	4.27 (1.97-9.21)	<0.001	38	12
≤24 hours (acute)	3	3			3	3
>24 hours to 30 days (subacute)	10	2			10	2
31 days to 1 year (late)	8	1			8	1
1-2 years (very late)	9	2			9	2
2-3 years (very late)	4	0			4	0
3-4 years (very late)	–	–			4	3
4-5 years (very late)	–	–			0	1
Any device thrombosis	42 (4.6%)	23 (2.6%)	1.84 (1.10-3.05)	0.017	48	28

◊*p*-values were calculated by the log-rank test. *No data sweep was performed, therefore no *p*-values or Kaplan-Meier-estimates are given.

higher rates of TV-MI and definite device thrombosis were seen in the Absorb arm. There was only one VLST in an Absorb-treated patient who continued on DAPT up to three years. The other patients with VLST were on single antiplatelet therapy. The three-year point after Absorb implantation is an important landmark as three years is the approximate period of scaffold polymer absorption[1]. Intraluminal scaffold dismantling and the bioresorption process are possibly underlying mechanisms of VLST[6]. Traces of scaffold have been seen beyond three years; whether DAPT should be continued after three years is still uncertain.

Limitations

The lack of systematic intravascular imaging precludes more definite conclusions about the mechanisms related to Absorb failure at different time points. Restarting or prolonging DAPT up to three years after scaffold implantation was recommended at the request of the data safety monitoring board. This recommendation might have influenced the occurrence of thrombosis-related outcomes.

Conclusions

Target vessel failure continued to accrue up to three years in both Absorb and XIENCE. However, the Absorb was associated with higher rates of TV-MI and definite scaffold thrombosis. Long-term follow-up is necessary to examine whether the annual rates of device-related events will decline in Absorb-treated patients after scaffold bioresorption.

Impact on daily practice

As in other trials, Absorb continued to demonstrate higher rates of scaffold thrombosis and TV-MI compared to XIENCE up to three-year follow-up. Longer-term follow-up of AIDA will provide insights into the long-term safety and potential benefit of Absorb and whether patients treated with Absorb should continue using DAPT.

Appendix. Study collaborators

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Conflict of interest statement

J. Tijssen served on the DSMB of the early ABSORB trials, including ABSORB II. J. Henriques received research grants from Abbott Vascular. J. Wykrzykowska received consultancy fees and research grants from Abbott Vascular. The other authors and collaborators have no conflicts of interest to declare.

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Supplementary data

Supplementary Table 1. Descriptive characteristics of cases of definite device thrombosis.

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Supplementary data

Supplementary Table 1. Descriptive characteristics of cases of definite device thrombosis.

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Case	**Group**	**Initial PCI indication**	**Treated vessel**	**Lesion type**	**Ref size (mm)**	**Predilatation (atm)**	**Stent size (atm)**	**Post-dilatation (atm)**	**Initial DAPT therapy**	**Days to DT**	**DAPT therapy Type of DT**	**Clinical outcome (worst)**	**Patient notes**
1	Absorb BVS	STEMI	Mid RCA	B2	4.0x15	3.0x15 (12)	3.5x18 (13)	4.0x12 (13)	ASA Ticagrelor	0	ASA Ticagrelor	Myocardial infarction	Dissection distal of stent (OCT)
2	Absorb BVS	STEMI	Prox LAD	B2	3.5x18	3.5x20 (6)	3.5x18 (14)	3.5x12 (20)	ASA Ticagrelor	1	ASA Ticagrelor	Myocardial infarction	Distal edge dissection (OCT)
3	Absorb BVS	AP	Mid RCA	B2	3.0x15	3.0x15 (10)	3.5x18 (14)	4.0x12 (14)	ASA Clopidogrel	2	ASA Clopidogrel	Myocardial infarction	Malapposition stent (OCT)
4	Absorb BVS	AP	Mid RCA	C	3.0x46	2.5x20 (16)	3.0x28 (12) 3.0x18 (14)	3.0x20 (18)	ASA Clopidogrel	3	ASA Clopidogrel	Myocardial infarction	
5	Absorb BVS	STEMI	Prox LAD	C	3.5x21	2.0x12 (12)	3.0x15 (14) 3.5x12 (16)	3.75x15 (22)	ASA Clopidogrel	4	ASA Clopidogrel	Myocardial infarction	
6	Absorb BVS	AP	Distal RcX	B2	2.5x28	2.5x20 (10)	2.5x28 (10)	2.5x20 (14)	ASA Clopidogrel	5	ASA Clopidogrel	Myocardial infarction	Possible low therapy compliance
7	Absorb BVS	Stabilised STEMI	Prox RCA	C	3.0x30	3.5x15 (12) Rotablation	3.5x18 (14) 3.5x18 (14)	3.5x15 (14)	ASA Ticagrelor	6	ASA	Myocardial infarction	Patient forgot to take ticagrelor
8	Absorb BVS	NSTEMI	Prox LAD	B2	2.5x15	2.5x15 (UN)	2.5x18 (10)	3.0x12 (12)	ASA Ticagrelor	11	ASA Ticagrelor	Myocardial infarction	
9	Absorb BVS	STEMI	Prox LAD Distal RCA	C C	3.0x25 2.7x25	2.5x20 (8) 3.5x20 (12)	3.0x28 (10) 2.5x28 (14)	3.5x15 (10) No	ASA	29	ASA	Myocardial infarction	ST in both LAD and RCA

