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Long-term outcome of first 300 implanted Absorb bioresorbable vascular scaffolds in an all-comers Middle East population

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Abstract

Objectives: To evaluate long-term clinical outcomes of the Absorb bioresorbable vascular scaffold (BVS) system (Abbott Vascular) in an all-comers Middle East population.

Methods: This prospective registry study included an initial set of patients with coronary lesions treated using Absorb BVS. Patients were followed for target vessel failure (TVF) including cardiac death, target vessel myocardial infarction (MI), and target lesion revascularization.

Results: A total of 217 patients (age, 55 ± 11 years; male, 169) with 300 treated lesions were included (median follow-up, 36 months [range, 26–41 months]; complete follow-up, 201 patients). Diabetes mellitus and acute coronary syndrome were present in 50% and 57% of patients, respectively. TVF rate was 32/201 (15.9%), including cardiac death in 10 (5%), target vessel MI in 13 (6.5%), and target lesion revascularization in 22 patients (10.9%). Definite or probable device thrombosis occurred in 11/201 patients (5.5%). TVF was associated with heart failure, worse ejection fraction, multi-vessel BVS, multi BVS in lesion, and total BVS length >50 mm.

Conclusions: Long-term outcome following Absorb BVS implantation in a population with high prevalence of high-risk and complex patients is acceptable, but heart failure, worse ejection fraction, and multi-vessel or long BVS implantation were associated with worse outcomes.

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Introduction

Bioresorbable vascular scaffolds (BVS) are designed to overcome the long-term limitations of metallic drug-eluting stents (DES) that primarily include late coronary events, such as restenosis, thrombosis, and neoatherosclerosis triggered by permanent caging.[1–4] The transient nature of the Absorb BVS (Abbott Vascular; Santa Clara, CA, USA) may provide significant long-term benefits by reducing the potential for late inflammation and thrombosis, as well as technical and practical patient-oriented benefits including no jailing of the side branch, no strut overhang at ostial lesions, no inability for subsequent grafting of coronary lesions, and no artefacts on computed tomography (CT).[2–5] In fact, the five-year clinical, multislice CT angiographic, and functional outcomes from the first-in-human ABSORB Cohort A trial demonstrated a low rate of major adverse cardiac events (MACE) without any scaffold thrombosis,[3] and opened the stage for a series of randomized trials and registries.

Initial one-year follow-up clinical data in randomized studies,[6–9] registries,[10] and pooled meta-analysis,[11] showed that the safety and efficacy of Absorb BVS is similar to best in class DES.[6–10] The results were sustained after 2 years,[12] but 3-year data from the ABSORB II cohort[13] raised questions regarding the long-term safety of Absorb BVS due to a higher rate of device-related thrombosis compared with DES. The Amsterdam Investigator-initiateD Absorb Strategy All-comers (AIDA) trial[14] also showed that 2-year cumulative event rates were similar between Absorb BVS and everolimus-eluting metallic stents, but BVS was associated with a higher incidence of device thrombosis than metallic stents, leading to earlier study termination. Therefore, the regulatory medical bodies[15] raised questions regarding the long-term safety of BVS, and limited the wider application of this promising technology.

Bearing in mind the relatively long dissolution profile of Absorb BVS and the scarcity of long-term outcome data, it seems prudent and beneficial to the future evolution of this technology to evaluate and analyse clinical outcomes in different centres with different patient populations. The experience, performance and clinical outcomes associated with Absorb BVS have not been evaluated in a specific middle East population with high prevalence of high-risk characteristics. Thus, the aim of the present registry study was to analyse the efficacy, safety and long-term clinical outcomes in an initial series of Absorb BVS implantations in an all-comers Middle East patient population in a single high-volume percutaneous coronary intervention (PCI) centre.

Patients and methods

Study population

This investigator-initiated prospective registry study evaluated the performance, safety and clinical outcome of Absorb BVS (Abbott Vascular) in treating an initial series of coronary lesions in an all-comers

Middle East patient population. Patients were enrolled between 19 March 2012 and 10 April 2014, and were derived from an all-comers patient population referred to the PCI centre, Cardiology Department, Al Qassimi Hospital, Sharjah, UAE, and who satisfied the eligibility criteria for implantation of Absorb BVS. Patients were eligible for the register if they were ≥18 years old with evidence of myocardial ischaemia, including stable angina, acute coronary syndrome, silent ischaemia or evidence of myocardial ischaemia on non-invasive testing. Patients with severe haemodynamic compromise including cardiogenic shock and/or severe congestive heart failure, limited life expectancy, and patients who could not adhere to prolonged dual antiplatelet therapy (DAPT) were excluded. All patients admitted for PCI were considered for participation in the registry, but the decision to implant Absorb BVS was left to the discretion of the operating physician performing standard PCI, and trained for Absorb BVS implantation.

