Predictors of early scaffold thrombosis: results from the multicenter prospective German–Austrian ABSORB RegIstRy

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Background **In randomized clinical trials, the risk of thrombotic events with the absorb bioresorbable vascular scaffold (BVS) was significantly higher than with metallic drug-eluting stents. We evaluated predictors of scaffold thrombosis in the large-scale, multicenter German–Austrian ABSORB RegIstRy.**

Methods and results **3178 patients with treatment of 4252 lesions using 5020 scaffolds were included. Follow-up rate at 6 months was 97.4%. Forty-five (1.42%) patients experienced definite/probable scaffold thrombosis during follow-up. Multiple regression analysis showed implantation of absorb BVS in bifurcation lesions [odds ratio (OR): 4.43; 95% confidence interval (CI): 1.69–11.59; $P = 0.0024$] or treatment in the years 2013/2014 (OR: 1.88; 95% CI: 1.02–3.47; $P = 0.04$) to be significant predictors of scaffold thrombosis. Excluding bifurcation lesions, the incidence of definite/probable scaffold thrombosis decreased from 1.8% (95% CI: 1.17–2.64%) in 2013/2014 to 0.89% (95% CI: 0.5–1.46%) in 2015/2016. In the latter period, absorb BVS were implanted more often in younger patients with less complex de novo lesions, and debulking devices and postdilatation were used more frequently. Between the two treatment periods, there was a significant reduction in myocardial infarction (2.73–1.24%, $P < 0.01$; OR: 0.45; 95% CI: 0.26–0.77), definite/probable scaffold thrombosis (1.79–0.88%, $P < 0.05$; OR: 0.49; 95% CI: 0.26–0.93), and target lesion failure and revascularization during follow-up.**

Conclusion **Improved procedural technique and more strict patient selection may explain a significant decrease in the absorb BVS thrombosis rates during the recruitment period of the large-scale German–Austrian ABSORB RegIstRy. In addition, treatment of bifurcation lesions was identified as an independent predictor of definite/probable scaffold thrombosis.** ***Coron Artery Dis*** **29:389–396**

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Introduction

Randomized clinical trials and meta-analyses showed a higher risk of thrombotic events with use of the absorb bioresorbable vascular scaffold (BVS) compared with metallic drug-eluting stents (DESs) for the treatment of de novo coronary artery disease [1–3]. In addition, early real-world registries also showed a high risk of thrombotic events [4]. After the initial learning curve with the absorb scaffold, the present state-of-the-art implantation strategy includes careful patient selection, predilatation, proper sizing, and postdilatation to improve outcome with the absorb BVS [5].

We sought to determine predictors of scaffold thrombosis and the impact of the learning curve in the large-scale, multicenter, German–Austrian ABSORB RegIstRy (GABI-R).

Methods

Between November 2013 and January 2016, 3264 patients underwent percutaneous coronary intervention (PCI) using the absorb BVS (Abbott Vascular, Santa Clara, California, USA) in 93 GABI-R centers in Germany and Austria. A detailed description of GABI-R has been published previously [6]. In brief, GABI-R is an international, multicenter, large-scale observational registry.

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The decision to perform PCI using an absorb BVS was at the operator's discretion. Patient treatment was based on local standards. The study was carried out in accordance with the Declaration of Helsinki and the International Conference on Harmonization Good Clinical Practice. The ethics committees of participating centers approved the registry protocol. All patients provided written, informed consent.

Procedure

Lesion preparation, including predilatation, use of debulking devices, or periprocedural use of intracoronary imaging, was left to the operator's discretion to reflect real-world use of the absorb BVS. Antiplatelet therapy consisted of aspirin (loading dose 250–500 mg and maintenance dose 100 mg/day) and either clopidogrel (loading dose $\geq$300 mg and maintenance dose 75 mg/day), prasugrel (loading dose 60 mg and maintenance dose 10 mg/day), or ticagrelor (loading dose 180 mg and maintenance dose 90 mg, twice daily). Dual antiplatelet therapy was recommended for at least 12 months.

Data management

Data were collected electronically using an internet-based application, and centrally stored and analyzed by the Institut für Herzinfarktforschung (IHF GmbH, Ludwigshafen, Germany). All events were adjudicated and classified by an independent event adjudication committee.

