Twelve-month outcomes after bioresorbable vascular scaffold implantation in patients with acute coronary syndromes. Data from the European Multicenter GHOST-EU Extended Registry

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Abstract
Aims: The aim of this study was to report on the midterm outcomes of patients undergoing percutaneous coronary intervention with bioresorbable vascular scaffolds (BVS) for the treatment of acute coronary syndromes (ACS) and compare with those of patients with stable coronary artery disease (sCAD).

Methods and results: One thousand four hundred and seventy-seven (1,477) patients underwent implantation of one or more BVS (Absorb BVS; Abbott Vascular, Santa Clara, CA, USA) at 11 European centres and were included in the GHOST-EU registry. Admissions comprised 47.1% of the patients (951 BVS) with ACS, and 52.8% (1,274 BVS) with sCAD. During a median follow-up of 384 (359-460) days, patient-oriented endpoints (PoCE), including all-cause death, any infarction, any revascularisation, were recorded in 271 patients (12-month incidence in ACS patients: 18.5% vs. 11.6% in the sCAD group, p<0.001). Device-oriented composite endpoints (DoCE), cardiac death, target vessel infarction and target lesion revascularisation, were observed in 98 patients (12-month incidence of 4.2% in the sCAD group, 6.4% in the ACS group; p=0.052). The 12-month incidence of definite scaffold thrombosis was 2.6% in ACS patients and 0.8% in XIENCE patients (p=0.006). In multivariate analysis, ACS was a predictor of DoCE (HR: 2.26 [1.34-3.81], p=0.002), PoCE (HR: 1.71 [1.13-2.58], p=0.011), and stent thrombosis (HR: 2.51 [1.13-5.60], p=0.025). In contrast, the incidence of target lesion revascularisation was not different between groups. There was no difference in the incidence of any of these endpoints among the different clinical presentations (unstable angina, non-ST-elevation infarction and ST-elevation infarction).

Conclusions: PoCE, DoCE and scaffold thromboses were more frequent in ACS patients, without any difference among different forms of ACS.

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Abbreviations

BVS	bioresorbable vascular scaffold(s)
DES	drug-eluting stent(s)
MI	myocardial infarction
ScT	scaffold thrombosis
TLF	target lesion failure
TLR	target lesion revascularisation
TVF	target vessel failure
TVR	target vessel revascularisation

Introduction

Bioresorbable vascular scaffolds (BVS) were introduced in the hope of addressing some of the late complications associated with implantation of metal stents. Particularly, late lumen enlargement, the restoration of the vasomotor properties of the coronary artery and the "sealing" of thrombotic plaques represent attractive opportunities for patients with acute coronary syndromes (ACS)[1,2]. Experiences reported to date, however, focus particularly on ST-elevation infarction patients; data on other forms of ACS are less well represented[3-6]. Further, reports available to date lack a control group without ACS (stable coronary artery disease [sCAD]). Clinical data from the international and multicentre GHOST-EU registry were recently published[7]. Reflecting clinical routine in tertiary centres, approximately 50% of the patients enrolled in this registry had a diagnosis of ACS as defined by unstable angina (uAP), non-ST-elevation myocardial infarction (NSTEMI) and ST-elevation myocardial infarction (STEMI). We report on the early and midterm outcomes of percutaneous intervention with BVS in these patients and compare them with those recorded in patients with sCAD.

Methods

PATIENT POPULATION AND PROCEDURES

The GHOST-EU registry is a retrospective, multicentre registry conducted at 11 European centres. All patients undergoing intervention with the everolimus-eluting BVS (Absorb; Abbott Vascular, Santa Clara, CA, USA) between November 2011 and June 2014 were eligible for recruitment. Further details on the structure of the registry can be found in our previous article[7].

OBJECTIVES

The primary aim of this study was to test whether ACS at index procedure was an independent predictor of patient-oriented composite endpoints (PoCE) and device-oriented composite endpoints (DoCE). An analysis was also performed for scaffold thrombosis. Major adverse cardiovascular events (MACE) were defined as the composite of cardiovascular death, any myocardial infarction (MI), and clinically driven target lesion revascularisation (TLR). PoCE were the composite of all-cause death, any myocardial infarction (MI) and any repeat revascularisation. DoCE were the combination of cardiac death, target vessel myocardial infarction and clinically driven target lesion revascularisation (TLR).

PROCEDURES AND FOLLOW-UP

Interventions were performed as previously described[7]. Follow-up data were collected during clinical visit and/or by direct telephone contact. When necessary, multiple attempts were made to contact patients by telephone, in writing and/or through the family physician. Patients for whom a 12-month follow-up was not available were censored at the time of last contact. Quantitative coronary analysis was performed on-site by experienced personnel using methods previously described[8].

Scaffold thrombosis was classified according to the Academic Research Consortium criteria[9]. Other definitions are reported in detail in previous papers from our group[7,8].

