Percutaneous coronary interventions with the Absorb Bioresorbable vascular scaffold in real life 1-year results from the FRANCE ABSORB registry

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Percutaneous coronary interventions with the Absorb bioresorbable vascular scaffold in real life: 1-year results from the FRANCE ABSORB registry

Abbreviated title: PCI with Absorb BVS: 1-year FRANCE ABSORB registry results

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Summary

Background. – Several randomized studies have shown that bioresorbable vascular scaffold (BVS) technology is associated with an increased risk of stent thrombosis.

Aim. – This study aimed to assess the rates of adverse outcomes at 1 year in patients treated with the Absorb BVS (Abbott Vascular, Santa Clara, CA, USA), using data from a large nationwide prospective multicentre registry (FRANCE ABSORB).

Methods. – All patients receiving the Absorb BVS in France were included prospectively in the study. Predilatation, optimal sizing and postdilatation were recommended systematically. The primary endpoint was a composite of cardiovascular death, myocardial infarction and target lesion revascularization at 1 year. Secondary endpoints were scaffold thrombosis and target vessel revascularization at 1 year.

Results. – A total of 2072 patients at 86 centres were included: mean age 55 ± 11 years; 80% men. The indication was acute coronary syndrome (ACS) in 49% of cases. Predilatation and postdilatation were done in 93% and 83% of lesions, respectively. At 1 year, the primary endpoint occurred in 3.9% of patients, the rate of scaffold thrombosis was 1.5% and the rate of target vessel revascularization was 3.3%. In a multivariable analysis, diabetes and total Absorb BVS length > 30 mm were independently associated with the occurrence of the primary endpoint, whereas oral anticoagulation and total Absorb BVS length > 30 mm were independently associated with occurrence of scaffold thrombosis.

Conclusions. – The Absorb BVS was implanted in a relatively young population, half of whom had ACS. Predilatation and postdilatation rates were high, and 1-year outcomes were acceptable.

Résumé

Contexte. – Plusieurs études randomisées ont montré que l'implantation d'un stent bioresorbable (BVS) était associée à un risque accru de thrombose de stent.

Objectif. – L'objectif de cette étude était d'évaluer dans un large registre national multicentrique prospectif, l'efficacité et de sécurité à 1 an du stent bioresorbable Absorb.

Méthodes. – Tous les patients recevant un stent bioresorbable Absorb en France ont été prospectivement inclus dans l'étude. Une pré-dilatation, un calibrage optimal et une post-dilatation ont été systématiquement recommandés. Le critère principal de jugement était un critère composite associant

décès cardiovasculaire, infarctus du myocarde et de revascularisation de la lésion cible à 1 an. Les critères secondaires étaient la thrombose de stent et la revascularisation du vaisseau cible à un an.
Résultats. – Un total de 2072 patients ont été inclus dans 86 centres, l'âge moyen était de 55 ± 11 ans; 80 % étaient des hommes. L'indication était un syndrome coronarien aigu (SCA) dans 49 % des cas. Des pré et post dilatations ont été réalisées respectivement dans 93 % et 83 % des lésions. Après un suivi de 1 an, le critère principal de jugement était de 3,9 % ; le taux de thrombose de BVS était de 1,5 % et le taux de revascularisation du vaisseau cible était de 3,3 %. En analyse multivariée, le diabète et la longueur totale des BVS > 30 mm étaient indépendamment associées à la survenue du critère principal de jugement alors que l'anticoagulation orale et la longueur totale des BVS > 30 mm étaient indépendamment associées à la survenue d'une thrombose de stent.
Conclusions. – Les BVS ont été implantés dans une population relativement jeune, dont la moitié avait un SCA. Les taux de pré et post dilatation étaient élevés. Les résultats cliniques à un an étaient acceptables.

KEYWORDS

Bioresorbable scaffolds;

Percutaneous coronary intervention;

Acute coronary syndrome

MOTS CLÉS

Stent bioresorbable ;

Angioplastie coronaire ;

Syndrome coronaire aigu

Abbreviations: ACS, acute coronary syndrome; BVS: bioresorbable vascular scaffold; CE, Conformité Européene (European Conformity); DAPT: dual antiplatelet therapy; MACE: major adverse cardiac events; PCI: percutaneous coronary intervention.

Background

Bioresorbable vascular scaffold (BVS) technology (Absorb BVS; Abbott Vascular, Santa Clara, CA, USA) was developed to overcome the limitations of drug-eluting stents, such as the development of neoatherosclerosis, vessel vasomotricity limitation and late thrombosis events [1].

The current generation of Absorb BVS consists of a balloon-expandable scaffold with a polymer backbone of poly-L-lactic acid coated with an amorphous matrix of poly-D- and poly-L-lactic acid polymers, covered by the antiproliferative drug everolimus [2]. The process of degradation of the scaffold is by hydrolysis, and full resorption of the device is expected approximately 3 years after implantation [3]. The Absorb BVS was approved by the Food and Drug Administration in 2016, and obtained a Conformité Européene (CE; European Conformity) mark in 2011.

