AsiaIntervention 2017;3:147-155

Two-year outcomes of a bioresorbable everolimus-eluting scaffold using a strategy of meticulous lesion preparation and routine post-dilation: the Australian ESHC-BVS registry

Daniel Robaei[1,2,3], MBBS; Liam Back[1], MBBS; Elizabeth Russell[1,3], RN; Sze-Yuan Ooi[1,3], MD; Mark Pitney[1,2,3], MBBS; Nigel Jepson[1,3]*, MBBS

1. Eastern Heart Clinic, Prince of Wales Hospital, Sydney, Australia; 2. Sutherland Heart Clinic, Sutherland Hospital, Sydney, Australia; 3. University of New South Wales, Sydney, Australia

KEYWORDS

- bioresorbable scaffold
- drug-eluting stent
- percutaneous coronary intervention

Abstract

Aims: The Absorb bioresorbable vascular scaffold (BVS) was the first commercially available coronary stent to provide vessel scaffolding of a temporary nature following percutaneous coronary intervention. While results in clinical trials have varied, outcomes using a BVS-specific implantation strategy have not been well studied. We report two-year real-world data on the Absorb BVS implanted following meticulous lesion preparation and with a strategy of routine post-dilation.

Methods and results: Absorb BVS implantation was attempted in 152 lesions in 100 patients at two Sydney hospitals as part of the prospective ESHC-BVS registry. Lesions treated included complex lesions reflective of real-world practice with lesion length being >20 mm in 24%, and 16% featuring moderate/severe calcification. In total, type C lesions made up 37% of all lesions treated. A BVS-dedicated implantation strategy was utilised encompassing meticulous lesion preparation and routine post-dilation. Predilation was performed in 100% of lesions and post-dilation in 95% of scaffolds to a mean of 19.6±4.6 atm. Two-year clinical follow-up data were available for 99% of patients. At two years, the rate of all-cause mortality was 3% and cardiac death 1%. The cumulative incidence of target lesion revascularisation at two years was 4%, while the incidence of myocardial infarction was 2% and scaffold thrombosis 1%.

Conclusions: Using a strategy of meticulous lesion preparation and routine post-dilation, the Absorb BVS was associated with good clinical outcomes at long-term follow-up with low rates of target lesion revascularisation, myocardial infarction and scaffold thrombosis at two years. These findings support the dedicated scaffold implantation technique employed in this registry.

**Corresponding author: Eastern Heart Clinic, Prince of Wales Hospital, Level 3 Campus Centre Building, Barker Street, Randwick, NSW 2031, Australia. E-mail: nigel.jepson@ehc.com.au*

SUBMITTED ON 08/03/2017 - REVISION RECEIVED ON 1st 17/07/2017 / 2nd 24/07/2017 - ACCEPTED ON 25/09/2017

DOI: 10.4244/AIJ-D-17-00014

Introduction

Contemporary drug-eluting stents have significantly improved outcomes following balloon angioplasty through preventing acute vessel closure and vessel recoil as well as providing drug delivery capability to inhibit neointimal hyperplasia[1,2]. Bioresorbable scaffolds aim to provide these benefits while in the longer term avoiding the disadvantages associated with permanent metallic caging of the treated vessel. Such disadvantages may include preventing positive vessel remodelling, inhibiting physiological vasodilatation, acting as a persistent nidus for stent thrombosis, stent fracture and/or neoatherosclerosis, as well as hindering assessment of the stented segment with CT angiography[3,4].

The Absorb™ bioresorbable scaffold (Abbott Vascular, Santa Clara, CA, USA) was the first bioresorbable scaffold to be commercially available, with promising early results in clinical trials, including non-inferiority to current-generation drug-eluting stents in multiple large randomised controlled trials[5-8]. Longer-term follow-up and results in real-world registries have, however, varied, which has been postulated to be influenced by differences in implantation techniques[9-14].

The properties of bioresorbable scaffolds, including the Absorb device, are different to contemporary metallic stents and, given these unique properties, the optimal implantation technique is likely to vary from that used for metallic stents. While expert consensus has highlighted the importance of lesion preparation and post-dilation, this has not been adequately validated through clinical data[15]. The concerning findings of ABSORB II long-term follow-up may reflect early operator experience with the device and a failure to employ currently recommended implantation techniques[16].

We report two-year clinical outcomes from the real-world ESHC-BVS registry, where the Absorb bioresorbable scaffold was implanted using a dedicated strategy of meticulous lesion preparation and routine post-dilation.

Methods

The ESHC-BVS registry is a Human Ethics Research Committee-approved single-arm, prospective, open-label registry utilising the Absorb bioresorbable vascular scaffold (BVS) in real-world coronary disease in the setting of stable angina and acute coronary syndrome (ACS). The design of this registry has been described previously[17]. All patients in whom treatment with an Absorb BVS was attempted at our two institutions were enrolled, with written consent obtained for follow-up of clinical outcomes. Funding for the Absorb BVS used in the registry was sourced internally. The series reported includes the first 100 patients in the registry who underwent percutaneous coronary intervention (PCI) using the Absorb BVS between December 2010 and October 2013, with a total of 152 lesions treated. The final decision to implant an Absorb BVS was made by the treating interventionalist. Factors influencing the decision to implant an Absorb BVS included young patient age (<70 years), long lesion length (>28 mm) and treatment of the mid-left anterior descending artery, the potential future site of attachment of a left internal mammary graft. Contraindications to BVS implantation included in-stent restenotic lesions, extreme proximal vessel tortuosity, extreme calcification, residual stenosis >30% after lesion preparation, planned major surgery within six months, or high likelihood of inability to tolerate or comply with dual antiplatelet therapy. Patients who were participating in another trial were also excluded. A wide spectrum of lesions was treated with patient and lesion complexity being a reflection of real-world clinical practice.

