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ORIGINAL PAPER

The influence of implantation techniques on lesion oriented-outcomes in Absorb BVS and Xience EES lesions treated in routine clinical practice at complete three year follow-up: AIDA trial QCA substudy

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Abstract

It has been hypothesized that dedicated optimized Absorb BVS implantation techniques might mitigate the risk of adverse events such as target vessel failure and device thrombosis. In this explorative AIDA trial QCA substudy, we sought to investigate the influence of implantation techniques on lesion-oriented outcomes in both the Absorb BVS and Xience EES arm at complete 3-year follow-up. The current analysis includes 2152 study lesions treated with at least one study device, of which the baseline angiogram was suited for offline QCA analysis, including Dmax analysis. The lesion-oriented composite outcome (LOCE) of this analysis was a composite of definite device thrombosis, target lesion revascularization and target-vessel myocardial infarction. In Absorb BVS, the Lesion-oriented composite endpoint (LOCE) occurred numerically less in correctly QCA sized vessels when compared to incorrectly sized vessels 8.5% (58/696) versus 11.1% (39/358), p = 0.151. In Xience EES, LOCE had occurred more frequently in incorrectly sized devices according to device diameter/RVD matching; 2.2% (4/187) in correctly sized devices versus 7.1% (63/911) in incorrectly sized devices (p = 0.014). In this AIDA trial QCA substudy, rates of LOCE were significantly lower in Xience EES treated lesions in which devices were correctly sized according to the definitions of device diameter/RVD matching.

Keywords Bioresorbable scaffolds · Drug eluting stents · Quantitative coronary angiography

Abbreviations

Absorb BVS	Absorb bioresorbable vascular scaffold
Dmax	Maximum diameter
LOCE	Lesion oriented composite endpoint
MACE	Major adverse cardiac events
MLD	Minimum lumen diameter
PCI	Percutaneous coronary intervention
TLF	Target lesion failure
TLR	Target lesion revascularization

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TVF	Target vessel failure
TV-MI	Target vessel myocardial infarction
QCA	Quantitative coronary angiography
Xience EES	Xience everolimus eluting stent

Introduction

Coronary bioresorbable scaffolds have been designed to overcome the limitations of metallic drug eluting stents which are caused by permanent caging of the coronary artery [1]. The most widely studied and implanted coronary scaffold is the Absorb bioresorbable vascular scaffold (Absorb BVS) (Abbott Vascular, Santa Clara, USA). Initial short and mid-term results of the first trials, in which Absorb BVS was used, were promising. Larger randomized trials reported alarming rates of device thrombosis when compared to Xience everolimus eluting stent (EES) (Abbott Vascular, Santa Clara, USA) [2–4]. The Absorb BVS has thicker struts, a lower radial strength and a limited ability to over-expand, when compared to conventional metallic drug-eluting stents (DES) [5]. These limitations make the Absorb BVS less forgiving and harder to optimally implant. Suboptimal implanted stents and scaffolds have been associated with higher rates of adverse events [6, 7]. It has therefore been hypothesized that dedicated optimized Absorb BVS implantation techniques might mitigate the risk of adverse events such as target vessel failure and device thrombosis [8, 9]. The exact definitions of dedicated Absorb BVS implantation techniques do vary between studies, however. Previously, in AIDA, we found that optimized Absorb BVS implantation techniques stratified by proposed reference vessel based (RVD) PSP scoring [8] showed numerically similar rates of target lesion revascularization (TLR) and scaffold thrombosis through 30 months follow-up, with a median follow-up 707 days [10].

In the current AIDA trial QCA substudy, we investigate the influence of dedicated device implantation techniques, including the more precise definition of Dmax based device sizing, on lesion-oriented outcomes in both Absorb BVS and Xience EES treated lesions at complete 3-year follow-up, a significant milestone in the device absorption process.

Materials and methods

Study design AIDA trial

The AIDA trial compared Absorb BVS versus Xience EES in routine clinical practice. The study design [11], the preliminary safety report [4], and the 2-year results [12] have been published previously. At complete 2-year follow-up, Absorb BVS was non-inferior to Xience EES for the primary endpoint of TVF (composite of cardiac death, target vessel revascularization and—myocardial infarction). Absorb BVS was, however, associated with increased rates of device thrombosis.

Design of the current analysis

QCA analysis

The current analysis includes all study lesions treated with at least one study device, of which the baseline angiogram was suited for offline QCA analysis, including Dmax analysis. QCA was performed with dedicated offline software (Cardiovascular Angiography Analysis System, version 5.11; Pie Medical Imaging, Maastricht). Offline QCA analyses were initially performed (January 2017) on the post-procedural angiograms with the Absorb BVS arm. We later added 5 experiences readers to our academic Corelab, in order to perform pre-procedural measures on the Absorb BVS arm, and perform both pre-procedural and post-procedural measures on the Xience EES arm. All QCA readers were blinded for events and were supervised by one QCA expert cardiologist [YO]. Pre-and post-procedural measurements were performed in either (1) multiple matched views or (2) a singled matched view. If no matched views were available, measurements were done within the view with the highest stenosis grade.

Definitions

Pre-dilatation was scored as 'performed' or not 'performed', and was further sub-categorized into 'performed with a balloon/reference vessel diameter (RVD) ratio of $\geq$1:1'. We used multiple definitions for 'sizing'. Vessel sizing was considered to be correct if the pre-procedural RVD was $\geq$2.25 mm and $\leq$ 3.75 mm.

