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ORIGINAL STUDIES

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Outcomes of 10,312 patients treated with everolimus-eluting bioresorbable scaffolds during daily clinical practice – results from the European Absorb Consortium

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Abstract

Objectives: To asses mid-term clinical outcomes of bioresorbable vascular scaffolds (BVS) for the treatment of coronary artery disease in a large-scale all-comers population.

Background: Several clinical settings are underrepresented in randomized studies investigating BVS against drug-eluting stents. Whether their results can be translated into the heterogeny patient population seen during daily routine requires further investigation.

Methods: The European ABSORB Consortium comprises the following European registries: GABI-R, ABSORB UK Registry, ABSORB France, BVS RAI Registry, and REPARA BVS Registry, which all prospectively collected patient-level data regarding outcomes following unrestricted BVS implantation. The primary endpoint of target lesion failure (TLF) includes cardiac death, target-vessel myocardial infarction (TVMI) and target-lesion revascularisation (TLR) at 12 months. The incidence of scaffold thrombosis (ST) according to ARC criteria was also assessed. Multivariable analysis was used to adjust for differences in patient and lesion characteristics.

Results: A total of 10,312 patients (mean age 58.4 ± 11.4 y) underwent BVS implantation during routine practice. The 12-month follow-up was complete in 95.5% of

Abbreviations: BVS, bioresorbable vascular scaffold; CAD, coronary artery disease; CI, confidence interval; DAPT, dual antiplatelet therapy; DES, drug-eluting stent; DS, diameter stenosis; ECG, electrocardiogram; MACE, major adverse cardiac event; MI, myocardial infarction; MLD, minimum lumen diameter; PLA, polylactide; PLLA, poly-L-lactide; QCA, quantitative coronary angiography; RCT, randomized controlled trial; RVD, reference vessel diameter; ST, scaffold or stent thrombosis; TLF, target lesion failure; TLR, target lesion revascularization; TVMI, target vessel myocardial infarction; TVR, target vessel revascularization.

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patients. At 12 months, the primary endpoint of TLF occurred in 3.6%; its components cardiac death, TVMI and TLR were documented in 1.2%, 1.8%, and 2.6%, respectively. The definite/probable ST rate was 1.7%. Absence of predilatation, discontinuation of DAPT and scaffold diameter below 3 mm were independent predictors of ST.

Conclusions: The EAC demonstrates reasonable real-world clinical outcome data after BVS implantation. However, the rate of scaffold thrombosis remains high.

KEYWORDS
all-comers, bioresorbable scaffold, coronary artery disease, percutaneous coronary intervention, stent

1 | INTRODUCTION

Bioresorbable scaffolds have been heralded as a breakthrough technology in interventional cardiology, with the aim of overcoming adverse long-term side effects of metallic drug-eluting stents (DES) related to the permanent metallic and/or polymer implant, linked to mechanisms of stent failure.

The Absorb Bioresorbable Vascular Scaffold (BVS, Abbott, Santa Clara, CA) is the most widely-investigated bioresorbable scaffold. Initially, BVS appeared to be similar in terms of safety and effectiveness compared to current-generation DES after 1 year, despite a higher risk of scaffold (or stent) thrombosis (ST).[1] However, long-term follow-up data were disappointing: The ABSORB II randomized trial did not meet its co-primary endpoints of BVS superiority in terms of vasomotor testing nor non-inferiority of late luminal enlargement after 3 years; additionally, a significantly increased ST rate after 4 years was noted.[2] Even the large-sized ABSORB III trail displayed a significant higher rate of ST after 5 years.[3] A recent individual patient-data meta-analysis from 4 randomized trials found consistently increased event rates, including ST and the composite of cardiac death, target-vessel myocardial infarction (TVMI) and target lesion revascularization (TLR).[4] These overall findings resulted in a global stop to sales for BVS.

However, daily clinical routine typically includes a large variety of different settings that are not represented in randomized trials, since they share strict inclusion and exclusion criteria. Thus, results from all-comer registries can provide crucial information. The European ABSORB Consortium (EAC) is currently the largest registry of unrestricted BVS use worldwide. The aim of the registry was to gain deeper insights into the efficacy of BVS and to investigate whether the performance of the BVS during routine clinical practice is consistent with outcomes observed in randomized trials.