Scaffold thrombosis was defined as definite or probable according to Academic Research Consortium criteria [7]. Cardiac death was defined as death from immediate cardiac causes or complications related to the procedure as well as any death in which a cardiac cause could not be excluded. Myocardial infarction (MI) was defined according to the WHO extended definition [8]. Target lesion failure (TLF) was defined as a composite of cardiac death, target vessel MI, and clinically driven target lesion revascularization (TLR).

Statistical analysis

Distributions of metric variables within the two groups (with and without scaffold thrombosis) are described by mean ± SD. Binary variables are described by absolute frequencies and percentages. Frequencies of outcomes are complemented by odds ratios and 95% confidence limits, where possible. All descriptive statistics are based on known values. A multiple logistic regression model was used to identify predictors of scaffold thrombosis among baseline and procedural variables. Predictor variables in the model were initially prespecified and then reduced after assessing the results of a preliminary model. To reduce the number of predictors, a stepwise algorithm was applied in which an empirical significance level of P value up to 0.1 was required for each variable to enter the final model. Missing values were imputed either by modal values (if binary variables were missing) or by median values (metrical variables). A two-tailed P-value less than 0.05 was considered to indicate statistical significance. Statistical analysis was carried out using SAS software, version 9.3 (SAS Institute Inc., Cary, North Carolina, USA).

Results

Patient and procedural characteristics

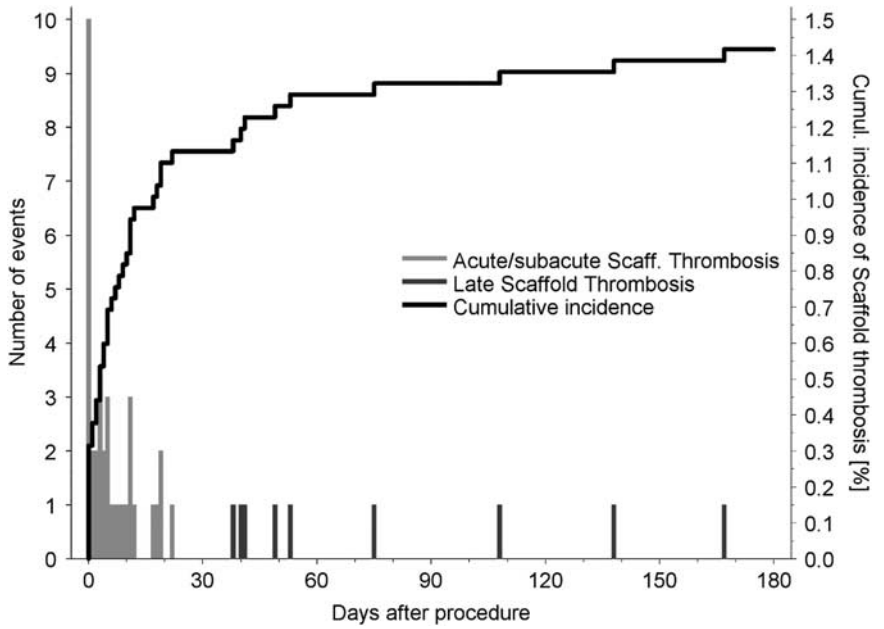
A total of 3264 patients who underwent PCI with absorb BVS implantation were enrolled in the GABI-R registry. The follow-up rate at 6 months was 97.4%, including 3178 patients with treatment of 4252 lesions using 5020 absorb BVS. Of the 3178 patients, 45 (1.42%) patients experienced a definite or probable scaffold thrombosis (Fig. 1). Baseline clinical parameters, including sex, cardiovascular risk factors, route of coronary intervention, number of diseased vessels, clinical presentation with an acute coronary syndrome, and use of antiplatelet therapy and oral anticoagulation, were similar in patients with and without scaffold thrombosis (Table 1). Angiographic and procedural characteristics of patients with and without scaffold thrombosis are detailed in Table 2. Between these two groups, there was no difference with respect to lesion complexity, presence of a de novo lesion, amount of calcification, use of predilatation or debulking devices, implantation pressure, use of postdilatation, and final thrombolysis in myocardial infarction (TIMI) 3 flow. There was a significantly higher rate of treated bifurcation lesions (7.5 vs. 2.9%, $P<0.05$) and a significantly higher rate of TIMI 3 flow before coronary intervention in patients with subsequent scaffold thrombosis than in patients without scaffold thrombosis (Table 2).

