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Implantation techniques (predilatation, sizing, and post-dilatation) and the incidence of scaffold thrombosis and revascularisation in lesions treated with an everolimus-eluting bioresorbable vascular scaffold: insights from the AIDA trial

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KEYWORDS

- bioresorbable scaffolds
- QCA
- stent thrombosis

Abstract

Aims: Specific implantation strategies have been proposed for the Absorb bioresorbable vascular scaffold (Absorb BVS) to optimise outcomes. We aimed to analyse whether the occurrence of definite scaffold thrombosis (ScT) and target lesion revascularisation (TLR) in Absorb-treated AIDA patients was influenced by scaffold implantation techniques.

Methods and results: Absorb BVS implantation in 1,074 lesions was graded according to definitions of optimal implantation based on predilatation, sizing, and post-dilatation (PSP). Lesion-oriented outcomes (definite ScT and TLR) that occurred during a median follow-up of 707 days were related to the presence or absence of PSP. Of 1,074 lesions, 158 (14.7%) lesions met PSP criteria. The most prevalent reason for not meeting PSP criteria was inadequate sizing: 863 (94.2%). Definite ScT occurred in four of 158 PSP-treated lesions compared with 27 of 916 non PSP-treated lesions, with two-year KM estimates of 3.0% vs. 4.1% and an HR of 1.14 (p=0.811). TLR occurred in eight of 158 PSP-treated lesions compared with 61 of 916 non PSP-treated lesions, with KM estimates of 5.6% vs. 7.1% and an HR of 1.29 (p=0.492).

Conclusions: In AIDA, lesions that underwent scaffold implantation according to an optimised Absorb BVS implantation technique did not have lower rates of ScT and TLR compared to scaffold-treated lesions that did not meet PSP criteria.

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Abbreviations

DES drug-eluting stent
DoCE device-orientated composite endpoint
PSP predilatation, sizing, post-dilatation
QCA quantitative coronary angiography
TLR target lesion revascularisation

Introduction

Metallic drug-eluting stents (DES) have become the cornerstone of percutaneous coronary intervention (PCI) for the treatment of coronary artery disease. However, they have some shortcomings: the presence of permanent metallic cages prevents arterial healing, impairs vasomotion and may be associated with neoatherosclerosis, incomplete endothelialisation, and polymer hypersensitivity with consequent stent thrombosis[1]. Bioresorbable scaffolds were designed potentially to overcome these remaining shortcomings of metallic DES.

Short-term results of randomised controlled trials comparing the Absorb bioresorbable vascular scaffold (Absorb BVS; Abbott Vascular, Santa Clara, CA, USA) with the XIENCE stent (Abbott Vascular) in non-complex populations were promising and showed acceptable results[2-4]. Long follow-up of these studies raised safety concerns, especially regarding an increased rate of (very) late scaffold thrombosis (ScT)[5-8]. The Amsterdam Investigator-Initiated Absorb Strategy All-comers (AIDA) randomised trial compared the Absorb BVS with the XIENCE in routine PCI[9]. The preliminary results of the trial were reported due to safety concerns. Up to a median follow-up of 707 days, no significant difference in target vessel failure was demonstrated, but a statistically significantly higher rate of definite or probable Absorb BVS thrombosis occurred as compared to XIENCE (3.5% vs. 0.9%).

Previous retrospective studies, with *post hoc* analysis, have demonstrated that an Absorb BVS-specific implantation technique could reduce the risk of ScT. This specific implantation technique consists of predilatation, sizing, and post-dilatation and is known as the PSP implantation strategy. The objective of our analysis was to investigate the relationship between the PSP implantation technique and subsequent lesion-specific outcomes in the AIDA trial.

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Methods

THE AIDA TRIAL STUDY DESIGN

AIDA randomised 1,845 patients undergoing PCI to receive either Absorb BVS or XIENCE. The design[10] and results[11] of the trial have been published previously. The trial enrolled patients with coronary artery disease who were undergoing PCI and had one or more target lesions that were considered, on the basis of clinical judgement, to be suitable for DES implantation.

DESIGN OF THE CURRENT ANALYSIS

The present analysis included lesions that received at least one Absorb BVS for which a baseline angiogram suitable for quantitative coronary angiography (QCA) was available. All Absorb BVS-treated lesions underwent QCA and were characterised as meeting or not meeting PSP criteria. The occurrence of lesion-oriented outcomes (ScT and TLR) was compared between lesions treated in accordance with PSP criteria and those which were not.

QCA was performed for all Absorb BVS-treated lesions with the use of validated offline software (Cardiovascular Angiography Analysis System, version 5.11; Pie Medical Imaging, Maastricht, the Netherlands). Analyses were performed by seven experienced readers, supervised by one QCA expert (Y. Onuma). All readers were blinded to events. Post-procedural angiograms were used to conduct QCA measurements (reference vessel diameter [RVD], minimum lumen diameter and % diameter residual stenosis), in a single projection. The RVD was taken as an interpolated average between the proximal and distal RVD. If multiple projections were available, the projection with the visually highest grade of stenosis was used.

PSP scoring was established according to the following criteria. Predilatation was scored as "performed" or "not performed". Scaffold sizing in lesions treated with a single scaffold was scored as "correct" if there was a match between scaffold and vessel diameter according to the following criteria: (1) a scaffold with a nominal diameter of 2.5 mm was implanted in a vessel with an RVD ≥2.5 mm and <2.75 mm; (2) a scaffold with a nominal diameter of 3.0 mm was implanted in a vessel with an RVD ≥2.75 mm and <3.25 mm; or (3) a scaffold with a nominal diameter of 3.5 mm was implanted in a vessel with an RVD ≥3.25 mm and <3.75 mm. In lesions in which multiple scaffolds were implanted, we applied three different definitions for correct PSP scaffold sizing: PSP-A (all), PSP-S (single), and PSP-M (mean). Sizing was correct according to PSP-A if all implanted scaffolds were sized correctly, according to PSP-S if at least one single implanted scaffold was sized correctly, and according to PSP-M if the mean nominal diameter of all implanted scaffolds fell within the correct window for the RVD. Post-dilatation was scored as correct if performed with a non-compliant balloon with a nominal diameter equal to or greater than that of the widest scaffold, but no greater than 0.5 mm over the nominal scaffold diameter.

LESION-ORIENTED OUTCOMES

The lesion-oriented outcomes of this analysis were definite ScT and target lesion revascularisation (TLR). All outcomes were adjudicated by an independent clinical events committee (Cardialysis B.V., Rotterdam, the Netherlands) according to the definitions of the Academic Research Consortium[11].

STATISTICAL ANALYSES

This report provides descriptive information on all lesion-oriented outcomes that occurred before December 2016, subdivided by PSP status. All statistical comparisons were descriptive without formal statistical testing. Event rates were based on Kaplan-Meier (KM) estimates in time-to-first-event analyses. Kaplan-Meier event curves were compared between the PSP groups by means of the log-rank test. Cox regression analysis was used to determine hazard ratios (HR) with 95% confidence intervals (CI). The Cox

regression analysis takes lesion-specific outcomes within patients as independent observations. A preliminary analysis, where clustering of lesions within patients was taken into account (a Cox model with patients as a random effect/frailty and PSP status), showed that within a patient correlation was virtually absent (p=1.00 for both TLR and ScT). Follow-up was censored in December 2016, or at the last known event-free time point. We used Fisher's exact test to compare categorical variables and independent t-tests to compare continuous variables. All statistical analyses were performed with SPSS Statistics, Version 23 (IBM Corp., Armonk, NY, USA).

