Original paper

Comparison of the everolimus-eluting bioresorbable vascular scaffold versus the everolimus-eluting metallic stent in real-world patients with ST-segment elevation myocardial infarction

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Abstract

Introduction: Despite the withdrawal of the ABSORB bioresorbable vascular scaffold (BVS) from clinical use, continuous observation of BVS-treated patients is necessary. In the vast majority of clinical trials, patients with ST-segment elevation myocardial infarction (STEMI) were excluded from the analysis.

Aim: To compare the early and long-term outcomes of the BVS with the everolimus-eluting metallic stent (EES) in patients with STEMI.

Material and methods: Consecutive patients treated with BVS or EES in our center were screened. For analysis, only patients with STEMI were enrolled. The primary endpoint was a comparison of the target lesion failure at 12 and 24 months. The secondary endpoints encompass occurrence of the patient-oriented cardiovascular endpoint (PoCE), stent thrombosis (ST), device, and procedural success.

Results: Between 2012 and 2016, 2,137 patients were hospitalized for STEMI. Of these, 123 patients received the BVS (163 scaffolds; 151 lesions), whereas in 141 patients the EES (203 stents; 176 lesions) was implanted. The median follow-up was 931 ±514 days. The primary endpoint at 12 months occurred in 9.7% in the BVS group and in 8.5% in the EES group (hazard ratio (HR) = 2.61; 95% confidence interval (CI): 0.90–7.56; $p = 0.076$). At 24 months the incidence of the primary endpoint was 15.2% in the BVS group and 14.9% in the EES group (HR = 2.46; 95% CI: 0.85–7.07; $p = 0.095$). The rates of PoCE, ST, device, and procedural success were also comparable in both groups.

Conclusions: STEMI patients treated with the BVS showed statistically similar rates of primary and secondary endpoints compared with the EES.

Key words: bioresorbable vascular scaffold, primary percutaneous coronary intervention, acute myocardial infarction/ST-segment elevation myocardial infarction, everolimus-eluting stent.

Summary

Despite the withdrawal of the ABSORB bioresorbable vascular scaffold (BVS) from clinical use, it is necessary to continue observation of BVS-treated patients. The purpose was to compare the early and long-term outcomes of the BVS with the everolimus-eluting metallic stent (EES) in patients with ST-segment elevation myocardial infarction (STEMI). We found that STEMI patients treated with the BVS showed statistically similar rates of primary and secondary endpoints compared with the EES. However, events of myocardial infarction, revascularization, and stent thrombosis in the BVS group were more frequent.

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Introduction

Over the last years, the prognosis of patients in the acute phase of myocardial infarction has improved, but the long-term outcomes are still disadvantageous [1]. The current generation of drug-eluting stent (DES) has demonstrated higher efficacy and safety in the treatment of coronary artery disease in comparison to previous generations of DES and bare-metal stents (BMS) [2]. Despite this, the DES has some limitations. It is well documented that the presence of permanent metallic cages can lead to the enhancement of local chronic inflammatory processes, persistent stimulation of cellular elements, delay of endothelialization, acceleration of neoatherosclerosis, impairment of vessel vasomotion restoration, and mechanical complications [3, 4]. A potential solution of the mentioned issues is the concept of the bioresorbable vascular scaffold (BVS) [5]. Outcomes of the first trials [6–8] of the most widespread BVS (Absorb, Abbott Vascular, Santa Clara, California) in clinical practice were promising. Nevertheless, data from contemporary studies have shown a significantly higher frequency of stent thrombosis (ST) in the BVS-treated patients compared to second-generation everolimus drug-eluting stents (EES) [9]. Based on these reports of an increased risk of scaffold thrombosis, routine implantation of the Absorb BVS was abandoned. Despite the withdrawal of ABSORB BVS from clinical use, it is necessary to continue observation of BVS-treated patients. In the vast majority of studies, patients with ST-segment elevation acute myocardial infarction (STEMI) or with fresh thrombus were excluded from the analyses [6–9].