2 | METHODS

2.1 | Study design and study population

The objective of the EAC was to provide an analysis of mid-term safety at 12 months as well as therapy outcomes of the BVS in patients suffering from coronary artery disease. The pooling of these registry data was performed to evaluate a large sample of patients with BVS implantation and to gain insights into the efficacy of BVS. The EAC comprises a secondary analysis of the individual datasets from five European BVS registries: GABI-R (German-Austrian registry to evaluate the short and long-term safety and therapy outcomes of the ABSORB everolimus-eluting bioresorbable vascular scaffold system in patients with coronary artery stenosis, Germany and Austria, $n = 3287$; NCT02066623), ABSORB UK Registry (post-market registry of patients with de novo lesions in previously untreated vessels treated with ABSORB BVS, United Kingdom, $n = 1005$; NCT01977534), France ABSORB (French Observatory Evaluating the Use of Intracoronary Prosthesis ABSORB BVS, France, $n = 2072$; NCT02238054), BVS RAI Registry (clinical study of ABSORB polylactic, rebsorbable coronary scaffold, Italy, $n = 1500$; NCT02298413) and REPARA BVS Registry (registry of patients with bioresorbable device in daily clinical practice, Spain, $n = 2448$; NCT02256449). All participating registries were open-label, prospective, single-arm registries that investigated the safety and efficacy of BVS in all-comer cohorts. Pseudonymized individual datasets from each participating national registry were collected and held centrally at IHF (Institut für Herzinfarktforschung, Ludwigshafen, Germany). Systematic follow-up was achieved by scheduled telephone interviews. All clinical endpoints were adjudicated by an independent clinical event committee. The

study was approved by all local ethics committees, and all patients provided written informed consent.

2.2 | Study device

The Absorb BVS (Abbott, Santa Clara, CA) is made of a poly-L-lactic acid backbone with zig-zag hoops and bridges. It elutes the anti-inflammatory agent everolimus combined with poly-D-L-lactic acid in a 1:1 ratio. Its strut thickness is approximately 150 μm and crossing profile 1.4 mm. Platinum radiopaque markers at both ends of the BVS ensure visualization during implantation. Full BVS resorption by hydrolysis is achieved within approximately 3 years.[5]

BVS implantation was performed according to local standards at each local site within each national registry. Nevertheless, thorough lesion preparation as well as optimal sizing and postdilatation were generally encouraged in every registry.

2.3 | Endpoint definitions

The primary device-oriented composite endpoint of target lesion failure (TLF) included cardiac death, TVMI and clinically-driven TLR, and was assessed at 12 months. Additionally, the following secondary endpoints were analyzed: individual components of the primary endpoint, all-cause death, any myocardial infarction, target vessel revascularization (TVR), and ST according to the Academic Research Consortium criteria (definite and probable). Furthermore, the secondary composite endpoint of target vessel failure (TVF) was assessed, which includes cardiac death, TVMI, and TVR.

2.4 | Statistical analysis

The analysis dataset included pooled individual, pseudonymized data from all five registries after plausibility testing and data transformation. The analysis dataset was stored and secured independently of the baseline dataset. In general, statistics for continuous variables included mean, median, standard deviation, minimum, maximum, 25th and 75th percentile, and sample size for each analysis group. The non-parametric Mann–Whitney U test was used to compare continuous variables. Binary variables were described with frequencies and percentages. Comparison of categorical variables was performed by Chi^2 test or Fisher's exact test. Event rates were calculated according to the Kaplan–Meier method. Cox modeling was also used to determine the independent correlates of TLF and ST events at 12 months. The following eight baseline clinical and angiographic covariates that were common to all datasets were entered into the Cox-regression model for TLF and ST at 12 months: age at baseline, diabetes mellitus, acute coronary syndrome at presentation time, PCI at baseline before 2015, multivessel disease, American College of Cardiology/American Heart Association type B2 or C lesion, scaffold diameter, bifurcation, predilatation, postdilatation, and dual antiplatelet therapy (DAPT). Results are shown as hazard ratios with 95% confidence intervals.

All statistical analyses were performed using SAS 9.4 statistical software. All statistical tests were interpreted at a two-sided significance level of 0.05.

3 | RESULTS

3.1 | Patient and procedural characteristics

A total of 10,312 patients with coronary artery disease who were treated with BVS were included in this registry. Overall, the mean age was 58.4 ± 11.4, 21.1% were female and 20.6% suffered from diabetes mellitus. Patients underwent catheterization due to acute coronary syndrome in 58.3%, of which 34.2% suffered from ST-elevation myocardial infarction, 44.2% from non-ST-elevation myocardial infarction, and 21.9% from unstable angina. Accordingly, stable coronary artery disease was documented in 28.1% of the cases. An overview of the clinical characteristics is presented in Table 1.