Results

POPULATION

In AIDA, 924 patients were randomised to treatment with the Absorb BVS, of whom 869 were available for this analysis **(Figure 1)**. Of the 1,169 lesions in these patients, 32 were excluded because the lesion was treated with a metallic stent. For another 63 lesions no QCA was available. The final cohort consisted of 1,074 lesions treated with one or more Absorb BVS and a baseline angiography suitable for QCA.

PSP GRADING AND PROCEDURAL CHARACTERISTICS

Table 1 shows the full PSP scoring of the Absorb BVS-treated lesions. Of the 1,074 lesions, 158 (14.7%) lesions met PSP-A, 174 (16.2%) PSP-S, and 162 (15.1%) PSP-M criteria. The most prevalent reason for not meeting PSP criteria was inadequate sizing. When the analysis was restricted to lesions that were treated with only one scaffold, 131 (14.8%) of 884 lesions met PSP criteria. **Table 2** depicts details of the lesions with inconsistent PSP scores. Full procedural characteristics of the lesions by PSP-A are displayed in **Table 3**.

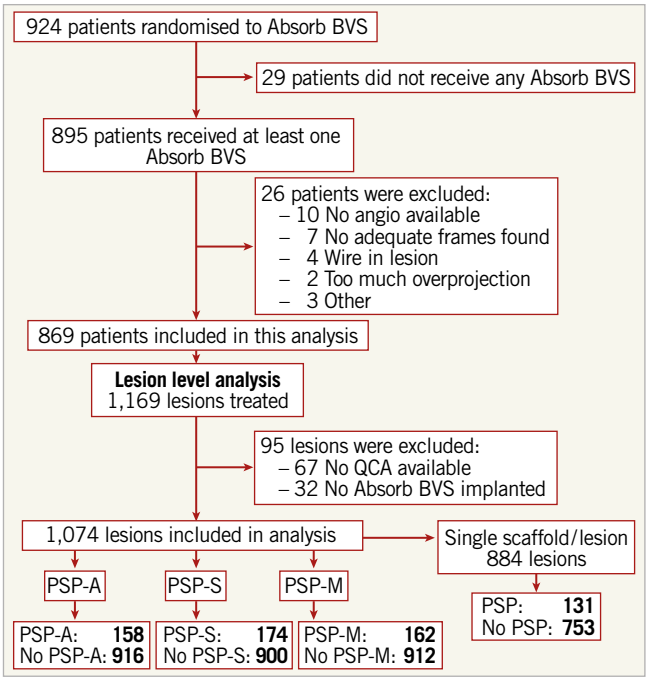

Figure 1. *Study flow chart. BVS: bioresorbable vascular scaffold; PSP: predilatation performed, scaffold(s) correctly sized, post-dilatation correctly performed; PSP-A: all scaffolds correctly sized; PSP-M: mean scaffold diameter correctly sized; PSP-S: at least one scaffold correctly sized; QCA: quantitative coronary angiography*

LESION-ORIENTED OUTCOMES

Table 4, **Figure 2**, and **Figure 3** show lesion-oriented outcomes by PSP scores. Definite ScT occurred in four of 158 PSP-A treated lesions compared with 27 of the 916 non-PSP-A treated lesions, with two-year KM estimates of 3.0% vs. 4.1% and

Table 1. PSP scoring for 1,074 lesions treated with the Absorb scaffold among 869 patients.

	All lesions (n=1,074)			Lesions with single scaffold (n=884)
	PSP-A	PSP-S	PSP-M	PSP
PSP criteria met	158	174	162	131
PSP criteria not met	916	900	912	753
Reasons for no PSP				
No predilation performed	25	25	25	20
Incorrect scaffold sizing	863 (94.2%)	824 (91.6%)	855 (93.8%)	707 (93.9%)
Scaffold undersized	63	54	55	50
Scaffold oversized	803	771	800	657
Scaffold undersized and oversized	3	1	n/a	
Incorrect post-dilation	300	300	300	234
No post-dilation	258	258	258	213
Undersized post-dilation	20	20	20	15
Oversized post-dilation	16	16	16	6
No complete post-dilation	6	6	6	0

PSP: predilation performed, correctly sized, post-dilation correctly performed; PSP-A: all scaffolds correctly sized; PSP-M: mean scaffold diameter correctly sized; PSP-S: at least one single scaffold correctly sized

Table 2. Details of lesions with inconsistent PSP scores.

Patient #	QCA diameter	# scaffolds	Diameter 1	Diameter 2	Diameter 3	Mean diameter	PSP-A	PSP-S	PSP-M
1	3.060	2	3.0	3.5		3.25	0	1	0
2	2.862	3	3.0	3.5		3.25	0	1	0
3	3.427	2	3.5	3		3.25	0	1	1
4	2.529	2	3.0	2.5		2.75	0	1	0
5	2.736	3	2.5	3.0	3.0	2.83	0	1	0
6	2.830	2	2.5	3.5		2.75	0	1	1
7	2.845	2	3.0	3.5		3.25	0	1	0
8	2.804	2	3.5	2.5		3.00	0	0	1
9	2.771	2	3.0	3.5		3.25	0	1	0
10	3.089	2	3.5	3.0		3.15	0	1	0
11	2.650	3	3.0	3.0	2.5	2.83	0	1	0
12	2.904	2	3.0	3.5		3.25	0	1	0
13	2.538	2	2.5	3.0		2.75	0	1	0
14	2.605	2	2.5	3.0		2.75	0	1	0
15	2.509	2	3.0	2.5		2.75	0	1	0
16	2.833	2	2.5	3.0		2.75	0	1	1
17	3.114	2	3.0	3.5		3.25	0	1	0

PSP: predilatation, sizing, post-dilatation; QCA: quantitative coronary angiography

Table 3. Procedural characteristics of 1,074 lesions treated with Absorb scaffold by PSP-A scoring.

		PSP-A*	No PSP-A	*p*-value
Treated lesions	Total number	158	916	
	Rotational atherectomy, n (%)	3 (1.9%)	19 (2.1%)	1.000
	Thrombus aspiration, n (%)	9 (5.7%)	81 (8.8%)	0.120
Predilatation	Predilatation of the complete lesion performed	158 (100%)	891 (97.3%)	0.039
Device implantation	Number of devices per lesion	1.19±0.45	1.20±0.46	0.740
	Single device per lesion, n (%)	131 (82.9%)	754 (82.3%)	0.910
	Multiple devices per lesion, n (%)	27 (17.1%)	162 (17.7%)	0.910
	Device diameter, mm mean±SD	3.16±0.31	3.06±0.37	0.001
	Total device length, mm mean±SD	23.20±10.97	24.28±12.50	0.304
Post-dilatation	Post-dilatation of the complete lesion performed	158 (100%)	652 (71.2%)	<0.001
	Post-dilatation maximum nominal balloon diameter, mm mean±SD	3.40±0.40	3.25±0.44	<0.001
	Max post-dilatation balloon pressure, atm mean±SD	15.32±3.41	15.26±3.66	0.834
Quantitative coronary angiography analysis	Reference vessel diameter	3.10±0.31	2.58±0.44	<0.001
	Residual stenosis (%)	18.12±8.85	17.02±9.59	0.182

*PSP-A: predilation performed; all scaffolds correctly sized, if post-dilation was correctly performed. PSP: predilatation, sizing, post-dilatation

an HR of 1.14 (95% CI: 0.40-3.25; p=0.811). TLR occurred in eight of 158 PSP-A treated lesions compared with 61 of 916 non-PSP-A treated lesions, with KM estimates 5.6% vs. 7.1% and an HR of 1.29 (95% CI: 0.62-2.70; p=0.492). Half of the TLRs were associated with ScT. There was one more case of ScT and TLR in PSP-S treated lesions. Results were similar when implantations were graded according to PSP-M criteria. Scaffold sizing and post-dilatation individually were not associated with an increased rate of ScT or TLR **(Supplementary Figure 1, Supplementary Figure 2)**.