For Absorb BVS, the available device diameters were 2.50 mm, 3.00 mm and 3.50 mm. For Xience EES, the available device diameters were 2.25 mm, 2.50 mm, 2.75 mm, 3.00 mm, 3.50 mm and 4.00 mm. We applied the sizing definitions of the Instructions for Use of Absorb BVS and Xience EES. We considered implanted device and QCA derived diameter to be matched if the QCA diameter minus the device diameter fell within the range of ≥ -0.25 to <0.25. For the smallest available Absorb BVS (2.50 mm) and Xience EES (2.25 mm) the QCA diameter minus the device diameter had to fell within the range of ≥ 0.00 to <0.25. The range of reference vessel implantation was therefore $\geq$ 2.50 mm to $\leq$ 3.75 mm for Absorb BVS, and $\geq$ 2.25 to $\leq$ 4.25 mm for Xience EES.

Lesion oriented endpoints

The lesion-oriented composite outcome (LOCE) of this analysis was a composite of definite device thrombosis, target lesion revascularization and target-vessel myocardial infarction (TV-MI). An independent clinical event committee adjudicated all reported events. All myocardial infarction were defined by the Academic Research Consortium definitions.

Statistical analysis

This report provides information of the influence of implantation techniques on lesion-oriented outcomes at 3-year follow-up within Absorb BVS and Xience EES treated lesions in the AIDA trial. Continuous variables are reported as mean ± SD. Event rates were based on Kaplan–Meier estimates. Kaplan–Meier event curves were compared by means of the log-rank test. The Cox regression analysis was used to determine hazard ratios with 95% confidence intervals. All statistical analyses were performed with use of SPSS software, version 23 (IBM Corp., Armonk NY, USA).

Results

Population

In AIDA, 924 patients were randomized to Absorb BVS and 921 were randomized to Xience EES. A total of 2446 lesions were treated; 1237 lesions within the Absorb BVS arm and 1209 within the Xience EES arm. We excluded 89 lesions that did not receive any study device. Complete QCA measures including pre-procedural proximal and distal Dmax assessment were available in 2152 lesions (87.9%). The total cohort included in the current analysis consists of 1054 Absorb BVS treated lesions and 1098 Xience EES treated lesions.

Procedural characteristics

Table 1 shows the baseline characteristics of the study lesions. Predilatation of the complete lesion, and multiple device implantation per lesion, occurred more frequently in Absorb BVS when compared versus Xience EES (97.4% versus 91.8%, $p < 0.001$ and 17.0% versus 12.6%, $p = 0.004$; respectively). Correct device to artery sizing according to the proximal Dmax occurred less often in Absorb BVS (27.7%) versus 33.9.3% in Xience EES (33.9%), ($p = 0.417$). Post-dilatation of the complete lesion occurred more frequently in Absorb BVS (76.8% versus 48.7%, $p < 0.001$).

Lesion-oriented outcomes

At complete 3-year follow-up the primary endpoint of LOCE had occurred in 97 Absorb BVS treated lesions versus 67 Xience EES treated lesions.

The effect of implantation technique(s) on the outcomes LOCE and definite device thrombosis in Absorb BVS treated lesions are shown in Table 2. In Absorb BVS treated lesions, LOCE occurred numerically less in correctly QCA based sized vessels when compared to incorrect sized vessels; 8.5% (58/696) versus 11.1% (39/358), $p = 0.151$. Absorb BVS implantation in vessels with a diameter < 2.25 mm showed a trend towards significance for higher rates of LOCE (12.6% versus 8.3%, $p = 0.091$) when compared to vessel with a diameter > 2.25 mm. In Absorb BVS devices, which were postdilated with a ≥ 1:1 NC balloon/device ratio at 18 atm., LOCE occurred in 11.2% (24/219) devices, whereas in devices, which weren't postdilated with a ≥ 1:1 NC balloon/device ratio at 18 atm, LOCE occurred in 6.3% (73/835) devices, ($p = 0.337$).

The effect of implantation technique(s) on the outcomes LOCE and definite device thrombosis in Xience EES treated lesions are shown in Table 3. At complete 3-year follow-up the primary endpoint of LOCE had occurred more frequently in incorrectly sized devices according to device diameter to RVD matching; 3.3% (7/220) in correctly sized devices versus 7.0% (60/878) in incorrectly sized devices ($p = 0.044$). In Xience EES devices, which were postdilatated with a ≥ 1:1 NC balloon/device ratio at 18 atm., LOCE occurred in 6.0% (9/157) devices, whereas in devices in which this was not performed, LOCE occurred in 6.3% (58/941) devices, ($p = 0.863$).

Figures 1 and 2 show the Kaplan–Meier curves of the influence of correct pre-dilatation, correct Dmax based device sizing, and correct post-dilation on LOCE in Absorb BVS and Xience EES treated lesions**.**

Landmark analyses from 0 to 30 days, and from 1 to 3 years, of the influence of small vessel sizing, and artery/RVD based sizing, on LOCE in the Absorb BVS and Xience EES arm are shown in Supplementary Figs. 1, 2, 3 and 4. The effect of implantation technique(s) on the outcomes of TLR and TV-MI in Absorb BVS and Xience EES treated lesions are shown in Supplementary Tables 1 and 2, respectively.