A total of 13,488 lesions were treated that were located in the LAD in 59.0%, LCX 24.3% and RCA in 23.9%. A substantial proportion of the lesions (41.3%) were classified as complex (B2/C) according to the ACC/AHA classification by operator assessment. The target lesion comprised a bifurcation in 8.2%, an ostial lesion in 2.5% and moderately or severe calcification was present in 36.5%. Predilatation was performed in 90.2%. The median of implanted BVS length per lesion was 23.0 [18.0, 35.0] mm and the median BVS diameter was 3.0 [2.5, 3.5] mm. Further details of angiographic and procedural findings are provided in Tables 2 and 3. Postdilatation was performed in 73.8% of

TABLE 1 Baseline patient characteristics

Age, years	58.4 ± 11.1
Male sex	78.9 (8141/10,312)
Diabetes mellitus	20.6 (2119/10,277)
Treated with oral medication	67.5 (558/827)
Treated with insulin	28.6 (402/1404)
Hypertension	58.5 (5998/10245)
Family history of coronary artery disease	31.6 (1979/6254)
Current or previous Smoker	49.3 (4988/10,127)
Previous stroke	2.8 (162/5732)
Previous myocardial infarction	19.8 (2027/10,252)
Previous PCI	24.9 (2081/8341)
Previous CABG	1.7 (172/10291)
Ejection fraction <30%	1.6 (96/6147)
Clinical presentation	
Stable angina	28.1 (2897/10,302)
Acute coronary syndrome	58.3 (6006/10,302)
Non-ST-elevation myocardial infarction	44.2 (2655/6002)
ST-elevation myocardial infarction	34.2 (2053/6002)
Unstable angina	21.9 (1317/6006)
Other presentation	13.7 (1420/10,302)

Note: Data shown as percentages (n/N) or mean ± standard deviation.

TABLE 2 Lesion characteristics at baseline

Target vessel	
Left main	0.6 (63/10,214)
Left anterior descending	59.0 (6021/10,214)
Left circumflex	24.3 (2479/10,213)
Right coronary artery	23.9 (3008/10,231)
Venous bypass graft	0.0 (4/10,214)
Number of treated segments	
1	75.8 (7765/10,247)
2	18.1 (1857/10,247)
3	5.0 (508/10,247)
more than 3	1.1 (117/10,247)
Multivessel disease	46.7 (4782/10,238)
De novo lesion	96.9 (13,061/13,484)
Ostial lesion	2.5 (227/8925)
Bifurcation lesion	8.2 (940/11,485)
Moderate or severe calcification	36.5 (4765/13,070)
AHA/ACC lesion classification	
A or B1	58.7 (6583/11,210)
B2 or C	41.3 (4627/11,210)

Note: Data shown as percentages (n/N).

TABLE 3 Procedural results

Total device length implantation, mm	23.0 (18.0–35.0)
Min. device diameter per patient, mm	3.0 (2.5–3.5)
Access route	
Femoral	32.0 (2139/6675)
Radial	67.8 (4523/6675)
Intravascular imaging	
Intravascular ultrasound	2.8 (274/9640)
Optical coherence tomography	4.7 (450/9640)
Patient with BVS treated	82.3 (8463/10,282)
Patient with BVS and DES treated	17.7 (1819/10,282)
Predilation	90.2 (12,068/13,382)
Max. balloon diameter of predilation, mm	3.0 (2.5–3.0)
Postdilation	73.8 (9858/13,365)
Max. balloon diameter of postdilation, mm	3.5 (3.0–3.5)

Note: Data shown as percentages (n/N) or median with interquartile range.

the lesions. Upon discharge 96.0% of the patients were prescribed aspirin, 95.3% a P2Y12 inhibitor, and 95.3% were on dual antiplatelet therapy (both aspirin and P2Y12 inhibitor).

