Mid- to long-term clinical outcomes of patients treated with the everolimus-eluting bioresorbable vascular scaffold. The BVS Expand Registry

CM Felix, JM Fam, R Diletti, Y Ishibashi, A Karanasos, BRC Everaert, NM van Mieghem, J Daemen, PP de Jaegere, F Zijlstra, ES Regar, Y Onuma, RJM van Geuns

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ABSTRACT

Objectives

To report on clinical outcomes beyond one year of the BVS Expand registry.

Background

Multiple studies have proven feasibility and safety of the Absorb bioresorbable vascular scaffold (BVS). However, data on medium to long-term outcomes are limited and available only for simpler lesions.

Methods

This is an investigator-initiated, prospective, single-center, single-arm study evaluating performance of the BVS in a lesion subset representative of daily clinical practice, including calcified lesions, total occlusions, long lesions and small vessels. Inclusion criteria were patients presenting with NSTEMI, stable/ unstable angina, or silent ischemia caused by a *de novo* stenotic lesion in a native previously untreated coronary artery. Procedural and medium to long-term clinical outcomes were assessed. Primary endpoint was major adverse cardiac events, defined as a composite of cardiac death, myocardial infarction and target lesion revascularization.

Results

From September 2012 to January 2015, 249 patients with 335 lesions were enrolled. Mean number of scaffolds per patient was 1.79±1.15. Invasive imaging was used in 39%. In 38.1% there were ACC/ AHA classification type B2/ C lesions. Mean lesion length was 22.16±13.79 mm. Post-procedural acute lumen gain was 1.39±0.59 mm. Median follow-up period was 622 days (interquartile range: 376-734). Using Kaplan-Meier methods, the MACE rate at 18 months was 6.8%. Rate of cardiac mortality, myocardial infarction and target lesion revascularization at 18 months were 1.8%, 5.2% and 4.0% respectively. Definite scaffold thrombosis rate was 1.9%.

Conclusions

In our study, BVS implantation in a complex patient and lesion subset was associated with an acceptable rate of adverse events at longer-term, while no cases of early thrombosis were observed.

INTRODUCTION

Drug-eluting stents (DES) currently form the mainstay of coronary devices used in percutaneous coronary interventions (PCI) in many parts of the world. Despite advantages in clinical outcomes such as reduction in target lesion revascularization rates, shortcomings related to the use of DES still exist such as delayed arterial healing, late stent thrombosis (ST) and hypersensitivity reactions to the polymer, with observations of ongoing very late stent failure beyond one year. [1, 2]

In addition, from a physiological point of view, a vessel that is indefinitely caged in a metal stent may not be desirable with both short- and long-term implications and potentially adverse consequences such as impaired endothelial function, the reduced potential for vessel remodelling, interference with the normal arterial healing process and the risk of occlusion of covered side branches by neointima hyperplasia. Furthermore, interference with non-invasive imaging (cardiac computed tomography or magnetic resonance imaging) during patient follow-up and possible impairment of future treatment options (re-PCI or coronary artery bypass surgery) are drawbacks of metallic stents. [3]

To overcome these issues, bioresorbable vascular scaffolds (BRS) were developed. The BRS most studied is the Absorb BVS (Abbott Vascular, Santa Clara, CA). The BVS provides transient vessel support and gradually elutes the anti-proliferative drug everolimus. After degradation of the polymer (after approximately three years) no foreign material remains and the risk for developing very late ST is potentially reduced.

Intravascular imaging observations 5 years after BVS implantation in a simple patient and lesion subset have demonstrated late luminal enlargement due to plaque reduction, a persistent restoration of vasomotion and a fully completed bioresorption process, [4, 5] and a low rate of major adverse cardiac events (MACE) rate (3.4%). [6] This is consistent in randomized controlled trials (ABSORB II and ABSORB Japan) which showed comparable clinical event rates in BVS compared with best in class with metallic DES (Xience V). [7, 8] However, as these studies included a selected group of patients, extrapolation to a more complex population is limited. Yet, the registry- level clinical data on the outcomes after BVS implantation in more complex patient and lesion subsets have not been well documented that such data are available from registries with a relatively short follow-up of 6 to 12 months, which have shown variable early clinical outcomes. [8-10] Thus, the medium to long-term outcomes beyond one year after BVS implantation in such complex 'real-world' lesions remain elusive.

In the current study, we report on extended follow-up beyond one year, of the BVS Expand Registry. This is a single-center registry initiated in September 2012 that investigates the clinical outcomes after BVS implantation in a more complex real-world population.

METHODS

Population

This is an investigator-initiated, prospective, single-center, single-arm study performed in an experienced, tertiary PCI center. Patients presenting with NSTEMI, stable or unstable angina (UA), or silent ischemia caused by a *de novo* stenotic lesion in a native previously untreated coronary artery with intention to treat with a BVS were included. Angiographic inclusion criteria included lesions with a Dmax (proximal and distal maximal lumen diameter) within the upper limit of 3.8 mm and the lower limit of 2.0 mm by online quantitative coronary angiography (QCA). Complex lesions such as bifurcation, calcified (as assessed by angiography), long and thrombotic lesions were not excluded. Exclusion criteria were patients with a history of coronary bypass grafting (CABG), presentation with cardiogenic shock, bifurcation lesions requiring kissing balloon post-dilatation, ST-elevation myocardial infarction (STEMI) patients, allergy or contra-indications to antiplatelet therapy, fertile female patients not taking adequate contraceptives or currently breastfeeding and patients with expected survival of less than one year. As per hospital policy patients with a previously implanted metal DES in the intended target vessel were also excluded. Also, although old age was not an exclusion criterion, BVS were in general reserved for younger patients, and left to operator's interpretation of biological age.

Ethics

This is an observational study, performed according to the privacy policy of the Erasmus MC, and to the Erasmus MC regulations for the appropriate use of data in patient-oriented research, which are based on international regulations, including the declaration of Helsinki. Approval of the ethical board of the Erasmus MC was obtained. All patients undergoing clinical follow-up provided written informed consent for the PCI and to be contacted regularly during the follow-up period of the study.