Randomized trials and meta-analyses have indicated a potentially increased risk of scaffold thrombosis using this new technology compared with an everolimus-eluting stent [4-7]. The reason for the increase is not fully understood, but recent analyses have suggested that the quality of the implantation procedure (predilatation, correct sizing and postdilatation) may improve the efficacy and safety of the scaffold [8].

When Absorb BVS technology was introduced in France in 2013, the Working Group for Interventional Cardiology of the French Society of Cardiology decided to conduct a prospective registry, aiming to include all patients with at least one Absorb BVS implanted, and with predilatation and postdilatation performed as frequently as possible. Such an exhaustive analysis of all Absorb BVS implantation procedures in French centres was also requested by the French Agence Nationale de Sécurité des Médicaments (ANSM; French National Agency for the Safety of Medicines and Health Products), to reflect the experiences and clinical outcomes of patients in a real-life setting. Accordingly, the nationwide FRANCE ABSORB registry was initiated in 2014; here we present the 1-year outcomes.

Methods

Study design and patient population

The FRANCE ABSORB registry (ClinicalTrial.gov unique identifier NCT02238054) is a prospective observational multicentre study designed to evaluate the clinical efficacy and safety of the Absorb BVS used in a real-life setting in patients presenting with de novo lesion(s).

Clinical and angiographic patient data were recorded anonymously in an electronic Clinical Research File, which was exported to an independent database under the responsibility of the French Cardiac Society.

All patients provided written informed consent, including consent for anonymous processing of their data. The registry was approved by the French National Agency for the Safety of Medicines and Health Products. The study was conducted in accordance with the Declaration of Helsinki.

Study procedure

Percutaneous coronary intervention (PCI) was performed according to current clinical practice standards. Implantations were performed without specific inclusion/exclusion criteria, but respecting the CE certification and the manufacturer's indications. Centres were recommended not to implant the Absorb BVS in highly calcified lesions, left main coronary artery lesions, bifurcation lesions with a side branch > 2 mm in diameter, in-stent restenosis lesions, bypass graft lesions or vessels with excessive tortuosity.

Procedural recommendations were as follows: predilatation, optimal Absorb BVS sizing, step-by-step optimal Absorb BVS deployment, systematic postdilatation with a non-compliant balloon (with a diameter up to 0.25 mm larger than the Absorb BVS diameter). When possible, the use of optical coherence tomography in the early implantation experience was encouraged.

The timing and type of antiplatelet therapy (aspirin, clopidogrel, prasugrel, ticagrelor) were according to each hospital's standard procedures. The use of glycoprotein IIb/IIIa inhibitors was left to the physicians' discretion. Dual antiplatelet therapy (DAPT) was recommended for a period of 12 months.

Data management

An independent clinical events committee, composed of physicians provided with all necessary and available data, adjudicated all major cardiovascular events and protocol endpoints. Data from 207 patients

(10% of the population), selected to be representative of the size and geographical location of the centres, were monitored by clinical research assistants from the French Society of Cardiology.

Endpoints

The primary endpoint was the occurrence of major adverse cardiac events (MACE) at 1 year, including death from cardiac causes, myocardial infarction (defined according to the third universal definition [9]) and target lesion revascularization. Secondary outcomes were rate of scaffold thrombosis (definite/probable/possible), defined according to the Academic Research Consortium, at 1 year [10], and rate of target vessel revascularization at 1 year. The FRANCE ABSORB registry is on-going, and outcomes will be evaluated yearly, over a 5-year follow-up period.

Study supervision

The study was initiated by the Interventional Working Group of Cardiology (GACI) of the French Society of Cardiology. The scientific study committee was responsible for the development of the protocol and the writing of the manuscript. The committee had unrestricted access to all study data.

Statistical analysis

The data were analysed descriptively. Categorical data are presented as numbers and percentages, and continuous data as means and standard deviations (or medians and interquartile ranges when skewed). For categorical data, differences between groups were tested using the χ^2 test or Fisher's exact test, as appropriate. For continuous data, differences between groups were tested using Student's *t* test (or the Mann-Whitney non-parametric test in case of skewed distribution).

Multivariable analyses were performed to identify factors associated with MACE or stent thrombosis occurrence during the first 12 months, using Cox proportional hazards models. Population and procedure characteristics that were associated with MACE or stent thrombosis with $P < 0.20$ in unadjusted analyses were included in the multivariable analysis.

All data handling and analyses were performed using Stata statistical software, release 10 (StataCorp, College Station, TX, USA).