3.2 | Clinical outcomes

The mean follow-up duration was 496 ± 235 days. The 12-month follow-up was completed in 95.5% of patients. The primary endpoint of TLF occurred in 3.6% of patients. Regarding the components of the primary endpoint, cardiac death was noted in 0.6%, TVMI in 1.8%, and TLR in 2.6% of the patients (Table 4). The overall cumulative incidence of definite and probable ST was 1.6% at 12 months. The cumulative incidence curve of definite/probable ARC-defined ST showed an initial steep rise for about 61.7% of cases (Figure 1). Death from any cause was noted in 1.2% of the patients, and 2.7% experienced a myocardial infarction at any location.

TABLE 4 Clinical outcomes after 12 months

Clinical events	
All-cause death	1.2 (120/9848)
Cardiovascular death	0.6 (56/9848)
Any myocardial infarction	2.7 (266/9860)
Target vessel myocardial infarction	1.8 (181/9852)
Target vessel revascularization	3.2 (319/9852)
Target lesion revascularization	2.6 (261/9852)
Composite endpoints	
Target vessel failure (cardiac death, target vessel myocardial infarction and target vessel revascularization)	4.5 (440/9855)
Target lesion failure (cardiac death, target vessel myocardial infarction and target lesion revascularization)	3.6 (356/9855)
Scaffold thrombosis	
Definite/probable scaffold thrombosis	1.6 (157/9849)
Acute (≤24 h)	0.3 (34/9848)
Subacute (>24 h to 30 days)	0.6 (63/9849)
Late (>30 days to 1 year)	0.6 (60/9848)

For further evaluation, a landmark analysis with a prespecified landmark set at 30 days was performed. At 30 days the risk for TLF was 1.3%, which tended to increase after 30 days. In contrast the ST rate at 30 days was 0.9%. After 30 days the ST rate decreased to 0.6% (Figure 2).

To exclude that a learning curve in the implantation technique affected the clinical outcome, we compared patients who were implanted before and after 2015. This particular cut-off was chosen because the instructions for use were changed by the manufacturers in November 2014 with regard to implantation technique. Most notably, the composite endpoints for TVF (5.0% vs. 4.1%; $p = 0.05$) and TLF (4.2% vs. 3.2%; $p = 0.01$) were significantly reduced. In contrast, the ST rate in the later population decreased from 1.8% to 1.4% after 12 months (Table 5) without reaching statistical significance.

As shown in Figure 3, after multivariable adjustment for differences in baseline clinical and angiographic characteristics, no predilatation and discontinuation of DAPT were associated with an increased risk of ST. Discontinuation of DAPT and bifurcation lesions were associated with higher risk of TLF.

4 | DISCUSSION

The EAC study is the largest individual dataset worldwide comprising patients undergoing BVS implantation in routine daily practice. The main findings of the EAC study are:

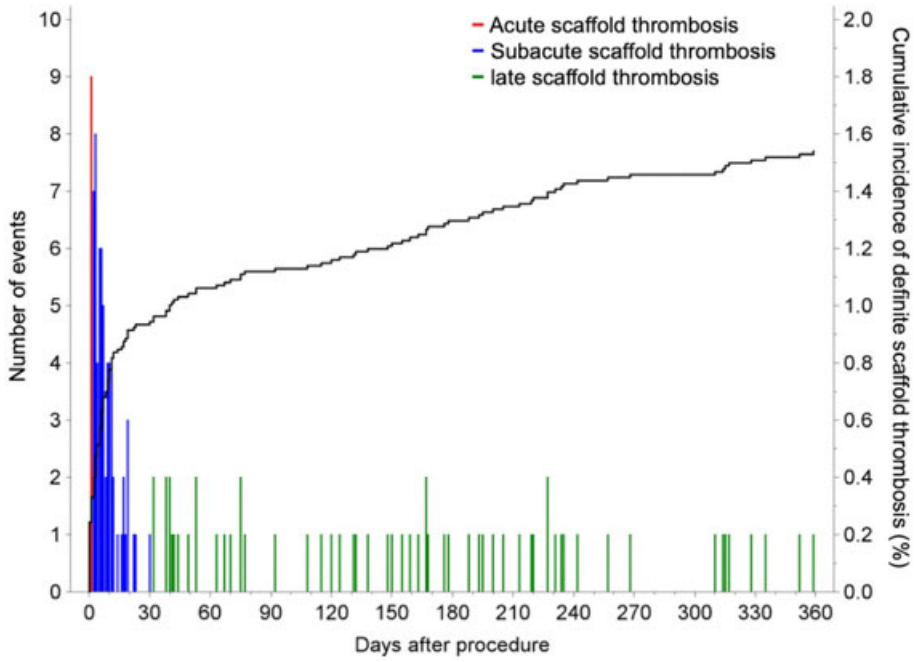

FIGURE 1 Scaffold thrombosis. Distribution and cumulative incidence of scaffold thrombosis within 1 year [Color figure can be viewed at wileyonlinelibrary.com]