Discussion

The main findings of this explorative AIDA QCA substudy at complete 3 year follow-up are:

Table 1 Procedural characteristics

	Absorb BVS	Xience EES	P value
Treated lesions			
Total number of lesions	1054	1098	
Rotational atherectomy	22/1051 (2.1%)	25/1097 (2.3%)	0.883
Thrombus present	145 (13.8%)	144 (13.1%)	0.704
Bifurcation lesion	54 (5.1%)	63 (5.7%)	0.569
Ostial lesion	55 (5.2%)	62/1097 (5.7%)	0.704
Pre-dilation			
Pre-dilatation of the complete lesion performed	1027 (97.4%)	1008 (91.8%)	< 0.001
Balloon diam/RVD ratio ≥ 1:1	617 (58.5%)	579 (52.7%)	0.007
Device implantation			
Number of devices per lesions	1.19 ± 0.45	1.14 ± 0.38	0.003
Single device per lesion, n (%)	875 (83.0%)	960 (87.4%)	0.004
Multiple devices per lesion, n (%)	179 (17.0%)	138 (12.6%)	0.004
Total device length	23.80 ± 11.75	22.87 ± 11.34	0.061
Correct vessel sizing (≥ 2.25 mm and ≤ 3.75 mm)	696/1095 (66.0%)	705/1095 (64.2%)	0.390
Vessel diameter < 2.25 mm	336 (31.9%)	365 (33.2%)	0.520
Vessel diameter > 3.75 mm	20 (1.9%)	25 (2.3%)	0.551
Correct device/artery sizing according to RVD	187 (17.7%)	220 (20.0%)	0.186
Correct device/artery sizing according to prox Dmax	292 (27.7%)	372 (33.9%)	0.002
Correct device/artery sizing according to prox and distal Dmax	128 (12.1%)	148 (13.5%)	0.367
Post-dilatation			
Of the complete lesion	809 (76.8%)	535 (48.7%)	< 0.001
Performed with ≥ 1:1 balloon/device ratio	773 (73.3%)	502 (45.7%)	< 0.001
Performed with a NC balloon	713 (67.6%)	445 (40.5%)	< 0.001
Performed > 16 atm	385 (36.5%)	270 (24.6%)	< 0.001
Performed > 18 atm	219 (20.8%)	157 (14.3%)	< 0.001
Target lesion measures			
Reference vessel diameter pre-procedure	2.53 ± 0.58	2.51 ± 0.62	0.435
Percentage diameter stenosis pre-procedure (%)	57.05 ± 16.07	57.59 ± 16.30	0.524
Percentage diameter stenosis post-procedure (%)	23.02 ± 10.42	25.85 ± 11.45	< 0.001
Post-procedural minimum lumen diameter	2.01 ± 0.55	1.95 ± 0.50	0.010

BVS bioresorbable vascular scaffold, *EES* everolimus eluting stent, *QCA* quantitative coronary angiography

1. The lesion-oriented composited endpoint occurred in 97 Absorb BVS treated lesions and in 67 Xience EES treated lesions. Event rates of LOCE were, significantly lower in Xience EES treated lesions, in which devices were correctly sized according to the definitions of device diameter / RVD matching. The event rates in Xience were also numerically lower in correctly sized vessel and in lesions in which devices were correctly sized according to either the proximal, or the proximal and distal, Dmax.
2. The results of this study indicate that lesion-oriented outcomes with Xience EES might improve with use of QCA dedicated implantation strategies whereas, in Absorb BVS no improvement was found.'

This study investigates the influence of implantation techniques on lesion-oriented outcomes of Absorb BVS or Xience EES treated lesions in routing clinical practice. Implantation techniques, or combined PSP implantation strategies, have been carefully analyzed in order to search for provoking factors that may attribute to higher rates of scaffold or stent failure [9]. To date, however, the exact definition of correct combined PSP implantation strategies and techniques, and the consequent effect and/or results, have been varying between studies [8–10]. In AIDA, we found no correlation between optimized Absorb BVS implantation techniques and lesion-oriented outcomes. Within the Xience EES treated lesions, however, we did find that correct RVD based sizing cut the rates of LOCE in half, indicating that