PROCEDURES

All patients were pre-treated with aspirin in combination with a $P2Y_{12}$ inhibitor. Procedural anticoagulation was at the discretion of the interventionalist and included unfractionated heparin or bivalirudin, with optional use of tirofiban. A dedicated BVS implantation strategy was employed placing emphasis on the importance of meticulous lesion preparation and scaffold post-dilation. Predilation was mandatory and encompassed use of non-compliant balloons, cutting balloons, and rotational atherectomy where deemed necessary. Scaffold implantation did not proceed without visual confirmation of complete expansion of the predilation balloon at the lesion, without the presence of balloon indentation.

The process of scaffold deployment followed the manufacturer's guidelines in all cases, using two atmosphere pressure increases every five seconds. At least 2 mm of non-diseased vessel proximal and distal to the target lesion was covered. Intracoronary imaging with intravascular ultrasound (IVUS) or optical coherence tomography (OCT) was available in all cases and was performed at the discretion of the interventionalist, but was not considered mandatory. Twelve months of dual antiplatelet therapy with aspirin in combination with clopidogrel, prasugrel or ticagrelor was prescribed for all patients on discharge.

OUTCOMES

Outcome data were collected prospectively by researchers independent of the interventionalists performing the procedures. This occurred primarily through phone call follow-up and completion of a patient questionnaire at 30 days, 12 months and two years, as well as review of clinical notes and reporting by the treating cardiologist. Where required, data were verified through review of coronary angiograms, and hospital documentation. Post-procedure high-sensitivity troponin-T levels were measured routinely on day 1.

The following clinical endpoints were assessed: cardiac death, and scaffold thrombosis (definite/probable/possible) as defined by the Academic Research Consortium criteria[18], myocardial infarction as defined by the universal criteria[19], and the need for target and non-target lesion revascularisation. Target lesion revascularisation included any revascularisation within 5 mm of the proximal or distal ends of the scaffold. Major adverse cardiac events (MACE) comprised a composite of death, myocardial infarction, or target lesion revascularisation. Procedural success was defined as successful delivery and deployment of a BVS at the intended target lesion without any major adverse cardiac event within seven days of the procedure. All cases of periprocedural myocardial infarction were included in the tally of MACE.

Results

Baseline patient characteristics, lesion and procedural data are summarised in **Table 1** and **Table 2**. This series includes one hundred patients with 152 lesions treated with a total of 167 scaffolds.

Table 1. Baseline characteristics.

Baseline characteristics		
Patient characteristics		
Patients, n		100
Male, %		68
Age, years		62.1±12.4
Diabetes mellitus, %		19
Hyperlipidaemia, %		71
Hypertension, %		74
Current smoker, %		13
Ex-smoker, %		32
Previous MI, %		15
Prior revascularisation, %		31
PCI, %		26
CABG, %		10
Clinical presentation		
Stable angina, %		56
NSTE-ACS, %		40
STE-ACS, %		4
Antiplatelet therapy on discharge		
Aspirin, %		100
Clopidogrel, %		64
Prasugrel, %		35
Ticagrelor, %		1
Lesion data		
Lesion characteristics		
Lesion number, n		152
Target vessel, %	Left main	1
	LAD (mid-LAD)	42 (30)
	Circumflex	13
	RCA	42
	SVG	2
Multivessel BVS, % of patients		15
ACC lesion type, %	A	10
	B1	34
	B2	19
	C	37
Length >28 mm, %		19
Moderate/severe calcification, %		16
Bifurcation, %		4
CTO, %		6
Quantitative coronary angiography		
Lesion length, mm		20.9±13.0
Range lesion length, mm		7.5-87.1
Dmax prox, mm		2.84±0.46
Dmax distal, mm		2.66±0.49
Minimal, mm		0.89±0.59

Table 2. Procedural and device data.

Lesion preparation	
Predilation, %	100
Rotational atherectomy, %	2.0
Scoring balloon, %	1.3
Procedural anticoagulation	
Unfractionated heparin, %	80.1
Bivalirudin, %	19.9
Tirofiban, %	8.3
Intracoronary imaging	
Intravascular ultrasound, %	6.5
Optical coherence tomography, %	9.3
Scaffold no. and size	
Mean no. of scaffolds per patient	1.67±0.94
Scaffold overlap, % lesions treated	18
Mean scaffold length, mm	22.74
Mean scaffold diameter, mm	2.98
2.5×18 mm	13.2%
2.5×28 mm	16.8%
3.0×18 mm	23.4%
3.0×28 mm	21.0%
3.5×12 mm	1.8%
3.5×18 mm	13.2%
3.5×28 mm	10.8%
Deployment and post-dilation	
Mean deployment pressure, atm	13.9±1.6
Post-dilation, %	95
Non-compliant post-dilation balloon, %	100
Mean post-dilation pressure, atm	19.6±4.6
Post-dilation balloon diameter	
Equal to scaffold, %	33
0.25 mm > than scaffold, %	45
0.5 mm > than scaffold, %	21

Patient selection was based on factors believed to provide the greatest advantage of temporary rather than permanent vessel scaffolding. This included younger patients (<70 years), patients with long segment disease (>28 mm), and those with disease involving the mid portion of the LAD (the site of future attachment of a left internal mammary artery graft). Financial constraints limited enrolment numbers with the treating institutions not receiving any reimbursement for the study device.