Results

Patients

From September 2014 to April 2016, 2072 patients receiving at least one Absorb BVS were prospectively and consecutively included at 86 sites in France (including la Reunion and New Caledonia); Table 1 summarizes their baseline demographics. The mean age was 55 ± 11 years, and 80% of patients were men. Acute coronary syndromes (ACSs) accounted for 49% of the indications, and 17% of subjects had ST-segment elevation myocardial infarction. A quarter of the population had undergone a previous PCI, and 16% had a history of myocardial infarction. Current smoking was found in 41% of patients, hypertension in 43% of patients, but diabetes in only 16% of patients.

The angiographic characteristics of the lesions treated with the Absorb BVS are shown in Table 2. Among lesions for which the type was known, 44% were type B2 or C, according to the American Heart Association/American College of Cardiology classification. Most (61%) were located on the left anterior descending artery or the diagonal branch. The diameter of the Absorb BVS was 2.5 mm for 24.2% of implants. Contrary to operator recommendations, Absorb BVSs were used to treat 13 lesions on the left main coronary artery, 22 in-stent restenosis lesions and two lesions in a bypass graft (Appendix Table A.1).

Procedural data

Details were recorded for 2818 Absorb BVSs implanted in 2072 patients and 2502 lesions. During the index procedure, the radial approach was used in 91% of patients. Unfractionated heparin, low-molecular-weight heparin and bivalirudin were used in 80%, 18% and 1% of cases, respectively. The mean number of Absorb BVSs per patient was 1.35 ± 0.68; 26.6% of patients received more than one Absorb BVS. In 18.5% of patients, a metallic drug-eluting stent or bare-metal stent was placed in another significant lesion.

As recommended by the study protocol, predilatation was performed in 93% of lesions. Among 2818 Absorb BVSs implanted, the mean length was 20.7 ± 5.7 mm, with a mean diameter of 3.05 ± 0.39 mm. Distributions of length and diameter of scaffolds are shown in Table 2. To optimize implantation, optical

coherence tomography was used for 15%, and postdilatation was performed in 83% of the lesions treated with the Absorb BVS.

Angiographic procedural success for all lesions treated with the Absorb BVS was achieved in 99.2% of patients. The median postprocedural stay was 2 days (interquartile range 2–3 days). Nearly all patients (98%) were discharged under DAPT (clopidogrel 42.9%; ticagrelor 36%; prasugrel 21%). Notably, 2.4% of patients were treated with an oral anticoagulant (vitamin K antagonist or non-vitamin K antagonist oral anticoagulant).

Clinical endpoints

One-year events are summarized in Table 3. Complete follow-up data at 1 year were available for 2039 patients (98.4%). After 1 year, a primary endpoint event (cardiovascular death, myocardial infarction or target lesion revascularization) had been observed in 41/2072 patients (3.9%). Cardiovascular death at 1 year occurred in 14/2072 patients (0.7%). Myocardial infarction and target lesion revascularization occurred in 2.6% (*n* = 54) and 2.4% (*n* = 49) of patients, respectively. Among secondary endpoints, the rate of definite/probable stent thrombosis was 1.5% (31/2072) (Fig. 1 and Fig. 2). The target vessel revascularization rate was 3.3% (68/2072).

Factors associated with occurrence of MACE and scaffold thrombosis

Multivariable analyses of factors associated with occurrence of MACE or definite/probable scaffold thrombosis at 1 year are presented in Tables 4 and 5 and Appendix Table A.2. Factors significantly associated with scaffold thrombosis were oral anticoagulation and the total Absorb BVS length per patient.

Discussion

In the FRANCE ABSORB registry, the use of the Absorb BVS in a selected population, with a large proportion of predilatation and postdilatation, was associated with a low rate of MACE and acceptable BVS thrombosis rates at 1 year.

FRANCE ABSORB registry population

Patients included in the FRANCE ABSORB registry are selected patients, as indicated by the low mean age compared with other studies [11, 12]. There may be particular advantages to using BVSs in younger patients (e.g. restoration of pulsatility, vasomotricity or the possibility of surgical lesion bypass) [1]. Half of the registry population presented with ACS, and most of the patients had single-vessel disease and normal left ventricular function, which probably also reflects the selection of patients and lesions.

Implantation and preparation of the lesion

The implantation success rate was high, despite the 150 µm strut thickness of the current Absorb BVS generation. The high success rate might be explained by closer adherence to current recommendations for the use of the Absorb BVS (no severe calcifications, no excessive tortuosity, no left main coronary artery, no bifurcation, no restenosis, no saphenous vein graft and strict lesion selection). Optimal Absorb BVS expansion requires adequate lesion preparation, especially in more complex lesions. Current recommendations highlight the importance of predilatation and high-pressure postdilatation to achieve optimal scaffold expansion and, possibly, better clinical outcomes [8, 13]. Here, we report high predilatation and postdilatation rates (93.0% and 82.7%, respectively).

Efficacy outcomes and scaffold thrombosis

Low rates of MACE and target lesion failure were found in the FRANCE ABSORB registry, which is in agreement with data from several randomized trials and meta-analyses [4, 6, 7, 12, 14-17].