Table 2 Outcomes in Absorb BVS treated lesions

	Lesion-oriented composite endpoint				Definite scaffold thrombosis			
	Performed	Not performed	HR (95% CI)	P value	Present	Not present	HR (95% CI)	P value
Predilation parameters								
Predilatation of the complete lesion performed	10.3% (94/1024)	10.4% (3/27)	0.80 (0.25–2.54)	0.708	3.0% (30/1054)	3.8% (1/27)	0.78 (0.11–5.75)	0.811
Predilatation balloon/RVD 1:1	10.2% (62/617)	8.2% (35/437)	1.29 (0.85–1.95)	0.232	3.0% (18/617)	3.0% (13/437)	0.99 (0.49–2.02)	0.976
Sizing								
Correct device/artery sizing according to RVD	10.8% (20/187)	9.0% (77/867)	1.19 (0.73–1.94)	0.498	4.9% (9/187)	2.6% (22/867)	1.88 (0.87–4.10)	0.105
Correct device/artery sizing according to prox Dmax	10.1% (29/292)	8.9% (68/762)	1.11 (0.72–1.71)	0.643	4.2% (12/292)	2.5 (19/762)	1.64 (0.80–3.38)	0.174
Correct device/artery sizing according to prox and distal Dmax	9.5% (12/128)	9.3% (85/926)	0.99 (0.54–1.82)	0.980	3.2% (4/128)	3.0% (27/926)	1.05 (0.37–3.00)	0.931
Correct QCA based artery sizing (≥ 2.25 and ≤ 3.75)	8.5% (58/696)	11.1% (39/358)	0.74 (0.50–1.12)	0.151	3.2% (22/696)	2.5% (9/358)	1.25 (0.57–2.70)	0.579
Small vessel (<2.25 mm)	12.6% (38/336)	8.3% (59/718)	1.42 (0.94–2.13)	0.091	2.7% (9/336)	3.1% (22/718)	0.88 (0.41–1.92)	0.753
Large vessel (>3.75 mm)	5.3% (1/20)	9.4% (96/1034)	0.54 (0.08–3.86)	0.530	0% (0/20)	3.0% (31/1034)	0.05 (0.00–>100)	0.440
Postdilatation parameters								
Postdilatation of the complete lesion	8.9% (79/809)	7.5% (18/245)	1.34 (0.80–2.23)	0.263	3.3% (26/809)	2.1% (5/245)	1.58 (0.61–4.13)	0.342
Performed with $\geq$ 1:1 balloon/device ratio	9.8% (74/773)	8.3% (23/281)	1.18 (0.74–1.88)	0.493	3.2% (24/773)	2.5 (7/281)	1.26 (0.54–2.91)	0.596
Performed with a NC balloon	9.7% (68/713)	8.6% (29/341)	1.13 (0.73–1.74)	0.591	3.3% (23/713)	2.4% (8/341)	1.39 (0.62–3.10)	0.422
Performed with $\geq$ 16 atm	10.3% (39/375)	8.8% (58/669)	1.17 (0.78–1.75	0.453	3.2% (12/375)	2.9% (19/669)	1.09 (0.53–2.25)	0.807
Performed with $\geq$ 18 atm	11.2% (24/219)	8.9% (73/835)	1.25 (0.79–1.99)	0.337	4.2% (9/219)	2.7% (22/835)	1.57 (0.72–3.40)	0.253
PSP parameters								
Lesion treated PSP (Correct Dmax/device sizing)	11.1% (2/18)	9.3% (95/1036)	1.17 (0.29–4.74)	0.828	(0/18)	(31/1036)	0.05 (0.00–>100)	0.456
Lesion treated PSP (Correct vessel sizing)	11.1% (12/110)	9.2% (85/944)	1.23 (0.67–2.26)	0.497	2.8% (3/110)	3.0% (28/944)	0.93 (0.28–3.04)	0.897

It shows the outcomes of the Lesion-Oriented Composite Endpoint (LOCE) and device thrombosis in Absorb BVS treated lesions

Table 3 Outcomes in Xience EES treated lesions

	Lesion-oriented composite endpoint				Definite stent thrombosis			
	Present	Not present	HR (95% CI)	P value	Present	Not present	HR (95% CI)	P value
Predilation parameters								
Predilatation of the complete lesion performed	6.3% (62/1008)	5.7% (5/90)	1.10 (0.44–2.72)	0.845	0.4% (4/1008)	1.1% (1/90)	0.36 (0.04–3.18)	0.333
Predilatation balloon/RVD 1:1	7.4% (42/579)	5.0% (25/519)	1.52 (0.92–2.49)	0.097	0.5% (3/579)	0.4% (2/519)	1.35 (0.23–8.05)	0.745
Sizing								
Correct device/artery sizing according to RVD	3.3% (7/220)	7.0% (60/878)	0.45 (0.21–1.00)	0.044	0.5% (1/220)	0.5% (4/878)	1.00 (0.11–8.91)	0.997
Correct device/artery sizing according to prox Dmax	6.0% (22/372)	6.4% (45/726)	0.96 (0.58–1.60)	0.882	0.8% (3/372)	0.3% (2/726)	2.94 (0.49–17.57)	0.215
Correct device/artery sizing according to prox and distal Dmax	4.8% (7/148)	6.5% (60/950)	0.74 (0.34–1.62)	0.450	0.7% (1/148)	0.4%(4/950)	1.61 (0.18–14.36)	0.669
Correct QCA based artery sizing (≥ 2.25 and ≤ 3.75)	5.6% (38/705)	7.5% (29/393)	0.73 (0.45–1.180	0.190	0.3% (2/705)	0.8% (3/393)	0.37 (0.62–2.22)	0.258
Small vessel (<2.25 mm)	7.5% (27/365)	5.6% (40/733)	1.36 (0.84–2.22)	0.215	0.8% (3/365)	0.3% (2/733)	3.01 (0.50–18.01)	0.204
Large vessel (>3.75 mm)	4.0% (1/25)	6.3% (66/1073)	0.67 (0.09–4.85)	0.693	0% (0/25)	0.5% (5/1073)	0.05 (0.00–>100)	0.734
Postdilatation parameters								
Postdilatation of the complete lesion	6.9% (36/535)	5.6% (31/563)	1.24 (0.77–2.00)	0.381	0.6% (3/535)	0.4% (2/563)	1.59 (0.27–9.48)	0.611
Performed with $\geq$ 1:1 balloon/device ratio	6.5% (32/502)	6.0% (35/596)	1.09 (0.68–1.77)	0.714	0.4% (2/502)	0.5% (3/596)	0.79 (0.13–4.74)	0.798
Performed with a NC balloon	6.4% (28/445)	6.1% (39/653)	1.06 (0.65–1.72)	0.822	0.4% (2/445)	0.5% (3/653)	0.98 (0.16–5.85)	0.981
Performed with $\geq$ 16 atm	6.4% (17/270)	6.2% (50/828)	1.04 (0.60–1.80)	0.888	0% (0/270)	0.6% (5/828)	0.03 (0.00–>100)	0.201
Performed with $\geq$ 18 atm	6.0% (9/157)	6.3% (58/941)	0.93 (0.46–1.88)	0.847	0% (0/157)	0.5% (5/941)	0.04 (0.00–>100)	0.361
PSP parameters								
Lesion treated PSP (Correct Dmax/device sizing)	11.8% (2/17)	6.2% (65/1081)	1.96 (0.48–8.01)	0.339	0% (0/17)	0.5% (5/1081)	0.05 (0.00–>100)	0.778
Lesion treated PSP (Correct vessel sizing)	6.9% (5/76)	6.2% (62/1022)	1.08 (0.44–2.70)	0.863	0% (0/76)	0.5% (5/1022)	0.05 (0.00–>100)	0.542