Mean patient age was 62.1 (±12.4) and ranged from 19 to 83 years. The majority of patients treated were male (68%). Diabetes mellitus was present in 19%, hyperlipidaemia in 71% and hypertension in 74%, with 13% being active smokers. The indication for BVS implantation was stable angina (or angina equivalent) in 56%, non-ST-elevation acute coronary syndrome (NSTE-ACS) in 40%, and ST-elevation acute coronary syndrome (STE-ACS) in 4%.

A wide range of lesions was treated, with lesion complexity being largely reflective of real-world practice **(Figure 1)**. The ACC lesion classification in the series was 10% type A, 34% type B1, 19% type B2, and 37% type C. Of the 152 lesions treated, 24% featured a length of >20 mm, 16% exhibited moderate/severe calcification, 7% were chronic total occlusions and 3% were vein grafts. Long lesion lengths necessitated a high rate of BVS to BVS overlap, being performed in 18% of lesions. The degree of scaffold overlap was minimised owing to concern regarding the greater strut thickness of the device when compared to metallic stents. Bifurcation lesions requiring an up-front two-wire strategy comprised 4% of lesions treated.

Vessel preparation was carried out prior to scaffold implantation in all cases. This involved predilation in 100%, rotational atherectomy in 2.0% and use of scoring balloons in 1.3%. Scaffold sizing to the vessel took into careful consideration the need to avoid exceeding the expansion limits of the implanted device. Scaffolds were deployed at moderately high pressure (mean 13.9±1.6 atm). Post-dilation was performed in 95% of scaffolds to a mean of 19.6±4.6 atm. The post-dilation balloon was sized 1:1 with the

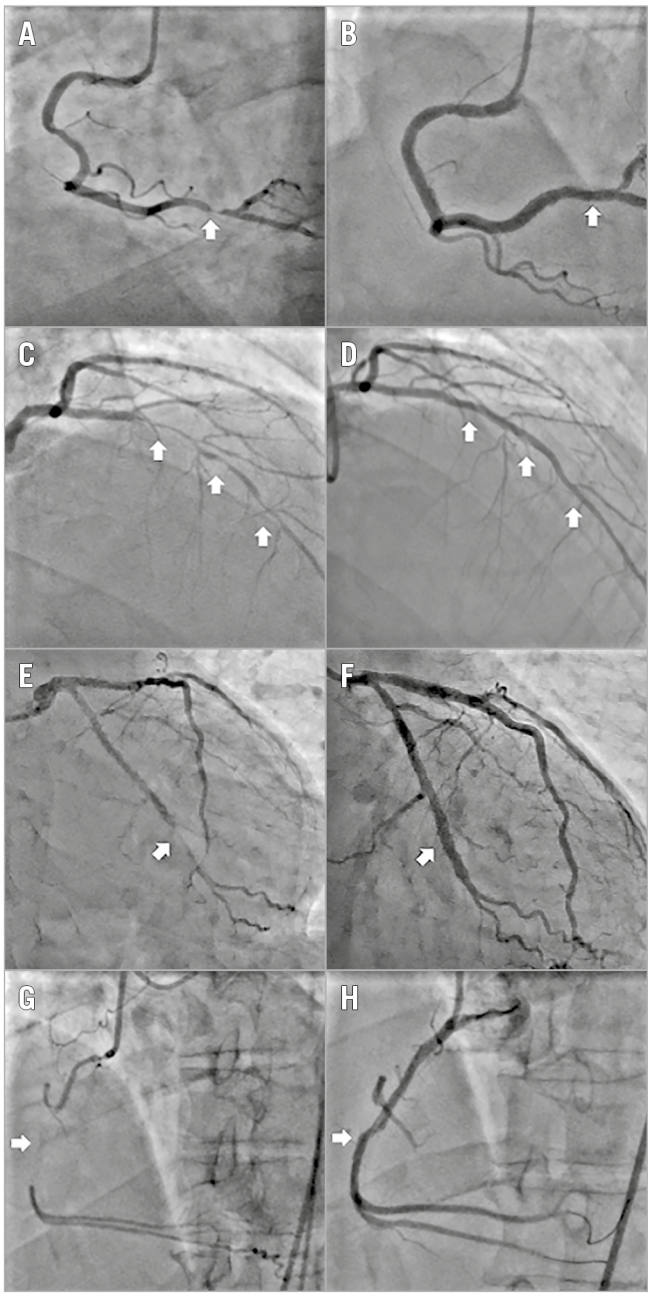

Figure 1. *Examples of lesions treated. A) & B) Severe mid RCA tortuosity and distal RCA disease treated with an Absorb BVS. C) & D) Severe diffuse disease of the LAD treated with two overlapping Absorb BVS in the mid and distal vessel with a further Absorb BVS more distally. E) & F) Severe circumflex disease treated with an Absorb BVS. G) & H) Mid RCA chronic total occlusion treated with an Absorb BVS following retrograde cross.*

scaffold in 33%, and was 0.25 mm and 0.5 mm larger than the scaffold in 45% and 21%, respectively.