When the analysis was restricted to lesions treated with a single scaffold, 131 of 884 (14.8%) lesions met PSP criteria. Definite ScT occurred in three of 131 PSP-treated lesions against 24 of 753 non-PSP-treated lesions, with two-year KM estimates of 2.9% vs. 3.3% and an HR 1.35 (95% CI: 0.41-4.49; p=0.622). TLR occurred in seven of 131 PSP-treated lesions compared with 50 of 753 non-PSP-treated lesions, with two-year KM estimates of 3.1% vs. 3.8% and an HR 1.22 (95% CI: 0.55-2.69; p=0.622). Scaffold sizing and post-dilatation individually were not associated with an increased rate of ScT or TLR **(Supplementary**

Table 4. Lesion-specific outcomes of 1,074 lesions treated with Absorb by PSP scoring.

	Patients with event		2-year cum event rate*		Hazard ratio (95% CI)	*p*-value¶
	PSP	No PSP	PSP	No PSP		
All lesions according to PSP-A (all scaffolds correct)	**n=158**	**n=916**				
Definite scaffold thrombosis	4	27	3.0%	4.1%	1.14 [0.40-3.25]	0.811
Any target lesion revascularisation	8	61	5.6%	7.1%	1.29 [0.62-2.70]	0.492
Target lesion revascularisation without scaffold thrombosis	4	35	2.6%	4.3%	1.48 [0.53-4.17]	0.452
All lesions according to PSP-S (single scaffold correct)	**n=174**	**n=900**				
Definite scaffold thrombosis	5	26	2.9%	2.9%	0.98 [0.38-2.56]	0.972
Any target lesion revascularisation	9	60	5.6%	8.1%	1.25 [0.62-2.52]	0.502
Target lesion revascularisation without scaffold thrombosis	4	35	2.4%	4.4%	1.67 [0.59-4.69]	0.328
All lesions according to PSP-M (mean scaffold correct)	**n=162**	**n=912**				
Definite scaffold thrombosis	4	27	3.0%	3.1%	1.17 [0.41-3.34]	0.770
Any target lesion revascularisation	8	61	5.4%	7.1%	1.33 [0.64-2.78]	0.445
Target lesion revascularisation without scaffold thrombosis	4	35	2.5%	4.3%	1.53 [0.54-4.29]	0.420
Lesions treated with a single scaffold according to PSP	**n=131**	**n=753**				
Definite scaffold thrombosis	3	24	2.9%	3.3%	1.35 [0.41-4.49]	0.622
Any target lesion revascularisation	7	50	6.0%	8.0%	1.22 [0.55-2.69]	0.622
Target lesion revascularisation without scaffold thrombosis	4	27	3.1%	3.8%	1.16 [0.41-3.30]	0.788

* Event rates were based on Kaplan-Meier estimates in time-to-event analyses. ¶*p*-values, calculated by the log-rank test, are descriptive.
PSP: predilatation, sizing, post-dilatation

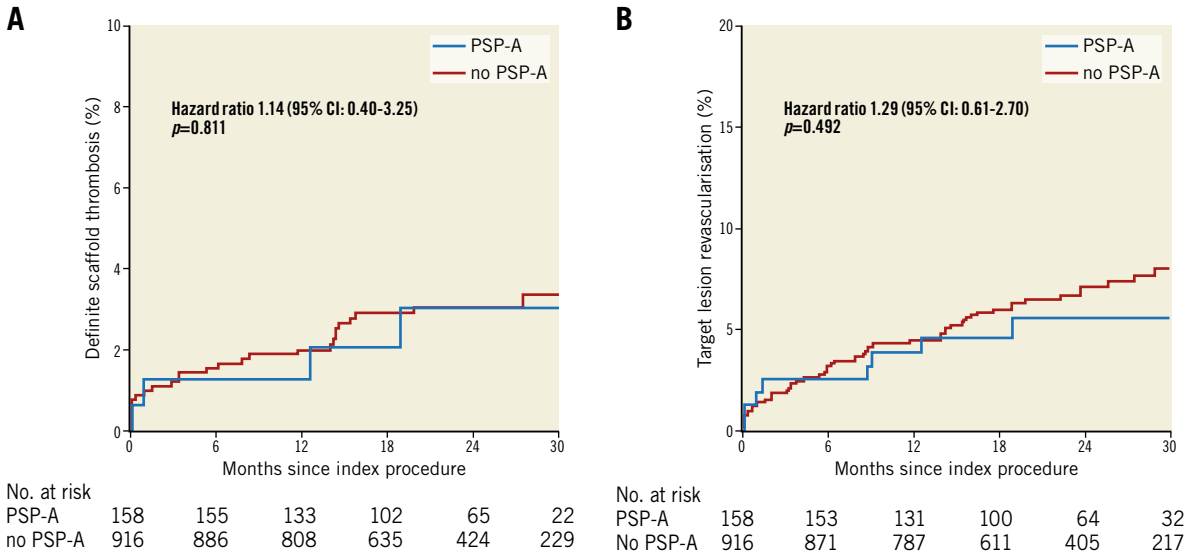

Figure 2. *Event rates of definite scaffold thrombosis (A) and target lesion revascularisation (B) in PSP-A or no PSP-A treated lesions. CI: confidence interval; PSP-A: predilatation performed, all scaffolds correctly sized, post-dilatation correctly performed*

Figure 3, Supplementary Figure 4). There were four cases of TLR not associated with ScT. Details of the five cases of ScT in implantations meeting any PSP criteria are shown in **Table 5**.

Discussion

The main findings of our analysis are:

1) We found no relationship between scaffold sizing or post-dilatation and the rate of ScT or TLR.
2) The definition for scaffold sizing in PSP score models was cumbersome in lesions treated with multiple scaffolds. We applied three different definitions, and we found discrepancies in PSP scoring in 17 of 1,074 lesions.
3) We found four cases of definite ScT occurring in 158 PSP-A treated lesions compared with 27 cases in 916 non-PSP-A treated lesions, with similar KM estimates of 3.0% and 4.1%, respectively. In addition, there were four more cases of TLR in PSP-A treated lesions, and 35 in non-PSP-A treated lesions.

When the analysis was restricted to lesions treated with a single scaffold, we found three cases of definite ScT in PSP-treated lesions, with similar KM estimates of 2.9% and 3.3%, respectively.