Theoretically, the advantages of BVS technology may appear appealing to the STEMI population. The physiological advantages of BVS in comparison with the current-generation DES may effectively prevent the occurrence of the no-reflow phenomenon [10]. Moreover, the resorption process with late lumen enlargement, restoration of normal vasomotion, shear stress, and cyclic strain could lead to plaque regression and reduction of late cardiovascular events [5, 11, 12]. Only one randomized trial [13] and a few studies [14–29] were designed to evaluate clinical outcomes in STEMI patients. Nevertheless, the mentioned studies were limited by small sample size or the highly selected nature of the study population.

Aim

The purpose of the present study based on single-center registry was to compare the early and long-term outcomes of real-world patients with STEMI treated with BVS or EES.

Material and methods

Study design

The study included data from the previously published ZABRZE-BVS registry [30]. ZABRZE-BVS, encompassing 456 patients treated with BVS, is an all-comers registry assessing the safety and efficacy of the BVS in the treatment of patients with coronary artery disease in routine clinical practice [30]. Simultaneously in our center the registry including patients treated with EES was conducted. Based on mentioned prospective data registries, we performed a retrospective analysis of consecutive patients with STEMI treated with BVS or EES. The study design was based on intention-to-treat with BVS or EES.

The management in the study population was in accordance with contemporary recommendations of the European Society of Cardiology (ESC) in STEMI [31]. Briefly, during or after transfer to the hospital, the loading dose of acetylsalicylic acid, P2Y12 inhibitor, and weight-adjusted unfractionated heparin were administered. In all cases, coronary angiography with standard techniques and equipment was performed. The decision on the access site (radial, femoral or other) and the type of diagnostic catheters was taken by the operator. Evaluation of the coronary arteries was made based on visual estimation and offline quantitative coronary angiography. If appropriate, the use of intravascular imaging (intravascular ultrasound or optical coherence tomography) was promoted. All therapeutic decisions after coronary angiography, balloon predilatation and postdilatation, use of stents, type of stents, glycoprotein IIb/IIIa receptor inhibitors and other established interventional techniques were at the operator's discretion.

Along with the new data on the BVS implantation technique, the appropriate management was recommended: 1) accurate measurement of the diameter of the treated segment using quantitative coronary angiography at the maximum extension of the treated vessel (via intracoronary administration of nitroglycerin); 2) optimal preparation of lesion involving the manual thrombectomy and selection of appropriate type and size of the balloon to predilatation with obtaining residual stenosis less than 40% of diameter stenosis; 3) proper BVS implantation technique associated with a gradual increase (2 atm per 5 s) and maintaining the target pressure of the expanded balloon for 30 s; 4) conducting postdilatation with a balloon of the diameter of not more than 0.5 mm from the nominal diameter of the stent. Not mentioned aspects of BVS implantation were consistent with the contemporary state-of-the-art.

After the procedure, the patients were transferred to the intensive care unit. In case of recurrence of ischemia, urgent coronary angiography was performed. After discharge, dual antiplatelet therapy was recommended for at least 12 months. Furthermore, each patient has been prescribed standard secondary prevention in accordance with the ESC guidelines [31].

Data collection

Baseline clinical and angiographic data of enrolled patients were recorded in the institutional database. In-

formation on follow-up, including causes and exact dates of death and cardiovascular events, were obtained from the official registry of the National Health Fund, guaranteeing complete data collection. Therefore, follow-up was available for all patients enrolled in the study.

Endpoints and definitions

Clinical endpoints used in the present study were consistent with the Academic Research Consortium consensus Clinical End Points in Coronary Stent Trials [32]. Briefly, the primary endpoint encompassed the device-oriented cardiovascular endpoint (DoCE) defined as cardiac death, target vessel myocardial infarction and ischemia-driven target lesion revascularization. Secondary endpoints included device success (per lesion), procedural success (per patient), ST and patient-oriented cardiovascular endpoint (PoCE) defined as all-cause death, all myocardial infarction, and all ischemia-driven revascularization. The device success was defined as successful delivery and deployment of the stent at the intended target lesion and successful withdrawal of the delivery system with the attainment of final in-stent residual stenosis of < 20%. The procedure success was defined as achievement of device success in all intended-to-treat lesions without the occurrence of cardiac death, target vessel myocardial infarction, or repeat ischemia-driven target lesion revascularization during the hospital stay. In a multiple target lesion setting, all lesions must meet clinical procedure success criteria to have a patient-level procedure success.