STATISTICAL ANALYSIS

Data for continuous variables were tested for normality by inspection of the Q-Q plots, and are correspondingly presented as mean±standard deviation or median (interquartile range) and compared using parametric or non-parametric tests. Categorical variables are presented as counts and percentages, and were compared using the Fisher's exact test. In order to assess differences of lesion-based parameters between groups, where multiple measurements on one patient may occur, we fitted linear mixed models (quantitative variables) and generalised linear mixed models (categorical variables) and tested whether there was a group effect. Unadjusted event rates during follow-up were estimated by the Kaplan-Meier method and compared by the log-rank test. In case of competing risks, cumulative incidence functions were computed. Cox proportional hazard models were used to obtain estimates for hazard ratios associated with potential explanatory variables **(Table 1, Table 2)**. Parameters associated with a p<0.1 in univariate analysis were entered in a multivariable model. P-values <0.05 were considered significant. Since the 12-month follow-up was performed by protocol, the Cox regression analysis was performed for this time point. Statistical analyses were performed using MedCalc (MedCalc Software, Mariakerke, Belgium).

Results

PATIENT POPULATION

Between November 2011 and June 2014, a total of 2,216 BVS were implanted in 1,477 patients; 47.1% (697) of the patients (951 BVS) were admitted with ACS, 52.8% (780, 1,274 BVS) with stable CAD. In the ACS group, 248 (35.5%) were admitted with STEMI, 259 (37.1%) with NSTEMI and 190 (27.3%) with unstable AP.

PROCEDURAL DETAILS AND MEDICATIONS

Clinical, lesion and procedural characteristics are presented in **Table 1** and **Table 2**. **Supplementary Table 1** and **Supplementary Table 2** report details of the patient and lesion characteristics according to presentation type (unstable angina, NSTEMI or STEMI) within the ACS group. There were major differences between groups in most clinical parameters **(Table 1, Table 2)**. Age (60.6±11.6 vs. 63.2±10.4 years, p<0.001), the prevalence of hyperlipidaemia, hypertension, diabetes, and of prior

Table 1. Patient characteristics.

Variable	ACS	Stable CAD	*p*-value
Age (years)	60.6±11.6 (697)	63.2±10.4 (780)	<0.001
Male sex	78.8% (549/697)	80.1% (631/780)	0.340
Hypertension	67.4% (474/697)	76.4% (596/780)	<0.001
Smoking	42.4% (296/697)	19.5% (152/780)	<0.001
Hyperlipidaemia	42.9% (299/697)	61.4% (479/780)	<0.001
Diabetes	21.0% (147/697)	30.0% (234/780)	<0.001
Family history of CAD	27.7% (193/697)	33.7% (263/780)	0.203
Prior revascularisation	19.2% (134/697)	46.5% (363/780)	<0.001
Prior CABG	3.4% (24/697)	6.0% (47/780)	0.028
Prior stroke or TIA	5.2% (36/697)	2.2% (17/780)	0.003
Glomerular filtration rate	88.6±28.1 (312)	82.5±25.8 (479)	0.076
LVEF	52.9±9.9 (549)	54.3±9.3 (505)	0.023
Multivessel disease	31.3% (690)	45.9% (777)	<0.001

Numbers are % (number/sample size) or mean±SD (sample size). ACS: acute coronary syndromes; BMI: body mass index; CABG: coronary artery bypass grafting; CAD: coronary artery disease; LVEF: left ventricular ejection fraction; MI: myocardial infarction; PCI: percutaneous coronary intervention; TIA: transient ischaemic attack

Table 2. Lesion and procedural characteristics.

Procedural characteristics (per patient)	ACS	Stable CAD	*p*-value
Radial access	42.5% (296/697)	38.0% (293/771)	0.091
No. of lesions treated with BVS	1.15±0.45 (697)	1.22±0.54 (780)	0.021
BVS per patient (n)	1.37±0.73 (697)	1.63±1.01 (780)	<0.001
OCT performed	6.9% (48/697)	19.8% (154/780)	<0.001
IVUS performed	6.6% (46/697)	22.4% (175/780)	<0.001
Lesion characteristics			
Ostial lesions	6.3% (37/606)	6.6% (46/698)	0.903
Left main (LM)	1.1% (9/877)	1.3% (12/835)	0.580
Left anterior descending (LAD)	49.2% (429/877)	48.3% (400/835)	0.723
Circumflex (RCX)	23.1% (202/874)	26.9% (213/835)	0.272
Right coronary artery (RCA)	27.1% (237/875)	26.0 (210/835)	0.392
Lesion type B2 or C	45.8% (352/768)	59.8% (506/846)	<0.001
Thrombus present	36.1% (278/771)	1.5% (14/925)	<0.001
Chronic total occlusion	21.0% (169/803)	10.4% (96/923)	<0.001
Bifurcation	16.2% (144/887)	26.1% (221/846)	<0.001
Proximal RVD before stenting, mm	3.00±0.56 (616)	2.96±0.53 (608)	0.226
Distal RVD before stenting	2.83±0.56 (616)	2.76±0.50 (608)	0.049
Mean RVD before stenting	2.93±0.54 (616)	2.89±0.47 (608)	0.196
Procedural characteristics (per lesion)			
Predilation	95.5% (851/891)	96.9% (819/845)	0.158
Hybrid (BVS+DES/BMS)	17.7% (123/692)	17.8% (121/679)	0.961
Total scaffold length (mm)	19 [18-28] (802)	28 [18-36] (833)	0.001
Minimum BVS diameter (2.5/3.0/3.5 mm)	26.5/37.5/36.0 (236/334/320)	30.6/41.9/28.2% (251/348/236)	0.003
Implantation pressure, atm	13.5 [11-14] (796)	12 [8-14] (905)	<0.001
Post-dilation	46.2% (408/883)	59.1% (500/845)	<0.001
P2Y$_{12}$ therapy at discharge			<0.001
Clopidogrel 75 mg	64.7% (469/724)	79.4% (579/729)	<0.001
Prasugrel 10 mg	32.0% (232)	17.7% (126)	
Ticagrelor 180 mg	3.2% (23)	3.1% (24)	