The 1-year rate of scaffold thrombosis reported in the FRANCE ABSORB study is in line with reports from other European registries (GABI-R [11], GHOST EU [18] and ABSORB UK [19]) and randomized studies [4, 6]. There has been concern about excess risk of BVS thrombosis after implantation. As with metallic stents [20], the mechanisms underlying scaffold thrombosis are multifactorial [21], and may be related to the technique of implantation, persistence of uncovered struts, strut malapposition or underexpansion of the scaffold [5]. Rates of probable and definite scaffold thrombosis of 1.8% at 30 days and 3% at 12 months were reported recently in a large multicentre registry of 1305 all-comer patients who

received a total of 1870 Absorb BVSs [13]. In this study, suboptimal postprocedural angiographic results were associated with an increase in risk of BVS thrombosis. The in-BVS thrombosis rate decreased over time with improvement of implantation techniques. A similar improvement over time was observed in the GABI-R registry [11]. Higher definite scaffold thrombosis rates with the Absorb BVS compared with the XIENCE stent (Abbott Vascular, Santa Clara, CA, USA) were recently reported in the ABSORB 2 and ABSORB 3 trials after 4 and 3 years of follow-up, respectively [14, 22].

Factors associated with the occurrence of MACE and scaffold thrombosis

We found that diabetes mellitus, total Absorb BVS length > 30 mm and oral anticoagulation were associated with the occurrence of MACE or scaffold thrombosis. A long Absorb BVS length was associated with more adverse events than shorter lengths. The management of long or multiple lesions using the Absorb BVS is particularly challenging. The negative association between scaffold length and scaffold thrombosis was recently described in a subgroup analysis from the GHOST registry [23]. An increased risk of restenosis and cardiovascular events in patients with diabetes has been described for metallic drug-eluting stents [24], and has also been observed more recently using the Absorb BVS [18].

An association between scaffold thrombosis and oral anticoagulation has not been reported before. The choice and duration of antiplatelet therapy after implantation of the Absorb BVS is difficult [25], particularly for patients who need oral anticoagulation in association with antiplatelet agents. Our data indicate that implantation of the Absorb BVS in patients with a high bleeding risk, including patients under an oral anticoagulant, should probably be discouraged. This is in line with the recent consensus document from the European Society of Cardiology/European Association for Cardio-Thoracic Surgery, which does not recommend the use of the Absorb BVS in patients who cannot tolerate an extended duration of DAPT or who require oral anticoagulation [26].

Study limitations

As FRANCE ABSORB was a prospective registry, the enrolment of the patients was not randomized, and therefore some selection bias cannot be excluded. All Absorb BVS implantations in France had to be included in the registry during the inclusion period. However, it cannot be excluded that some subjects

with the Absorb BVS implanted in France during this period were not included in the registry. As there was no control group, a comparison with other treatment options is not possible. We acknowledge that the details of the DAPT regimen at 1 year were not available, and that a core laboratory was not used for the angiographic analysis.

Conclusions

The FRANCE ABSORB registry is one of the largest registries conducted with the Absorb BVS. High proportions of young patients and patients with ACS were included. Current recommendations were followed to a large degree, with high predilatation and postdilatation rates. Absorb BVS implantation was associated with low rates of 1-year MACE. BVS thrombosis rates were acceptable at 1 year, although the results may be different in a non-selected population that includes older patients. The scheduled 5-year follow-up in the whole population is justified by the indication of possible late scaffold thrombosis.

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Disclosure of interest

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Figure legends

Figure 1. Occurrence of bioresorbable vascular scaffold (BVS) definite/probable scaffold thrombosis during 1-year (1Y) follow-up.

Figure 2. Occurrence of bioresorbable vascular scaffold (BVS) definite/probable scaffold thrombosis during 1-year (1Y) follow-up, according to total length of scaffold.

Table 1 Baseline characteristics of the study cohort (*n* = 2072).

Age (years)	55.2 ± 11.2
Men	1654 (79.8)
Body weight (kg) (*n* = 2069)	80.2 ± 15.6
Body mass index (*n* = 2062)	27.0 ± 4.4
Medical history and risk factors	
Diabetes	332 (16.0)
Dyslipidaemia	1076 (51.9)
Hypertension	880 (42.5)
Current smoking	850 (41.0)
History of MI	330 (15.9)
History of PCI	498 (24.0)
History of CABG	21 (1.0)
Indication for PCI	
ACS	1016 (49.0)
Unstable angina	217 (10.5)
NSTEMI	442 (21.3)
STEMI	357 (17.2)
Stable/elective/other	1056 (51)
Index procedure	
Number of lesions treated with the Absorb BVS	
1	1746 (84.3)
2	285 (13.8)
3	39 (1.9)
4	2 (0.1)
Other lesions treated by metallic stent	382 (18.5)
Radial access	1884 (91.3)