Procedural anticoagulation was achieved with unfractionated heparin in 80.1% and bivalirudin in 19.9%, with the addition of tirofiban in 8.3%. Intracoronary imaging with IVUS or OCT was available in all cases, with IVUS utilised in 6.5% and OCT in 9.3%.

Failure to deliver the BVS to the target lesion occurred on two occasions, both in the setting of a highly tortuous and heavily calcified right coronary artery. This resulted in a BVS device failure rate of 1.2%. On both occasions a metallic drug-eluting stent was successfully delivered to the target lesion. There were no cases of scaffold dislodgement from the delivery balloon.

There were four cases of periprocedural myocardial infarction, all of which were not associated with ST-elevation or Q-wave formation, and did not result in any further adverse events in follow-up. Two-year clinical follow-up data were available for 99% of patients. The one patient who was lost to follow-up withdrew consent for surveillance after relocating overseas.

Outcomes in clinical follow-up are summarised in **Table 3-Table 5**. There was one cardiac death, resulting in a cardiac death rate of 1% at two-year follow-up. This case was also classified as a possible scaffold thrombosis by ARC criteria, occurring in a 71-year-old smoker who died suddenly while on vacation overseas, 17 months following treatment of a mid-LAD bifurcation where through-the-scaffold balloon inflation into the small diagonal side branch had not been attempted.

The incidence of myocardial infarction in the follow-up period was 2% at two years, excluding the periprocedural events. Target lesion revascularisation was required in 4% of patients at two years. All cases of target lesion revascularisation occurred in the first 12 months, with no further cases recorded between 12 months and two years.

Table 3. Clinical outcomes.

	30-day (%)	6-month (%)	12-month (%)	24-month (%)
Death (all-cause)	0	0	0	3
Cardiac death	0	0	0	1
Myocardial infarction (type 1)	0	2	2	2
STE-ACS	0	1	1	1
NSTE-ACS	0	1	1	1
Scaffold thrombosis* (any)	0	1	1	2
Definite/probable	0	1	1	1
Possible	0	0	0	1
In-scaffold restenosis	0	1	2	2
TLR	0	2	4	4
PCI	0	1	2	2
CABG	0	1	2	2
Non-TLR	0	2	2	2
MACE**	4	7	8	9

*Definite/probable/possible stent thrombosis by ARC criteria.
**Composite of cardiac death, target lesion revascularisation, and myocardial infarction (including periprocedural myocardial infarction).

The rate of definite/probable scaffold thrombosis at two years was 1% per patient and 0.6% per scaffold, owing to a single case which occurred in the setting of premature interruption to dual antiplatelet therapy four months following scaffold implantation. The patient had been treated with two overlapping 3.0×18 mm Absorb BVS in the proximal LAD for long segment disease. Repeat coronary angiography at three months showed the scaffolds to be widely patent. Ticagrelor was transiently ceased for non-cardiac surgery at

Table 4. Clinical outcome – case summary.

Case	Age	Gender	DM	Vessel	ACC/AHA class	Predilation	OCT/IVUS guidance	BVS device	Post-dilation	Clinical event
1	77	M	N	LAD	C	Yes	No	3.0×18 mm. Further 3.0×18 mm distally with overlap	Yes. 3.25 non-compliant balloon at 20 atm	STE-ACS at 4 months due to scaffold thrombosis following cessation of DAPT. Suboptimal scaffold apposition on IVUS at time of STEMI. BMS implanted within scaffold following angioplasty with 3.5 mm non-compliant balloon.
2	76	M	N	RCA	C	Yes	No	3.0×28 mm	Yes. 3.25 non-compliant balloon at 16 atm	NSTE-ACS at 10 months. Severe in-scaffold restenosis on angiography with severe neointimal hyperplasia confirmed on OCT. No scaffold malapposition. Treated with 3.0×38 mm zotarolimus-eluting stent across entire scaffolded segment.
3	60	M	Y	RCA	C	Yes	No	3.5×28 mm. Further 3.5×28 mm, 2.5×28 mm, 2.5×18 mm distally with overlap	Yes. 4.0 non-compliant balloon at 20 atm	Unstable angina at 7 months. Coronary angiography showing severe in-scaffold restenosis of proximal RCA and progression of circumflex atheroma. Treated with CABG.
4	62	M	N	LAD	C	Yes	No	3.0×28 mm	Yes. 3.25 non-compliant balloon at 20 atm	Recurrence of exertional angina at 5 months. Coronary angiography showing severe focal disease at proximal edge of scaffold. Treated with CABG.
5	71	M	N	LAD	C	Yes	No	3.0×28 mm	Yes. 3.0 non-compliant balloon at 16 atm	Sudden death at 17 months. Possible scaffold thrombosis by ARC criteria.