Absorb BVS implantation

The Absorb BVS system (Abbott Vascular) is a bioresorbable composite comprising a poly L-lactide polymer scaffold with an everolimus drug and bioresorbable poly D, L-lactide polymer coating.[2,3] Lesion/vessel evaluation was based on physician's angiography-guided visual assessment, and scaffold size was selected according to commercially available devices consistent with reference diameter. As a general strategy, vessel pre-dilatation was performed with a balloon that was 0.5 mm less than, or equal to, the scaffold device diameter. The scaffold was deployed with a slow increase of 2 atm every 5 s until completely expanded. Scaffold optimization was recommended, including post-dilatation with a non-compliant balloon equal to, or 0.5 mm bigger than, the scaffold size. Patients received DAPT for ≥12 months following the implant procedure. Additional intraoperative optical coherence tomography (OCT) (OPTIS system; Abbott, St. Paul, MN, USA) or intravascular ultrasound (IVUS) imaging (Boston Scientific, Marlborough, MA, USA) were recommended, but was performed during the procedure at the discretion of the operating physician. In the absence of intracoronary imaging by IVUS or OCT, adequate sizing for Absorb BVS implantation was obtained according to the reference diameter of the proximal and distal segment next to the lesion (range, 2.5–4.0 mm) following pre-dilatation and a 200 µg intracoronary bolus of nitroglycerine. The available scaffold lengths were 12, 18 and 28 mm, with scaffold diameters of 2.5, 3.0 and 3.5 mm. The study protocol defined no limits regarding Absorb BVS implantation in terms of lesion length, number of target lesions, or number of vessels treated. In patients with numerous lesions, there were no limitations on concomitant implantation of metallic second-generation DES (various models) if the operating physician considered the lesion not suitable for Absorb BVS implantation.

All patients who underwent a PCI procedure provided written informed consent prior to the procedure, according to hospital policy. The registry was reviewed and approved by the Al Qassimi Hospital Ethics Committee.

Data collection, clinical follow-up and adverse events

Baseline clinical characteristics were prospectively collected. Procedural data were obtained from catheterization laboratory records including all relevant information during the PCI. Pre- and post-procedural angiographic characteristics were analysed off-line by quantitative coronary angiography (QCA) using Cardiovascular

Angiography Analysis System (CAAS) software, version 5.11.2, 2013 (Pie Medical Imaging, Maastricht, The Netherlands) by an independent core laboratory (KCRI, Krakow, Poland) that was blinded to the patients' clinical or other procedural characteristics. QCA data included reference diameter in the lesion, reference diameter of the proximal and distal segment, minimal luminal diameter, percent diameter stenosis, length of the lesion before and after scaffold implantation, and acute gain (defined as the difference between pre-procedural minimal luminal diameter and post-procedural minimal luminal diameter within the scaffold). Qualitative angiographic characteristics included qualitative lesion assessment (according to the modified joint American college of cardiology/American heart association [ACC/AHA] stenosis morphology classification: A, B1, B2, or C), tortuosity (none, moderate, severe), angulation (<45, 45–90, >90), calcification (none, moderate, severe), presence of thrombus, ostial lesions (origin of the coronary vessel from aorta), and bifurcations (Medina classification). Semi-quantitative analyses included Thrombolysis In Myocardial Infarction (TIMI) flow grade and quantitative corrected TIMI frame count (cTFC) flow before and after the procedure.

Clinical follow-up was obtained by telephone contact, and/or from national health-care system medical records if telephone contact was not available. Reported clinical events were checked by medical records and verified by an interventional cardiologist unrelated to the PCI procedure, following criteria for adverse clinical events defined in the study protocol. There was no systematic or planned repeated angiography for this registry; thus, all repeated angiograms were clinically-driven and performed only in cases of symptoms and signs of myocardial ischaemia.

Angiographic success was defined as <30% residual diameter stenosis by QCA with TIMI grade 3 flow in the treated target vessel. Procedural success was defined as angiographic success in the absence of in-hospital death, MI, or revascularization. Target vessel failure (TVF) was defined as a composite of cardiac mortality, target vessel MI, and target lesion revascularization. In addition, all deaths were considered to be cardiac-related unless an unequivocal non-cardiac cause was established. Target lesion revascularization was defined as any revascularization within 5 mm of the scaffold. Revascularization was defined as ischaemia-driven consistent with positive functional testing in the territory served by target vessel, electrocardiogram changes at rest corresponding to the target vessel territory, typical ischaemic symptoms referable to the target vessel, and/or fractional flow reserve of the target vessel ≤ 0.80. MI was defined according to the latest MI definition,[16] and stent (scaffold) thrombosis according to Academic Research Consortium criteria.[17]