			Mid RCA	C	2.7x25	2.5x20 (10)	3.0x28 (14)	No	Ticagrelor		Ticagrelor		
			Mid RCA	C	2.7x25	3.5x20 (10)	2.5x28 (14)	No					
10	Absorb BVS	NSTEMI	Mid LAD	B2	3.0x45	2.5x20 (14)	2.5x23 (16) 3.0x28 (18)	4.0x15 (18)	ASA Ticagrelor	46	Clopidogrel	Myocardial infarction	Malapposition stent (OCT)
			Prox LAD	B1	4.0x15	2.5x20 (14)	3.5x18 (18)	4.0x15 (18)	OAC		OAC		
11	Absorb BVS	UAP	Mid LAD	B1	3.0x12	2.5x15 (10)	3.0x18 (12)	No	ASA Ticagrelor	86	ASA	Myocardial infarction	Interaction ticagrelor and HIV medication
12	Absorb BVS	NSTEMI	Prox RCA	B1	3.5x10	3.0x15 (12)	3.5x12 (14)	3.5x8 (22)	ASA Clopidogrel OAC	100	Clopidogrel OAC	Non-fatal MI followed by cardiac death	
13	Absorb BVS	UAP	Mid LAD	B1	3.5x15	2.0x15 (18)	3.5x18 (10)	3.5x15 (16)	ASA Ticagrelor	161	None	Myocardial infarction	DAPT cessation during surgery
14	Absorb BVS	NSTEMI	Prox RcX	B2	3.0x28	2.5x15 (12)	3.0x28 (14)	3.5x15 (14)	ASA Ticagrelor	185	None	Myocardial infarction	DAPT cessation during surgery
15	Absorb BVS	STEMI	Mid LAD	B1	2.5x23	2.0x20 (14)	2.5x23 (14)	2.5x15 (18)	ASA Ticagrelor	234	ASA Ticagrelor	Myocardial infarction	
16	Absorb BVS	AP	RcX, OM	B1	2.5x12	2.5x15 (8)	2.5x18 (6)	No	ASA Ticagrelor	249	ASA	Myocardial infarction	History of low therapy compliance
17	Absorb BVS	NSTEMI	Prox RcX	B2	2.5x15	2.5x15 (8) Rotablation	2.5x18 (14)	2.75x15 (16)	ASA Ticagrelor	352	ASA	Myocardial infarction	Dissection after stent implantation (angio)
18	Absorb BVS	AP	Mid RCA	B2	3.5x25	2.5x20 (12)	3.5x28 (12)	4.0x15 (10)	ASA	376	ASA	Myocardial infarction	Malapposition distal stent (OCT)
			Distal RCA	B2	3.0x15	2.5x20 (12)	3.0x18 (14)	No	Ticagrelor				
19	Absorb BVS	STEMI	Distal RCA	B2	3.0x24	2.0x20 (10)	3.0x27 (8)	3.5x15 (18)	ASA Ticagrelor	419	ASA	Myocardial infarction	
20	Absorb BVS	AP	Dist RcX	B1	3.0x10	3.0x15 (18)	3.0x18 (12)	No	ASA Ticagrelor	427	OAC	Myocardial infarction	