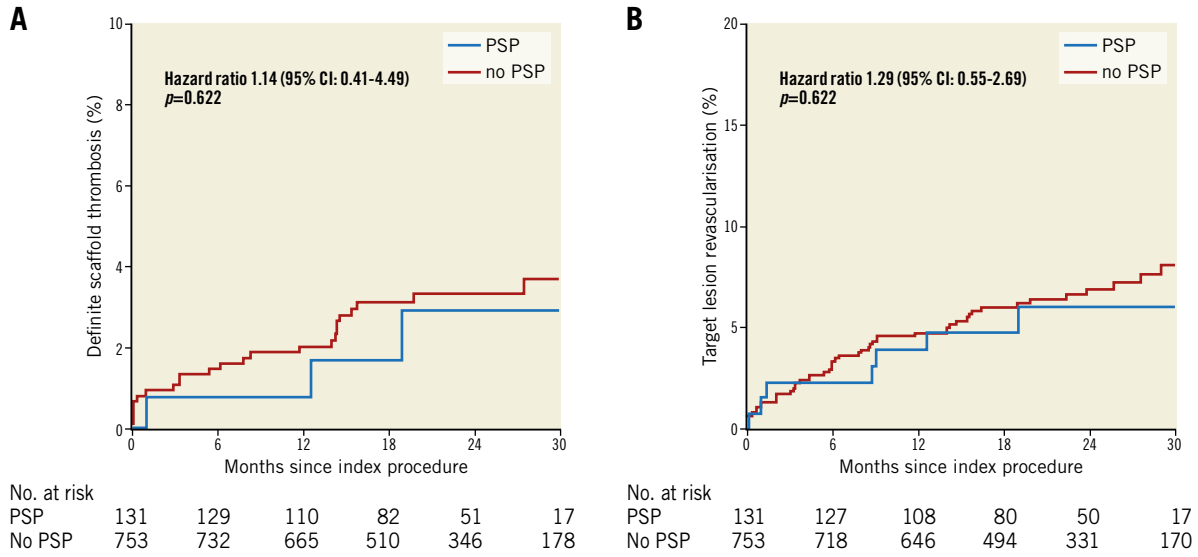

Figure 3. *Event rates of definite scaffold thrombosis (A) and target lesion revascularisation (B) in PSP or no PSP treated lesions in the single scaffold per lesion model. CI: confidence interval; PSP: predilatation performed, scaffold correctly sized, post-dilatation correctly performed*

Table 5. Details of the five cases of scaffold thrombosis meeting any PSP criterion.

Patient	Lesion #	Lesion location (segment)	Ref diam (mm)	# scaffolds	Diam 1	Diam 2	Diam 3	Lesion PSP	Reason no PSP	ScT¶	Time (days)
1	1	LAD (6)	2.8792	1	3.0			Yes		Yes	29
	2	RCA (2-3)	2.2611	3	3.0	2.5	2.5	No	Inadequate sizing		
2	1	RCA (1-2)	3.3207	2	3.5	3.5		Yes		Yes	6
3	1	RCA (2)	3.4658	1	3.5			Yes		Yes	376
	2	RCA (3)	3.0908	1	3.0			No	No post-dilatation		
4	1	RCA (1)	3.5181	1	3.5			Yes		Yes	567
	2	RCx (13)	2.2420	2	3.0	3.0		No	Inadequate sizing		
	3	RCx (11)	N/A	1	3.0			N/A			
5*	1	LAD (6)	3.1137	2	3.5	3.0		Yes		Yes	4

*Lesion 1 in patient 5 only met PSP-S criteria, all other lesions which were treated PSP met PSP-A, PSP-S and PSP-M criteria. ¶All scaffold thromboses underwent target lesion revascularisation. PSP: predilatation, sizing, post-dilatation; ScT: scaffold thrombosis

The Absorb BVS has several limitations over metallic DES, such as transparency to X-ray, lower radial and tensile strength, increased strut width and thickness and limited expansion abilities. These limitations require the Absorb BVS to be implanted in a meticulous fashion[12]. Absorb-specific implantation strategies have been proposed to improve the safety and clinical outcomes of patients treated with the Absorb BVS. In the GHOST-EU registry, a specific scaffold implantation strategy predicted the patient-level one-year device-oriented composite endpoint[13].

The GHOST-EU registry and the AIDA trial included a high-risk population with a high prevalence of multivessel disease, overlapping scaffolds, and multiple scaffolds per lesion[11,14]. Assessment of PSP sizing in lesions treated with multiple (overlapping) scaffolds is uncharted territory and has yet to be defined. Herein, we analysed PSP scaffold sizing in lesions treated with multiple scaffolds in three different ways (PSP-A, PSP-S and PSP-M). These models provided different PSP scores in a number of lesions. Nevertheless, none of these models showed any predictive value for the occurrence of ScT or TLR.

The recently published "pooled ABSORB PSP analysis" showed that vessel sizing and operator technique were strongly associated with Absorb BVS-related outcomes during three-year follow-up[15]. This analysis used an *ad hoc* definition for appropriate sizing based on vessel diameter only and ignored the scaffold to vessel diameter ratio, and its potential mismatch. Avoiding scaffold and vessel mismatch is associated with less frequent ischaemia-driven TLR, whereas scaffold oversizing in small coronary vessels may be associated with higher rates of MACE at one-year follow-up[16]. In our analysis, we have applied the conventional definition of scaffold sizing[13,17]. In AIDA, inappropriate sizing was the major reason for not meeting PSP criteria (94%). If we had applied the pooled ABSORB PSP definition of sizing,

we would have identified 79.6% of AIDA Absorb-treated lesions as appropriately sized. This percentage is in stark contrast with the 19.6% appropriately sized lesions in AIDA under the conventional definition of scaffold sizing. In the pooled ABSORB PSP analysis, optimal predilatation required "balloon to core laboratory-derived reference vessel diameter ratio ≥1:1 and optimal post-dilatation required post-dilatation with a non-compliant balloon at ≥18 atm and larger than the nominal scaffold diameter, but not by >0.5 mm larger". We note that the predilatation and post-dilatation criteria in the "pooled ABSORB PSP analysis" are more stringent than ours, in contrast with the criterion for sizing, which is much less stringent. Only 72 of 1,074 AIDA lesions satisfied the PSP criteria of the pooled ABSORB PSP analysis. We did not observe a relationship between the aggregate PSP according to this definition, and its individual components of aggressive predilatation and aggressive post-dilatation, and the subsequent risk of TLR and ScT **(Supplementary Figure 5-Supplementary Figure 7)**.

PSP is a lesion-specific implantation characteristic. Therefore, we present lesion-oriented outcomes. Notably, we found five cases of ScT that occurred in PSP-treated lesions, of which three occurred in patients with multiple lesion PCI **(Table 5)**. All three patients would have been classified as not meeting PSP criteria because the other lesion(s) were not PSP. A per-patient analysis assigns ScT occurring in PSP-treated lesions to non-PSP-treated patients. This observation shows that classifying patients as meeting or not meeting PSP criteria, with subsequent per-patient outcome analyses, might lead to incorrect conclusions. It explains the discrepancy between our findings and the patient-level analyses reported in the pooled ABSORB PSP and GHOST-EU cohorts.