The diagnosis of STEMI was in accordance with the Third Universal Definition of Myocardial Infarction: 1) symptoms of ischemia; 2) the presence of ST-segment elevation consistent with an infarction of ≥ 2 mm in contiguous chest leads, ST-segment elevation of ≥ 1 mm in 2 or more standard leads, or a new left bundle branch block; 3) detection of rising and/or falling of high-sensitive cardiac troponin with at least one value above the 99th percentile of the upper reference limit [31].

Statistical analysis

The comparison of baseline and angiographic characteristics, and early and long-term outcomes between both study groups was performed. Normality of the distribution was verified by the Shapiro-Wilk test. Continuous variables were summarized using the arithmetic mean with standard deviation or median with quartile 1 and 3. Student's *t*-test for comparison of continuous parameters with normal distribution was performed, whereas the Mann-Whitney *U* for parameters with non-normal distribution was used. Categorical variables were compared using Pearson's χ^2 test with the Yates correction if the expected number of observations was less than 5. Additionally, for the primary and secondary clinical endpoints, we used the Cox proportional hazards

and logistic regression models to adjust for differences in patients' baseline characteristics. The factors considered in models were as follows: age, chronic total occlusion in non-culprit lesion, creatinine level on admission, glucose level on admission, hemoglobin level on admission, history of atrial fibrillation, history of diabetes mellitus, left ventricular ejection fraction, male sex, multivessel coronary artery disease, prior myocardial infarction, prior percutaneous coronary intervention, peripheral artery disease, white blood cells on admission. Results were presented as hazard ratio (HR) or odds ratio with a 95% confidence interval (CI). For DoCE and PoCE at 24 months, analysis with the Kaplan-Meier method with the log-rank comparison of curves was performed. A two-sided *p*-value < 0.05 was considered significant. The Statistica 12 software (StatSoft Inc., Tulsa, Oklahoma) was used for all calculations.

Results

From January 2012 until December 2016, 2,137 patients were hospitalized for STEMI in our center. Of these, 123 patients received the BVS (126 procedures; 163 scaffolds; 151 lesions), whereas in 141 patients the EES (144 procedures; 203 stents; 176 lesions) was implanted. The average age of the study population was 57.7 ±11.8 years, and 78.4% were male. The overall prevalence of diabetes mellitus was 21.6%, mean left ventricular ejection fraction was 43.4 ±8.5%, and the presence of multivessel coronary artery disease was found in 43.2% of patients. Baseline clinical characteristics and risk factors of the study groups are summarized in Table I. Patients treated with BVS were younger, more often had dyslipidemia and less often were obese in comparison to the EES group. Moreover, cardiac arrest on admission was present four times more frequently in the BVS than in the EES group.

The analysis of coronary angiography and procedural parameters is presented in Table II. In BVS in comparison with EES patients femoral vascular access and intervention in restenotic lesions were less frequent. The proximal left anterior descending artery was revascularized more often, while the left main and right coronary artery were revascularized less often in the BVS than in the EES group. In the BVS group, the percentage of balloon predilatation was 95.4%, manual thrombectomy was 14.6%, whereas postdilatation was performed in 60.9% of cases. The rates of slow/no-reflow phenomenon were low and similar in both groups.