Table 5. Predictors of clinical events.

	Target lesion revascularisation (%)	Myocardial infarction (type 1) (%)	Scaffold thrombosis (definite/probable) (%)	In-scaffold restenosis (%)	Cardiac death (%)
OCT/IVUS guidance	0	0	0	0	3.8
No OCT/IVUS guidance	3.2	1.6	0.8	1.6	0
Relative risk (95% CI)	0.52 (0.03-9.42)	0.94 (0.05-19.04)	1.57 (0.07-37.46)	0.94 (0.05-19.04)	14.11 (0.59-337.16)
p-value	0.660	0.968	0.781	0.968	0.102
Scaffold diameter 2.5 mm	0	0	0	0	0
Scaffold diameter ≥3.0 mm	3.4	1.7	0.8	1.7	0.8
Relative risk (95% CI)	0.26 (0.01-4.69)	0.46 (0.02-9.47)	0.77 (0.03-18.62)	0.46 (0.02-9.47)	0.77 (0.03-18.62)
p-value	0.359	0.617	0.873	0.617	0.873
Lesion length ≥28 mm	6.8	3.4	3.4	0	3.4
Lesion length <28 mm	1.6	0.8	0	0.8	0
Relative risk (95% CI)	4.24 (0.62-28.87)	4.24 (0.27-65.83)	12.40 (0.52-296.91)	1.38 (0.06-32.99)	12.40 (0.52-296.91)
p-value	0.140	0.302	0.120	0.843	0.120
Scaffold overlap	3.7	3.7	3.7	0	3.7
No scaffold overlap	2.4	0.8	0	1.6	0
Relative risk (95% CI)	1.54 (0.17-14.28)	4.63 (0.30-71.73)	13.50 (0.56-322.81)	0.90 (0.44-18.23)	13.50 (0.56-322.81)
p-value	0.702	0.273	0.108	0.945	0.108

which time the patient experienced an anterior ST-elevation myocardial infarction, with scaffold thrombosis confirmed on coronary angiography. Intravascular ultrasound revealed suboptimal apposition of the proximal scaffold, which was corrected by balloon angioplasty and implantation of a 3.0×12 mm bare metal stent within the proximal scaffold. Post-dilation was performed with a 3.5 mm non-compliant balloon to high pressure. There were no further events recorded up to two-year follow-up.

The second case of target lesion revascularisation involved a patient treated with a 3.0×28 mm Absorb BVS to the mid LAD, who experienced a recurrence of angina five months following BVS implantation, with a stress test being positive for myocardial ischaemia. Coronary angiography revealed a patent BVS but significant progression of disease at the proximal edge of the scaffold and in the circumflex artery. Revascularisation options were discussed and the patient underwent coronary artery bypass surgery (CABG).

The third case of target lesion revascularisation involved a patient treated with a total of four BVS to the posterior descending artery (PDA) and proximal, mid and distal right coronary artery (RCA), who experienced recurrence of angina seven months after RCA intervention. Coronary angiography revealed diffuse restenosis of the proximal RCA BVS as well as progression of previously moderate disease in the circumflex artery. The three remaining scaffolds in the PDA and mid/distal RCA were patent. The patient underwent coronary artery bypass surgery.

The final instance of target lesion revascularisation occurred in a patient treated with a 3.0×28 mm BVS to the mid RCA. The patient experienced non-ST-elevation ACS 10 months following BVS implantation with coronary angiography revealing severe in-scaffold restenosis of the BVS. OCT confirmed this to be due to diffuse neointimal hyperplasia. No malapposition or underexpansion of the BVS was demonstrated. Predilation of the restenotic segment was performed with a 3.0 mm AngioSculpt scoring balloon (Biotronik, Bülach, Switzerland) prior to implantation of a 3.0×38 mm metallic zotarolimus-eluting stent (Resolute™; Medtronic, Minneapolis, MN, USA) across the entire length of the BVS. Post-dilation was performed using a 3.5 mm non-compliant balloon to 18 atmospheres. The patient did not have any further events recorded during the two-year follow-up period.

Non-target lesion revascularisation occurred in a further two cases in the two-year period, both due to progression of disease remote from the target segment. There were two cases of non-cardiac death. Follow-up of patients in the registry is ongoing.

Discussion

Bioresorbable scaffolds are a recent advance in PCI. In the short term, such devices are designed to seal intimal flaps to avoid acute vessel closure following balloon angioplasty, provide radial strength to prevent vessel recoil and deliver an antiproliferative drug to inhibit neointimal hyperplasia[1,2]. In the longer term, bioresorbable scaffolds are intended to address the drawbacks of conventional metallic stents. Persistence of metallic caging of the vessel inhibits vasodilation in response to ischaemia and anti-anginal therapy, and may act as a nidus for late clinical events through late stent thrombosis, neoatherosclerosis and stent fracture[3,4].

Despite the promised long-term advantages of bioresorbable scaffolds, such devices should not be associated with any increase in early or late major clinical events when compared to current-generation drug-eluting stents. The Absorb BVS, the first commercially available bioresorbable scaffold, has been found to be non-inferior to a current-generation metallic drug-eluting stent in multiple large randomised controlled trials with respect to clinical events at 12 months[5-8].