Numbers are count/sample size (%) or mean±SD (sample size) or N (sample size). BMS: bare metal stent; BVS: bioresorbable vascular scaffold; DES: drug-eluting stent; DS: diameter stenosis; IVUS: intravascular ultrasound; LAD: left anterior descending; LCX: left circumflex; LMCA: left main coronary artery; OCT: optical coherence tomography; RCA: right coronary artery

revascularisations or stroke was higher in the sCAD group, while a smoking history was more frequent in ACS patients (all p<0.0001). Except for coronary thrombus, characteristics of lesion complexity, including bifurcation lesions and chronic total occlusions, were more frequent in the sCAD group (all p<0.0001). The total implanted scaffold length was shorter (19 [18-28] vs. 28 [18-36] mm, p=0.0001) and scaffolds tended to be larger (3.5 mm BVS used: 36% vs. 28.2%) in patients with ACS. Predilation was performed in most lesions in both groups (95.5% vs. 96.9%, p=0.158); post-dilation was more often performed in the sCAD group (46.2% vs. 59.1%, p<0.001). Intracoronary imaging was less frequently performed in patients with ACS (optical coherence tomography: 19.5% vs. 7.0%; p<0.001, intravascular ultrasound: 23.3% vs. 6.4%; p<0.001). Antiplatelet therapy with prasugrel or ticagrelor was more often prescribed in the ACS group.

CLINICAL OUTCOMES

The median follow-up was 365 (359-365) days. Twelve-month follow-up data were available in 1,207 (82%) patients. The incidence of intraprocedural complications was similar between groups **(Table 3)**. Event rates during follow-up are described in **Table 4**, **Table 5**, **Figure 1A**, **Figure 1B** and **Figure 2**. At 12 months, the incidence of MACE (49 [7.6%] vs. 39 [4.6%], p=0.016) and PoCE (n=123 [18.5%] vs. 83 [11.6%], p<0.001) was higher in the ACS group, while that of DoCE (42 [6.4%] vs. 30 [4.2%], p=0.052) and of the single endpoints showed a trend in the same direction. Also, the incidence of both definite and definite+probable scaffold thrombosis (ScT) (n=18 [2.6%] vs. 6 [0.8%], p=0.006 and 19 [2.8%] vs. 10 [1.4%], p=0.047) **(Table 5)** was higher in the ACS group.

The type of ACS (unstable angina, NSTEMI or STEMI) had no impact on the incidence of these events **(Figure 3)**, even though a slightly lower incidence of PoCE was observed in unstable angina patients.