Procedure

PCI was performed according to current clinical practice standards. The radial or femoral routes were the principal routes of vascular access and 6 or 7 French catheters were used depending on the discretion of the operator. Pre-dilatation and post dilation were recommended with a balloon shorter than the planned study device length and with a non-compliant balloon without overexpanding the scaffold beyond its limits of expansion (0.5mm > nominal diameter) respectively. Intravascular imaging with the use of Intravascular Ultrasound (IVUS) or Optical Coherence Tomography (OCT) was used for pre-procedural sizing and optimization of stent deployment on the discretion of the operator. All patients were treated with unfractionated heparin (at a dose of 70-100 UI/kg). Patients with stable angina were preloaded with 300 mg of aspirin and 600 mg of

clopidogrel. Patients presenting with ACS were preloaded with 300 mg of aspirin and 60 mg of prasugrel or 180 mg of ticagrelor.

Angiographic analysis

Quantitative Coronary Analysis (QCA) was performed by three independent investigators. Coronary angiograms were analyzed with the CAAS 5.10 QCA software (Pie Medical BV, Maastricht, the Netherlands). The QCA measurements provided reference vessel diameter (RVD), percentage diameter stenosis, minimal lumen diameter (MLD), and maximal lumen diameter (Dmax). Acute gain was defined as post-procedural MLD minus pre-procedural MLD (in an occluded vessel MLD value was zero by default). For the purpose of this study we defined underexpansion as a ratio of post-procedural minimal lumen diameter (MLD) to the nominal device diameter of less than 0.7. The ratio of pre-procedural reference vessel diameter (RVD) to the nominal device diameter was used to assess pre-procedural sizing.

Follow-up

Clinical demographic data of all patients were obtained from municipal civil registries. Follow-up information specific for hospitalization and cardiovascular events was obtained through questionnaires. If needed, medical records or discharge letters from other hospitals were requested. Events were adjudicated by an independent clinical events committee (CEC). All information concerning baseline characteristics and follow-up was gathered in a clinical data management system.

Definitions

The primary endpoint was MACE, defined as the composite endpoint of cardiac death, myocardial infarction (MI) and target lesion revascularization (TLR). Deaths were considered cardiac unless a non-cardiac cause was definitely identified. TLR was described as any repeated revascularization of the target lesion. Target vessel revascularization (TVR) was defined as any repeat percutaneous intervention or surgical bypass of any segment of the target vessel. Non-target vessel revascularization was described as any revascularization in a vessel other than the target lesion. Scaffold thrombosis (ST) and MI were classified according to the Academic Research Consortium (ARC). [11] Clinical device success (lesion basis) was defined as successful delivery and deployment of all intended scaffolds at the target lesion and successful withdrawal of the delivery system with attainment of final in-scaffold residual stenosis of < 30% as evaluated by QCA. When bailout device was used, the success or failure of the bailout device delivery and deployment is not one of the criteria for device success. Clinical procedure success (patient basis) was described as achievement of final in-scaffold residual stenosis of less than 30% by QCA with successful delivery and deployment of all intended scaffolds at

the target lesion and successful withdrawal of the delivery system for all target lesions without major peri-procedural complications or in-hospital MACE (maximum of 7 days). In dual target lesion setting, both lesions must meet clinical procedure success criteria to have a patient level procedure success.

The intention-to-treat (ITT) group includes all the patients regardless of whether or not the scaffold was successfully implanted. The per-treatment (PT) group consists of all patients in whom the BVS was successfully implanted. Only events in the per-treatment population were analysed.

The off-registry population consisted of patients that were excluded in this study, mainly STEMI patients.

Statistical analysis

Categorical variables are reported as counts and percentages, continuous variables as mean ± standard deviation. The student's t test and the chi square test (or Fishers' exact test) were used for comparison of means and percentages. The cumulative incidence of adverse events was estimated according to the Kaplan-Meier method. Patients lost to follow-up were considered at risk until the date of last contact, at which point they were censored. All statistical tests were two-sided and the P value of < 0.05 was considered statistically significant. To investigate possible predictors for clinical outcomes MACE and ST, univariate analysis using a Cox regression model was used investigating variables that are frequently present. Statistical analyses were performed using SPSS, version 21 (IL, US).

RESULTS

From September 2012 up to January 2015, 3373 patients were treated with PCI in our center. The majority of patients were considered not suitable for BVS either to their biological age related to comorbidities, indication for stent > 3.5mm or smaller < 2.5 mm, previous CABG, previous PCI with metal DES in the target vessel or STEMI as indication for PCI shortly after the commercial introduction of BVS in Europe. These patients were in general older (64.5 ± 11.6 years) and presented with more risk factors compared to the BVS population (previous CABG: 9.5%, previous PCI: 31.3%, previous MI: 25.6%) and presented more frequently with multivessel disease (57.8%). Finally, 485 patients were treated with one or more BVS in the registry period. Most excluded patients (N = 169) presented with STEMI and entered a separate registry starting later, 5 had a previous CABG, 1 needed kissing balloon post-dilatation for bifurcation, 2 had a previous implanted metal DES in the target vessel as formal exclusion criteria for this analysis and

58 patients did not return their informed consent because they declined to participate, emigrated abroad or participated in another trial investigating BVS.

249 signed the informed consent for follow-up and were eligible based on protocol inclusion and exclusion criteria. In 5 patients delivery failure occurred (intention-to-treat, ITT group). The per-treatment (PT) group thus consisted of 244 patients. The flowchart of the registry is given in Figure 1.