Multiple regression analysis for predictors of scaffold thrombosis

Predictors of scaffold thrombosis are listed in Table 3. There was a somewhat higher, but insignificant risk of scaffold thrombosis in patients with diabetes mellitus and in those presenting with acute coronary syndromes, for the implantation of longer scaffolds, the lack of postdilatation, smaller scaffold diameters, and the use of clopidogrel versus prasugrel/ticagrelor after the intervention. The only significant predictors of scaffold thrombosis were the implantation of a scaffold in a bifurcation lesion [odds ratio (OR): 4.50; 95% confidence interval (CI): 1.68–12.06; $P=0.003$] and treatment within the time period 2013/2014 versus the time period 2015/2016 (OR: 1.91; 95% CI: 1.03–3.57; $P=0.041$). After stepwise variable selection, implantation of an absorb BVS in a bifurcation (OR: 4.43; 95% CI: 1.69–11.59; $P=0.0024$) or treatment in 2013/2014 (OR: 1.88; 95% CI: 1.02–3.47; $P=0.04$) remained significant predictors of the occurrence of scaffold thrombosis.

We analyzed the dataset for additional predictors of scaffold thrombosis by excluding patients with scaffold implantation in bifurcation lesions, but including the

Fig. 1



Cumulative incidence of definite/probable scaffold thrombosis within 6 months after absorb bioresorbable vascular scaffold implantation. Daily occurrence of acute or subacute scaffold thrombosis is shown in gray and late scaffold thrombosis in black.

Table 1 Baseline clinical characteristics

	With scaffold thrombosis	Without scaffold thrombosis	*P* value
Number of patients	45	3123	
Age (years)	64.1 ± 10.5	60.8 ± 11.0	0.07
Women	26.7% (12/45)	23.1% (721/3123)	0.57
Diabetes mellitus	32.6% (14/43)	20.9% (647/3097)	0.06
History of smoking	52.4% (22/42)	58.2% (1721/2957)	0.45
Arterial hypertension	82.2% (37/45)	73.1% (2251/3079)	0.17
Hyperlipoproteinemia	55.6% (25/45)	56.4% (1685/2986)	0.91
Chronic kidney disease	11.1% (5/45)	7.9% (245/3099)	0.43
History of PCI	29.5% (13/44)	27.8% (885/3071)	0.80
History of aorto-coronary bypass surgery	4.4% (2/45)	2.4% (75/3110)	0.38
Atrial fibrillation	11.1% (5/45)	6.8% (209/3077)	0.26
ACS at presentation	51.1% (23/45)	51.6% (1610/3122)	0.95
ACS presenting with STEMI	17.4% (4/23)	33.8% (544/1610)	0.10
Heart rate (bpm)	76 ± 15	72 ± 14	0.09
Left ventricular ejection fraction (%)	51 ± 13	56 ± 10	0.11
Radial access	51.1% (23/45)	47.7% (1489/3122)	0.65
Severity of CAD			
Single-vessel CAD	35.6% (16/45)	41.8% (1305/3123)	0.40
Two-vessel CAD	35.6% (16/45)	31.1% (970/3123)	0.52
Three-vessel CAD	28.9% (13/45)	27.1% (847/3123)	0.79
Periprocedural MI	4.4% (2/45)	0.2% (6/3122)	< 0.01
Prasugrel at discharge	26.2% (11/42)	34.1% (1041/3049)	0.28
Ticagrelor at discharge	16.7% (7/42)	22.0% (671/3049)	0.41
Oral anticoagulation at discharge	13.6% (6/44)	7.9% (245/3121)	0.16

Values are mean ± SD or % (absolute number/number of available records).
ACS, acute coronary syndrome; CAD, coronary artery disease; MI, myocardial infarction; PCI, percutaneous coronary intervention; STEMI, ST-elevation myocardial infarction.

other variables (Table 3). The implantation of an absorb BVS in the years 2013/2014 was the only remaining significant predictor of scaffold thrombosis (OR: 1.98; 95% CI: 1.03–3.82; $P = 0.04$).

Absorb bioresorbable vascular scaffold thrombosis

As shown in Fig. 2, the incidence of scaffold thrombosis was 5.81% (95% CI: 1.91–13.05%) in bifurcation lesions treated with an absorb BVS. Excluding bifurcation lesions, the incidence of definite/probable scaffold thrombosis decreased from 1.8% (95% CI: 1.17–2.64%) in the treatment period 2013/2014 to 0.89% (95% CI: 0.5–1.46%) in the treatment period 2015/2016. The cumulative incidence of definite scaffold thrombosis and the daily occurrence of scaffold thrombosis for both treatment periods are shown in Fig. 3. The majority of thrombotic events occurred within the first 30 days.