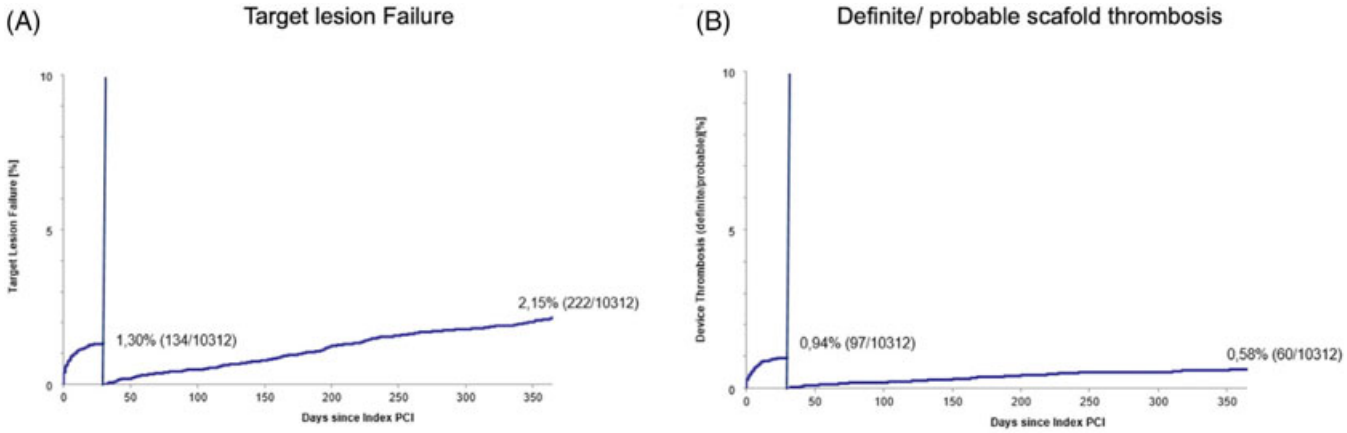

FIGURE 2 Landmark analysis. A landmark analysis after 30 days is shown for the incidence of (A) the composite endpoint of target lesion failure (including cardiac death, target vessel myocardial infarction and target lesion revascularization) and for the incidence of (B) scaffold thrombosis [Color figure can be viewed at wileyonlinelibrary.com]

1. Overall event rates observed within 1 year of follow-up were lower than expected, especially regarding the primary endpoint of TLF. However, the ST rate was broadly in line with other studies.
2. The landmark analysis demonstrated clustering of events within the first 30 days without an exceptional rate of ST beyond that point.
3. A learning curve for the adapted implantation technique was associated with lower rates for TLF and TVF.
4. Independent predictors of ST at 12 months were identified to be no predilatation and discontinuation of DAPT.

The ABSORB II trial randomized 501 patients to be treated with either BVS or DES, and the one-year analysis did not reveal any relevant differences between the two groups: TLF occurred in 5% versus 3%, TLR in 1% versus 2%, and the definite ST rate was 0.6% versus 0%.[6] Moreover, 2008 patients were randomized in a 2:1 ratio to BVS or DES treatment in the ABSORB III trial: after 1 year, the TLF rate was 7.8% vs. 6.1%, whereas the TLR rate was 3.0% versus 2.5% and the definitive ST rate was 1.4% vs. 0.7%.[7] Both randomized trials as well as 3 other randomized trials were analyzed in a meta-analysis that confirmed the increased ST risk at 1 year.[1] Although these randomized trials share strict inclusion and exclusion criteria, and despite the fact that patients with acute myocardial infarction or bifurcation lesions were significantly underrepresented, the present analysis from the EAC study demonstrates lower event rates: TLF occurred in 3.6%, TLR in 2.6%, and the definite or probable scaffold thrombosis rate