PREDICTORS OF EVENTS AND THE ROLE OF IMPLANTATION STRATEGY IN ACS

The list of the variables considered for this analysis along with the corresponding HRs and p-values are presented in **Supplementary Table 3**-**Supplementary Table 5**. ACS at implantation was an independent predictor of 12-month DoCE (p=0.002, HR: 2.26 [1.34-3.81]), PoCE (p=0.011, HR: 1.71 [1.13-2.58]), and stent thrombosis (p=0.025, HR: 2.51 [1.13-5.60]). In patients with ACS, implantation of BVS with a nominal diameter at least 10% larger than the reference vessel diameter was associated with PoCE (27% vs. 11.2%, p<0.001, HR: 2.65 [1.65-4.32]), DoCE (9% vs. 4.6%, p=0.044, HR: 2.28 [1.03-5.08]) and ScT (6.2% vs. 0.9%, p=0.011, HR: 7.80 [1.63-37.43]). Also, reference vessel diameter (RVD) (data available in
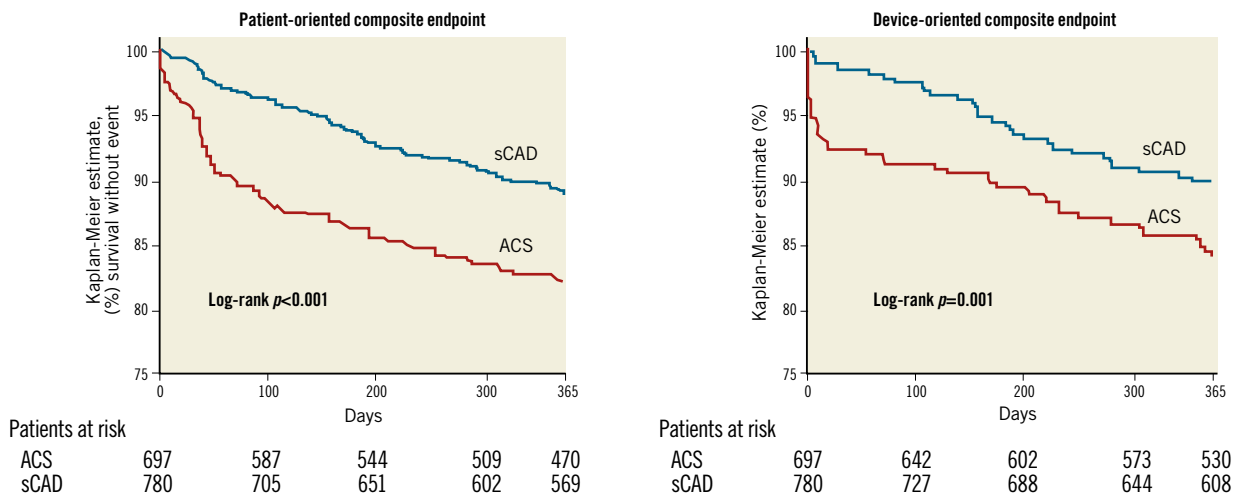
Figure 1. *The incidence of device-oriented and patient-oriented composite endpoints.*
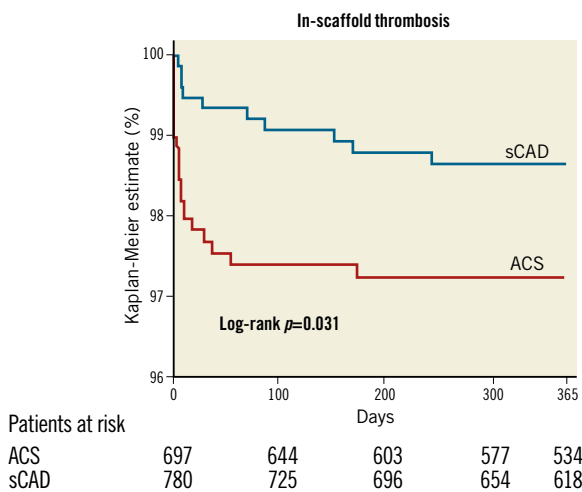

Figure 2. *The incidence of scaffold thrombosis (definite, probable and possible).*

Table 3. Periprocedural complications.

	ACS	Stable CAD	*p*-value
BVS fracture	1/618	8/692	0.066
Perforation	0/677	3/757	0.289
Dissection	12/678	16/757	0.780
Acute target vessel occlusion	10/678	19/757	0.229
Side branch occlusion	8/676	11/757	0.828
BVS dislodgement	3/677	2/757	0.900
No reflow	6/480	10/709	0.983
Intubation	3/694	1/771	0.544
Defibrillation	5/694	1/771	0.174
Asystole	1/693	0/763	0.962
Cardiogenic shock	6/693	1/763	0.100
Intraprocedural death	2/693	0/764	0.467
Numbers are counts/sample size. BVS: bioresorbable vascular scaffold			

Table 4. Cardiac events at 12 months.

12 months	ACS	Stable CAD	*p*-value
All-cause death	12 (1.8)	5 (0.7)	0.054
CV death	9 (1.3)	4 (0.5)	0.113
Any MI	26 (2.1)	15 (3.9)	0.034
Target vessel MI	20 (3.0)	12 (1.7)	0.076
TLR	30 (4.7)	30 (4.2)	0.635
TVR	49 (7.8)	39 (5.6)	0.065
MACE	49 (7.6)	33 (4.6)	0.016
PoCE	123 (18.5)	83 (11.6)	<0.001
DoCE	42 (6.4)	30 (4.2)	0.052

Numbers are count (Kaplan-Meier estimate). 12-month follow-up available in 550 (79%) patients with ACS and 631 (81%) patients with stable CAD. CV: cardiovascular; DoCE: device-oriented composite endpoints (cardiovascular death, target vessel MI and TLR); MACE: major adverse cardiac events (composite of CV death, any MI, clinically driven TLR); MI: myocardial infarction; PoCE: patient-oriented composite endpoints (composite of all-cause death, any MI and any repeat revascularisation); TLR: target lesion revascularisation; TVR: target vessel revascularisation

n=1,227 lesions, 1,020 patients, 465 with ACS) was a predictor of PoCE (p<0.001, HR: 0.47 [0.33-0.66]), DoCE (p=0.023, HR: 0.51 [0.28-0.91] and ScT (p=0.025, HR: 0.40 [0.18-0.89]). In contrast, the choice of a BVS with a nominal diameter smaller than the RVD

Table 5. Scaffold thromboses (ScT) at 12 months.