Differences between the two treatment periods

In the treatment period 2015/2016 with a lower rate of thrombotic events, patients were significantly younger and hyperlipoproteinemia or chronic kidney disease was significantly less frequent (Table 4). Scaffold implantation was performed more often in de novo lesions and in less complex lesions, and debulking devices and post-dilatation were used more frequently. After excluding patients with scaffold implantation in bifurcation lesions, we compared the two treatment periods for the occurrence of various events (Fig. 4). In 2015/2016 versus

Table 2 Angiographic and procedural characteristics

	With scaffold thrombosis	Without scaffold thrombosis	*P* value
Number of total lesions	67	4248	
Number of implanted scaffolds	81	4319	
Treated vessel			
Left main coronary artery	0.0% (0/67)	0.5% (22/4248)	0.55
Left anterior descending artery	56.7% (38/67)	45.6% (1935/4248)	0.07
Left circumflex artery	20.9% (14/67)	21.5% (914/4248)	0.90
Right coronary artery	22.4% (15/67)	32.3% (1374/4248)	0.08
Venous graft	0.0% (0/67)	0.1% (3/4248)	0.83
Complex lesions (AHA/ACC type B2/C)	31.3% (21/67)	36.4% (1542/4240)	0.40
De novo lesion	94.0% (63/67)	94.2% (3997/4242)	0.95
Intravascular imaging after PCI	4.5% (3/67)	3.7% (155/4245)	0.72
Treated bifurcation lesion	7.5% (5/67)	2.9% (121/4242)	<0.05
Lesion length >34 mm	7.6% (5/66)	5.6% (235/4228)	0.48
Calcified lesion			
None	28.4% (19/67)	36.0% (1527/4240)	0.19
Mild	50.7% (34/67)	41.8% (1774/4240)	0.14
Moderate	20.9% (14/67)	18.6% (787/4240)	0.63
Severe	0.0% (0/67)	3.6% (152/4240)	0.11
Coronary artery flow before PCI			
TIMI 0	9.0% (6/67)	13.5% (571/4236)	0.28
TIMI 1	1.5% (1/67)	8.0% (337/4236)	0.05
TIMI 2	11.9% (8/67)	15.4% (654/4236)	0.43
TIMI 3	77.6% (52/67)	63.1% (2674/4236)	<0.05
Predilatation	94.0% (63/67)	91.7% (3890/4244)	0.49
Debulking device use	6.3% (4/63)	8.8% (342/3890)	0.50
Implanted device size (mm)	3.0 ± 0.38 (81)	3.1 ± 0.6 (4920)	0.13
Mean total device length (mm)	20.5 ± 6.0 (81)	19.7 ± 6.2 (4920)	0.21
Device implantation pressure (bar)	13.1 ± 2.5	13.5 ± 2.7	0.23
Scaffolds and DES implantation	4.5% (3/67)	2.9% (122/4248)	0.44
Postdilatation performed	67.2% (45/67)	72.5% (3073/4241)	0.34
Postdilation balloon size (mm)	3.3 ± 0.4 (45)	3.3 ± 0.5 (3068)	0.57
Postdilation balloon pressure (atm)	16.4 ± 4.6	16.7 ± 4.1	0.46
Final TIMI flow 3	100% (67/67)	98.1% (4156/4237)	0.25
Overlapping scaffolds	13.3 (6/45)	12.6% (394/3123)	0.89
Coronary perforation[a]	0.0% (0/44)	0.5% (17/3120)	0.62

Values are mean $\pm$ SD or % (absolute number/number of available records).
AHA/ACC, American Heart Association/American College of Cardiology; DES, metallic drug-eluting stent; PCI, percutaneous coronary intervention; TIMI, thrombolysis in myocardial infarction.
[a]The majority of perforations occurred with the scaffold implantation.