The main reason for not meeting PSP criteria in our study was inadequate scaffold sizing, mainly due to oversizing. Accurate sizing is particularly problematic in long lesions in tapered vessels because the Absorb BVS cannot be expanded more than 0.5 mm above the nominal size. The lack of relationship between the PSP score and the individual components of scaffold sizing and post-dilatation, and the risk of ScT or TLR implies that operator technique cannot surmount the sizing problems due to the expansion limits of the device. Although the Absorb BVS is not available anymore, these new insights provided by our study can be useful for the development of the next generation of devices with broader expansion limits and better tensile strength, potentially resolving the scaffold sizing issue[18].

Limitations

This analysis has several limitations. First, with only 158 PSP and 916 non-PSP lesions the analysis is statistically underpowered. Second, our analysis provides only limited information on the relationship between PSP implantation and the risk of long-term ScT and TLR. Third, as post-dilatation was not mandated in the study protocol, lesions which received post-dilatation might have been lesions with the greatest % residual stenosis after scaffold implantation, and therefore potential bias in this analysis might have been introduced. Fourth, OCT and QCA after predilatation were not performed, as in many other published PSP analyses. Therefore, we cannot distinguish between successful and unsuccessful predilatation.

Conclusions

In this AIDA substudy, lesions that underwent scaffold implantation according to an optimised Absorb BVS implantation technique stratified by PSP score showed numerically similar rates of ScT and TLR. The major reason for not meeting PSP criteria was inappropriate sizing. The lack of relationship between the PSP score, predilatation, correct scaffold sizing, or post-dilatation and the risk of ScT or TLR indicates that operator technique cannot surmount the sizing problems due to the expansion limits of the Absorb BVS.

Impact on daily practice

In AIDA, lesions that underwent scaffold implantation according to an optimised Absorb BVS implantation technique stratified by PSP score did not have lower rates of ScT and TLR. The lack of a relationship between the PSP score and the individual components of scaffold sizing and post-dilatation, and the risk of ScT or TLR suggests that operator technique cannot surmount the sizing problems due to the expansion limits of the current-generation device. Although the Absorb BVS is not commercially available anymore, these new insights provided by our study could be useful for the development of the next generation of devices with broader expansion limits and better tensile strength, potentially resolving the scaffold sizing issue.

Guest Editors

This paper was guest edited by Adnan Kastrati, MD; Deutsches Herzzentrum, Munich, Germany, and Alec Vahanian, MD, PhD; Department of Cardiology, Hôpital Bichat-Claude Bernard and University Paris VII, Paris, France.

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Conflict of interest statement

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Supplementary data

Supplementary Figure 1. Lesion-oriented outcomes of the individual component of scaffold sizing in PSP-A or no PSP-A treated lesions.

Supplementary Figure 2. Lesion-oriented outcomes of the individual component of post-dilatation in PSP-A or no PSP-A treated lesions.

Supplementary Figure 3. Lesion-oriented outcomes of the individual component of scaffold sizing in lesions treated with a single scaffold.

Supplementary Figure 4. Lesion-oriented outcomes of the individual component of post-dilatation in lesions treated with a single scaffold.

Supplementary Figure 5. Lesion-oriented outcomes by PSP-PA or no PSP-PA treated lesions.

Supplementary Figure 6. Lesion-oriented outcomes by aggressive predilatation.

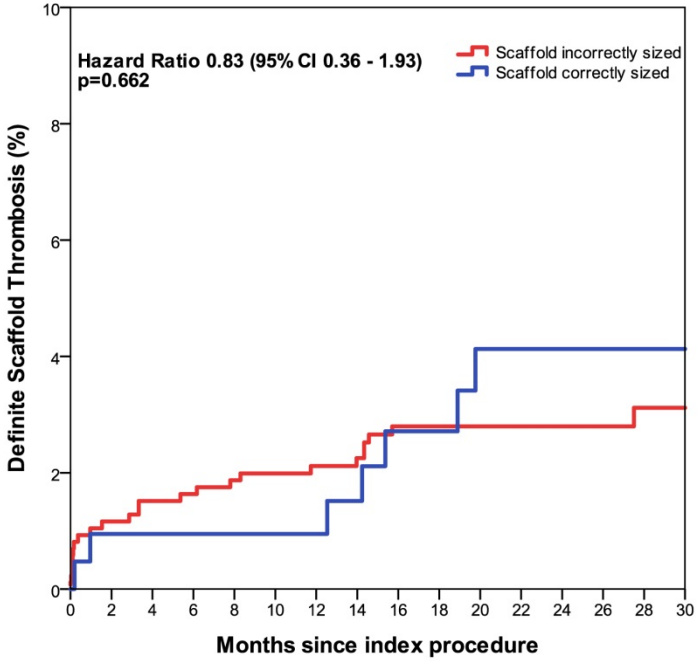
Supplementary Figure 7. Lesion-oriented outcomes by aggressive post-dilatation.

The supplementary data are published online at: http://www.pcronline.com/eurointervention/137th_issue/77

Supplementary data

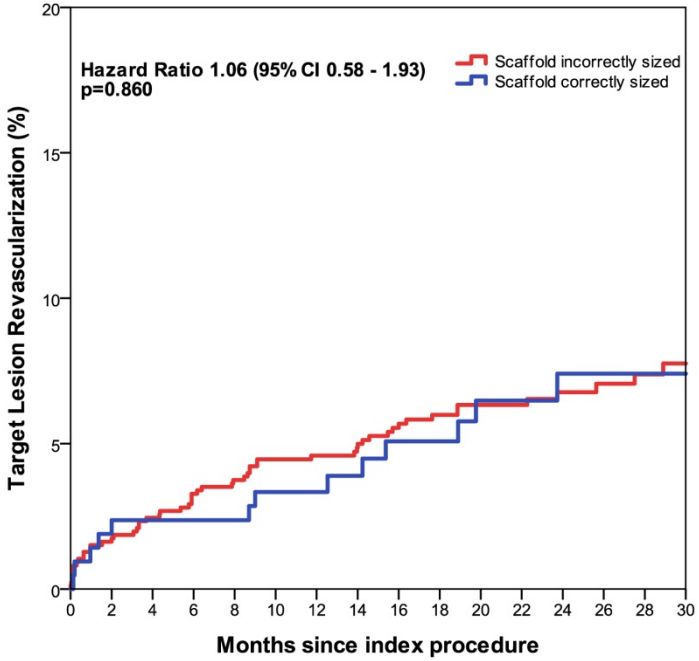
Supplementary Figure 1. Lesion-oriented outcomes of the individual component of scaffold sizing in PSP-A or no PSP-A treated lesions. Shown is the event rate of definite scaffold thrombosis (A) or target lesion revascularisation (B) of the individual component of correct scaffold sizing in the PSP-A model. CI: confidence interval; PSP-A: predilatation; all scaffolds correctly sized; post-dilatation correctly performed

A.