Long-term outcomes with adjusted hazard ratios at 12 and 24 months in both analyzed groups are presented in Table III. In Figure 1, the Kaplan-Meier curves with log-rank comparison are shown. The median follow-up period was 931 ±514 days. The primary endpoint at 12 months occurred in 9.7% in the BVS group and 8.5% in the EES group (adjusted HR = 2.61; 95% CI: 0.90–7.56; *p* = 0.076). At 24 months the incidence of the primary

Table I. Baseline characteristics of study population

Factor	BVS (*n* = 123)	EES (*n* = 141)	*P*-value
Age, mean ± SD [years]	53.8 ±10.1	61.0 ±12.2	< 0.0001
Male, %	78.9	78.0	0.87
Arterial hypertension, %	56.1	65.2	0.13
Prior MI, %	12.2	17.0	0.27
Prior PCI, %	9.8	9.8	0.27
Atrial fibrillation, %	5.7	9.2	0.28
Diabetes mellitus, %	21.9	21.3	0.89
Dyslipidaemia, %	68.3	53.9	0.017
Cigarette smoking, %	37.4	43.3	0.33
Cardiac arrest*, %	8.9	2.1	0.014
Killip class IV*, %	5.7	3.6	0.40
eGFR*< 60 ml/min/1.73 m²*, %	8.5	17.7	0.030
LVEF*, mean ± SD, %	43.8 ±8.3	43.0 ±8.6	0.48
LVEF< 35%*, %	16.3	15.0	0.78
Antithrombotic therapy, %:			
Acetylsalicylic acid	100.0	100.0	0.99
Clopidogrel	74.0	95.4	< 0.0001
Ticagrelor	13.8	1.5	< 0.0001
Prasugrel	12.2	0.7	0.0001
Oral anticoagulant	4.9	5.4	0.84

On admission. BVS – bioresorbable vascular scaffold, CABG – coronary artery bypass grafting, EES – everolimus-eluting cobalt chromium stent, eGFR – estimated glomerular filtration rate, LVEF – left ventricular ejection fraction, MI – myocardial infarction, PCI – percutaneous coronary intervention.

endpoint was 15.2% in the BVS group and 14.9% in the EES group (HR = 2.46; 95% CI: 0.85–7.07; *p* = 0.095). Occurrence of PoCE was similar at 12 months (13.6% vs. 12.8%; *p* = 0.16) and at 24 months (21.2% vs. 21.8%; *p* = 0.25). The percentage of device (95.4% vs. 96.6%; *p* = 0.82) and procedural success (95.1% vs. 94.3%; *p* = 0.62) was comparable in both groups. Other clinical outcomes were similar in the BVS and the EES group.

During 24-month follow-up, five definite ST in the BVS group (one acute, three subacute, one late) and two definite ST in the EES group (one late, one very late) were observed (HR = 5.20; 95% CI: 0.73–36.78; *p* = 0.10). Baseline characteristics, pharmacological treatment and procedural results of patients with ST of the BVS group are presented in Table IV.

Discussion

The principal findings of the presented data can be summarized as follows: 1) selection of the BVS during the primary PCI procedure is closely related to the baseline and angiographic characteristics of patients; 2) results show similar rates of DoCE, PoCE, device and procedural success in both groups; 3) there were no statistically significant differences in the incidence of ST and other clin-

ical outcomes. There were no significant differences in the frequency of target vessel myocardial infarction, target vessel and lesion revascularization, and ST between BVS and EES groups. However, they occurred two to three times more frequently in the BVS than in the EES group. Therefore, due to the sample size of our study, the above observations should be interpreted with caution.

A significantly higher frequency of ST in BVS-treated patients compared to second-generation DES in clinical trials was a cause of the withdrawal of ABSORB BVS from clinical use [9]. According to our knowledge, the BVS was implanted in over 150,000 patients on a global scale [30]. Therefore, continuous observation of BVS-treated patients is necessary.