Other results have been variable, there having been an unacceptably high incidence of scaffold thrombosis of 1.5% at 30 days and 2.1% at six months in the GHOST-EU study[9], and a large meta-analysis substantiating the possible increased risk of device thrombosis associated with the Absorb BVS[20]. Moreover, longer-term follow-up of ABSORB II has revealed an increased relative risk of target vessel myocardial infarction in the Absorb group at three years compared to the XIENCE stent (Abbott Vascular)[14]. These safety concerns have prompted removal of the device from commercial use.

Whether unfavourable outcomes relate to fundamental shortcomings of the device, or represent early challenges of understanding the bioresorbable technology and its optimal use is uncertain. The variability in clinical outcomes among various registries and randomised controlled trials has been postulated to be related to differences in implantation techniques among the different studies.

Adverse ABSORB II findings at three-year follow-up may reflect a lack of early insight regarding the optimal implantation technique for the device[14,16]. Expert consensus now recommends a dedicated BVS-specific implantation strategy, emphasising the importance of meticulous lesion preparation and routine post-dilation[15]. Such an approach gives consideration to the unique properties of the Absorb BVS in terms of factors such as strut thickness, crossing profile and deliverability, radial/longitudinal strength and finite expansion limits. While implementation of this strategy has been linked to a possible reduction in the incidence of scaffold thrombosis, more comprehensive clinical data have been lacking[21].

Implantation of all Absorb BVS at our two institutions occurred as part of the prospective ESHC-BVS registry. A strategy of meticulous lesion preparation and routine high-pressure post-dilation has been strongly advocated at our institutions since the inception of this registry.

Patient and lesion characteristics treated in this cohort were reflective of real-world practice with 19% of patients being diabetic, 44% being treated for ACS, and 56% of lesions being of B2/C complexity. The mean patient age of 62.1 years reflected a tendency to treat younger patients given the longer duration of benefit of avoiding permanent vessel caging in these individuals. Other factors influencing the decision to implant a BVS included long segment disease (>28 mm) where the use of metallic stents could act as a nidus for late target lesion failure, and could impede future revascularisation options. Treatment of the mid-left anterior descending artery was seen as an indication for use of a BVS over a metallic stent, so that the potential for future revascularisation by left internal mammary artery grafting could be maintained[22].

Predilation was performed in all cases. This included presentations with ACS where the benefits of adequate lesion preparation were believed still to outweigh the risks of distal embolisation induced by balloon angioplasty.

Full expansion of the predilation balloon was seen as mandatory prior to scaffold implantation, with there being a low threshold to utilise non-compliant balloons. Cutting balloons and rotational atherectomy were used as adjunct techniques where necessary. Meticulous lesion preparation was considered essential to avoid scaffold underexpansion, with this having been shown to be a major factor contributing to scaffold thrombosis[15,20,21]. This strategy also helped to overcome the higher crossing profile and reduced deliverability of the Absorb BVS, facilitating successful delivery of the device in 98.8% of cases.

Scaffold selection paid particular attention to vessel size to avoid exceeding the limited expansion limits of the implanted scaffold. Quantitative coronary angiography (QCA) and vessel sizing relative to predilation balloons was used to assist in this regard. Scaffold implantation was performed at moderately high pressure (mean 13.9±1.6 atm) to assist in achieving full scaffold expansion and maximising strut apposition. This also served to facilitate delivery of the post-dilation balloon with reduced risk of scaffold fracture arising from the passage of post-dilation balloons against malapposed proximal struts. Post-dilation was performed in 95% of scaffolds. Non-compliant balloons were used in all cases sized to at least the nominal pressure of the scaffold, to a maximum of 0.5 mm larger than the scaffold, with balloon inflation performed to high pressures (mean 19.6±4.6 atm). This post-dilation strategy further maximised scaffold apposition to the vessel wall while improving scaffold expansion in the minority of cases where this remained suboptimal despite previous measures.

Good clinical outcomes were achieved in long-term follow-up with the BVS-specific implantation strategy employed. At two years, the rate of target lesion revascularisation was 4%, definite/probable scaffold thrombosis 1% and cardiac death 1%. Furthermore, the BVS-specific implantation strategy allowed results to be accomplished while minimising the need for intracoronary imaging. Use of OCT and IVUS combined was limited to only 15.8% of cases, thereby contributing to minimising cost.

Our results confirm that minimising scaffold underexpansion and malapposition through the BVS-specific implantation technique described allows use of the Absorb BVS with limited events in the first two years of follow-up in a real-world cohort.

Our findings help to validate expert consensus guidelines regarding optimal implantation strategies for the Absorb BVS, including meticulous lesion preparation, careful consideration of scaffold sizing, and high-pressure post-dilation. A BVS-specific implantation strategy incorporating these principles should be employed in all cases where the Absorb BVS is utilised.

Limitations

While the rate of clinical events in follow-up was low, the findings are limited by relatively small patient numbers. In addition, the prospective, single-arm design of the registry does not specifically allow comparison of different implantation techniques as would be made through a randomised controlled trial.

Conclusions

Good outcomes were achieved to two-year follow-up with the Absorb BVS in real-world coronary disease utilising a dedicated

strategy incorporating meticulous lesion preparation, judicious scaffold sizing and routine high-pressure post-dilation. These findings support the implantation strategy employed in this registry.