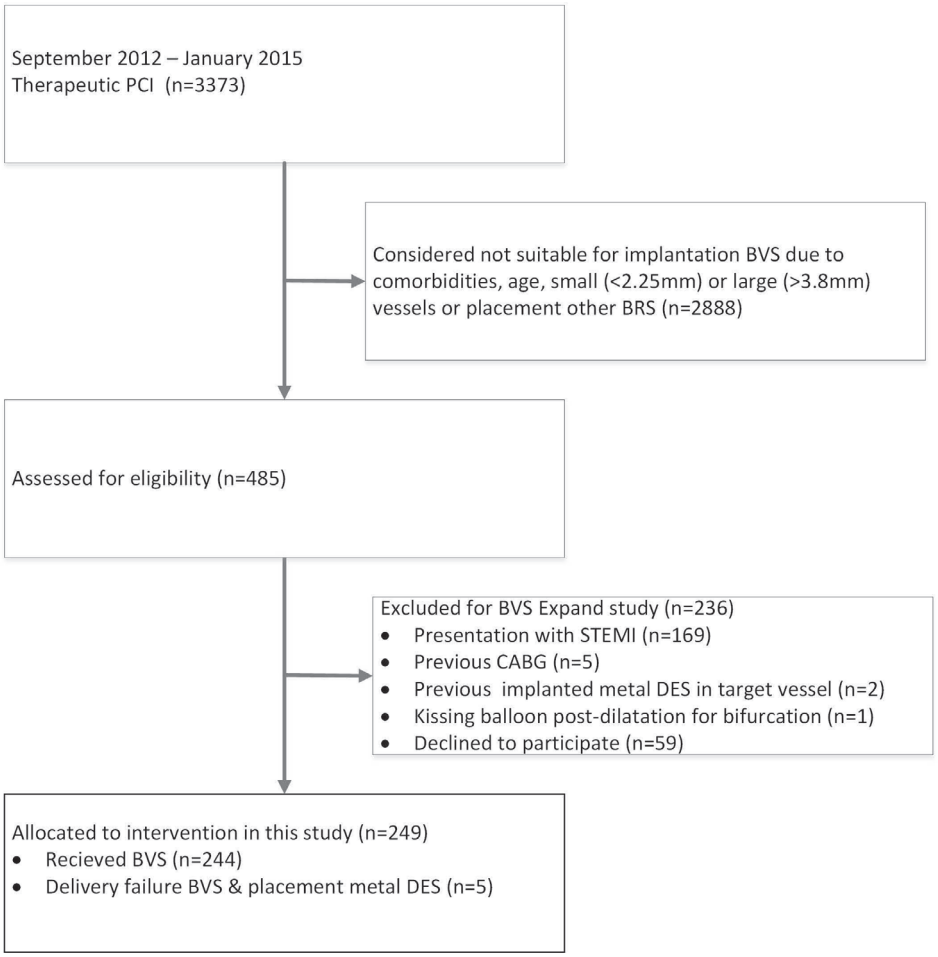

Figure 1 Flowchart of the study

Baseline characteristics

Baseline characteristics of all BVS treated patients are presented in Table 1. Mean age was 61.3 ± 10.2 years, 73.5% were male, 18.5% diabetic and 59.1% presented with an acute coronary syndrome (NSTEMI or UA; STEMI patients were excluded). Multivessel disease

was present in 45.6%. The off-registry patients were younger, with less comorbidities and presented more frequently with STEMI.

Table 1 Baseline characteristics

Patients characteristics	ITT population	Off-registry population	P value
Number of patients	249	236	
Gender (%)			0.57
Men	73.5	75.6	
Women	26.5	24.4	
Mean age in years (±SD)	61.3 ± 10.2	55.4 ± 10.6	P<0.001
Smoking (%)	55.0	59.0	0.24
Hypertension (%)	59.4	41.9	P<0.001
Dyslipidaemia (%)	51.0	29.9	P<0.001
Diabetes Mellitus (%)	18.5	13.2	0.14
Family history of CAD (%)	44.6	37.6	0.23
Prior MI (%)	17.7	6.0	P<0.001
Prior PCI (%)	9.2	4.7	0.05
Prior CABG (%)	0.0	2.6	0.01
Presenting with multiple vessel disease (%)	45.6	28.2	0.07
Indication for PCI (%)			P<0.001
Stable angina	40.6	9.8	
Unstable angina	16.1	2.1	
STEMI	0.0	71.4	
NSTEMI	43.0	16.7	
Silent ischemia	0.4	0.0	
Periphery artery disease (%)	8.8	1.7	P<0.001
COPD (%)	7.2	3.9	0.10
Heart failure (%)	4.8	0.9	0.01
Renal insufficiency (%)	6.4	2.1	0.02
CVA/ TIA (%)	9.6	4.3	0.03

CAD coronary artery disease, *COPD* chronic obstructive pulmonary disease, *CVA* cerebrovascular accident, *TIA* transient ischemic attack

Lesion characteristics are presented in table 2. The left anterior descending coronary artery (LAD) was most commonly treated (50.0% of lesions). Moderate or severe calcification (as assessed by angiography) was present in 42.2% and a chronic total occlusion in 4.2% of the lesions. Bifurcation lesions (involving lesions within 3 mm of the bifurcation and with side branches ≥ 2 mm by visual estimation in diameter, treated with implantation of at least one BVS) were present in 21.3% with significant side branch involvement (true bifurcations: Medina 1,1,1, 1,0,1 and 0,1,1 lesions) in 32% of these. Overall, 38.1%

Table 2 Lesion characteristics

		N= 249; L= 335
Target vessel (%)		
	LAD	50.0
	LCX	23.7
	RCA	26.0
	Ramus intermedius	0.3
	SVG	0.0
Lesion AHA A/B1/B2/C		16.2/ 45.8/ 24.3/ 13.8
Bifurcation (%)		21.3
Moderate/ severe calcification (%)		42.2
(Chronic) Total occlusions (%)		4.2
TIMI (%)		
Pre-procedure		
	TIMI 0	8.4
	TIMI 1	1.8
	TIMI 2	13.8
	TIMI 3	75.4
Post-procedure		
	TIMI 0	0.0
	TIMI 1	0.3
	TIMI 2	3.0
	TIMI 3	96.4
QCA Analysis		
Pre-procedure		
	Lesion length (mm)	22.10 ± 13.90
	RVD (mm)	2.42 ± 0.74
	MLD (mm)	0.91 ± 0.45
	Diameter stenosis (%)	59.13 ± 20.72
Post-procedure		
	RVD (mm)	2.77 ± 0.46
	MLD (mm)	2.30 ± 0.42
	Diameter stenosis (%)	16.90 ± 9.04
	Acute lumen gain (mm)	1.39 ± 0.59

Values are expressed as percentages or mean ± standard deviation when appropriate. *LAD* left anterior descending artery, *LCX* left coronary artery, *MLD* minimal lumen diameter, *QCA* quantitative coronary angiography, *RCA* right coronary artery, *RVD* reference vessel diameter, *SVG* saphenous vein graft

of lesions were ACC/ AHA type B2 or C. Mean lesion length was 22.16 ± 13.79 mm. Pre-procedural QCA showed a RVD of 2.42 ± 0.74 mm, a MLD of 0.91 ± 0.45 mm and a %DS of 59.12 ± 20.72%.