Procedural characteristics

The most common pathophysiological mechanism of STEMI is a ruptured atherosclerotic plaque with a large necrotic core, resulting in delayed healing and chronic inflammation of the vessel [33]. Implementation of BVS technology in this field could lead to potential benefits. The presence of twice as large struts in comparison to the second-generation DES can allow the maintenance of the thrombotic material between the scaffold and the

Table II. Procedural characteristics of study population

Factor	BVS (*n* = 123)	EES (*n* = 141)	*P*-value
Coronary angiography, %:			
Single-vessel CAD	61.8	52.5	0.13
Double-vessel CAD	30.1	34.0	0.49
Triple-vessel CAD	8.1	13.5	0.17
CTO in non-target lesion	8.9	17.0	0.054
Total number of procedures, *n*:	126	144	
Femoral access, %	85.7	93.1	0.048
Radial access, %	14.3	6.9	0.048
Total number of target lesions, *n*:	151	176	
Lesions per patients, mean ± SD, *n*	1.22 ±0.52	1.25 ±0.54	0.66
Percent diameter stenosis, mean ± SD, %	90.1 ±11.0	90.7 ±10.3	0.65
Left main, %	0.0	4.5	0.0080
Left anterior descending, %	60.3	50.6	0.046
Left circumflex, %	22.5	12.5	0.017
Right coronary artery, %	17.2	31.2	0.0039
Bypass, %	0.0	1.1	0.19
Bifurcation, %	17.9	18.2	0.94
Thrombus, %	24.5	25.0	0.92
Thrombectomy, %	14.6	9.1	0.12
Restenotic, %	0.7	6.2	0.0074
Predilatation, %	95.4	77.3	< 0.0001
Postdilatation, %	60.9	27.8	< 0.0001
Pre-intervention TIMI flow 0–1, %:	44.4	38.1	0.25
Post-intervention TIMI flow 3, %	96.0	97.7	0.37
Total number of device, *n*:	163	203	
Device per patients, mean ± SD, *n*	1.32 ±0.59	1.44 ±0.80	0.15
Total device length, mean ± SD [mm]	21.69 ±5.67	22.10 ±8.03	0.57
Nominal device diameter, mean ± SD [mm]	3.06 ±0.38	2.98 ±0.51	0.092
Deployment pressure, mean ± SD [atm]	13.16 ±2.52	14.26 ±2.83	0.13
Procedure characteristics (per procedure):			
Glycoprotein IIb/IIIa inhibitors, %	21.4	16.7	0.32
Intravascular imaging, %	3.2	0.0	0.031
Cardiogenic shock, %	2.4	3.5	0.60
Dissection, %	4.8	5.6	0.77
Perforation, %	0.8	0.7	0.92
Side branch (≥ 2 mm) occlusion, %	1.6	1.4	0.89
Slow/no-reflow, %	3.9	2.8	0.56

BVS – bioresorbable vascular scaffold, CAD – coronary artery disease, CTO – chronic total occlusion, EES – everolimus-eluting cobalt chromium stent, PCI – percutaneous coronary intervention, TIMI – thrombolysis in myocardial infarction.

Table III. Long-term outcomes of study population

Factor	BVS (*n* = 123)	EES (*n* = 141)	HR/OR (95% CI)	*P*-value
Primary endpoints:				
TLF:				
12-month, %	9.7	8.5	2.61 (0.90–7.56)	0.076
24-month, %	15.2	14.9	2.46 (0.85–7.07)	0.095
Secondary endpoints:				
PoCE:				
12-month, %	13.6	12.8	1.77 (0.79–3.95)	0.16
24-month, %	21.2	21.8	1.60 (0.72–3.56)	0.25
Device success (lesion basis)*	95.4	96.6	1.15 (0.34–3.86)	0.82
Procedural success (patient basis)*	95.1	94.3	1.40 (0.36–3.55)	0.62
Clinical outcomes, %:				
All-cause death:				
12-month	4.9	5.7	3.17 (0.72–13.86)	0.13
24-month	7.6	10.3	2.47 (0.64–9.51)	0.19
Cardiac death:				
12-month	3.9	5.7	2.44 (0.52–11.49)	0.26
24-month	6.1	10.3	1.83 (0.44–7.65)	0.41
All-MI:				
12-month	7.8	5.0	1.59 (0.52–4.87)	0.41
24-month	9.1	8.0	0.90 (0.28–2.88)	0.85
TV-MI:				
12-month	6.8	2.8	2.66 (0.69–10.32)	0.16
24-month	9.1	4.6	1.72 (0.44–6.76)	0.44
ID-TVR:				
12-month	7.8	2.8	3.96 (0.99–15.70)	0.052
24-month	12.1	4.6	3.31 (0.81–13.54)	0.096
ID-TLR:				
12-month	6.8	2.1	3.85 (0.83–17.72)	0.084
24-month	10.6	4.6	2.20 (0.58–8.41)	0.25
Scaffold/stent thrombosis:				
Definite*	4.0	1.4	5.20 (0.73–36.78)	0.10
Acute*	0.8	0.0	–**	0.94
Subacute*	2.4	0.0	–**	0.20
Late*	0.8	0.7	–**	0.54
Very late*	0.0	1.1	–**	0.95