No. at risk						
Incorrect sizing	863	833	761	592	398	210
Correct sizing	211	208	180	142	92	41

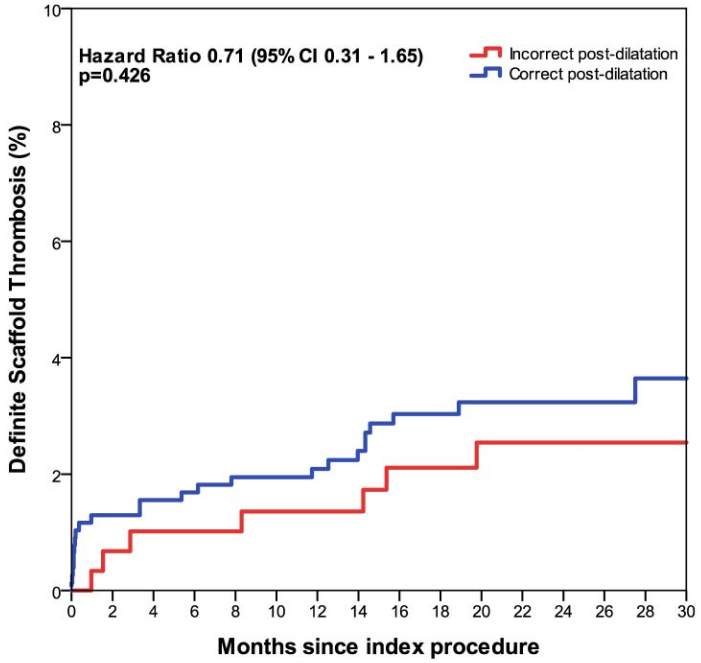
B.



No. at risk						
Incorrect sizing	863	833	761	571	379	199
Correct sizing	211	208	180	140	90	40

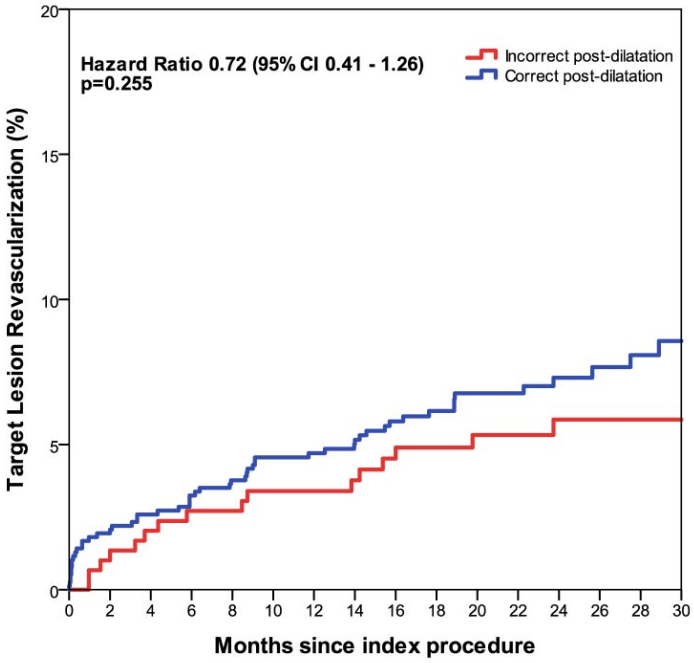
Supplementary Figure 2. Lesion-oriented outcomes of the individual component of post-dilatation in PSP-A or no PSP-A treated lesions. Shown is the event rate of definite scaffold thrombosis (A) or target lesion revascularisation (B) of the individual component of correct post-dilatation in the PSP-A model. CI: confidence interval; PSP-A: predilatation; all scaffolds correctly sized; post-dilatation correctly performed

A.



No. at risk						
Incorrect post-dilatation	300	289	272	239	170	110
Correct post-dilatation	774	752	670	495	321	140

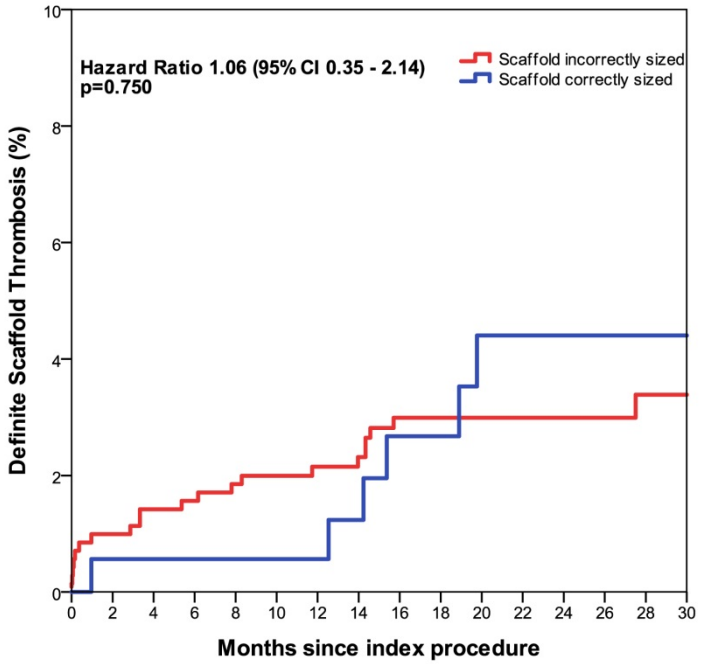
B.



No. at risk						
Incorrect post-dilatation	774	740	653	478	307	133
Correct post-dilatation	300	284	266	233	163	105

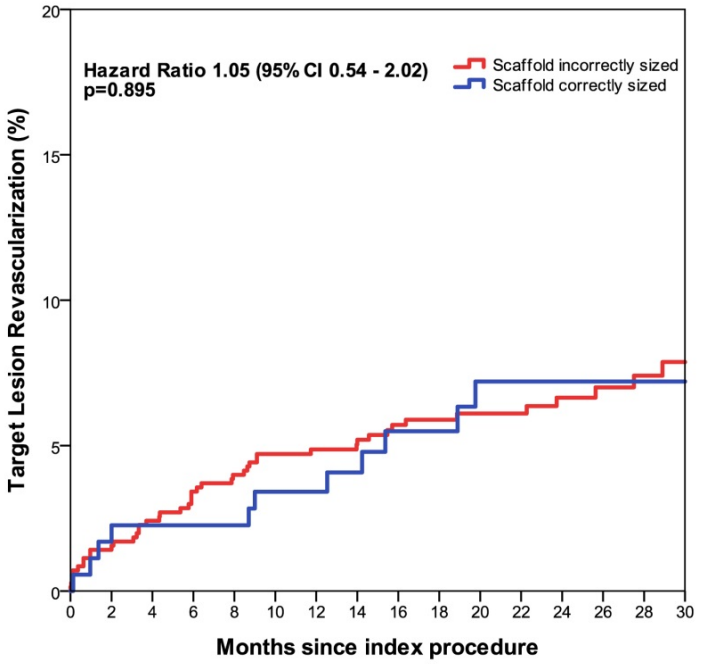
Supplementary Figure 3. Lesion-oriented outcomes of the individual component of scaffold sizing in lesions treated with a single scaffold. Shown is the event rate of definite scaffold thrombosis (A) or target lesion revascularisation (B) of the individual component of correct scaffold sizing in the single scaffold per lesion model. CI: confidence interval

A.