		ACS	Stable CAD	*p*-value
At 12 months	Definite	18 (2.6)	6 (0.8)	0.006
	Probable	1 (0.2)	4 (0.5)	0.226
	Definite+probable	19 (2.8)	10 (1.4)	0.047
	Possible	1 (0.2)	0	0.286
	All types	20 (2.9)	10 (1.4)	0.031
Timing of thrombosis	Acute	7 (1)	0	0.005
	Subacute (>24 hours, <30 days)	9 (1.3)	5 (0.7)	0.200
	Late (>30, <365 days)	4 (0.6)	5 (0.7)	0.884

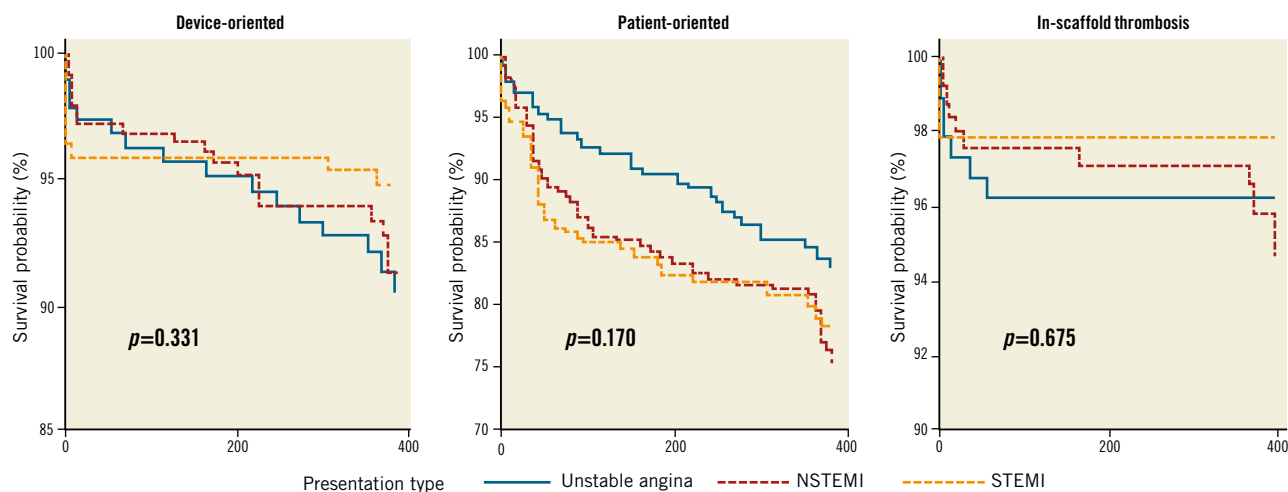Numbers are count/sample size (Kaplan-Meier estimate).

Figure 3. *The incidence of the three endpoints by presentation type.*

("undersizing") was not associated with any of the endpoints (PoCE: p=0.53, HR: 0.82 [0.45-1.51], DoCE: p=0.83, HR: 1.11 [0.44-2.78], and ScT: p=0.92, HR: 0.92 [0.19-4.40]). Post-dilation alone had no impact on DoCE (p=0.656, HR: 0.86 [0.47-1.60]), PoCE (p=0.779, HR: 0.95 [0.67-1.36]) or ScT (p=0.58, HR: 0.80 [0.37-1.76]).

All these associations remained valid also when only STEMI patients were included.

Discussion

SUMMARY OF THE RESULTS

In the present report, ACS was an independent predictor of both DoCE and PoCE. These results are not surprising: the incidence of events in our BVS group was in line with that reported in previous drug-eluting stent studies[10,11]. Similarly, while no difference was observed in terms of TLR, BVS implantation in the setting of ACS was also associated with a higher incidence of ScT. Importantly, no difference was observed in terms of DoCE and ScT among patients admitted for unstable angina, NSTEMI or STEMI.

In line with recently reported data[12,13], a higher incidence of events was observed in patients in whom a BVS at least 10% larger than the target vessel was implanted. Beyond the risk of vessel trauma and edge dissection associated with oversizing, there are additional considerations that are specific to BVS to explain this observation[12,14]. Due to the larger strut width, the implantation of BVS results in a larger strut to artery ratio (footprint) as compared to DES. As a consequence, the risk of underexpansion is higher than with DES. Particularly when associated with inaccurate lesion preparation (no predilation or predilation with small balloons as often performed in the treatment of ACS lesions), this may ultimately lead to decreased luminal flow area and increased inter-strut flow turbulence. In analogy, small RVDs were a predictor of all event types, a finding that was also observed in the ABSORB III study[13]. These data highlight the importance of target vessel size and scaffold deployment also in the setting of ACS. Further supporting this important concept, while ACS at index was an important determinant

of outcomes in the overall population in our recently published report, this association did not reach significance when BVS were implanted using a technique specifically aimed at improving BVS expansion[12]. Also, in the current analysis, ACS was not a predictor of device endpoints in patients in whom post-dilation was performed. While post-dilation might potentially represent a risk factor for no reflow in thrombotic lesions of patients with ACS, and while post-dilation as a single parameter was not a predictor of events in our database **(Supplementary Table 3-Supplementary Table 5)**, the fact that this manoeuvre is part of the optimal BVS implantation strategy is recognised[15].