Procedural details

Table 3 shows the procedural characteristics. Pre-dilatation was performed in 89.9% (pre-dilatation balloon to artery ratio of 1.05 ± 0.23). Post-dilatation was performed in 53.3% with a balloon to scaffold ratio of 1.08 ± 0.11. Advanced lesion preparation using rotational artherectomy and scoring balloon was done in 3.1% and 2.7%. Pre-procedural evaluation and device optimization using invasive imaging with IVUS and OCT was done in 14.4% and 24.6% of the procedures, respectively. A total of 445 BVS were implanted with a mean number of 1.34 ± 0.69 scaffolds per lesion and a mean number of 1.79 ± 1.15 scaffolds per patient. For the bifurcation lesions, the provisional side branch treatment was standard in this study. Side branch wiring before main vessel stenting was employed in 37.5%. Side branch dilation after main vessel stent was performed for 31% and bailout stenting only in one BVS. Side branch fenestration was performed in 25%. Side branch dilation was followed by mini-kissing post-dilation of just sequential ballooning with proximal optimization.

Post-procedural QCA characteristics were: RVD 2.77 ± 0.46 mm, MLD 2.30 ± 0.42 mm and %DS 16.90 ± 9.04. Acute lumen gain was 1.39 ± 0.59 mm.

Clinical device success was 97.3% and clinical procedural success was 96.8%. In 5 patients delivery failure of the BVS occurred because the scaffold could not pass the lesion, for example due to severe calcification or tortuosity. After multiple attempts, metal DES were placed in these cases.

Clinical outcomes

Survival data was available in 100% with a median follow-up period of 622 days (interquartile range [IQR], 376-734 days). Two patients withdrew their informed consent within a few weeks after the index procedure.

One-year clinical outcomes are reported in Table 4. Event rates are described as Kaplan-Meier estimates. Figures 2A – 2C give an impression of the event rates during late follow-up. At 18 months, there were 4 fatalities (all cardiac death) with a Kaplan-Meier estimate of 1.8%. In the per-treatment group, MACE rate at 18 months was 6.8%, mainly driven by the rate of MI (5.2%). There were two cases of peri-procedural MI. TLR at 18 months was performed in 4.0%, TVR in 4.0%. Rate of non-TVR was 5.4%. Rate of overall ST at 18 months was 2.7%, with a definite ST rate of 1.9%.

Details of ST cases are summarized in Table 5. Narratives of each case are presented in the supplemental material. In Figure 3 we present MACE, its components and definite/ probable ST rates in various subgroups. There was no increased rate of both MACE and definite/ probable ST in patients presenting with ACS (NSTEMI and unstable angina) compared to the overall population.

Bar graphs demonstrating the rate of major adverse cardiac event (MACE) rate, its components, and scaffold thrombosis in subgroups of population (e.g. calcification, bifurcation, small vessel). *MI* myocardial infarction, *NS* non-ST-segment elevation

Table 3 Procedural characteristics

		N= 249; L= 335
Treated lesion per procedure		1.35 ± 0.62
Aspiration thrombectomy (%)		4.2
Rotablation (%)		3.1
Scoring balloon (%)		2.7
Intracoronary imaging (%)		
	IVUS	14.4
	OCT	24.6
Pre-dilation (%)		89.8
Max pre-dilation diameter (mm)		2.61 ± 0.44
Pre-dilation balloon: artery ratio		1.05 ± 0.23
Maximum pre-dilation inflation pressure (atm)		12.80 ± 5.91
Buddy wire (%)		8.1
Mean number of scaffolds/ lesion		1.34 ± 0.69
Mean number of scaffolds/ patient		1.79 ± 1.15
Number of scaffolds		445
	1 (%)	72.6
	2 (%)	20.3
	3 (%)	4.5
	4 (%)	2.5
Scaffold diameter (mm)		3.08 ± 0.35
Scaffold length implanted (mm)		28.31 ± 17.06
Lesions with Overlapping scaffolds (%)		25.4
Overlap scaffolds diameters 3.5 mm–3.5 mm (%)		24
Overlap scaffolds diameters 3.5 mm–3.0 mm		23
Overlap scaffolds diameters 3.5 mm–2.5 mm		7
Overlap scaffolds diameters 3.0 mm–3.0 mm		21
Overlap scaffolds diameters 3.0 mm–2.5 mm		29
Overlap scaffolds diameters 2.5 mm–2.5 mm		11
Maximum scaffold implantation pressure (atm)		15.08 ± 1.82
Post-dilation (%)		53.3
Post-dilation balloon: mean scaffold diameter ratio		1.08 ± 0.11
Max post-dilation balloon (mm)		3.20 ± 0.46
Maximum post-dilation inflation pressure (atm)		15.50 ± 3.42
Procedural complications (%)		
	Dissection	5.1
	Slow flow/ no reflow	2.7
Clinical device success (%)		97.3
Clinical procedural success (%)		96.8

Values are expressed as percentages or mean ± standard deviation when appropriate.

Table 4 Kaplan-Meier estimates at one-year for clinical events rates

Clinical event rates at one year		ITT (N=249)	PT (N=244)
MACE (%)		5.5	5.1
All cause death (%)		1.3	1.3
	Cardiac death	1.3	1.3
	Non-cardiac death	0.0	0.0
All myocardial infarction (%)*		3.8	3.4
	Target-vessel	2.8	2.5
Target lesion revascularization (%)		3.8	3.4
Target vessel revascularization (%)		3.8	3.4
Non-target vessel revascularization (%)		3.9	3.7
Total scaffold thrombosis (%)		2.1	2.1
Definite scaffold thrombosis (%)		1.3	1.3
	Acute	0.0	0.0
	Subacute	0.0	0.0
	Late	1.3	1.3
Probable scaffold thrombosis (%)		0.4	0.4
	Acute	0.0	0.0
	Subacute	0.0	0.0
	Late	0.4	0.4
Possible scaffold thrombosis (%)		0.4	0.4
	Acute	0.0	0.0
	Subacute	0.0	0.0
	Late	0.4	0.4
Bleeding (Gusto) (%)		2.1	2.2
CVA/ TIA (%)		0.9	0.9