It shows the outcomes of the Lesion-Oriented Composite Endpoint (LOCE) and device thrombosis in Xience EES treated lesions

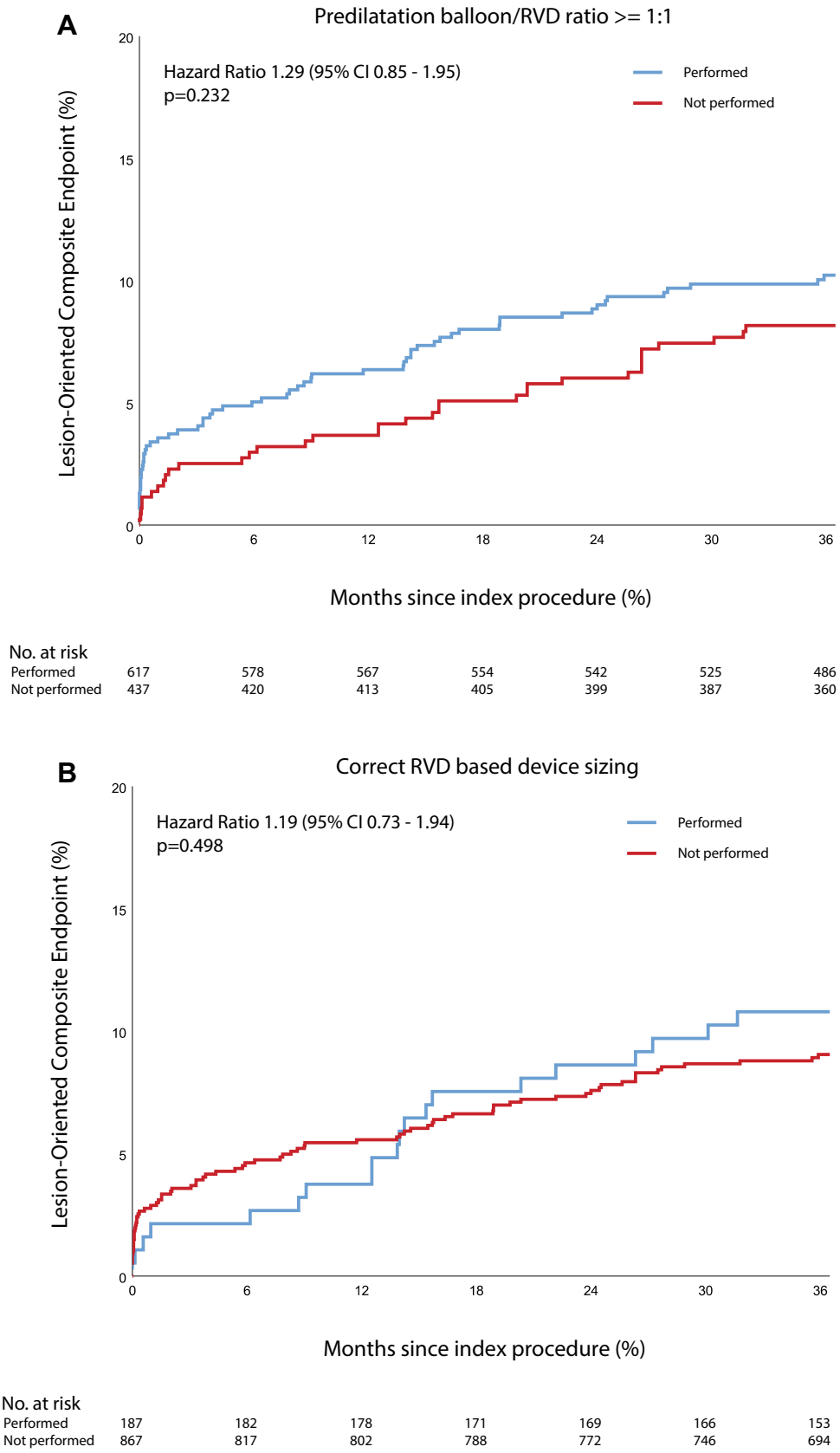
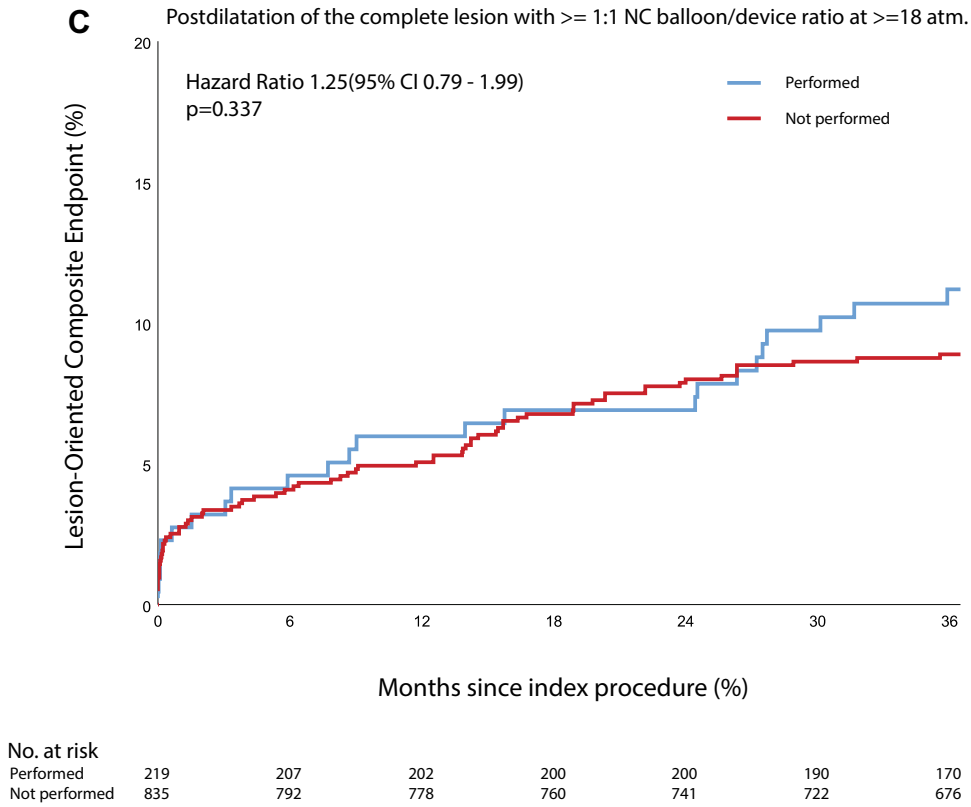