TABLE 5 Comparison of early versus late experience of BVS use

Clinical events	Total	Early BVS experience	Late BVS experience	*p*-value
All-cause death	1.2 (120/9848)	1.5 (64/4137)	1.0 (56/5711)	0.01
Cardiovascular death	0.6 (56/9848)	0.6 (25/4137)	0.5 (31/5711)	0.69
Any myocardial infarction	2.7 (266/9860)	3.0 (126/4143)	2.4 (140/5717)	0.07
Target vessel myocardial infarction	1.8 (181/9852)	2.1 (85/4138)	1.7 (96/5714)	0.17
Target vessel revascularization	3.2 (319/9852)	3.7 (155/4139)	2.9 (164/5713)	0.02
Target lesion revascularization	2.6 (261/9852)	3.3 (135/4140)	2.2 (126/5712)	<0.01
Composite endpoints				
Target vessel failure (cardiac death, target vessel myocardial infarction and target vessel revascularization)	4.5 (440/9855)	5.0 (205/4139)	4.1 (235/5716)	0.05
Target lesion failure (cardiac death, target vessel myocardial infarction and target lesion revascularization)	3.6 (356/9855)	4.2 (172/4140)	3.2 (184/5715)	0.01
Scaffold thrombosis				
Definite/ probable	1.6 (157/9849)	1.8 (75/4138)	1.4 (82/5711)	0.14
Acute (≤24 h)	0.3 (34/9848)	0.4 (15/4137)	0.3 (19/5711)	0.80
Subacute (>24 h to 30 days)	0.6 (63/9849)	0.7 (28/4138)	0.6 (35/5711)	0.70
Late (>30 days to 1 year)	0.6 (60/9848)	0.8 (32/4137)	0.5 (28/5711)	0.07

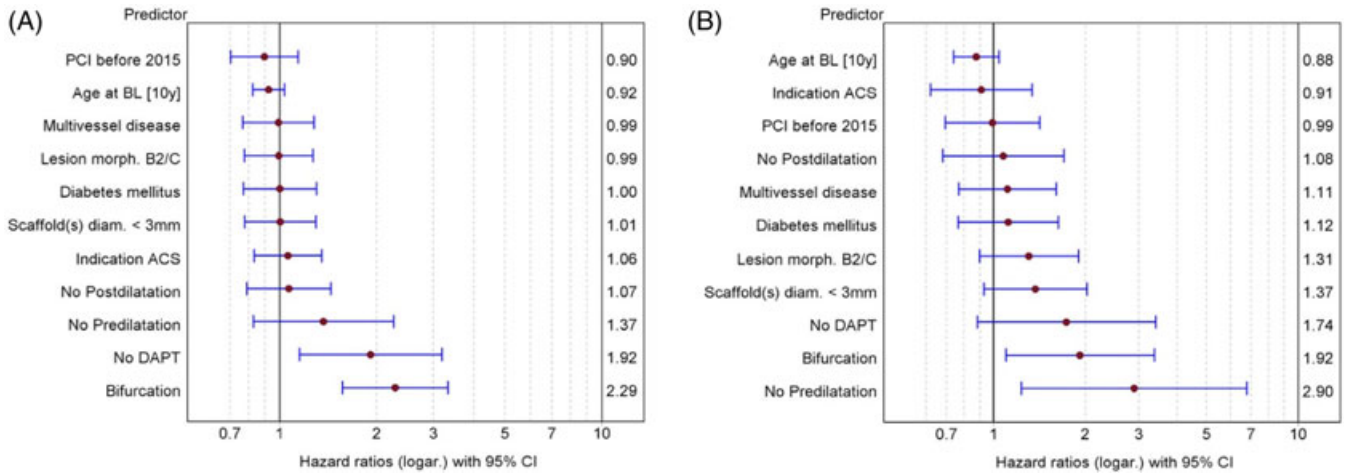

FIGURE 3 Predictors of outcomes. Multivariable adjustment for differences in baseline clinical and angiographic characteristics determining independent correlates for (A) target lesion failure (cardiac death, target vessel myocardial infarction and target lesion revascularization) and (B) scaffold thrombosis [Color figure can be viewed at wileyonlinelibrary.com]

was 1.6% after 1 year. Most notably, landmark analysis confirmed clustering of events within the first 30 days without an exceptional rate of ST beyond 0.6%.