BVS IN ACS

While they provide effective mechanical revascularisation of culprit lesions, permanent metallic stents also have important drawbacks, and ACS represents a setting in which bioresorbable technologies might provide important advantages. Profound differences in plaque biology and pathophysiology exist between sCAD and ACS, which has profound implications with regard to the goal of revascularisation. In addition to the acute improvement of coronary haemodynamics and resolution of the stenosis, plaque stabilisation assumes a central role in ACS, and the inflammatory/oxidative reactions associated with permanent implantation of metal stents might represent a disadvantage of traditional stents[16-22]. In contrast, recent intracoronary imaging data of ACS patients treated with BVS described the formation of a neointimal layer 12 months after implantation[6,23-27] associated with an increase in (stable) fibrous and fibro-fatty content and a decrease in features of unstable necrotic core and dense calcium tissue[28]. Along with the mechanical resolution of the stenosis, it has been proposed that this layer, with characteristics compatible with those of fibrous tissue, might prevent repeat rupture/ulceration, reducing the risk of intracoronary thrombosis[24]. As such, a biological rationale exists to suggest that permanent implants might also not be necessary in ACS patients.

To date, data on the outcome after BVS treatment of ACS are available but remain limited. With regard to acute and short-term procedural outcomes, data from the POLAR-ACS, the Polish National Registry (about 50% of the patients with ACS), the GHOST-EU (47% ACS) and AMC PCI registries (39% ACS), as well as STEMI-specific registries[29-31] have documented the safety of BVS implantation[4,7,32-34]. At six months, admission for ACS was not a predictor of outcomes in the GHOST-EU database, but, similar to the Mainz registry[4], an unexpectedly high incidence of ScT was reported[12]. Similarly, ACS at index did not influence outcomes in the ABSORB III trial[13]. In the BVS-EXAMINATION trial, a propensity score-based comparison of Absorb BVS and XIENCE drug-eluting stents (Abbott Vascular) in STEMI, the DoCE rate was similar between groups, but a numerically higher incidence of ScT was recorded in the BVS group[2].

Limitations

Patients with ACS differed in many parameters from those without ACS. Even though the Cox regression analysis was adjusted for these factors, and even though it has already been shown that parameters like diabetes do not influence the prognosis of patients treated with BVS[35], interactions may be complex and difficult to correct for. This registry was not a randomised, controlled trial, there was no external monitoring or event adjudication, and the follow-up in the whole population was not possible. Also, patients were treated at a time when the importance of the implantation technique remained to be demonstrated. As a consequence, the present data reflect early BVS experiences. A recent paper from our group demonstrates that the use of a BVS-specific implantation strategy is associated with a marked reduction in events, offsetting the risk associated with an unstable clinical presentation[12]. Although these limitations are to be acknowledged, this registry provides real-life data, demonstrating the importance of careful lesion preparation, vessel sizing, and BVS expansion. Further, QCA data were not analysed centrally and, due to logistical reasons, data from some of the centres were not available. However, the subgroup of patients in which these data were available did not differ from the overall study cohort with respect to both clinical/procedural parameters and outcomes. Finally, ACS patients are not a homogeneous population and important differences exist between presentation types. Whether these differences also result in differences in the predictors of events will need to be investigated in future studies.

Conclusions

We report 12-month follow-up data from the early experience with BVS in the setting of ACS. In line with previous data from metal stents[36], a history of ACS was associated with an increased incidence of DoCE, PoCE and ScT, but not TLR. Oversizing, and not undersizing, appeared to be a determinant of events. These observations offer further information on the importance of the deployment technique in this setting.

Impact on daily practice

In patients treated with bioresorbable scaffolds, a history of acute coronary syndrome at index procedure was a predictor of device-oriented and patient-oriented endpoints, including scaffold thrombosis. As for stable patients, relative oversizing at the time of implantation appeared to be a determinant of events.

Conflict of interest statement

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Supplementary data

Supplementary Table 1. Patient characteristics.
Supplementary Table 2. Lesion and procedural characteristics.
Supplementary Table 3. Predictors of DoCE at 12 months.
Supplementary Table 4. Predictors of PoCE at 12 months.
Supplementary Table 5. Predictors of ScT at 12 months.

The supplementary data are published online at:
http://www.pcronline.com/
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Supplementary data

Supplementary Table 1. Patient characteristics.

Variable	Unstable angina	NSTEMI	STEMI	p-value
Age (years)	63±11	61±12	58±12	0.001
Male sex	81% (190)	80% (259)	76% (248)	0.255
Hypertension	78% (190)	70% (259)	60% (248)	0.001
Smoking	31% (190)	42% (259)	52% (248)	0.001
Hyperlipidaemia	53% (190)	38% (259)	40% (248)	0.009
Diabetes	26% (190)	24% (259)	15% (248)	0.003
Family history of CAD	34% (190)	25% (259)	25% (248)	0.040
Prior revascularisation	37% (190)	17% (259)	8% (248)	0.001
Prior CABG	7% (190)	4% (259)	0.4% (248)	0.001
Prior stroke or TIA	9% (190)	4% (259)	3% (248)	0.009
Glomerular filtration rate	87±26	83±30	88±28	0.379
LVEF	55±8	54±10	50±11	0.001
Multivessel	33% (190)	32% (259)	29% (248)	0.697

Numbers are % (number/sample size) or mean±SD (sample size).
CABG: coronary artery bypass grafting; CAD: coronary artery disease; LVEF: left ventricular ejection fraction; TIA: transient ischaemic attack

Supplementary Table 2. Lesion and procedural characteristics.