Fig. 1 The influence of correct predilatation (**a**), correct Dmax based sizing (**b**) and correct post-dilatation (**c**) on lesion-oriented outcomes in Absorb BVS treated lesions. Predilatation was score correct if performed with a balloon/reference vessel diameter (RVD) ratio of ≥ 1:1. Dmax based sizing was score correct if there was a match between proximal device diameter and proximal Dmax, and the distal device diameter and distal Dmax. Correct was scored as correct if performed with a balloon/RVD ratio ≥ 1:1 (but no greater than 0.5 than that of the widest scaffold) with 18 atm.'

Fig. 1 (continued)



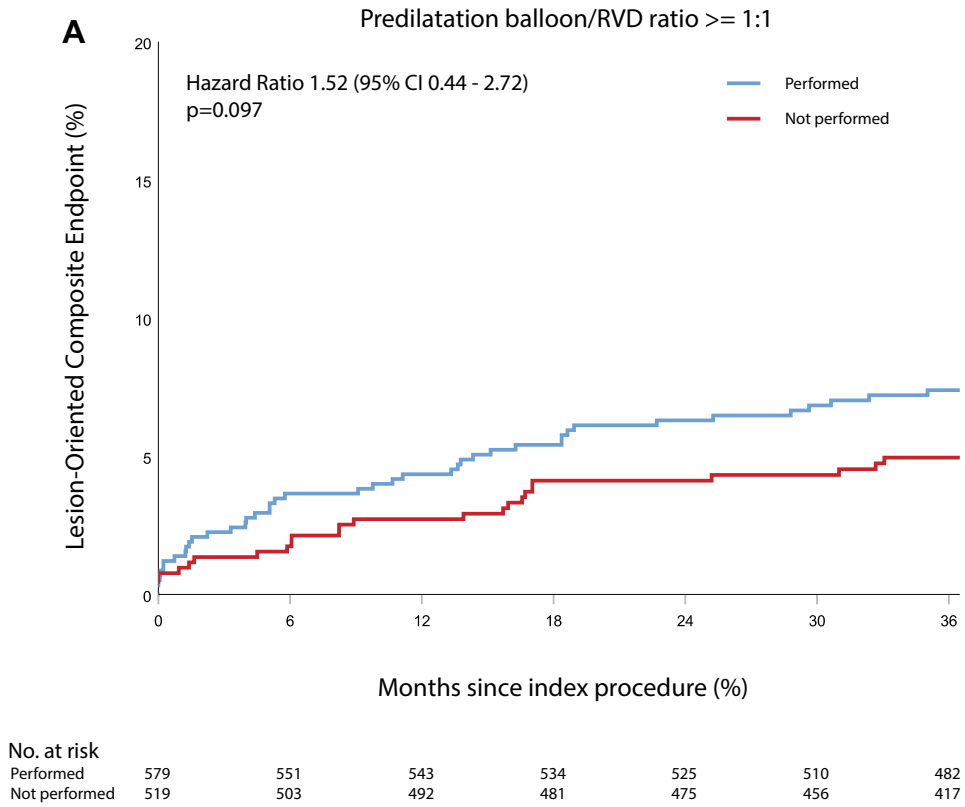
optimized device implantation techniques may improve patients outcomes. Hence, we actually do not doubt that an adequate implantation strategy with structured predilatation, device sizing and post-dilatation, supported by additional QCA, intra-coronary imaging and/or (non)-invasive physiology testing, is a correct stent or scaffold implantation strategy. In the case of the Absorb BVS treated lesions, however, the intrinsic device limitations, and the device its inability to overexpand, may have likely attributed to the lack of effect of implantation techniques on lesion-oriented outcomes, and the consequent failure of the device.