No. at risk						
Incorrect sizing	707	686	624	476	325	164
Correct sizing	177	175	151	116	72	31

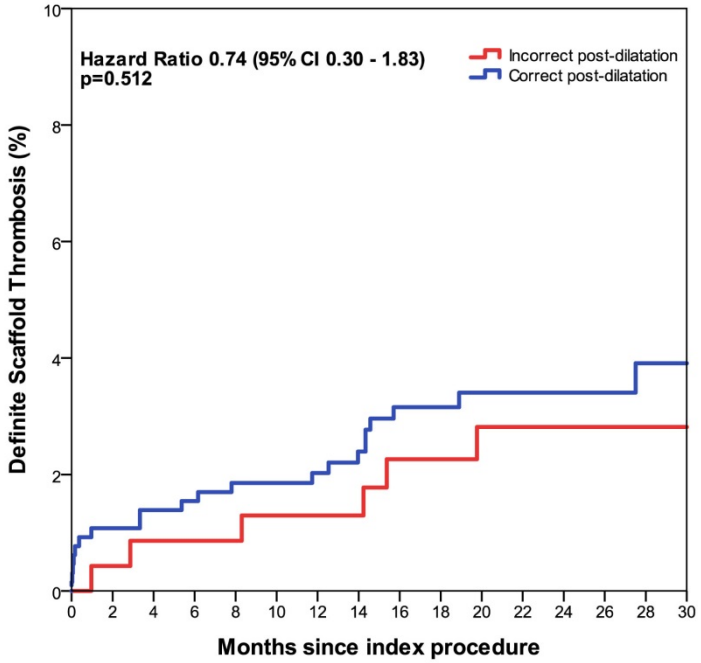
B.



No. at risk						
Incorrect sizing	707	673	606	460	310	156
Correct sizing	177	172	148	115	71	31

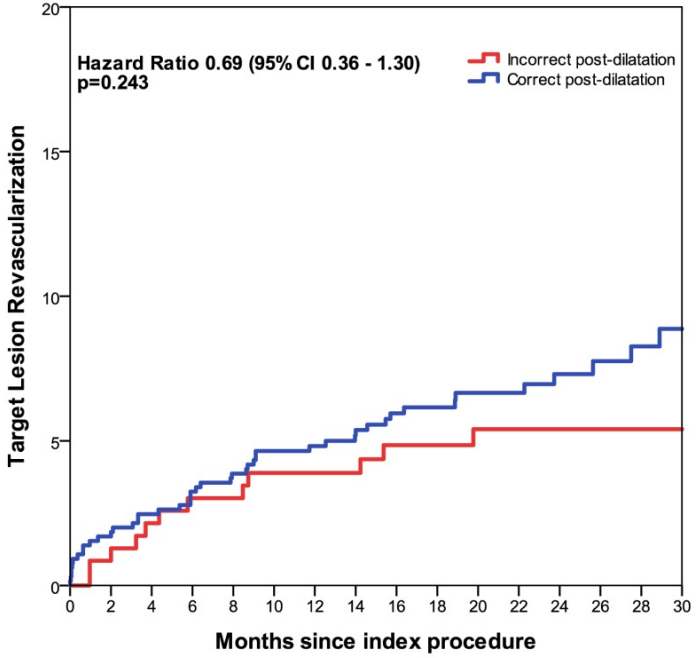
Supplementary Figure 4. Lesion-oriented outcomes of the individual component of post-dilatation in lesions treated with a single scaffold. Shown is the event rate of definite scaffold thrombosis (A) or target lesion revascularisation (B) of the individual component of correct post-dilatation in the single scaffold per lesion model. CI: confidence interval

A.



No. at risk						
Incorrect post-dilatation	234	227	214	187	133	83
Correct post-dilatation	650	634	561	407	265	111

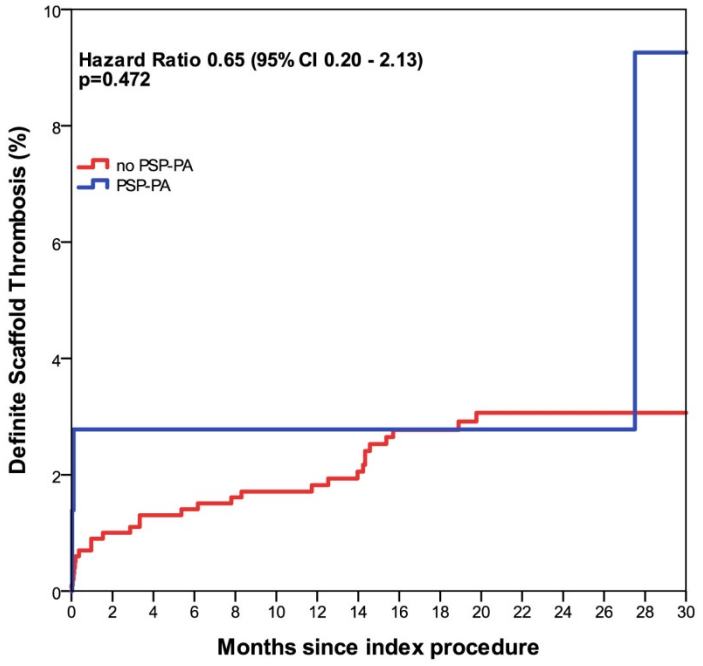
B.



No. at risk						
Incorrect post-dilatation	234	222	208	183	129	81
Correct post-dilatation	649	623	547	391	253	100

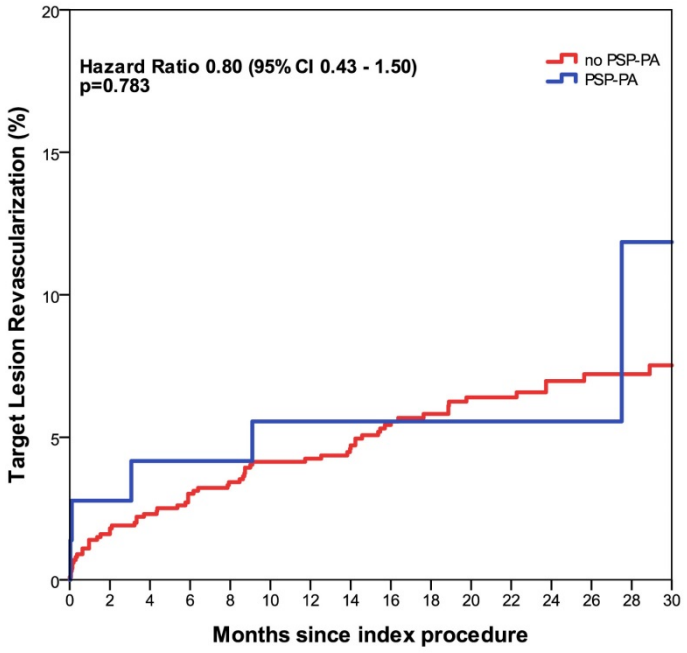
Supplementary Figure 5. Lesion-oriented outcomes by PSP-PA or no PSP-PA treated lesions. Shown is the event rate of definite scaffold thrombosis (A) or target lesion revascularisation (B) according to the PSP definition of the "pooled ABSORB analysis" (PSP-PA). PSP-PA = (1) predilatation performed with a maximum dilatation balloon diameter ≥reference vessel diameter; (2) vessel correctly sized (reference vessel diameter ≥2.25 or ≤3.75; and (3) post-dilatation performed at ≥18 atmospheres with a non-compliant balloon with a nominal diameter equal to or greater than that of the widest scaffold, but no greater than 0.5 mm over the nominal scaffold diameter. CI: confidence interval

A.