Impact on daily practice

The properties of bioresorbable scaffolds are different to metallic stents, which may influence the optimal implantation technique and account for the variability of long-term results with the Absorb BVS in clinical trials. Our findings demonstrate the good outcomes which can be achieved at two years with the Absorb BVS in real-world coronary disease, utilising an implantation strategy tailored for the device. An implantation strategy comprising meticulous lesion preparation, judicious scaffold sizing and routine high-pressure post-dilation should be strongly considered when evaluating future poly-lactide bioresorbable stent platforms.

Conflict of interest statement

N. Jepson has received speaker's fees from Abbott Vascular. D. Robaei has received an educational grant from Abbott Vascular. The other authors have no conflicts of interest to declare.

References

1. Serruys PW, Ong AT, Piek JJ, Neumann FJ, van der Giessen WJ, Wiemer M, Zeiher A, Grube E, Haase J, Thuesen L, Hamm C, Otto-Terlouw PC. A randomized comparison of a durable polymer Everolimus-eluting stent with a bare metal coronary stent: The SPIRIT first trial. *EuroIntervention.* 2005;1:58-65.

2. Fischman DL, Leon MB, Baim DS, Schatz RA, Savage MP, Penn I, Detre K, Veltri L, Ricci D, Nobuyoshi M, et al. A randomized comparison of coronary-stent placement and balloon angioplasty in the treatment of coronary artery disease. Stent Restenosis Study Investigators. *N Engl J Med.* 1994;331:496-501.

3. Ormiston JA, Serruys PW. Bioresorbable coronary stents. *Circ Cardiovasc Interv.* 2009;2:255-60.

4. Strandberg E, Zeltinger J, Schultz DG, Kaluza GL. Late positive remodeling and late lumen gain contribute to vascular restoration by a non-drug eluting bioresorbable scaffold: a four-year intravascular ultrasound study in normal porcine coronary arteries. *Circ Cardiovasc Interv.* 2012;5:39-46.

5. Serruys PW, Chevalier B, Dudek D, Cequier A, Carrié D, Iniguez A, Dominici M, van der Schaaf RJ, Haude M, Wasungu L, Veldhof S, Peng L, Staehr P, Grundeken MJ, Ishibashi Y, Garcia-Garcia HM, Onuma Y. A bioresorbable everolimus-eluting scaffold versus a metallic everolimus-eluting stent for ischaemic heart disease caused by de-novo native coronary artery lesions (ABSORB II): an interim 1-year analysis of clinical and procedural secondary outcomes from a randomised controlled trial. *Lancet.* 2015;385:43-54.

6. Ellis SG, Kereiakes DJ, Metzger DC, Caputo RP, Rizik DG, Teirstein PS, Litt MR, Kini A, Kabour A, Marx SO, Popma JJ, McGreevy R, Zhang Z, Simonton C, Stone GW; ABSORB III Investigators. Everolimus-Eluting Bioresorbable Scaffolds for Coronary Artery Disease. *N Engl J Med.* 2015;373:1905-15.

7. Kimura T, Kozuma K, Tanabe K, Nakamura S, Yamane M, Muramatsu T, Saito S, Yajima J, Hagiwara N, Mitsudo K, Popma JJ, Serruys PW, Onuma Y, Ying S, Cao S, Staehr P, Cheong WF, Kusano H, Stone GW; ABSORB Japan Investigators. A randomized trial evaluating everolimus-eluting Absorb bioresorbable scaffolds vs. everolimus-eluting metallic stents in patients with coronary artery disease: ABSORB Japan. *Eur Heart J.* 2015;36:3332-42.

8. Puricel S, Arroyo D, Corpataux N, Baeriswyl G, Lehmann S, Kallinikou Z, Muller O, Allard L, Stauffer JC, Togni M, Goy JJ, Cook S. Comparison of everolimus- and biolimus-eluting coronary stents with everolimus-eluting bioresorbable vascular scaffolds. *J Am Coll Cardiol.* 2015;65:791-801.

9. Capodanno D, Gori T, Nef H, Latib A, Mehilli J, Lesiak M, Caramanno G, Naber C, Di Mario C, Colombo A, Capranzano P, Wiebe J, Araszkiewicz A, Geraci S, Pyxaras S, Mattesini A, Naganuma T, Münzel T, Tamburino C. Percutaneous coronary intervention with everolimus-eluting bioresorbable vascular scaffolds in routine clinical practice: early and midterm outcomes from the European multicentre GHOST-EU registry. *EuroIntervention.* 2015;10:1144-53.

10. Wöhrle J, Naber C, Schmitz T, Schwencke C, Frey N, Butter C, Brachmann J, Ingwersen M, Drabik A, Markovic S, Mathey DG. Beyond the early stages: insights from the ASSURE registry on bioresorbable vascular scaffolds. *EuroIntervention.* 2015;11:149-56.

11. Robaei D, Back L, Ooi SY, Pitney M, Jepson N. Twelve-Month Outcomes With a Bioresorbable Everolimus-Eluting Scaffold: Results of the ESHC-BVS Registry at Two Australian Centers. *J Invasive Cardiol.* 2016;28:316-22.