CVA cerebrovascular accident, *ITT* intention-to-treat, *MACE* major adverse cardiac events (composite end-point of cardiac death, myocardial infarction and target lesion revascularization), *PT* per-treatment, *TIA* transient ischemic attack

myocardial infarction, *ST* scaffold thrombosis, *TLR* target lesion revascularization, *UA* unstable angina

Univariate analysis was performed to identify predictors for the occurrence of MACE and definite/ probable ST (Table 6 and 7). Due to lack of power, none of the factors were significant. However, regarding MACE, the following characteristics tended to be associated with ≥ 2 times increased risk of MACE: male (HR 4.079, P = 0.18), more than 2 scaffolds/ lesion (HR 2.41, P = 0.19), underexpansion (HR 2.25, P = 0.16 and age > 65 years (HR 2.11, P = 0.20) (Table 6). Regarding ST, the following characteristics tended to be associated with ≥ 3 times increased risk of ST: age > 65 years (HR 4.49, P = 0.19), long

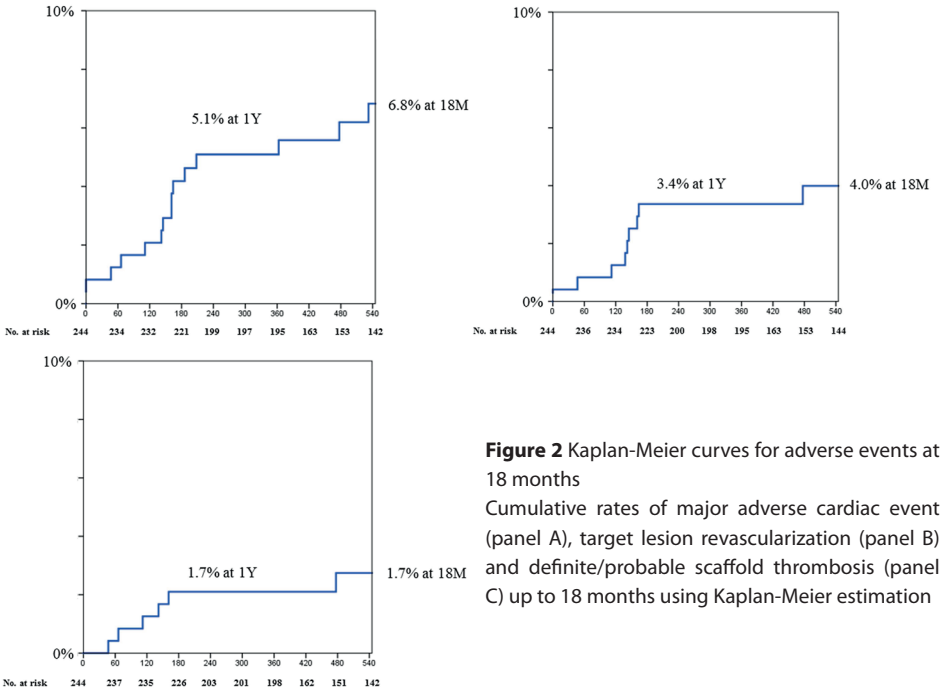

Figure 2 Kaplan-Meier curves for adverse events at 18 months
Cumulative rates of major adverse cardiac event (panel A), target lesion revascularization (panel B) and definite/probable scaffold thrombosis (panel C) up to 18 months using Kaplan-Meier estimation

lesions (HR 3.55, P = 0.27 for lesions of 20 mm and HR 3.42, P = 0.22 for lesions of 32 mm), calcified lesion (HR 3.55, P = 0.27) and RVD ≤ 2.5 mm (HR 3.26, P = 0.31).

Concerning intravascular imaging at baseline, patients who did not undergo baseline imaging had a TLR rate of 4.0%, compared to 2.3% in patients who did undergo baseline imaging (P Log Rank = 0.29). Intravascular imaging was performed more often in patients who had a complex lesion (AHA classification type B2/ C lesion): 44.5% vs 31.1%, P = 0.03.

To examine the relationship between underexpansion, sizing and MACE, a scatterplot of the pre-procedural sizing and post-procedural expansion divided by nominal diameter was created based on QCA (Figure 4). When a cut-off value of MLD post-procedure / nominal device diameter of < 0.70 is applied, the scaffold was underexpanded in 26% of the lesions. Patients, in whom underexpansion occurred, tended to have an increased rate of MACE: 8.0% versus 3.8% (P = 0.15, log rank test).

Table 5 Overview cases ST

Case	Time (d)	Type ST	Age (yr)	Presentation at baseline	Vessel	BVS	Pre-dil	Post-dil	Baseline imaging	Patient related factor	DAPT	Possible mechanism ST	Treatment during event
1	47	Def	69	NSTEMI	LAD	3.0x28, 3.5x18, 3.5x18	Yes	Yes	Yes	Yes (PCI for ACS)	Yes	Residual thrombus, total occlusion, long lesion, calcification, bifurcation	Thrombectomy, eptifibatide, Xience (3.5x38)
2	66	Poss	76	SAP	LAD	3.0x18	Yes	Yes	Yes	Yes (KD, SM)	Yes	Bifurcation, calcification	None, sudden death
3	112	Def	58	SAP	LAD	3.5x28	Yes	Yes	Yes	Yes (SM, ↓ LVF)	Yes	NIH, calcification, underexpansion, long lesion, small vessel	Thrombectomy, Promus (3.5x32), eptifibatide
4	142	Prob	65	NSTEMI	LAD	3.0x18	Yes	Yes	No	Yes (PCI for ACS, SM)	Yes	Geographical miss, edge restenosis, trifurcated lesion	Thrombectomy, Promus (3.5x38mm)
5	161	Def	70	Decreased LVF	LAD	2.5x18 3.0x18	Yes	Yes	Yes	Yes (KD, SM, ↓ LVF)	No	Interruption anticoagulants due to surgery, calcification, long lesion, small vessel	POBA, eptifibatide

DAPT dual antiplatelet therapy, *Def* definite, *DM* diabetes mellitus, *KD* kidney disease, *LVF* left ventricular function, *NSTEMI* non-ST elevation myocardial infarction, *POBA* plain old balloon angioplasty, *Poss* possible, *Post-dil* post-dilatation, *Pre-dil* pre-dilatation, *Prob* probable, *SAP*: stable angina pectoris, *SM* smoking, *ST* scaffold thrombosis