*Logistic regression with odds ratio and 95% confidence interval was performed. **Due to distribution of variables in both groups, logistic regression analysis was not possible. χ^2 test with the Yates correction was performed. BVS – bioresorbable vascular scaffold, CI – confidence interval, EES – everolimus-eluting cobalt chromium stent, ID-TLR – ischemia-driven target lesion revascularization, ID-TVR – ischemia-driven target vessel revascularization, HR – hazard ratio, MI – myocardial infarction, OR – odds ratio, PoCE – patient-oriented composite endpoint, TLF – target lesion failure, TV-MI – target vessel myocardial infarction.*

arterial wall [10]. On the other hand, the current state-of-the-art of BVS implantation techniques indicate proper preparation of the lesion by balloon predilatation, which can potentially increase the risk of distal embolization in unstable lesions. The solution of this problem could be the use of manual thrombectomy resulting in the reduction of distal embolization. However, the latest ESC guidelines do not recommend the routine use of thrombectomy in STEMI patients [31]. In BVS registries of ACS patients, the percentage of thrombectomy was from 37% to 84%, whereas direct stenting technique ranged from 53% to 100% [13–29]. In the current study, in almost 25% of patients, evidence of thrombus was found, manual thrombectomy was performed in less than 15%, whereas direct stenting was implemented in less than 5% of cases. Despite a lower frequency of these techniques, the slow/no-flow phenomenon was relatively uncommon and comparable to other real-world registries of STEMI patients [34]. At present, there is a lack of convincing evidence that omission of predilatation is associated with relevant benefits in BVS implantation in the STEMI population.

Adverse events

It has been demonstrated that during BVS implantation there is higher platelet aggregation, stronger adhesion of inflammatory cells, and less intense endothelialisation in comparison to second-generation EES [35]. Furthermore, in STEMI patients, difficult assessment of the reference vessel diameter may result in suboptimal scaffold implantation with incomplete lesion coverage or malposition. These factors could consequently lead to abnormal flow, activation of coagulation factors and thrombocytes, and impaired arterial healing, resulting in a higher risk of both early and late ST [36, 37]. In the present study, the total rate of ST in the BVS group was 4.0%, of which early thrombosis was 3.2%. Late ST was observed in only 1 patient, while there was no occurrence of very late ST. It is noteworthy that the majority
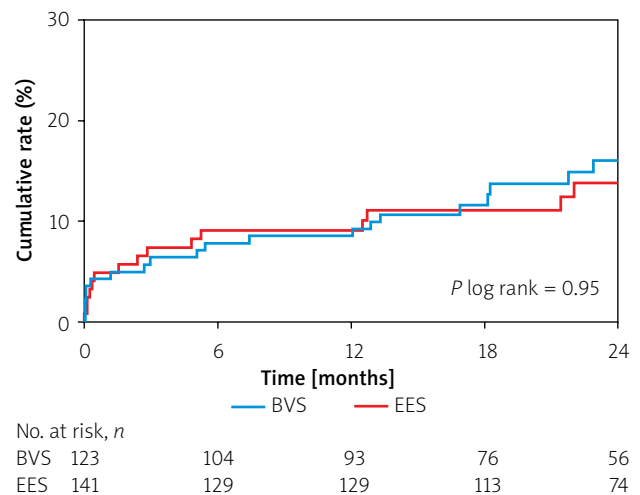