Statistical analyses

Quantitative variables are presented as mean value $\pm$ SD, or median (interquartile range). Dichotomous variables are presented as *n* (%) prevalence or incidence. Univariate analyses were used to evaluate the relationship between clinical outcome in the follow-up period and various clinical, procedural and angiographic variables. To select covariates independently associated with the outcome (TVF, cardiac-related death, target vessel MI, target lesion revascularization, and scaffold thrombosis), statistically significant univariable predictors were reassessed by multivariable logistic regression analysis, with values for inclusion and elimination set at $P < 0.05$. Variables entered into the model included all clinical, procedural, and quantitative, semi-quantitative, and qualitative angiographic data. Cumulative event rates were based on Kaplan-Meier estimates in time-to-event

analysis. Follow-up of the patients were censored on the last day of contact or available medical record in case of patients' unavailability. Data were analysed using SPSS software, version 19.0 (IBM, New York, USA) and a P value <0.05 was considered statistically significant.

Results

Clinical and angiographic characteristics

Baseline clinical and angiographic characteristics are presented in Table 1. The register included 217 patients (mean age 55 ± 11 years; 169 male and 48 female patients) with 300 lesions treated using Absorb BVS between March 2012 and April 2014. For the same time period, a total of 2128 PCI procedures were performed, thus, Absorb BVS implantation represented 10% of all performed PCI procedures, with the individual Absorb BVS implantation rate being as high as 35% for the main operating physician (AN). Diabetes mellitus was present in 50% of patients, whereas hypertension, hyperlipidaemia and current smoking history were present in 66%, 66%, and 34% of patients, respectively. Acute coronary syndrome was present in 124 (57%) patients, including 61 (28%) with ST-segment elevation MI (STEMI). Previous PCI was performed in 51 (24%) patients, and previous MI was present in 47 (22%) patients. Coronary artery disease (CAD) severity was equally distributed between one-, two-, and three-vessel disease. Lesion characteristics are summarised in Table 2. Complex B2/C lesion type was present in 88% of lesions, and bifurcations were present in 34% of lesions.

Table 1. Baseline clinical characteristics in an all-comers Middle East patient population treated with the Absorb bioresorbable vascular scaffold system by Abbott Vascular.

Characteristic	Study population $n = 217$
Age (years)	55 ± 11
Sex (male/female)	169 (78%)/ 48 (22%)
Smoking history	
Non-smoker	129 (59%)
Former smoker	15 (7%)
Current smoker	73 (34%)
Hyperlipidaemia	144 (66%)
Hypertension	143 (66%)
Diabetes mellitus	108 (50 %)
Diabetes treatment	
Diet only	2 (2%)
Oral hypoglycaemics	70 (65%)
Insulin	36 (33%)
Heart failure	34 (16%)
Chronic renal failure	20 (9%)
Previous myocardial infarction	47 (22%)
Left ventricular ejection fraction (%)	50 ± 12
Previous PCI	51 (24%)
Previous CABG	4 (2%)
Peripheral vascular disease	11 (5%)
Atrial fibrillation	5 (2%)
Stable angina/positive stress test	93 (43%)
Acute coronary syndrome	
STEMI	61 (28%)
non-STEMI	22 (10%)
Unstable angina	41 (19%)
CAD burden	
One-vessel CAD	73 (33.6%)
Two-vessel CAD	71 (32.7%)
Three-vessel CAD	73 (33.6%)

Data presented as mean $\pm$ SD or n (%) prevalence.
PCI, percutaneous coronary intervention; CABG, coronary artery bypass graft; STEMI, ST-segment elevation myocardial infarction; CAD, coronary artery disease.

Procedural data and quantitative coronary angiography

Pre- and post-implantation procedure characteristics and QCA data are presented in Tables 3 and 4. Pre-dilatation was performed in 85% of the lesions. Thrombus aspiration was performed in 33% of patients with STEMI, reflecting the current

Table 2. Baseline angiographic characteristics in an all-comers Middle East patient population treated with the Absorb bioresorbable vascular scaffold system by Abbott Vascular.

Lesion characteristic	Number of lesions $n = 300$
Treated vessel	
LAD	149 (49.7%)
CX/OM	65 (21.7%)
RCA	74 (24.7%)
LM	3 (1%)
Diagonal branch/ ramus intermedius	9 (3%)
Lesion type	
A	9 (3%)
B1	28 (9%)
B2	134 (45%)
C	129 (43%)
Bifurcation	93/275 (34%)
Ostial	29/292 (10%)
Tortuosity (moderate and severe)	60/287 (21%)
Angulation (>45)	50/271 (18%)
Calcification (moderate and severe)	47/280 (17%)
IVUS and/or OCT	174 (58%)

Data presented as *n* (%) prevalence.
LAD, left anterior descending coronary artery; CX, circumflex coronary artery; OM, obtuse marginal branch; RCA, right coronary artery; LM, left main coronary artery; IVUS, intravascular ultrasound; OCT, optical coherence tomography.