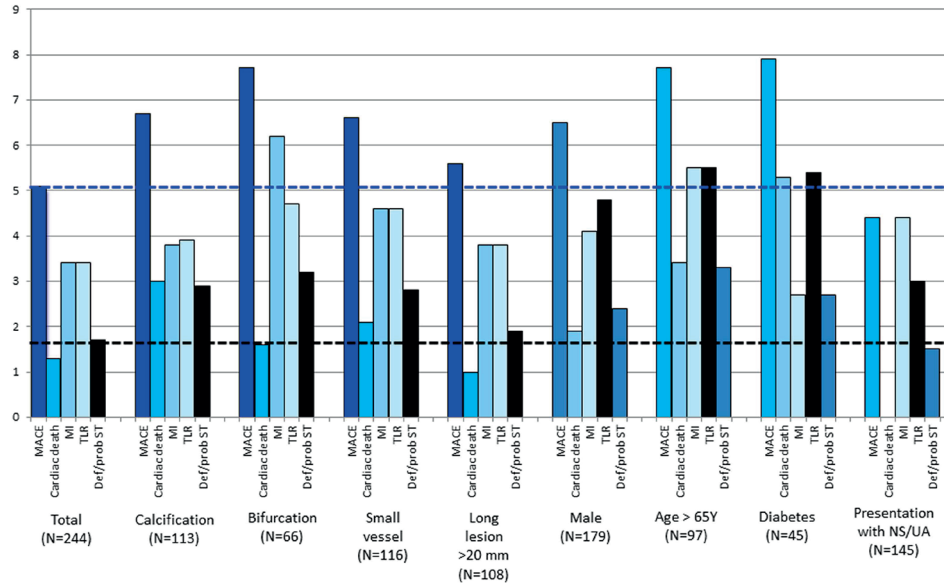

Figure 3 Rate of MACE and Definite/Probable ST, divided by subgroups
Bar graphs demonstrating the rate of major cardiac adverse event (MACE) rate, its components, and scaffold thrombosis in subgroups of population (e.g., calcification, bifurcation, small vessel). MI = myocardial infarction; NS = non-ST-segment elevation myocardial infarction; ST = scaffold thrombosis; TLR = target lesion revascularization; UA = unstable angina.

Table 6 Univariate analysis of MACE

	Hazard Ratio (95% confidence interval)	P value
Male	4.07 (0.53 – 31.51)	0.18
> 2 scaffolds/ lesion	2.41 (0.66 – 8.84)	0.19
Underexpansion	2.25 (0.73 – 6.98)	0.16
Age > 65 years	2.11 (0.67 – 6.64)	0.20
Bifurcation lesion	1.97 (0.63 – 6.21)	0.25
Long lesion (>32mm)	1.73 (0.52 – 5.76)	0.37
Long lesion (>20mm)	1.67 (0.53 – 5.27)	0.38
Calcified lesion	1.64 (0.52 – 5.17)	0.39
Overlap	1.59 (0.49 – 5.17)	0.44
RVD ≤ 2.5mm	1.56 (0.49 – 4.91)	0.45
Diabetes Mellitus	1.51 (0.41 – 5.57)	0.54
Presentation with ACS	0.71 (0.23 – 2.20)	0.55
Imaging at baseline	0.55 (0.15 – 2.03)	0.37

ACS acute coronary syndrome (NSTEMI and unstable angina pectoris), *MACE* major adverse cardiac events (composite endpoint of cardiac death, myocardial infarction and target lesion revascularization), *MLD* minimal lumen diameter, *RVD* reference vessel diameter (pre-procedural), *Underexpansion* (PostMLD/ nominal device diameter) < 0.7

Table 7 Univariate analysis of probable/ definite ST

	Hazard Ratio (95% confidence interval)	P value
Age > 65 years	4.49 (0.47 – 43.15)	0.19
Long lesion (>20mm)	3.55 (0.37 – 34.13)	0.27
Calcified lesion	3.55 (0.37 – 34.13)	0.27
Long lesion (>32mm)	3.42 (0.48 – 24.26)	0.22
RVD ≤ 2.5mm	3.26 (0.34 – 31.34)	0.31
Bifurcation lesion	2.72 (0.38 – 19.31)	0.32
Overlap	2.20 (0.30 – 15.92)	0.44
Underexpansion	2.19 (0.31 – 15.53)	0.43
> 2 scaffolds/ lesion	1.74 (0.21 – 14.70)	0.61
Diabetes Mellitus	1.52 (0.16 – 14.64)	0.72
Presentation with ACS	0.70 (0.10 – 4.96)	0.72

ACS acute coronary syndrome (NSTEMI and unstable angina pectoris), *MLD* minimal lumen diameter, *RVD* reference vessel diameter (pre-procedural), *ST* scaffold thrombosis, Underexpansion: (PostMLD/ nominal device diameter) < 0.7

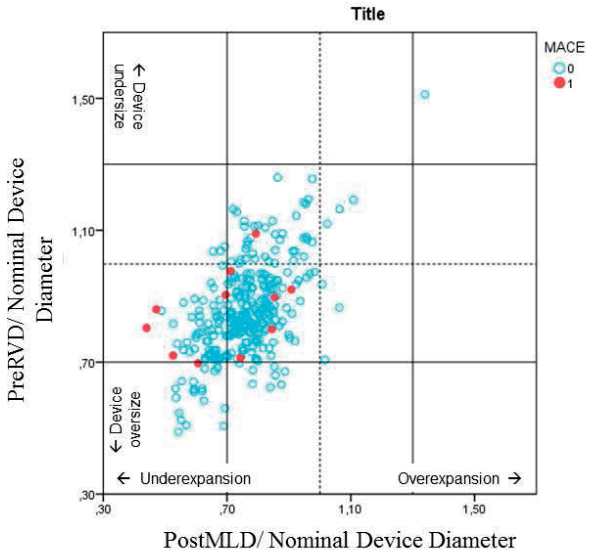

Figure 4 Relation of BVS underexpansion and MACE
BVS = bioresorbable vascular scaffold; MACE = major adverse cardiac events; MLD = minimal lumen diameter; RVD = reference vessel diameter.