2013/2014, all-cause mortality was 1.24% (95% CI: 0.77–1.76%) versus 1.08% (95% CI: 0.60–1.77%, $P=0.68$; OR: 1.15; 95% CI: 0.59–2.24), cardiac death 0.47% (95% CI: 0.20–0.93%) versus 0.22% (95% CI: 0.04–0.63%, $P=0.23$; OR 2.19; 95% CI: 0.58–8.29), MI 1.24% (95% CI: 0.77–1.88%) versus 2.73% (95% CI: 1.94–3.72%; $P<0.01$; OR: 0.45; 95% CI: 0.26–0.77), definite/probable scaffold thrombosis 0.88% (95% CI: 0.50–1.45%) versus 1.79% (95% CI: 1.16–2.64%; $P<0.05$; OR: 0.49; 95% CI: 0.26–0.93), TLF 1.83% (95% CI: 1.24–2.58%) versus 3.01% (95% CI: 2.18–4.05%; $P<0.05$; OR: 0.60; 95% CI: 0.37–0.96) and TLR 1.18% (95% CI: 0.72–1.81%) versus 2.51% (95% CI: 1.75–3.47%; $P<0.01$; OR: 0.46; 95% CI: 0.27–0.81).

Discussion

Our data indicate that in the large-scale, international, multicenter GABI-R registry, the risk of thrombotic events after absorb BVS implantation decreased significantly from the first to the second half of the 4-year recruitment period. In addition, we found that implantation of an absorb BVS in a bifurcation lesion was associated with a significantly higher risk of subsequent scaffold thrombosis. The reduction of thrombotic events between the two implantation periods was probably because of a combination of various factors such as more careful patient selection, improved implantation technique with predilatation and postdilatation using a high-pressure balloon, a shift to younger patients with less complex lesions, and an increased focus on de novo coronary artery disease.

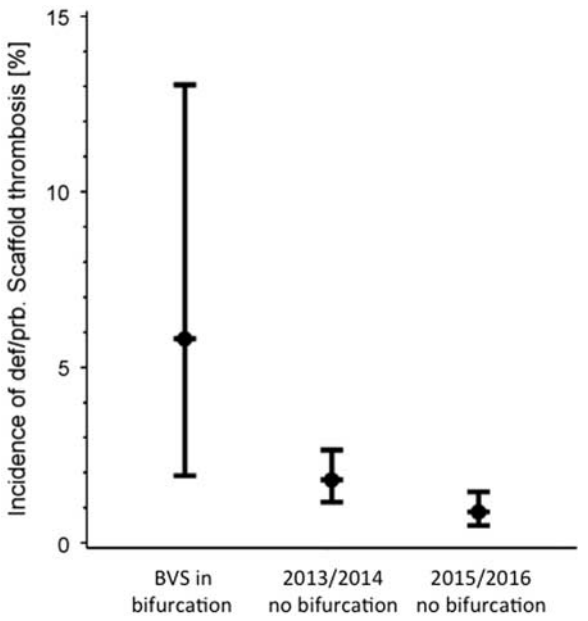
In randomized clinical trials and meta-analyses, the risk of thrombotic events after implantation of the absorb BVS was shown to be higher than after implantation of metallic DES [1,9–11]. The risk of absorb scaffold thrombosis has been shown to be significantly higher in lesions with smaller reference diameters and for procedures without postdilatation versus those with balloon postdilatation. However, randomized-controlled trials included predominantly noncomplex de novo lesions. In a real-world population, the rate of scaffold thrombosis was 2.1% within 6 months [4]. In the recently published Amsterdam Investigator-Initiated Absorb Strategy All-Comers trial, 1845 patients with lesions up to 70 mm were randomized to absorb BVS or everolimus-eluting DES. The risk of a thrombotic event with absorb BVS