Table 3. Pre- and post-procedural characteristics in an all-comers Middle East patient population treated with the Absorb bioresorbable vascular scaffold system by Abbott Vascular.

Procedural characteristic	Lesions $n = 300$
Thrombus aspiration in STEMI	20/61 (33%)
Pre-dilatation	255 (85%)
Pre-dilatation balloon size (mm)	2.8 ± 0.4
Pre-dilatation balloon length (mm)	16.4 ± 5.3
Pre-dilatation balloon pressure (Atm)	13.8 ± 3.6
Cutting balloon	3 (1%)
Rotablation	2 (1%)
Multi-vessel BVS, proportion of patients	62/217 (29%)
Absorb BVS diameter (mm)	3.1 ± 0.9
Absorb BVS length (mm)	23.2 ± 5.5
Absorb BVS implantation pressure (Atm)	13.0 ± 2.7
Post-dilatation	241 (80%)
Post-dilatation balloon size (mm)	3.3 ± 0.5
Post-dilatation balloon pressure (Atm)	16.3 ± 3.7
Acute gain (mm)	1.51 ± 0.8
PSP implantation technique	223 (74%)
Angiographic success	274 (91%)
Procedural success	271 (90%)

Data presented as *n* (%) prevalence or mean ± SD.
STEMI, ST-segment elevation myocardial infarction; BVS, bioresorbable vascular scaffold; PSP, defined as pre-dilatation, adequate sizing, and post-dilatation.

practice of primary PCI. A total of 404 Absorb BVS were implanted, comprising multi-vessel Absorb BVS implantation in 29% of patients, 1.3 Absorb BVS implants per lesion and 1.9 Absorb BVS implants per patient. The maximum number of implanted BVS was eight in two patients. Post-dilatation was performed in 80% of lesions. Final residual dissection was detected in 11 lesions (4%), and in two patients treated with additional stenting. Thus, pre- and post-dilatation with adequate sizing was performed in 74% of lesions. Finally, angiographic success, accounting for final diameter stenosis and TIMI flow grade, was obtained in 91% of patients, whereas procedural success was attained in 90%, as three patients experienced intra-hospital complications (including puncture site bleeding with contrast-induced nephropathy, and two patients with acute and subacute stent thrombosis). In patients without STEMI, angiographic and procedural success was

Table 4. Pre- and post-procedural quantitative coronary angiography data in an all-comers Middle East patient population treated with the Absorb bioresorbable vascular scaffold system by Abbott Vascular.

	Lesions, $n = 300$	
Parameter	Pre-procedure	Post procedure
RD in lesion (mm)	2.8 ± 0.5	2.8 ± 0.5
RD in proximal segment (mm)	3.2 ± 0.6	3.1 ± 0.4
RD in distal segment (mm)	2.6 ± 0.6	2.5 ± 0.5
Minimal luminal diameter (mm)	0.9 ± 0.6	2.4 ± 0.5
Diameter stenosis (%)	66.6 ± 19.4	10.8 ± 8.6
Length (mm)	22.6 ± 15.2	29.4 ± 15.7
TIMI flow grade 3 (%)	212 (71%)	281 (94%)
TFC	36.4 ± 30.7	18.6 ± 14.3
cTFC	31.8 ± 31.1	15.6 ± 14.1

Data presented as mean ± SD or *n* (%) prevalence.
RD, reference diameter; TIMI, Thrombolysis In Myocardial Infarction; TFC, TIMI frame count; cTFC, corrected TIMI frame count.

attained in 93% and 92% of patients, respectively.

Clinical outcome

Median follow-up was 36 months (interquartile range, 26–41 months), and complete follow-up was obtained in 201/217 patients (93%). Representative angiography and OCT images obtained immediately following Absorb BVS implantation, and at 2 and 5 years following implantation are shown in Figure 1 a–c, and demonstrate complete disappearance of scaffold struts and filling defects over 5 years. Analysis of clinical outcome data for the study cohort (Table 5) showed that TVF rate was 32/201 (15.9%), including cardiac-related death in 10 (5%), target vessel myocardial infarction in 13 (6.5%), and target lesion revascularization in 22 (10.9%) patients (including 1 patient with coronary artery bypass graft). Cumulative MACE rate, including TVF (cardiac-related death, target vessel myocardial infarction, target lesion revascularization), non-cardiac death and non-target lesion revascularization was present in 49/201 patients (24.4%).