DISCUSSION

To the best of our knowledge this is the first registry reporting on the extended follow-up beyond one year, with a median follow-up duration of 622 days. The main findings of our study are that: 1) 12-month MACE incidence for the per-treatment group was 5.1%, mainly driven by rate of MI (approximately 70% due to target vessel MI), with a further flattening of Kaplan-Meier after one year (6.8% at 18 months); 2) the rate of definite/probable ST at one year was 1.7% which is higher compared to second generation metal DES; [12] 3) patients with acute coronary syndrome did not have increased risk of MACE and ST; and 4) underexpansion of the BVS was a rather frequent finding and there was a trend for an increased rate of MACE.

The BVS Expand registry describes the procedural and medium to long-term clinical outcomes of BVS in patients with native, de novo coronary artery disease. Other studies investigating clinical outcomes of BVS were often characterized by small sample size and inclusion of patients with non-complex lesions. In this single-center study we report event rates in a more complex lesions including long lesions (mean lesion length 22.10 ± 13.90 mm), calcified and bifurcated lesions, with a relatively high proportion of ACC/AHA type B2 or C lesions (38.1%). Furthermore and different from other registries [10], all events were adjudicated by an independent CEC and all angiograms were analysed using QCA, creating a complete QCA database. Finally, in the present registry there were limited angiographic exclusion criteria that allowed a study population that is more reflective of a 'real-world' population.

Taking into account the complexity of the treated lesions, the one-year MACE rate of 5.1% observed in the current registry is low and in line with previous trials using BVS in relatively simple lesions: 5% in the ABSORB II trial [7], 5.0% in the ASSURE BVS registry [9], 4.3% in the BVS Extend trial. [13] Recently, several European registries reported on the 6-month clinical outcomes after implantation of BVS in all-comer settings (Table 8). In our registry, 6-month MACE rate was 4.7% which is comparable to the other registries.

Recently, some concerns were raised regarding a potentially increased rate of ST after implantation of the Absorb BVS. [10, 14, 15] Stent thrombosis in the case of metallic DES is an entity with complex multifactorial pathomechanisms, something that probably applies to the case of BVS. [16] The importance of patient selection, lesion preparation, pre- and post-dilatation and the consideration of invasive imaging for optimal device deployment have to be emphasized [17, 18], while DAPT (dual antiplatelet therapy) continuation for at least one year is recommended. Pilot imaging observations in real-world patients with BVS thrombosis suggest suboptimal implantation with underexpansion, malapposition, and incomplete lesion coverage, often in combination with DAPT discontinuation to be the major substrate both for acute and late events. [19] Although it is not clear why this complication is observed in high incidence with BVS, a potential explanation could

Table 8 Overview BVS Registries

	ABSORB A	ABSORB B	ABSORB II	BVS EXTEND	ASSURE	ABSORB FIRST	AMC	Milan	GHOST-EU	Robaei et al.	Polish National Registry	BVS EXPAND
N	30	101	355	512	183	800	135	92	1189	100	591	249
Sites	4	9	46	56	6	95	1	2	10	2	30	1
Period	03/06-07/06	03/09-11/09	11/11-06/13	1/10-12/12	4/12-3/13	1/13-3/14	8/12-8/13	5/12-8/13	11/11-1/14	12/10-10/13	10/12-11/13	9/12-01/15
ACS	27%	-	20%	0%	21.3%	38%	48.8%	10.9%	47.4%	44%	52%	59.1%
Single vessel PCI	100%	99%	-	93%	-	90.7%	81.1%	-	-	85%	-	76.7%
Lesions/ patient	1.0	1.0	1.0	1.1	1.1	1.2	1.2	1.5	1.2	1.5	-	1.4
Lesion length	8.2 mm	9.7 mm	21.1mm	11.9 mm	15 mm	18.3 mm	-	36.5 mm	19.4 mm	20.9mm	-	22.1 mm
Calcification	-	-	13%	15%	15.7%	20.4%	11.3%	20.4%	-	-	-	45.8%
B2	40%	53.5%	44.0%	41%	43.4%	23.1%	42.1%	83.9%	23.6%	19%	-	24.3%
C	0.0%	5.9%	2.0%	2%	21.2%	23.6%	25.2%		27.6%	37%	-	13.8%
Baseline Imaging	100% (IVUS documentary)	100% (IVUS, documentary)	100% (IVUS documentary)	-	-	-	25.0%	-	28.2%	15.8%	-	39.0%
Device success	94%	100%?	99.0%	98.6%	-	98.9%	96.0%	-	99.7%	98.8%	100%	97.3%
TLR	3.4% at 5 years	5.0%	1%	1.8% at 1 year	2.8% at 1 year	-	5.0% at 6 months	3.3% at 6 months	2.5% at 6 months	0%	-	3.1% at 1 year
TVR	10.3.% at 5 years	-	2%	-	-	-	6.6% at 6 months	3.3% at 6 months	4.0% at 6 months	0%	-	3.1% at 1 year
Definite scaffold thrombosis	0% at 5 years	0%	0.6%	0.8% at 1 year	0% at 1 year	0.3% at 30 days	3.2% at 6 months	0% at 6 months	1.7% at 6 months	0% at 30 days	-	1.3% at 1 year
Acute Def ST	0%	0%	0.3%	0.0%	0%	-	0.0%	0%	1.2% (def/ prob ST)	0%	-	0%
Subacute Def ST	0%	0%	0.3%	0.4%	0%	-	2.4%	0%	1.2% (def/ prob ST)	0%	-	0%
Late Def ST	0%	0%	0%	0.4%	0%	-	0.8%	0%	0.5%	0%	-	1.3%
MACE	3.4% at 5 years	9.9% at 3 years	5.0% at 1 year	4.3% at 1 year	5% at 1 year	-	-	3.3% at 6 months	TLF: 4.4% at 6 months	4% at 30 days	-	5.3% at 1 year

ACS acute coronary syndrome, *BVS* bioresorbable vascular scaffold, *Def* definite, *IVUS* intravascular ultrasound, *MACE* major adverse cardiac events, PCI percutaneous coronary intervention, *Prob* probable, *ST* scaffold thrombosis, *TLF* target lesion failure, *TLR* target lesion revascularization, *TVR* target vessel revascularization

be the increased thickness of the BVS struts, which can cause convective flow patterns, potentially triggering platelet deposition and subsequent thrombosis, especially in settings with suboptimal flow conditions. [20] For this reason, BVS with thinner struts are currently being developed and animal studies are ongoing.