Table 3 Multivariable logistic analysis

	Odds ratio	95% Confidence interval	*P* value
Multivariable logistic analysis including all patients			
Diabetes mellitus	1.69	0.88–3.23	0.116
Oral anticoagulants	0.73	0.17–3.17	0.678
Acute coronary syndrome	1.50	0.77–2.91	0.233
Total implanted scaffold length (cm)	1.12	0.96–1.32	0.155
Predilatation	1.95	0.46–8.25	0.366
Postdilatation	0.79	0.41–1.51	0.472
Scaffold diameter <3.0 mm	1.26	0.66–2.39	0.487
Intravascular imaging after PCI	1.74	0.71–4.26	0.223
TIMI 0–2 vs. 3 after PCI	0.00	–	0.981
AHA/ACC type A/B1 versus B2/C	1.85	0.91–3.77	0.088
Clopidogrel versus prasugrel/ ticagrelor at discharge	1.73	0.89–3.37	0.109
Bifurcation lesion	4.50	1.68–12.06	0.003
Procedure in 2015/2016 versus 2013/2014	1.91	1.03–3.57	0.041
Multivariable logistic analysis excluding patients with bifurcations			
Diabetes mellitus	1.36	0.67–2.76	0.393
Oral anticoagulants	0.75	0.17–3.22	0.696
Acute coronary syndrome	1.37	0.68–2.73	0.376
Total implanted scaffold length (cm)	1.11	0.93–1.33	0.231
Predilatation	1.65	0.39–7.05	0.499
Postdilatation	0.79	0.40–1.56	0.490
Scaffold diameter <3.0 mm	1.19	0.60–2.39	0.615
Intravascular imaging	1.62	0.62–4.27	0.326
TIMI 0–2 vs. 3 after PCI	0.00	–	0.985
AHA/ACC type A/B1 versus B2/C	1.45	0.69–3.06	0.327
Clopidogrel versus prasugrel/ ticagrelor at discharge	1.81	0.89–3.65	0.100
TMI 0–2 vs. 3 before PCI	0.52	0.24–1.13	0.099
Procedure in 2015/2016 versus 2013/2014	1.98	1.03–3.82	0.041

AHA/ACC, American Heart Association/American College of Cardiology; PCI, percutaneous coronary intervention; TIMI, thrombolysis in myocardial infarction.

Fig. 2



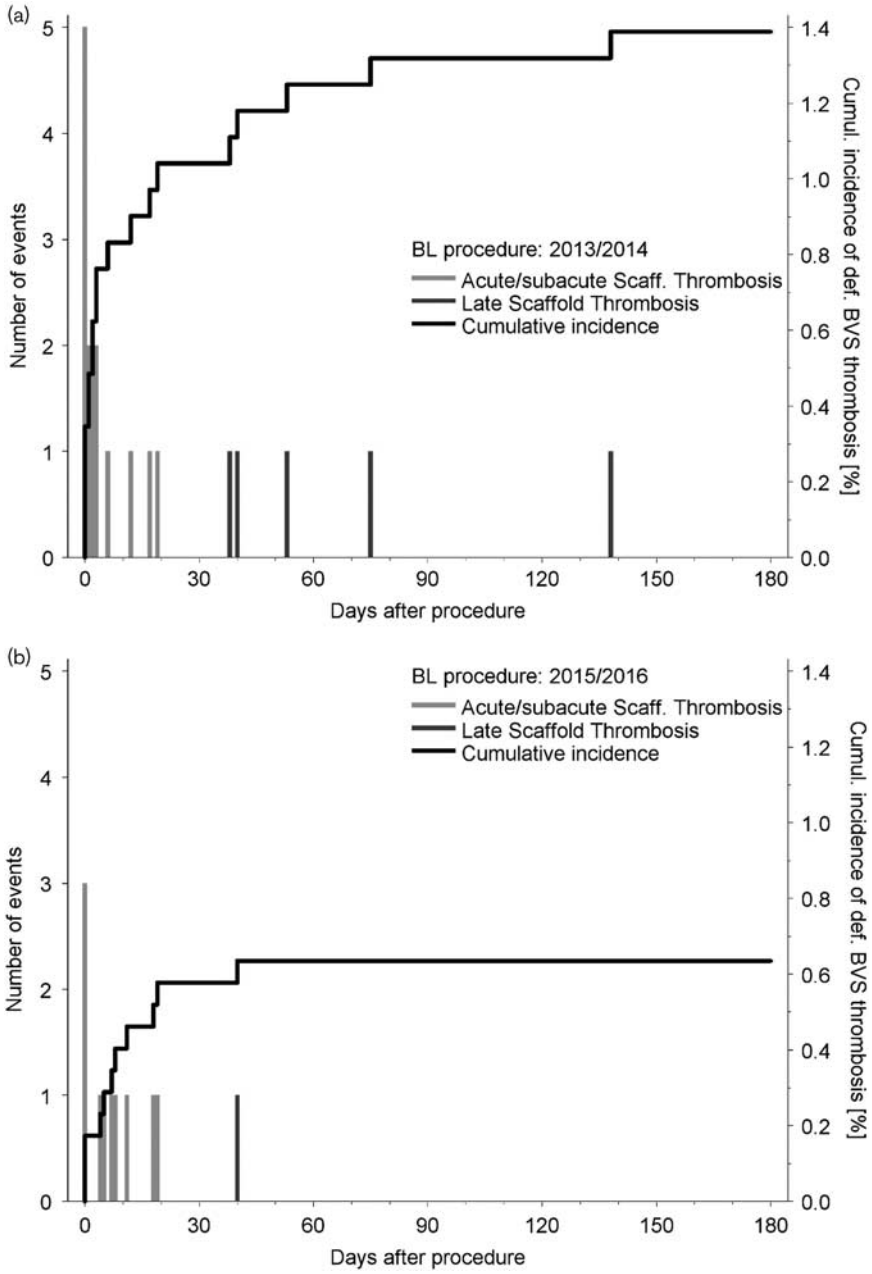
Incidence (and 95% confidence intervals) of absorb bioresorbable vascular scaffold thrombosis in bifurcation lesions (left), treatment period 2013/2014 without bifurcation lesions (middle), and treatment period 2015/2016 without bifurcation lesions (right).