Initial univariate analyses revealed that variables associated with TVF were heart failure ($P = 0.011$), worse ejection fraction ($P = 0.027$), multi-vessel BVS ($P = 0.018$), multi-BVS in the lesion ($P = 0.008$), and total BVS length >50 mm ($P = 0.010$). In subsequent multivariable regression analysis, only multi-vessel BVS remained significantly associated with TVF ($P = 0.032$; Table 6). Event-free survival for TVF was found to be 84.1% (Figure 2).

Definite or probable BVS thrombosis occurred in 11 (5.5%) patients. Possible BVS thrombosis occurred in two patients, thus, BVS thrombosis events occurred in a total of 13 patients (6.5%). The timing of BVS thrombosis was acute in one patient; subacute in five patients; late in four patients; and very late in three patients. Very late thrombosis occurred between 12 and 15 months in all three patients and no device thrombosis was observed beyond this time period. No statistically significant interaction was observed regarding BVS thrombosis and

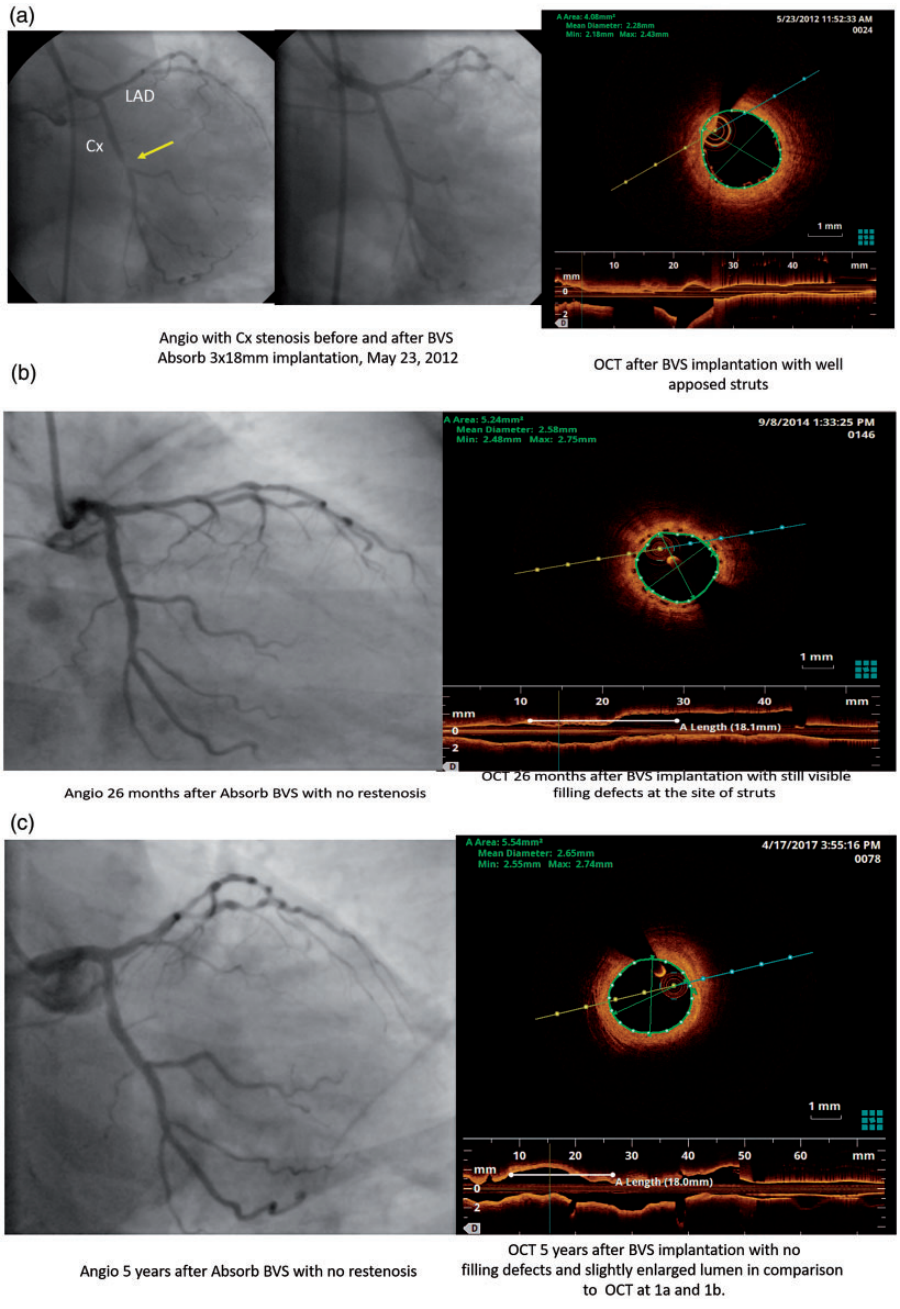

Figure 1. Representative angiography and optical coherence tomography (OCT) images from a patient treated with the Absorb bioresorbable vascular scaffold (BVS) system by Abbott Vascular, obtained: (a) immediately following implantation; (b) at 26 months following implantation; and (c) at 5 years following implantation; Cx, circumflex coronary artery; LAD, left anterior descending coronary artery.