Due to expansion limits of the Absorb bioresorbable scaffold a meticulous implantation with correct sizing is required. In routine PCI, intracoronary imaging is not mandatory, and therefore the ability to correctly size a coronary vessel, and to consequently match the device to coronary artery diameter, is limited. Implantation of Absorb BVS in small vessels, has been widely associated with increased rates of adverse events at short and long-term follow-up [9]. In our study, we found that Absorb BVS implantation in smalls vessel was also associated with LOCE, but we did not find an association between Absorb BVS implantation in small vessels and scaffold thrombosis. We also found no relation between any correct device/artery matching based scaffold sizing strategy in Absorb BVS treated lesions. In contrast in Xience EES treated lesions alone correct device diameter / RVD based sizing was associated with significantly lower rates of LOCE. These results might indicate a certain unpredictability or incorrigibility in the occurrence of LOCE in Absorb BVS treated lesions, perhaps caused by the thicker and wider struts of the Absorb BVS and its inability to over-expand and embed deeply into the vessel.

We furthermore found slightly increased event rates when Absorb BVS was aggressively post-dilated. In contrast within Xience EES treated lesions, event rates dropped slightly when the device was more aggressively post-dilated.

In routine PCI, lesions which received post-dilatation might have been lesions with the greatest % residual stenosis after Absorb BVS implantation. Potentially, in these more complex lesions, the device limitations of the Absorb BVS, such as the limited ability to over-expand and the lower radial and tensile strength, are therefore more likely to be unmasked, making it impossible to improve the implantation with any technique and eventually resulting in higher event rates. Combined PSP strategies, should be interpreted with some caution, since bias is likely to be introduced when combining aggregate implantation strategies in (more) complex lesions.

The real potential benefits of BRS lays in the long-term, well after the period of complete scaffold absorption and resorption. Long-term follow-up of Absorb BVS treated patients therefore still remains necessary, in order evaluate whether the risk of adverse events declines after time. In



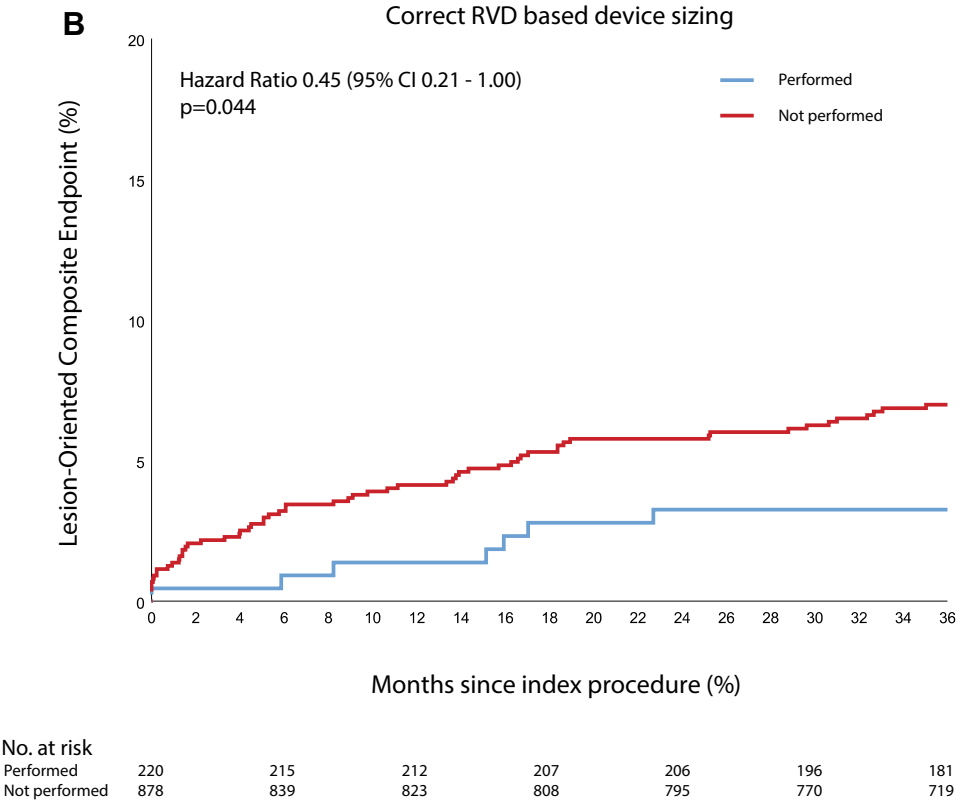
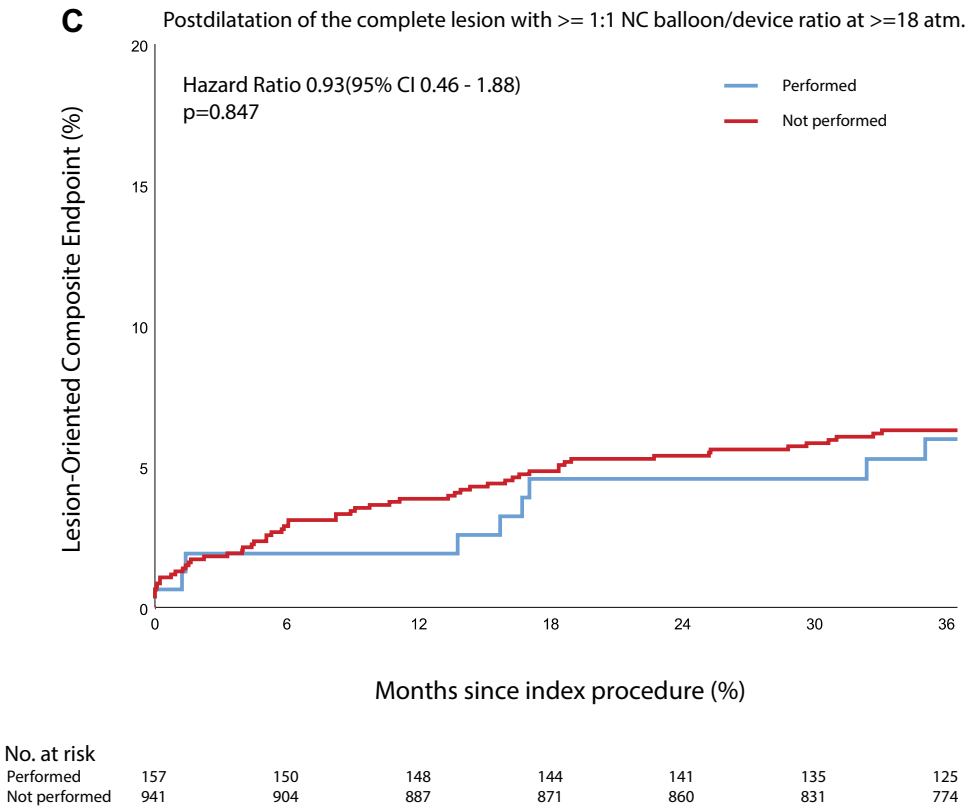