LVEF (%) (*n* = 1071)	58.6 ± 10.6
Perprocedural anticoagulant treatment (n=1799)[a]	
UFH	1438 (80.0)
LMWH	335 (18.6)
Bivalirudin	14 (0.8)
Other	26 (1.4)
Postprocedural medication (discharge)	
DAPT (*n* = 2036)	1997 (98.1)
VKA (*n* = 2026)	28 (1.4)
NOAC (*n* = 2025)	22 (1.1)

Data are expressed as mean ± standard deviation or number (%). ACS: acute coronary syndrome; BVS: bioresorbable vascular scaffold; CABG: coronary artery bypass graft; DAPT: dual antiplatelet therapy; LMWH: low-molecular-weight heparin; LVEF: left ventricular ejection fraction; MI: myocardial infarction; NOAC: non-vitamin K antagonist oral anticoagulant; NSTEMI: non-ST-segment elevation myocardial infarction; PCI: percutaneous coronary intervention; STEMI: ST-segment elevation myocardial infarction; UFH: unfractionated heparin; VKA: vitamin K antagonist.

[a] For index procedure.

Table 2 Characteristics of lesions treated with the Absorb bioresorbable vascular scaffold (*n* = 2502), and procedural data.

Lesion localization	
LAD/Diag	1512 (60.9)
CX/Mg	394 (15.9)
RCA/PLV/PAD	563 (22.6)
Graft	2 (0.1)
Left main coronary artery	13 (0.5)
De novo lesion	2479 (99.1)
Bifurcation	195 (7.8)
Total occlusion	214 (8.6)
TIMI flow grade 3 preprocedure	1869 (82.9)
Lesion type	
A	263 (11.7)
B1	990 (44.0)
B2	519 (23.0)
C	480 (21.3)
Not specified	247 (9.9)
Vessel tortuosity	
No	1702 (77.9)
Mild	334 (15.3)
Moderate	121 (5.5)
Severe	28 (1.3)
Not specified	314 (12.6)
Calcified lesion	
No	1739 (77.1)
Mild	346 (15.4)

Moderate	141 (6.3)
Severe	28 (1.2)
Not specified	245 (9.8)
Lesion preparation and treatment	
Balloon predilatation (*n* = 2430)	2260 (93.0)
Rotablator (*n* = 2419)	5 (0.2)
Thromboaspiration (*n* = 2422)	118 (4.9)
Postdilatation	2068 (82.7)
Predilatation and postdilatation (*n* = 2430)	1928 (79.3)
Endoluminal imaging (*n* = 2126)	375 (15.0)
Balloon postdilatation (*n* = 2488)	2057 (82.7)
More than one Absorb BVS implanted in target lesion (*n* = 2126)	280 (13.2)
Total BVS length implanted in target lesion (mm)	23.3 ± 10
8 mm	13 (0.5)
12 mm	469 (16.8)
18 mm	1017 (36.3)
23 mm	501 (17.9)
28 mm	798 (28.5)
BVS diameter implanted in target lesion (mm)	3.05 ± 0.39
2.5 mm	604 (24.2)
3.0 mm	930 (37.2)
3.5 mm	991 (35.4)
Final TIMI flow grade 3	2481 (99.2)
Angioplasty success[a]	2481 (99.2)

Data are expressed as number (%) or mean ± standard deviation. BVS: bioresorbable vascular scaffold; CX/Mg: circumflex coronary artery or marginal branch; LAD/Diag: left anterior descending coronary artery or diagonal branch; PDA: posterior descending artery; PLV: posterior left ventricular artery; RCA: right coronary artery; TIMI: Thrombolysis in Myocardial Infarction.

[a] Achievement of final in-scaffold stenosis of < 30% and TIMI flow grade 3.

Table 3 One-year clinical events (*n* = 2072).

	Number of clinical events	%
Death from any cause	14	0.7
CV death or unknown cause	12	0.6
Non-CV death	2	0.1
MI[a]	54	2.6
Target vessel MI[b]	39	1.9
Non-target vessel MI	11	0.5
Undetermined	4	0.2
Revascularization	108	5.2
Target lesion revascularization[c]	49	2.4
Target vessel revascularization[d]	68	3.3
Non-target vessel revascularization	51	2.5
Stroke	5	0.2
MACE[e]	80	3.9
BVS thrombosis (all)	33	1.6
Definite	25	1.2
Probable	6	0.3
Possible	2	0.1
Definite or probable BVS thrombosis	31	1.5
Acute	11	0.5
Subacute	11	0.5
Late	9	0.4
Target lesion failure[f]	73	3.5
Target vessel failure[g]	90	4.3
Patient-oriented endpoint[h]	132	6.4

BVS: bioresorbable vascular scaffold; CV: cardiovascular; MACE: major adverse cardiac events; MI:

myocardial infarction.

[a] MI: according to the third universal definition of MI, all types (1, 2, 3, 4 and 5) were considered.