Table 5. Clinical outcome data in an all-comers Middle East patient population treated with the Absorb bioresorbable vascular scaffold system by Abbott Vascular.

Outcome	Patients with complete follow-up records $n = 201$
Target vessel failure	32 (15.9%)
MACE	49 (24.4%)
All-cause mortality	15 (7.5%)
Cardiac mortality	10 (5.0%)
Target vessel myocardial infarction	13 (6.5%)
Target lesion revascularization	22 (10.9%)
Non-target lesion revascularization	18 (9.0%)
CABG	1 (0.5%)
TIA/Stroke	3 (1.5%)
Device thrombosis	13 (6.5%)
Acute and early scaffold thrombosis	6 (3.0%)
Late scaffold thrombosis	4 (2.0%)
Very late scaffold thrombosis	3 (1.5%)
Patients on DAPT after 1 year	111 (55.2%)

Data presented as *n* (%) prevalence.
MACE, major adverse cardiac events; CABG, coronary artery bypass graft; TIA, transient ischaemic attack; DAPT, dual antiplatelet therapy.

age, cardiovascular risk factors, lesion or procedural characteristics. A total of 55% of patients received DAPT beyond 1 year. Univariate predictors of BVS thrombosis were heart failure ($P = 0.001$), worse ejection fraction ($P = 0.032$), and procedural success of the intervention in terms of angiography and TIMI flow grade ($P = 0.047$). Event-free survival for BVS thrombosis was 93.5% (Figure 3).

One or more than one DES were implanted in 19% and 9% of patients, respectively. No interaction was observed between concomitant DES implantation and TVF (Absorb BVS only, 15.4% versus Absorb BVS plus DES, 13.1%, $P = 0.555$), or between DES implantation and device thrombosis (Absorb BVS only, 7.1% versus Absorb BVS plus DES, 3.3%, $P = 0.253$).

Discussion

To the best of the authors' knowledge, this is the first long-term Absorb BVS registry to present efficacy, safety and long-term outcome of Absorb BVS in a real-world all-comers specific group of Middle East patients with a significant prevalence of high risk and complex patients. Considering the complexity of the patient group, Absorb BVS demonstrated acceptable efficacy and safety, with the rate of TVF comparable to other studies.[12–14,18] The rate and timing of scaffold (BVS) thrombosis was also similar to previously reported rates.[19,20] Predictors of TVF and BVS thrombosis were associated primarily with complexity of the patients and lesions, including patients with heart failure, worse ejection fraction, and extensive CAD that required multi-vessel and multi-lesion long scaffolding.

The initial experience[21–24] with Absorb BVS has generally demonstrated good procedural safety and angiographic success, as well as short to mid-term clinical outcome and safety. After two years following implantation, however, the AIDA trial[14] showed higher definite and probable BVS thrombosis compared with DES, which was associated with more MI events, but no significant difference was observed in TVF, or death and revascularization.[14] In addition, the recently reported ABSORB II with 3-year follow-up[13] found significantly worse outcomes regarding device-oriented composite endpoints for Absorb BVS compared with Xience DES (10% versus 5%). Interestingly, neither angina status nor coronary functional vasomotion appeared to be superior in patients with Absorb BVS compared with metallic stents.[13] These findings led to an FDA safety alert,[15] followed by an announcement from Abbot Vascular