was significantly higher than with metallic DES within a 2-year period (3.5 vs. 0.9%, hazard ratio 3.87; 95% CI: 1.78–8.42; $P < 0.0001$). Within the first 12 months, the risk of definitive thrombotic events was 4.25 times higher (95% CI: 1.43–12.64) for absorb BVS than for metallic DES. On comparing 31 patients with definite scaffold thrombosis with 1106 patients without definite scaffold thrombosis in the randomized Amsterdam Investigator-Initiated Absorb Strategy All-Comers trial, the authors could not identify differences between the two groups with respect to predilatation, device diameter, device length, or postdilatation, except for a higher rate of postprocedural diameter stenosis in lesions with subsequent thrombotic events. In the large-scale GABI-R registry, 45 patients with scaffold thrombosis were compared with 3123 patients without scaffold thrombosis. We were able to show that use of a scaffold in a bifurcation lesion and implantation during the first half of the study period were significant predictors of scaffold thrombosis. Indeed, the risk of scaffold thrombosis in bifurcation lesions was 5.81%. In addition, the risk of scaffold thrombosis within 6 months in lesions without bifurcations halved in GABI-R from 1.8% in the treatment period 2013/2014 to 0.89% in the treatment period 2015/2016. In addition to a more careful patient and lesion selection in the later period (younger patients with less complex lesion morphology), there was a significant change in implantation technique, with a higher usage of predilatation, postdilatation, debulking devices, and high-pressure balloons. These multiple, influencing variables resulted in a significantly lower rate of MI, significantly lower rates of definite or probable scaffold thrombosis, and also significantly lower rates of TLF and TLR.

Although a higher risk of thrombotic events for absorb BVS than for metallic DES is well documented [1,3,12, 13], the usage of predilatation or postdilatation could not be differentiated as significant predictors of thrombotic events in a recent meta-analysis including 10 510 patients [14]. In contrast, small, single-center, and multicenter registries reported low rates of thrombotic events [15], even in complex lesions with overlapping scaffolds [16] or chronic total occlusions [17,18].

An important issue is the use of an optimized implantation strategy with BVS, which has been shown to significantly reduce the occurrence of scaffold thrombosis within the first 12 months [19]. In addition, we could show that reducing scaffold thrombosis in absorb BVS (to rates that are probably comparable to those in metallic DES) is a multivariable process that cannot be attributed to a single parameter such as the use of postdilatation or intracoronary imaging. Nevertheless,

Fig. 3



Occurrence of definite scaffold thrombosis within the treatment period 2013/2014 (a) and 2015/2016 (b). Acute or subacute scaffold thrombosis is depicted in gray and late scaffold thrombosis is depicted in black. There was a lower rate of cumulative definite scaffold thrombosis in the later treatment period. Most thrombotic events occurred within the first 30 days in both treatment periods.

even with a similar rate of thrombotic events between absorb BVS and metallic DES, the advantages of using bioresorbable scaffolds over metallic stents remain to be determined.

Limitations

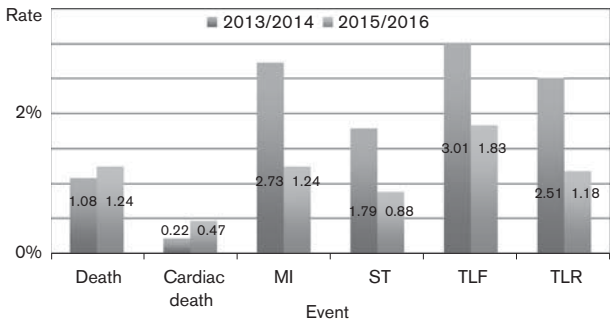
Our study has several limitations. First, the follow-up is relatively short of 6 months. However, the majority of scaffold thrombosis occurs within this early time period. In addition, although GABI-R is a large multicenter registry, there were only 45 cases with scaffold thrombosis, which limits the power to analyze predictors for this relatively rare event. Predictors for scaffold thrombosis may differ within the first 6 months to the later period, which may be addressed in future analysis.