[b] Target vessel MI: all infarcts that could not clearly be attributed to a vessel other than the target vessel were considered related to the target vessel.

[c] Target lesion revascularization was defined as any repeat revascularization of the target lesion for restenosis or other complications of the target lesion; all target lesion revascularizations clinically indicated and not clinically indicated were considered.

[d] Target vessel revascularization was defined as any repeat revascularization of any segment of the target vessel.

[e] Cardiac death or MI or target lesion revascularization.

[f] Cardiac death or target vessel MI or target lesion revascularization.

[g] Cardiac death or target vessel MI or target vessel revascularization or target lesion revascularization.

[h] Any death or any MI or any revascularization.

Table 4 Factors associated with major adverse cardiac events at 1 year: multivariable Cox regression.

	Univariate analysis			Multivariable analysis		
	Hazard ratio	95% CI	*P*	Hazard ratio	95% CI	*P*
Baseline						
Male sex	1.10	0.63–1.93	0.74			
Age	1.00	0.98–1.02	0.88			
Medical history						
Diabetes mellitus	2.29	1.42–3.69	0.001	2.33	1.44–3.75	0.001
Hypertension	1.17	1.75–1.81	0.49			
Hypercholesterolaemia	0.92	0.60–1.43	0.72			
Current smoker	1.30	0.84–2.02	0.24			
Body mass index ≥ 30 kg/m²	1.13	0.68–1.89	0.64			
History of MI	1.03	0.57–1.86	0.93			
History of PCI	0.85	0.50–1.45	0.55			
Preprocedure oral anticoagulant treatment	1.91	0.88–4.15	0.102			
Clinical presentation						
Indication is STEMI/NSTEMI	0.96	0.61–1.51	0.85			
Index procedure						
More than one lesion treated with the Absorb BVS[a]	1.58	0.93–2.66	0.089			
Radial access[a]	1.17	0.51–2.70	0.71			

LVEF if measured[a]	0.99	0.96–1.02	0.45			
UFH perprocedural treatment (versus others)[a]	1.07	0.60–1.92	0.81			
GpIIb/IIIa inhibitor[a]	0.94	0.45–1.94	0.86			
VKA or NOAC at discharge	2.29	0.84–6.26	0.107			
Lesions treated with the Absorb BVS						
Number of Absorb BVSs implanted in one or several lesions						
1	1.00	(reference)				
2	1.67	0.99–2.81	0.057			
> 2	3.15	1.73–5.74	< 0.001			
Overlapping	2.01	1.06–3.79	0.032			
Restenosis lesion treated with the Absorb BVS	1.16	0.16–8.31	0.89			
Bifurcation lesion treated with the Absorb BVS	1.53	0.79–2.97	0.21			
Total occlusion lesion treated with the Absorb BVS	0.85	0.39–1.85	0.69			
Complex lesion (B2/C) treated with the Absorb BVS	1.35	0.85–2.13	0.198			
Calcified lesion treated with the Absorb BVS (moderate or severe)	1.79	0.89–3.60	0.101			
Total Absorb BVS length per patient						
Tertile 1 (< 20 mm)	1.00	(reference)		1.00	(reference)	
Tertile 2 (20–29 mm)	1.03	0.58–1.84	0.91	0.98	0.55–1.76	0.96
Tertile 3 (≥ 30 mm)	2.07	1.24–3.44	0.005	2.04	1.23–3.39	0.006
Minimum Absorb BVS diameter = 2.5 mm	1.58	1.01–2.47	0.044			

Endoluminal imaging used for lesion(s) treated with the Absorb BVS	0.98	0.53–1.82	0.96
PSP[b] for all lesions treated with the Absorb BVS	0.85	0.51–1.43	0.55
Successful angioplasty for all lesions treated with the Absorb BVS	0.42	0.06–3.00	0.39

BVS: bioresorbable vascular scaffold; CI: confidence interval; Gp: glycoprotein; LVEF: left ventricular ejection fraction; MI: myocardial infarction; NOAC: non-vitamin K antagonist oral anticoagulant; NSTEMI: non-ST-segment elevation myocardial infarction; PCI: percutaneous coronary intervention; PSP: predilatation, sizing and postdilatation; STEMI: ST-segment elevation myocardial infarction; UFH: unfractionated heparin; VKA: vitamin K antagonist..

[a] For index procedure.

[b] Fisher's exact test.

Table 5 Factors associated with bioresorbable vascular scaffold thrombosis (definite and probable) occurrence at 1 year: multivariable Cox regression.