12. Gao R, Yang Y, Han Y, Huo Y, Chen J, Yu B, Su X, Li L, Kuo HC, Ying SW, Cheong WF, Zhang Y, Su X, Xu B, Popma JJ, Stone GW; ABSORB China Investigators. Bioresorbable Vascular Scaffolds Versus Metallic Stents in Patients With Coronary Artery Disease: ABSORB China Trial. *J Am Coll Cardiol.* 2015;66:2298-309.

13. Kraak RP, Hassell ME, Grundeken MJ, Koch KT, Henriques JP, Piek JJ, Baan J, Vis MM, Arkenbout EK, Tijssen JG, de Winter RJ, Wykrzykowska JJ. Initial experience and clinical evaluation of the Absorb bioresorbable vascular scaffold (BVS) in real-world practice: the AMC Single Centre Real World PCI Registry. *EuroIntervention.* 2015;10:1160-8.

14. Serruys PW, Chevalier B, Sotomi Y, Cequier A, Carrié D, Piek JJ, Van Boven AJ, Dominici M, Dudek D, McClean D, Helqvist D, Haude M, Reith S, de Sousa Almeida M, Campo G, Iñiguez A, Sabaté M, Windecker S, Onuma Y. Comparison of an everolimus-eluting bioresorbable scaffold with an everolimus-eluting metallic stent for the treatment of coronary artery stenosis (ABSORB II): a 3 year, randomised, controlled, single-blind, multicentre clinical trial. *Lancet.* 2016;388:2479-91.

15. Tamburino C, Latib A, van Geuns RJ, Sabate M, Mehilli J, Gori T, Achenbach S, Alvarez MP, Nef H, Lesiak M, Di Mario C, Colombo A, Naber CK, Caramanno G, Capranzano P, Brugaletta S,

Geraci S, Araszkiewicz A, Mattesini A, Pyxaras SA, Rzeszutko L, Depukat R, Diletti R, Boone E, Capodanno D, Dudek D. Contemporary practice and technical aspects in coronary intervention with bioresorbable scaffolds: a European perspective. *EuroIntervention.* 2015;11:45-52.

16. Byrne RA, Kastrati A. Disappearing scaffolds, dissolving expectations. *Lancet.* 2016;388:2451-2.

17. Robaei D, Back LM, Ooi SY, Pitney MR, Jepson N. Everolimus-eluting Bioresorbable Vascular Scaffold Implantation in Real World and Complex Coronary Disease: Procedural and 30-day Outcomes at Two Australian Centres. *Heart Lung Circ.* 2015;24:854-9.

18. Cutlip DE, Windecker S, Mehran R, Boam A, Cohen DJ, Van Es GA, Steg PG, Morel MA, Mauri L, Vranckx P, McFadden E, Lansky A, Hamon M, Krucoff MW, Serruys PW; Academic Research Consortium. Clinical end points in coronary stent trials: a case for standardized definitions. *Circulation.* 2007;115:2344-51.

19. Thygesen K, Alpert JS, Jaffe AS, Simoons ML, Chaitman BR, White HD; Writing Group on the Joint ESC/ACCF/AHA/WHF Task Force for the Universal Definition of Myocardial Infarction, Thygesen K, Alpert JS, White HD, Jaffe AS, Katus HA, Apple FS, Lindahl B, Morrow DA, Chaitman BA, Clemmensen PM, Johanson P, Hod H, Underwood R, Bax JJ, Bonow RO, Pinto F, Gibbons RJ, Fox KA, Atar D, Newby LK, Galvani M, Hamm CW, Uretsky BF, Steg PG, Wijns W, Bassand JP, Menasché P, Ravkilde J, Ohman EM, Antman EM, Wallentin LC, Armstrong PW, Simoons ML, Januzzi JL, Nieminen MS, Gheorghiade M, Filippatos G, Luepker RV, Fortmann SP, Rosamond WD, Levy D, Wood D, Smith SC, Hu D, Lopez-Sendon JL, Robertson RM, Weaver D, Tendera M, Bove AA, Parkhomenko AN, Vasilieva EJ, Mendis S; ESC Committee for Practice Guidelines (CPG). Third universal definition of myocardial infarction. *Eur Heart J.* 2012; 33:2551-67.

20. Lipinski MJ, Escarcega RO, Baker NC, Benn HA, Gaglia MA Jr, Torguson R, Waksman R. Scaffold Thrombosis After Percutaneous Coronary Intervention With ABSORB Bioresorbable Vascular Scaffold: A Systematic Review and Meta-Analysis. *JACC Cardiovasc Interv.* 2016;9:12-24.

21. Puricel S, Cuculi F, Weissner M, Schmermund A, Jamshidi P, Nyffenegger T, Binder H, Eggebrecht H, Münzel T, Cook S, Gori T. Bioresorbable coronary scaffold thrombosis: multicenter comprehensive analysis of clinical presentation, mechanisms, and predictors. *J Am Coll Cardiol.* 2016;67:921-31.

22. Robaei D, Carlyle A, Jepson N. "Full bioresorbable jacket": Alternative to very long segment metallic stenting in a young patient with diffuse coronary artery disease. *Int J Cardiol.* 2016; 223:361-3.