									OAC				
21	Absorb BVS	STEMI	Mid RCA	B2	3.5x23	3.5x20 (10)	3.5x28 (12)	3.5x15 (12)	ASA Prasugrel OAC ASA stop after 3 months	430	None	Non-fatal MI followed by cardiac death	OAC cessation during surgery (Clexane)
22	Absorb BVS	Angio-driven	Prox RCA	B1	4.0x16	3.0x20 (16)	3.5x28 (16)	4.0x20 (12)	ASA	437	Unknown	Myocardial infarction	
			Prox RcX	A	3.5x12	3.0x12 (14)	3.0x23 (16)	3.5x40 (16)	Clopidogrel				
23	Absorb BVS	STEMI	Prox RCA	B2	2.5x15	2.5x15 (10)	3.0x18 (12)	No	ASA	461	ASA	Myocardial infarction	
		Staged	Prox RcX	B1	3.0x12	3.0x15 (10)	3.0x18 (14)	No	Ticagrelor				
24	Absorb BVS	AP	Distal LAD	B1	3.0x8	2.5x28 (14)	3.0x28 (14)	3.0x28 (14)	ASA	471	ASA	Myocardial infarction	
			Prox LAD	A	3.5x12	3.0x12 (14)	3.5x12 (14)	3.5x14 (14)	Ticagrelor		Ticagrelor		
25	Absorb BVS	STEMI	Prox RCA	C	3.5x18	3.0x15 (12)	3.5x23 (16)	4.0x20 (16)	ASA Prasugrel	567	ASA	Myocardial infarction	
26	Absorb BVS	STEMI	Mid RCA	B2	3.0x25	3.0x15 (12)	3.0x28 (10)	2.25x20 (13)	ASA Ticagrelor	593	ASA	Myocardial infarction	
27	Absorb BVS	STEMI	Prox LAD	C	3.5x21	2.5x20 (10)	3.5x23 (18)	3.5x15 (18)	ASA Ticagrelor	733	ASA	Myocardial infarction	Patient refused to re-start DAPT
28	Absorb BVS	NSTEMI	AO-MO graft	B2	3.0x18	2.0x15 (12)	3.0x18 (10)	3.0x12 (14)	ASA Clopidogrel	769	ASA	Myocardial infarction	
29	Absorb BVS	AP	Prox LAD	A	3.5x8	3.0x15 (12)	2.5x12 (12)	3.5x8 (20)	ASA Clopidogrel	817	ASA	Myocardial infarction	Malapposed non-covered struts distally (OCT)
30	Absorb BVS	NSTEMI	RcX, MO	B1	2.5x10	2.5x15 (20)	2.5x12 (16)	2.75x15 (18)	ASA Ticagrelor Clopidogrel	825	ASA	Myocardial infarction	
31	Absorb BVS	Stabilised STEMI	Distal LAD	C	2.5x45	2.5x30 (12)	2.5x28 (16)	No	ASA	1,277	Unknown	Myocardial infarction	ST in LAD
			First Diagonal	B2	3.5x12	3.5x15 (16)	3.5x12 (14)	4.0x9 (14)	Ticagrelor				

32	Absorb BVS	AP	Distal RcX	B1	3.0x18	2.5x15 (12)	2.5x18 (14)	2.5x12 (16)	ASA Ticagrelor	1,312	ASA	Myocardial infarction	
33	Absorb BVS	UAP	First Diagonal	B2	2.5x10	2.5x10 (10)	2.5x12 (12)	No	ASA Clopidogrel	1,330	ASA	Myocardial infarction	
1	XIENCE EES	Stabilised STEMI	Mid RCA Distal RCA	B2 C	3.5x15 2.5x25	No 2.5x20 (14)	3.5x10 (18) 2.75x28 (14)	3.5x18 (14) 2.5x15 (8)	ASA Ticagrelor	0	ASA Ticagrelor	Myocardial infarction	
2	XIENCE EES	STEMI	Prox LAD	B2	3.0x28	3.0x20 (6)	3.0x38 (14)	3.5x15 (12)	ASA Ticagrelor	0	ASA Ticagrelor	Myocardial infarction	
3	XIENCE EES	STEMI	Prox LAD	B2	3.5x15	3.0x15 (16)	3.5x15 (12)	No	ASA Ticagrelor	1	ASA Ticagrelor	Myocardial infarction	Jailing stent (angio)
4	XIENCE EES	AP	Distal RcX	A	3.0x15	2.5x15 (10)	3.0x18 (12)	No	ASA Clopidogrel	3	ASA Clopidogrel	Myocardial infarction	
5	XIENCE EES	STEMI	Prox RCA	B2	3.0x15	3.0x15 (10)	3.0x12 (16)	No	ASA Prasugrel	511	ASA	Myocardial infarction	Malapposition prox stent (OCT)
6	XIENCE EES	STEMI	Mid LAD	B1	3.0x16	3.0x15 (6)	3.0x18 (12)	No	ASA Ticagrelor	1,222	ASA	OHCA	
7	XIENCE EES	UAP	Distal RCA	B1	3.0x10	2.5x10 (13)	3.0x15 (14)	No	ASA Clopidogrel	1,391	ASA Clopidogrel	Myocardial infarction	
8	XIENCE EES	AP	Mid LAD	B1	3.0x15	2.5x12 (10)	30x18 (12)	No	ASA	1,472	ASA	Myocardial infarction	

Absorb BVS: Absorb bioresorbable vascular scaffold; XIENCE EES: XIENCE everolimus-eluting stent; AP: angina pectoris; ASA: aspirin; DAPT: dual antiplatelet therapy; HIV: human immunodeficiency virus; LAD: left anterior descending coronary artery; NSTEMI: non-ST-elevation myocardial infarction; OAC: oral anticoagulant medication; OCT: optical coherence tomography; OHCA: out-of-hospital cardiac arrest; OM: obtuse marginal; RCA: right coronary artery; RcX: ramus circumflex; STEMI: ST-elevation myocardial infarction; UAP: unstable angina pectoris