	Univariate analysis			Multivariable analysis		
	Hazard ratio	95% CI	*P*	Hazard ratio	95% CI	*P*
Baseline						
Male sex	2.37	0.72–7.79	0.156			
Age	0.99	0.56–1.02	0.45			
Medical history						
Diabetes mellitus	2.16	0.99–4.69	0.052			
Hypertension	1.11	0.55–2.26	0.76			
Hypercholesterolaemia	0.99	0.49–2.00	0.97			
Current smoker	1.35	0.67–2.72	0.41			
Body mass index ≥ 30 kg/m²	0.87	0.36–2.12	0.76			
History of MI	2.53	1.19–5.37	0.016			
History of PCI	0.92	0.40–2.14	0.85			
Preprocedure oral anticoagulant treatment	3.83	1.47–9.97	0.006			
Clinical presentation						
Indication is STEMI/NSTEMI	1.32	0.65–2.67	0.45			
Index procedure						
More than one lesion treated with the Absorb BVS[a]	1.57	0.68–3.65	0.29			

Radial access[a]	0.64	0.22–1.83	0.41			
LVEF if measured[a]	0.99	0.95–1.03	0.62			
UFH perprocedural treatment (versus others)[a]	1.25	0.48–3.28	0.64			
GpIIb/IIIa inhibitor[a]	0.58	0.14–2.42	0.45			
VKA or NOAC at discharge	4.73	1.43–15.63	0.011	4.68	1.42–15.46	0.011
Lesion(s) treated with the Absorb BVS						
Number of Absorb BVSs implanted in one or several lesions						
1	1.00	(reference)				
2	2.24	1.03–4.89	0.043			
> 2	2.40	0.81–7.13	0.116			
Overlapping	1.85	0.65–5.27	0.25			
Restenosis lesion treated with the Absorb BVS	(not calculable)					
Bifurcation lesion treated with the Absorb BVS	1.57	0.55–4.48	0.40			
Total occlusion lesion treated with the Absorb BVS	0.95	0.29–3.13	0.94			
Complex lesion (B2/C) treated with the Absorb BVS	1.15	0.56–2.35	0.71			
Calcified lesion treated with the Absorb BVS (moderate or severe)	2.05	0.72–5.90	0.181			
Total Absorb BVS length per patient						
Tertile 1 (< 20 mm)	1.00	(reference)		1.00	(reference)	
Tertile 2 (20–29 mm)	2.19	0.85–5.64	0.105	2.19	0.85–5.64	0.11
Tertile 3 (≥ 30 mm)	3.11	1.24–7.80	0.015	2.66	1.03–6.86	0.043

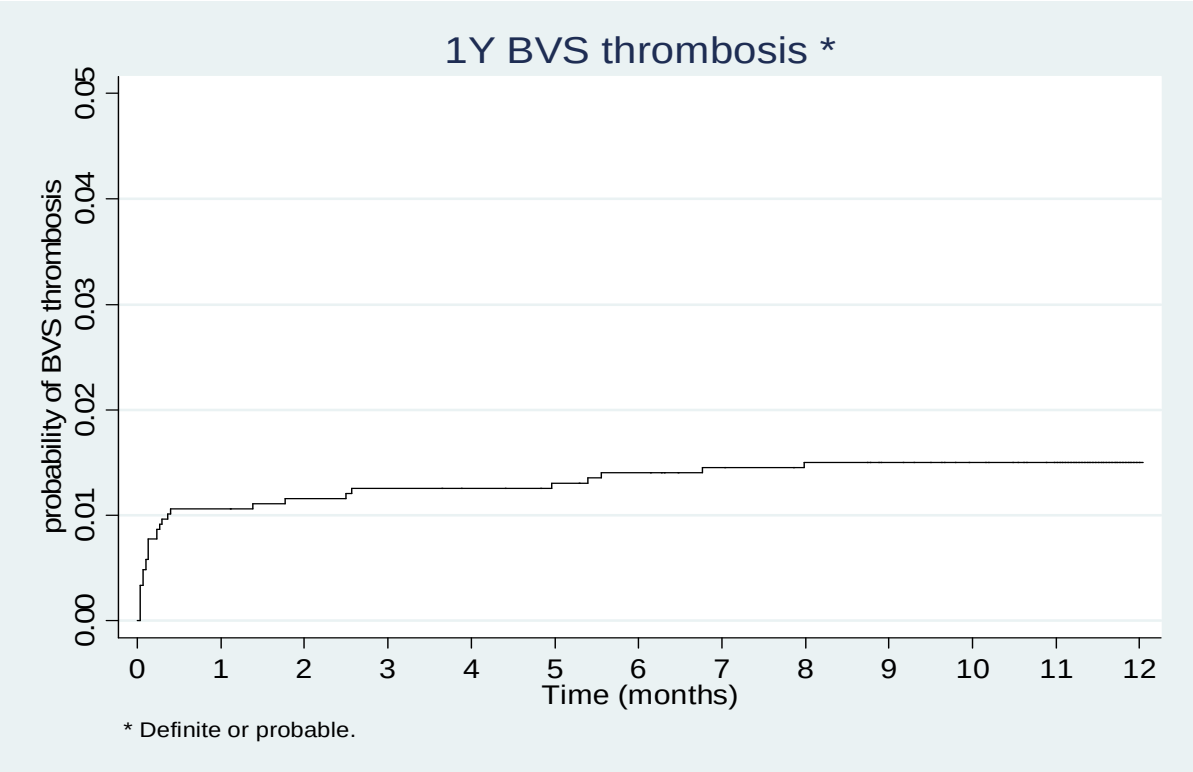
Minimum Absorb BVS diameter = 2.5 mm	1.70	0.83–3.47	0.144
Endoluminal imaging used for lesion(s) treated with the Absorb BVS	1.06	0.41–2.77	0.90
PSP[b] for all lesions treated with the Absorb BVS	1.11	0.45–2.70	0.83
Successful angioplasty for all lesions treated with the Absorb BVS	0.16	0.02–1.18	0.072