Rate of definite ST in the AMC registry was 3.0% at six months. [14] However, in the latter trial, STEMI patients were also included. The annual rate of definite/ probable ST in the GHOST-EU trial was 3.4% and 70% of the ST cases occurred in the first 30 days. In our study, there were three cases of definite ST (1.3%) within one year (table 5 and electronic supplements). In most of these cases, suboptimal implantation in complex lesions was the main finding, with also inadequate DAPT duration in one case. Notably and in contrast to the other registries, no cases of acute or subacute ST occurred. The lower rate of ST in the BVS Expand could presumably be due to the good procedural performance: usage of invasive imaging in almost 40% and pre-dilatation in 89%. Unlike the above-mentioned registries, STEMI patients were excluded in our study. The enrolled patients were all appropriately preloaded with P2Y12 inhibitors which could attribute to the absence of acute and subacute ST, whereas this is not always the case in STEMI patients.

In this study, the presence of with NSTEMI/ UA was not associated with an additional risk of MACE or ST. Theoretically, the lesions in patients with ACS are generally lipid-rich with or without thrombus which will not hinder the deployment nor the expansion of the BVS.

Our analysis shows that underexpansion of BVS occurs frequently and had a non-significant association with an increased risk of MACE and probable/definite ST. Compared to other BVS registries rate of post-dilatation in our study is somewhat low (53.3%) and this could partly explain the frequent occurrence of underexpansion. This low post-dilatation rate was an extension of the ABSORB-EXTEND and ABSORB II studies, where post-dilatation was discouraged as a reflex to a single case where strut fractures were observed due to severe undersizing and post-dilatation with an oversized balloon beyond the expansion limits of the scaffold. This is a different situation compared to underexpansion due to atherosclerotic disease where struts are still apposed but the initial lesions are difficult to dilate. It is now clear that for underexpansion high pressure post-dilatation do not result in strut fractures as long as non-compliant post-dilatation balloons are used within the maximum expansion limit of the implanted device.

Nevertheless, the arbitrary definition of underexpansion we used for this manuscript was partly based on QCA measurements, which are known to underestimate vessel dimensions when compared to invasive imaging methods like IVUS and OCT which is considered the standard at the moment [21, 22]. The difference for IVUS might be even larger compared to OCT, with an underestimation of approximately of QCA of 0.2 mm vs OCT and 0.3 mm vs IVUS. Use of intravascular imaging might improve pre-procedural

vessel sizing, whereas a more liberal use of post-dilatation has to be underlined, with the aim of minimizing BVS underexpansion and, eventually, improving the clinical outcome.

LIMITATIONS

This is a single-center, single-arm registry with no direct comparison with metallic DES. The total number of patients in this study was limited. Thus, these findings warrant further confirmation in a large-scale trial. Ongoing and upcoming trials such as the ABSORB III, IV and the Compare Absorb will provide data derived from larger patient cohorts and in direct comparison to metallic DES.

Furthermore, deciding which patient or lesion was suitable for BVS implantation could have led to selection bias. Almost 80% of the patients returned their study informed consent and thus follow-up is only investigated in these patients. The event rate is unknown in the remaining patients.

CONCLUSION

In our study, BVS implantation in a more complex patient and lesion subset was associated with an acceptable rate of adverse events at the longer term, comparable to rates reported with contemporary second generation metallic drug-eluting stents, while no cases of early thrombosis were observed. This study supports a more extensive use of BVS and launch of randomized trials aiming to demonstrate superiority in the longer term, when optimal implantation strategies are used.

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SUPPLEMENT – NARRATIVES OF CASES WITH ST

Case 1. Neointima hyperplasia and recurrent failure

A 59 year old male patient with a history of CVA and stable angina visited the outpatient clinic. His ECG revealed new T-top inversions. Subsequently, angiography was performed which revealed one vessel disease with narrowing of the proximal LAD (AHA/ACC classification type C lesion) at the origin of the first diagonal (Medina 1,1,0) and a diffusely diseased 2nd ramus marginalis. One BVS (3.5x28mm) was placed with a good results for the main branch without impact on the side branch. 112 days after in the index PCI the patient developed a NSTEMI due to a definite ST. Angiography with additional OCT showed mild scaffold underexpansion (3mm in diameter) with severe neointima development but also areas with late malapposition due to potential vasodilatation and thrombus resorption. Treatment consisted of thrombectomy, eptifibatide and a 3.5x32mm DES (Promus). He was using DAPT (clopidogrel and aspirin) at the time of the event. The patient returned almost 4 months later with unstable angina. There was a severe ISR on angiography (DES failure) with total occlusion and collaterals suggesting resistance to everolimus. It was decided to perform a semi-urgent CABG, which took place four days later.

Case 2. Residual thrombus after BVS implantation

This 69 year old male patient with risk factors of dyslipidaemia and hypertension presented with a NSTEMI. Angiography showed one-vessel disease with narrowing of the proximal and mid LAD (AHA/ACC classification type C lesion). Three BVS (3.0x28mm, 3.5x18mm, 3.5x18mm) were implanted. After implantation, there was pinching and thrombus in the 1st diagonal for which fenestration with a 2.0 mm balloon followed by proximal optimization was performed. Invasive imaging post-procedure revealed organized thrombus behind the struts of the proximal scaffold and thrombus protrusion at the overlapping scaffolds. After 47 days the patient presented with a non-Q wave MI due to a definite ST in the proximal LAD. OCT at the time of the event revealed areas of late malapposition and massive thrombosis. He was treated with thrombectomy, eptifibatide and PCI with a 3.5x38mm DES (Xience) with good angiographic result. The patient was using DAPT (clopidogrel and aspirin). The diagnostic angiography made 110 days later displayed good scaffold and stent apposition on OCT with good coverage of the struts of the new DES.

Case 3. Cardiac death and possible ST

A 76 year old male patient with cardiac risk factors of smoking, diabetes and hypertension, developed angina and dyspnea 66 days after the baseline procedure (one