The reasons for the lower event rates in the EAC study remain speculative. However, it has been shown that the implantation technique and a learning curve have an influence on the ST rate.[8,9] In particular, predilatation was performed in more than 90% and postdilatation in almost 74% of the cases in the EAC study, whereas pre- and postdilatation were performed in 83% and 49% in the GHOST-EU registry, respectively, the first large-scale, all-comers registry on routine BVS use.[10] The GHOST-EU registry also included the very early experience with BVS technology, and, remarkably, the definite/ probable ST rate after 6 months (2.1%) was higher than the 12-month definite/ probable ST rate in the EAC study (1.6%). In contrast, the most recent ABSORB IV randomized trial included 2604 patients with stable coronary artery disease in a 1:1 ratio. Patients were treated with a refined and optimized implantation technique. TLF at 1 year was similar to previous trials with 7.8% in patients in the BVS group (vs. 6.4% in the DES group), but the ST rate was substantially lower (0.7% vs. 0.3%) than observed before.[11] In addition, Puricel et al. were able to demonstrate a reduction of the 12-month ST rate from 3.3% to 1.0% by implementing a dedicated BVS implantation protocol.[12] Comparable results have also been published by Ortega-Paz et al., who analyzed the 12-month outcome according to the use of predilatation, optimal scaffold sizing, and postdilatation.[8]

ST rates from large-scale DES registries show lower event rates. For example, the randomized RESOLUTE All-Comers Trial compared zotarolimus-eluting DES with an everolimus-eluting DES in 2292 patients. The 12-month rate for definite ST was 1.2% in the zotarolimus-eluting DES group and 0.3% in the everolimus-eluting DES group.[13] The XIENCE V USA trial was a prospective, multicenter, single-arm study that evaluated an everolimus-eluting DES in 5054 unselected patients. After 12 months of follow-up, the definite ST rate was 0.5% (vs. 1.6% definite/probable ST in the EAC study).[14] Interestingly, a matched comparison of patients from the XIENCE V USA trial and patients from the GHOST-EU Registry (both studies with unrestricted DES/ BVS use) found no statistically relevant differences between the two groups regarding probable/definite stent or scaffold thrombosis, although scaffold thrombosis was numerically higher (1.8% vs. 1.1%).[15]

Despite reasonable 1-year results of the randomized trials, the pronounced risk of ST became apparent at later time points in those trials. In the ABSORB II trial, for example, the definite scaffold thrombosis rate after 4 years was 3% in the BVS group, whereas no stent thrombosis occurred in the DES group.[16] Furthermore, the scaffold thrombosis rate after 3 years was 2.3% vs. 0.7% stent thrombosis for the DES group in the ABSORB III trial.[17] These findings were also confirmed in a recent meta-analysis.[4] Pathophysiological methods are currently under investigation and device- and degradation-related factors were presumed.[18] Thus, long-term follow up of the EAC is a future goal.

4.1 | Limitations

The present study has several limitations intrinsic to its design as a non-randomized, single-arm observational study. Since the final discretion to use BVS was left to the implanting physician, selection bias cannot be ruled out. Furthermore, no systematic angiographic or intravascular imaging follow-up data are available. Differences in follow-up procedures of each registry might have affected the event rates. In the present analysis, only mid-term data are reported and long-term follow-up will be needed, especially since a significant increase in event rates after 1 year was observed in randomized studies. However, long-term data is not available for this study cohort due to substantial differences regarding follow-up protocols of the participating registries. An underreporting of events cannot be ruled out; however, this should be almost negligible due to the establishment of an independent clinical event committee.

5 | CONCLUSION

The EAC evaluated more than 10,000 patients treated with BVS and is the largest study on BVS worldwide. During a follow-up period of 12 months, clinical event rates were lower than expected from randomized trials, especially the rate of scaffold thrombosis, but remained higher than observed with DES. These data should be considered exploratory given the nature of this analysis.

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CONFLICT OF INTEREST

Nick West was affiliated at the Royal Papworth Hospital, Cambridge, UK and reported to be a consultant for Abbott Vascular at the time of the analysis. He has since become an employee of Abbott Vascular; Andreas Baumbach reports grants from Abbott Vascular; Guillaume Cayla reports grants and personal fees from Abbott; Felipe Hernandez Hernandez reports personal fees from Abbott Vascular; René Koning reports grants from Abbott Vascular; Bruno Loi reports personal fees from Abbott Vascular; Christian Hamm reports personal fees from Abbott Vascular; Holger Nef reports speaker honoraria and research grants from Abbott Vascular. All other authors did not report a conflict of interest regarding this manuscript. The European ABSORB Consortium (EAC) was supported by Abbott Vascular, Santa Clara, CA, USA.

DATA AVAILABILITY STATEMENT

Data not available publicly.

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