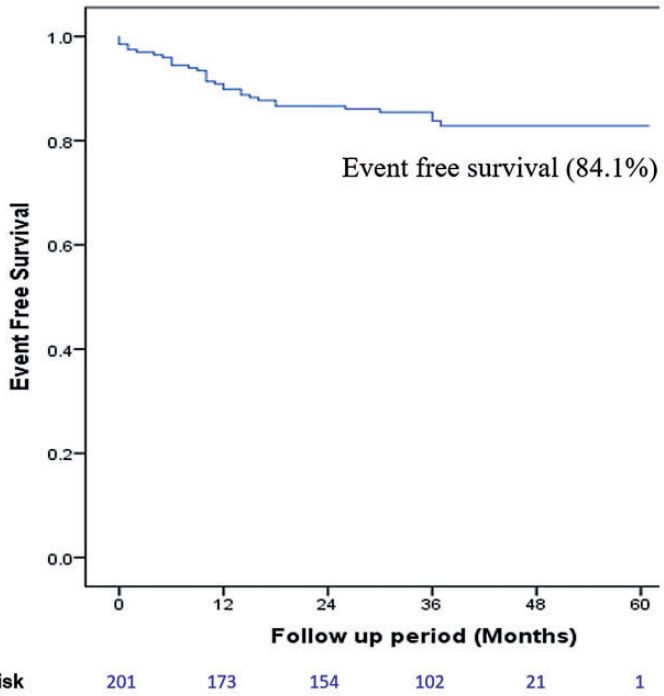

Figure 2. Kaplan-Meier curve showing event free survival for target vessel failure in an all-comers Middle East patient population ($n = 217$) treated with the Absorb bioresorbable vascular scaffold system by Abbott Vascular.

regarding discontinuation of normal sales, and national society warnings to prolong the duration of DAPT.[25] Generally, the indications for Absorb BVS have been significantly downgraded, limited to registries providing an upgraded implementation protocol, and prolonged DAPT.

The rate of device thrombosis, particularly late and very late scaffold thrombosis,[20] that became obvious in the reported randomized trials and case series,[26,27] remains a major concern. In a meta-analysis of 5 583 patients from seven randomized trials,[28] higher rates of device-related adverse events, together with significantly higher rates of definite and probable device thrombosis were observed in BVS compared with Xience. Reasons for increased rates of late and very late scaffold thrombosis are multifactorial, are not well understood and are speculated, but they include suboptimal implementation techniques[19] that may account for incomplete BVS expansion, heterogeneous endothelisation of disintegrated scaffold struts with incomplete integration into the vessel wall and/or protrusion of scaffold struts that may trigger thrombosis, as well as prolonged resorption with vascular inflammation. However, it is interesting to note that in the present patient group, the vast majority of device thromboses occurred during the first year, few in the second year, and no device thrombosis was observed beyond the second year following implantation.

Regarding the procedure per se, it is becoming obvious that Absorb BVS requires more time and a specific implantation

Table 6. Univariate and multivariate regression analysis of TVF in an all-comers Middle East patient population treated with the Absorb bioresorbable vascular scaffold system by Abbott Vascular.

	Study group		Statistical significance		
Variable	TVF ($n = 32$)	No TVF ($n = 169$)	Univariate analysis	Multivariable analysis OR (95% CI)	
Age, years	55.3 ± 11.9	55.5 ± 11.2	NS	–	
Sex, male	26 (81.3%)	128 (75.7%)	NS	–	
Hyperlipidaemia	23 (71.9%)	109 (64.5%)	NS	–	
Hypertension	25 (78.1%)	107 (63.3%)	NS	–	
Diabetes mellitus	19 (59.4%)	80 (47.3%)	NS	–	
Current smoker	10 (31.3%)	55 (32.5%)	NS	–	
Heart failure	9 (28.1%)	19 (11.2%)	$P = 0.011$	NS	0.786 (0.157, 3.927)
Chronic renal failure	4 (12.5%)	16 (9.5%)	NS	–	
Left ventricular EF (%)	46.5 ± 12.8	51.4 ± 10.8	$P = 0.027$	NS	0.029 (0, 8.487)
Acute coronary syndrome	16 (50.0%)	98 (58.0%)	NS		
Pre-dilatation	31 (96.9%)	151 (89.3%)	NS	–	
Multi-vessel BVS	15 (16.9%)	44 (26%)	$P = 0.018$	$P = 0.032$	2.646 (1.089, 6.428)
Multi BVS in lesion	17 (53.1%)	49 (29%)	$P = 0.008$	NS	0.428 (0.161, 1.136)
Total length of BVS >50mm	9 (29%)	19 (11.4%)	$P = 0.010$	NS	0.611 (0.192, 1.939)
Absorb BVS = 2.5mm	4 (12.5%)	40 (23.7%)	NS	–	
Post-dilatation	28 (87.5%)	131 (77.5%)	NS	–	
Bifurcation	10 (31.2%)	48 (28.4%)	NS	–	
Use of IVUS and/or OCT	23 (71.9%)	94 (55.6%)	NS	–	

Data presented as mean ± SD or *n* (%) prevalence.
TVF, total vessel failure; EF, ejection fraction; BVS, bioresorbable vascular scaffold; IVUS, intravascular ultrasound; OCT, optical coherence tomography; OR, Odds ratio; CI, confidence interval.
NS, no statistically significant association ($P > 0.05$).

technique that includes aggressive pre-dilatation and post-dilatation, with unlimited application of intracoronary imaging. When implanted in such an optimal way, Tanaka et al.[29] showed that cumulative target-lesion failure and safety becomes comparable to metallic stents (target-lesion failure after 1 and 2 years, 7.9%, and 11.6%, respectively, with definite/scaffold thrombosis of 1.2% at 1 and 2 years). In addition, a study of 1 232 patients from three study cohorts (ABSORB Cohort B, ABSORB EXTEND and ABSORB II)[30] showed that oversized scaffolds may be associated with worse outcome, whereas the ABSORB III trial[13] showed worse outcome in small vessels (<2.5 mm).