Procedural characteristics	Unstable angina	NSTEMI	STEMI	*p*-value
Radial access	43% (190)	44% (259)	40% (248)	0.579
No. of lesions treated with BVS	1.1±0.4	1.2±0.5	1.1±0.4	0.239
BVS per patient (n)	1.5±0.8	1.3±0.7	1.3±0.7	0.057
OCT performed	6% (190)	7% (259)	7% (248)	0.569
IVUS performed	15% (190)	3% (259)	3% (248)	0.001
Lesion characteristics				
Ostial lesions	4.6% (196)	7% (257)	6% (251)	0.819
LMCA	2% (222)	1% (288)	0.4% (282)	0.063
LAD	54% (222)	44% (288)	52% (282)	0.030
Circumflex (RCX)	28% (222)	52 (288)	12 (282)	0.001
RCA	23% (222)	23% (288)	36% (288)	0.001
Lesion type B2 or C	45% (216)	39% (285)	53% (268)	0.004
Thrombus present	7% (214)	33% (288)	63% (288)	0.001
Chronic total occlusion	4% (222)	2% (295)	0.7% (284)	0.076
Bifurcation	19% (223)	13% (295)	14% (284)	0.118
Proximal RVD before stenting, mm	3.0±0.5	3.0±0.5	3.0±0.6	0.605
Procedural characteristics (per lesion)				
Predilation	99% (223)	97% (295)	92% (284)	0.001
Total scaffold length (mm)	25.9±13.6	23.7±13.8	23.1±10.0	0.033
Minimum BVS diameter (2.5/3.0/3.5 mm)	34%/36%/30% (223)	32%/39%/29% (295)	45%/39%/17% (283)	0.001
Implantation pressure	12.6±3.4	12.9±2.2	13.4±2.8	0.006
Post-dilation	56% (223)	35% (295)	41% (284)	0.003
P2Y$_{12}$ therapy at discharge				0.001
Clopidogrel 75 mg	6% (197)	0.7% (258)	0% (242)	
Prasugrel 10 mg	78% (197)	51% (258)	78% (242)	
Ticagrelor 180 mg	16% (197)	48% (258)	22% (242)	

Numbers are count/sample size (%) or mean±SD (sample size) or N (sample size).
BVS: bioresorbable vascular scaffold; IVUS: intravascular ultrasound; LAD: left anterior descending; LMCA: left main coronary artery; OCT: optical coherence tomography; RCA: right coronary artery

Supplementary Table 3. Predictors of DoCE at 12 months.

Variable	HR [95% CI]	*p*-value	HR [95% CI]	*p*-value
	Univariate analysis		Multivariable analysis	
Age	0.99 [0.97-1.02]	0.655		
Male sex	0.82 [0.48-1.40]	0.466		
Hypertension	1.22 [0.71-2.10]	0.472		
Smoking	1.14 [0.70-1.86]	0.590		
Hyperlipidaemia	0.72 [0.45-1.14]	0.168		
Diabetes	1.84 [1.15-2.95]	0.012	1.89 [1.13-3.14]	0.016
Family history of CAD	0.83 [0.50-1.39]	0.479		
Prior revascularisation	1.03 [0.64-1.67]	0.906		
Prior CABG	1.12 [0.41-3.05]	0.827		
Prior stroke or TIA	0.77 [0.19-3.10]	0.711		
Glomerular filtration rate <30 ml/min	1.59 [0.79-3.21]	0.196		
LVEF <30%	1.04 [0.26-4.20]	0.962		
Multivessel disease	0.92 [0.67-1.26]	0.585		
ACS	1.59 [0.99-2.53]	0.054	2.26 [1.34-3.81]	0.002
Access	0.72 [0.44-1.18]	0.191		
OCT performed	1.37 [0.74-2.53]	0.323		
IVUS performed	1.04 [0.55-1.98]	0.896		
Ostial lesions	2.87 [1.46-5.62]	0.002	3.26 [1.64-6.50]	<0.001
LM	2.54 [0.63-10.29]	0.194		
LAD	1.30 [0.81-2.07]	0.279		
RCX	0.71 [0.40-1.27]	0.255		
RCA	0.88 [0.50-1.54]	0.464		
Lesion type B2 or C	1.20 [0.75-1.92]	0.450		
Chronic total occlusion	0.76 [0.28-2.07]	0.589		
Bifurcation	1.52 [0.92-2.52]	0.108		
Mean RVD <2.5 mm	1.64 [0.79-3.41]	0.186		
Mean RVD >3.5 mm	0.79 [0.32-1.98]	0.616		
Predilation	0.53 [0.22-1.32]	0.177		
Total scaffold length (mm)	1.01 [1.00-1.02]	0.027	1.01 [0.99-1.02]	0.269
Minimum BVS diameter (2.5/3.0/3.5 mm)	0.48 [0.26-0.88]	0.017	0.41 [0.21-0.81]	0.011
Implantation pressure	1.007 [0.934 to 1.086]	0.851		
Post-dilation	1.018 [0.643 to 1.612]	0.941		
$P2Y_{12}$ therapy at discharge	1.177 [0.782 to 1.770]	0.437		

Supplementary Table 4. Predictors of PoCE at 12 months.