Table 4 German–Austrian ABSORB RegIstRy treatment period 2013/2014 versus 2015/2016

	2015/2016	2013/2014	*P* value
Number of patients	1735	1443	
Number of lesions	2322	1930	
Number of implanted scaffolds/DES	2777	2243	
Age (years)	60.5 ± 11.1	61.4 ± 10.9	< 0.05
Diabetes mellitus	20.3% (350/1721)	21.9% (313/1429)	0.28
Hyperlipoproteinemia	53.1% (881/1659)	60.4% (835/1382)	< 0.01
Chronic kidney disease	7.0% (120/1717)	9.1% (131/1437)	< 0.05
ACS at presentation	52.8% (916/1734)	49.9% (720/1443)	0.10
ACS presenting with STEMI	34.8% (319/916)	31.9% (230/720)	0.22
Only scaffolds implanted	85.2% (1479/1735)	87.3% (1260/1443)	0.09
Mean scaffold length (mm)	19.7 ± 6.2	19.8 ± 6.3	0.83
Overlapping implantations	14.9% (259/1735)	12.6% (182/1443)	0.06
Predilatation	91.3% (2149/2354)	92.1% (1816/1971)	0.32
Postdilatation	76.8% (1807/2353)	67.0% (1319/1969)	< 0.0001
High-pressure balloon	91.6% (1653/1804)	86.6% (1142/1319)	< 0.0001
Maximum balloon diameter (mm)	3.3 ± 05	3.3 ± 0.5	0.44
Maximum balloon pressure (bar)	16.8 ± 4.0	16.5 ± 4.2	< 0.01
Debulking device	12.5% (268/2149)	4.3% (78/1816)	< 0.0001
Intravascular imaging after PCI	3.9% (91/2355)	3.4% (67/1971)	0.42
Radial access	50.1% (869/1734)	45.0% (649/1443)	< 0.01
AHA/ACC type B2/C lesion	32.5% (766/2354)	40.9% (804/1967)	< 0.0001
De novo lesion	95.7% (2253/2354)	92.5% (1821/1969)	< 0.0001
Prasugrel	34.2% (578/1690)	33.8% (477/1411)	0.82
Oral anticoagulation	7.8% (135/1733)	8.1% (117/1442)	0.74
Statin therapy	89.6% (1552/1733)	90.3% (1302/1442)	0.49

Values are mean ± SD or % (absolute number/number of available records).
ACS, acute coronary syndrome; AHA/ACC, American Heart Association/American College of Cardiology; DES, metallic drug-eluting stent; PCI, percutaneous coronary intervention; STEMI, ST-elevation myocardial infarction; TIMI, thrombolysis in myocardial infarction.

Fig. 4



Confirmed event rates for the population without scaffold implantation in a bifurcation lesion for the two treatment groups 2013/2014 (black columns in left) and 2015/2016 (white columns in right). MI, myocardial infarction, ST, definite/probable scaffold thrombosis; TLF, target lesion failure; TLR, target lesion revascularization.

Conclusion

The risk of scaffold thrombosis with absorb BVS in the large-scale, international, multicenter GABI-R registry was shown to be the highest in bifurcation lesions. This risk decreased during the treatment period because of a more careful patient selection and implantation procedure, resulting in significantly lower rates of MI, definite or probable scaffold thrombosis, and TLR.

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Conflicts of interest

Julinda Mehilli received grants and personal fees from Abbott Vascular, personal fees from Terumo, personal fees from Biotronik, grants and personal fees from Edwards LifeScience, personal fees from Boston Scientific, personal fees from BMS and personal fees from Lilly, Steffen Schneider received grants from Abbott, Pfannebecker employee of Abbot, Gert Richardt received personal fees from Abbott Vascular, Tommaso Gori received speakers honoraria from Abbott Vascular, and Christian W. Hamm received personal fees from Abbott Vascular and personal fees from Medtronic. For the remaining authors there are no conflicts of interest.

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