Fig. 2 The influence of correct predilatation (**a**), correct Dmax based sizing (**b**) and correct post-dilatation (**c**) on lesion-oriented outcomes in Xience EES treated lesions. Predilatation was score correct if performed with a balloon/reference vessel diameter (RVD) ratio of ≥ 1:1. Dmax based sizing was score correct if there was a match between proximal device diameter and proximal Dmax, and the distal device diameter and distal Dmax

Fig. 2 (continued)



future studies, the selection bias may also be avoided by better, and more specified, patient and lesion selection potentially supported by the use of the SYNTAX (II) score, which has shown to be a feasible and clinically applicable tool for rapid risk stratification in patients who undergo PCI presenting with a wide range of symptoms that may vary from stable coronary artery disease, to presentation with STEMI complicated by cardiogenic shock [13, 14]. Moreover, in future pre-clinical and clinical studies, careful longitudinal intracoronary imaging should play an important role in the investigation of (1) the device resorption and absorption process and (2) the effect of device specific implantations techniques.

Although Absorb BVS has been withdrawn from the commercial market, the insights provided by this study could be helpful for the development of future coronary bioresorbable scaffolds, with optimized device characteristics and better resorption profiles.

Limitations

In AIDA and in routine PCI, device sizing based on online QCA is not mandatory, and therefore, incorrect device sizing is likely to have occurred more frequently. Second, routine intracoronary imaging, such as OCT or IVUS, is not a part of routine PCI and therefore the study does not provide mechanistic insights in the occurrence of events due to a device/artery mismatch. Third, the role of lesion morphology and typology stratification as a prognostic facture for device failure has not been analyzed in the current explorative analysis. The gold standard for lesion morphology and typology stratification is intracoronary imaging. The AIDA population reflects routine PCI, and since intracoronary imaging is not a part of routine PCI (used in less than 10% of the cases), it was not possible to explore the exact role of these factors in this substudy. Furthermore, as with all post-hoc analyses, this AIDA trial sub-study is subject to under powering.

Conclusions

In this AIDA trial QCA substudy, rates of LOCE were significantly lower in Xience EES treated lesions in which devices were correctly sized according to the definitions of device diameter/RVD matching. The results of this study indicate that lesion-oriented outcomes with Xience EES might improve with use of QCA dedication implantation strategies whereas in Absorb BVS no potential improvement was found.

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Compliance with ethical standards

Conflict of interest The Amsterdam UMC Heart Center received an unrestricted educational research grant from Abbott Vascular for the AIDA trial. The Research Department of the cardiology division of the Medical Center Leeuwarden received non-study related unrestricted educational research grants from Abbott Vascular. J.J. Wykrzykowska receives consultancy fees and research grants from Abbott Vascular. J.P.S Henriques receives research Grants from Abbott Vascular. J.G.P. Tijssen served on the DSMB of the early ABSORB trials, including ABSORB II. The other co-authors declare that they have no conflicts of interest.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. All patients provided written informed consent. Staged informed consent (oral followed by written consent) was allowed for urgent procedures.

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