Variable	HR [CI]	*p*-value	HR [CI]	*p*-value
	Univariate analysis		Multivariable analysis	
Age	1.00 [0.99-1.01]	0.930		
Male sex	0.85 [0.61-1.17]	0.325		
Hypertension	1.42 [1.02-1.97]	0.040	1.91 [1.08-3.38]	0.027
Smoking				
Hyperlipidaemia	1.00 [0.76-1.31]	0.140		
Diabetes	1.15 [0.85-1.56]	0.356		
Family history of CAD	0.90 [0.67-1.21]	0.488		
Prior revascularisation	0.81 [0.60-1.08]	0.155		
Prior CABG	0.84 [0.43-1.64]	0.619		
Prior stroke or TIA	0.78 [0.35-1.75]	0.550		
Glomerular filtration rate <30 ml/min	1.45 [0.91-2.30]	0.121		
LVEF <30%	0.72 [0.27-1.94]	0.520		
Multivessel disease	1.24 [0.95-1.64]	0.120		
ACS	1.74 [1.32-2.39]	<0.001	1.71 [1.13-2.58]	0.011
Access	1.18 [0.90-1.56]	0.234		
OCT performed	0.89 [0.59-1.37]	0.609		
IVUS performed	0.81 [0.54-1.22]	0.309		
Ostial lesions	1.84 [1.16-2.92]	0.010	1.76 [0.81-3.82]	0.152
LM	1.29 [0.42-4.02]	0.659		
LAD	1.08 [0.82-1.42]	0.580		
RCX	0.88 [0.63-1.23]	0.464		
RCA	0.99 [0.72-1.36]	0.946		
Lesion type B2 or C	0.93 [0.71-1.23]	0.635		
Chronic total occlusion	0.78 [0.44-1.40]	0.412		
Bifurcation	1.25 [0.91-1.71]	0.167		
Mean RVD <2.5 mm	2.04 [1.36-3.07]	<0.001	2.16 [1.43-3.27]	<0.001
Mean RVD >3.5 mm	0.82 [0.48-1.40]	0.479		
Predilation	1.37 [0.61-3.06]	0.452		
Total scaffold length (mm)	1.00 [1.00-1.01]	0.213		
Minimum BVS diameter (2.5/3.0/3.5 mm)	0.61 [0.43-0.88]	0.008		
Implantation pressure	1.05 [1.00-1.09]	0.046	1.08 [1.02-1.15]	0.008
Post-dilation	0.92 [0.70-1.21]	0.571		
P2Y$_{12}$ therapy at discharge	1.19 [0.93-1.52]	0.162		

Supplementary Table 5. Predictors of ScT at 12 months.

Variable	HR [95% CI]	p-value	HR [95% CI]	p-value
	Univariate analysis		Multivariable analysis	
Age	1.01 [0.97-1.04]	0.700		
Male sex	1.01 [0.42-2.47]	0.976		
Hypertension	1.51 [0.62-3.67]	0.363		
Smoking	0.84 [0.37-1.87]	0.664		
Hyperlipidaemia	0.79 [0.39-1.60]	0.511		
Diabetes	1.66 [0.79-3.47]	0.181		
Family history of CAD	0.66 [0.29-1.54]	0.343		
Prior revascularisation	0.97 [0.46-2.07]	0.945		
Prior CABG	1.37 [0.33-5.72]	0.665		
Prior stroke or TIA	1.94 [0.46-8.07]	0.367		
Glomerular filtration rate <30 ml/min	0.45 [0.06-3.40]	0.441		
LVEF <30%	0.00	0.966		
Multivessel disease	0.91 [0.43-1.90]	0.795		
ACS	2.25 [1.06-4.79]	0.036	2.51 [1.13-5.60]	0.025
Access	1.01 [0.49-2.09]	0.981		
OCT performed	1.33 [0.51-3.45]	0.564		
IVUS performed	0.41 [0.10-1.69]	0.218		
Ostial lesions	2.56 [0.89-7.36]	0.083	2.98 [1.03-8.63]	0.045
LM	2.99 [0.41-21.72]	0.282		
LAD	2.19 [1.00-4.80]	0.0504		
RCX	0.66 [0.25-1.71]	0.490		
RCA	0.45 [0.16-1.29]	0.140		
Lesion type B2 or C	1.08 [0.52-2.23]	0.844		
Chronic total occlusion	0.94 [0.23-3.91]	0.930		
Bifurcation	1.57 [0.72-3.41]	0.259		
Mean RVD <2.5 mm	1.66 [0.56-4.92]	0.364		
Mean RVD >3.5 mm	0.41 [0.06-3.05]	0.386		
Predilation	1.15 [0.16-8.37]	0.890		
Total scaffold length (mm)	1.00 [0.98-1.02]	0.802		
Minimum BVS diameter (2.5/3.0/3.5 mm)	0.43 [0.17-1.10]	0.0791	0.34 [0.13-0.93]	0.036
Implantation pressure	1.08 [0.97-1.21]	0.156		
Post-dilation	0.94 [0.46-1.93]	0.876		
$P2Y_{12}$ therapy at discharge	1.24 [0.66-2.33]	0.503		