BVS: bioresorbable vascular scaffold; CI: confidence interval; Gp: glycoprotein; LVEF: left ventricular ejection fraction; MI: myocardial infarction; NOAC: non-vitamin K antagonist oral anticoagulant; NSTEMI: non-ST-segment elevation myocardial infarction; PCI: percutaneous coronary intervention; PSP: predilatation, sizing and postdilatation; STEMI: ST-segment elevation myocardial infarction; UFH: unfractionated heparin; VKA: vitamin K antagonist..

[a] For index procedure.

[b] Fisher's exact test.

Figure 1


1Y BVS thrombosis *
probability of BVS thrombosis
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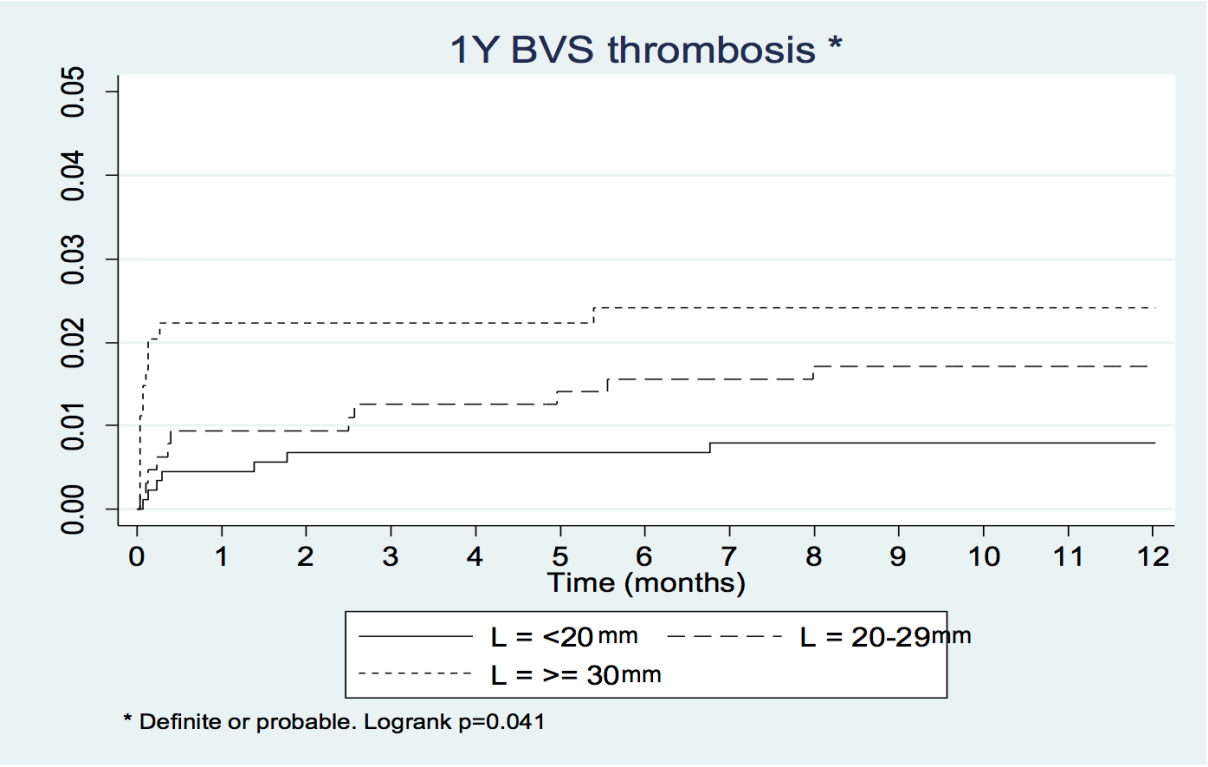
0.01
0.02
0.03
0.04
0.05
0
1
2
3
4
5
6
7
8
9
10
11
12
Time (months)
* Definite or probable.

Figure 2


1Y BVS thrombosis *
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0.01
0.02
0.03
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1
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11
12
Time (months)
L = <20 mm
L = 20-29mm
L = >= 30mm
* Definite or probable. Logrank p=0.041