No. at risk						
no PSP-PA	1002	971	880	691	464	242
PSP-PA	72	70	62	43	26	9

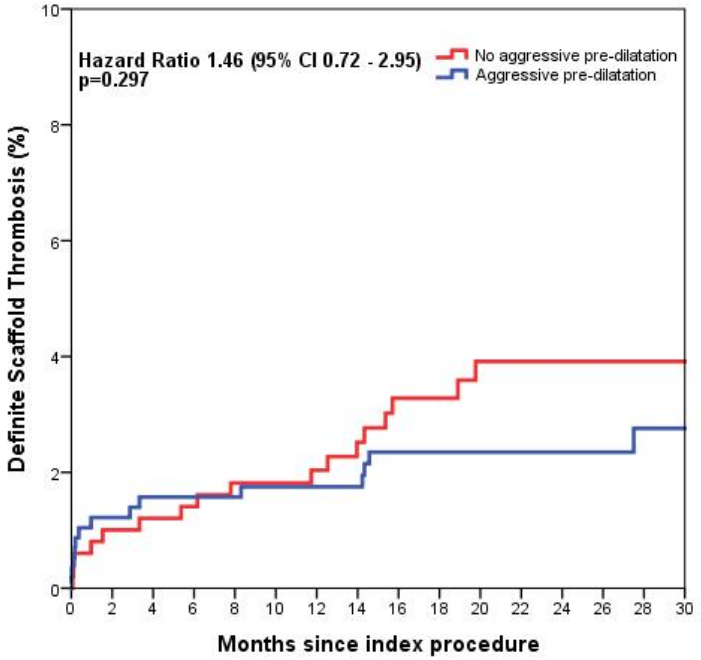
B.



No. at risk						
no PSP-PA	1002	955	859	670	444	230
PSP-PA	72	69	60	41	25	9

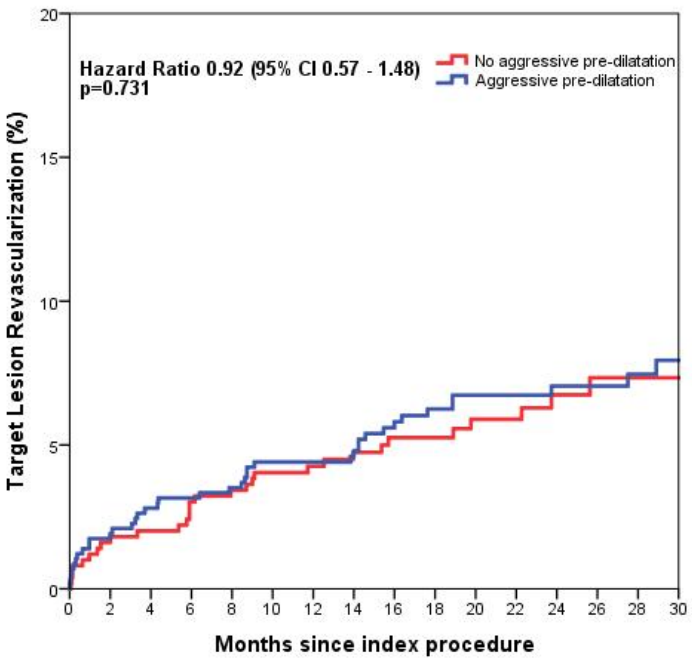
Supplementary Figure 6. Lesion-oriented outcomes by aggressive predilatation. Shown is the event rate of definite scaffold thrombosis (A) or target lesion revascularisation (B) by aggressive predilatation as defined in the pooled ABSORB PSP analysis. Aggressive predilatation: predilatation performed with a maximum dilatation balloon diameter ≥reference vessel diameter; CI: confidence interval

A.



No. at risk						
No aggressive pre-dilatation	498	488	428	320	197	93
Aggressive pre-dilatation	576	553	514	414	293	157

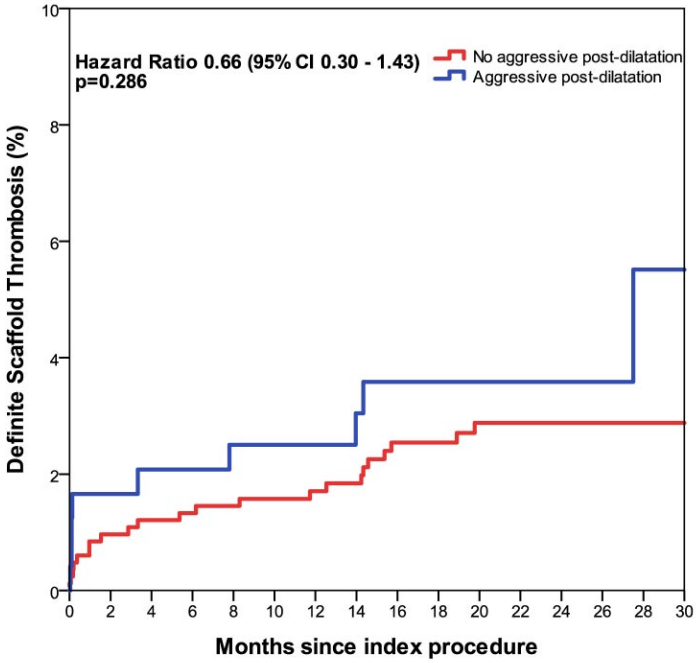
B.



No. at risk						
No aggressive pre-dilatation	498	480	419	313	191	s91
Aggressive pre-dilatation	576	544	500	427	278	147

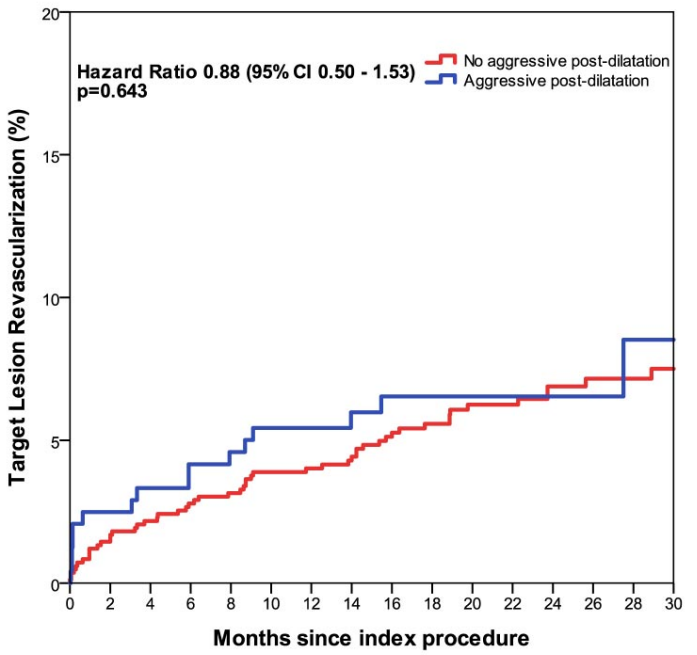
Supplementary Figure 7. Lesion-oriented outcomes by aggressive post-dilatation. Shown is the event rate of definite scaffold thrombosis (A) or target lesion revascularisation (B) by aggressive post-dilatation as defined in the pooled ABSORB PSP analysis. Aggressive post-dilatation: post-dilatation performed on ≥18 atm, with a non-compliant balloon with a nominal diameter equal to or greater than that of the widest scaffold, but no greater than 0.5 mm over the nominal scaffold diameter; CI: confidence interval

A.



No. at risk						
No aggressive post-dilatation	833	807	742	599	412	223
Aggressive post-dilatation	241	234	199	135	78	28

B.



No. at risk						
No aggressive post-dilatation	833	795	725	582	395	211
Aggressive post-dilatation	241	229	193	129	74	28