The practice of prolonging DAPT beyond one year following implantation varied between different studies, and was only 16% in the EVERBIO trial,[18] 36.2% in the ABSORB II trial,[12] and up to 50% in the ABSORB Japan study.[7] In the present study, more than 50% of patients were receiving DAPT after 1 years following PCI, which most probably reflects the complex and high-risk nature of the patients in the present registry, and might be also be associated with the acceptable clinical outcome.

Results from the present registry may be summarized within the context of a recent meta-analysis of seven randomized studies,[31,32] where all the present outcome data fits within the higher range of previously reported values. Clinical outcomes following BVS implantation in the current patient cohort should be considered in relation

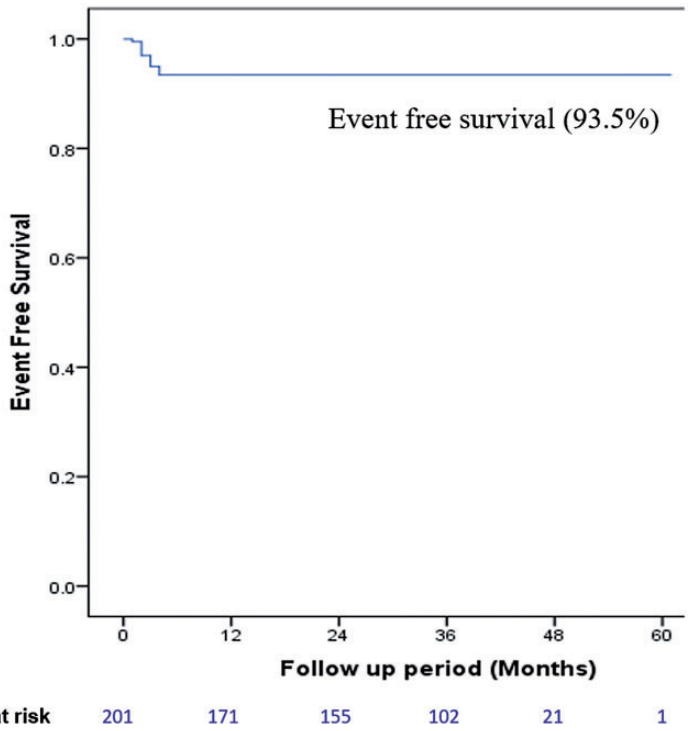

Figure 3. Kaplan-Meier curve showing event free survival for scaffold thrombosis in an all-comers Middle East patient population ($n = 217$) treated with the Absorb bioresorbable vascular scaffold system by Abbott Vascular.

to the high prevalence of patients with diabetes in this region, the complexity of lesions, and also adequate implementation technique and prolonged DAPT in a substantial number of patients. On the other hand, the higher rate of all-cause mortality and cardiac-related death may reflect the high-risk profile of the all-comers, real-world patients in the present study. In fact, TVF and cardiac-related death were associated with heart failure, worse left ventricular function, and multi-vessel BVS implantation. In addition, it is interesting to note that patients with diabetes were not associated with poorer clinical outcome.

The results of the present study are limited by the inherent nature of the registry, including the absence of comparison with the last generation of drug-eluting metallic stents. However, at this interim phase, data from real-world registries represent important input for further development of this promising BVS technology. The present results emphasize the importance of patient and lesion selection for BVS implantation, but by revealing the influence of patient complexity on clinical outcome, the study may mask the particular association between other co-variates and clinical outcome, as demonstrated in randomized studies with lower rates of complex patients. In addition, the outcome of this and other registries was directed to clinically-driven events with no systematic imaging. The rate of complete follow-up was relatively low in the present study, and it reflects the patient population

profile in high-volume interventional centres with a high proportion of mixed nationalities and races. Finally, in patients with the most serious outcome of sudden death, as well as scaffold thrombosis, the use of DAPT could not be proven with certainty on the basis of available medical records.

In conclusion, the results of the present registry study with a high prevalence of high-risk clinical and lesion features, are comparable to previous studies, and underline the potential for this developing and promising new device if properly indicated and implanted. Patients with heart failure, worse ejection fraction, multi-vessel BVS and longer multi-BVS in lesion implantation were associated with worse clinical outcomes and should be carefully addressed in future clinical trials.

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Declaration of conflicting interest

The authors declare that there is no conflict of interest.

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