Figure 1. Kaplan-Meier survival curves of 24-month rates of target lesion failure (primary endpoint)

BVS – bioresorbable vascular scaffold, EES – everolimus-eluting stent.

of confirmed thromboses occurred in the scaffolds implanted in the first 2 years after introducing BVS technology in our center. In 2 cases of ST, postdilatation was not performed. Moreover, all patients with ST were initially treated with clopidogrel, in most of them resistance to clopidogrel was reported, while 1 patient admitted not to have been using antiplatelet drugs.

In our study, the rate of DoCE was 9.7% at 12 months and 15.2% at 24 months. These outcomes seem to be relatively high in comparison to other studies on the BVS in STEMI [14, 17–23], but similar to large retrospective registries in the STEMI population [1, 2]. It is noteworthy that almost 11% of patients in the BVS arm presented cardiac arrest or cardiogenic shock and 16% had severe systolic dysfunction on admission. These results show a clear reflection of real-world patients. Despite the lack of statistical significance, nearly two to three times higher percentages of target myocardial infarction and target revascularization were observed.

Table IV. Clinical and procedure characteristics of patients with definite scaffold thrombosis in the BVS group

Year of implantation	Age of patient	Predilatation	Post-dilatation	Device size	Location of MI	Time of ST	Antiplatelet regimen at the time of ST	Clopidogrel resistance (ADP test)
2013	66	Yes	No	2.5 × 18	CX	87	ASA + clopidogrel	N/A
2014	63	Yes	Yes	3.0 × 28	LAD	4	ASA + clopidogrel	YES
2014	51	Yes	No	3.0 × 18	LAD	1	ASA + clopidogrel	YES
2014	68	Yes	Yes	2.5 × 28	LAD	11	ASA + clopidogrel	YES
2015	60	Yes	Yes	2.5 × 23/3.0 × 23/3.5 × 18	LAD	15	ASA + clopidogrel	YES

ASA – acetylsalicylic acid, BVS – bioresorbable vascular scaffold, Cx – left circumflex, LAD – left anterior descending artery, MI – myocardial infarction, RCA – right coronary artery, ST – scaffold thrombosis, STEMI – ST-segment elevation myocardial infarction.

Antithrombotic treatment

Another controversial issue of the BVS technology in STEMI is the choice and duration of appropriate anticoagulant therapy [38]. The duration of dual antiplatelet therapy (DAPT) is a hot topic of discussion in the context of data on late thrombosis in the clinical trials [9]. Analysis of Räber *et al.* suggested that discontinuation of DAPT after 12 months, scaffold discontinuity and restenosis during the resorption, malapposition and de-endothelialisation may cause the occurrence of very late ST [39]. Regarding the present data, 12 months of DAPT was routinely recommended in all patients in the BVS arm. In general, patients manifested a low risk of bleeding based on a relatively young age, a low percentage of arterial hypertension and chronic kidney disease. Only one-quarter of patients have been prescribed ticagrelor or prasugrel. We did not have post-discharge data on the use of medication and frequency of continuation of DAPT after 12 months. It is also worth emphasizing that in all patients with documented ST, ticagrelor was prescribed and no re-thrombosis was observed. Nevertheless, very long-term observation and pharmacotherapy follow-up data are necessary to fully assess the rate of late scaffold thrombosis.

The percentage of STEMI patients with new-onset atrial fibrillation is estimated as from 6% to almost 21% [40]. Because of the above data, the use of triple antithrombotic therapy in patients after BVS implantation may be associated with an increased risk of bleeding. On the other hand, discontinuation of antiplatelet drugs before 12 months from the discharge may increase the risk of ischemia. Frequently, atrial fibrillation in STEMI is diagnosed after pPCI. There is a lack of data on the use of oral anticoagulation including novel anticoagulants in patients with STEMI after BVS implantation. In our study, triple antithrombotic therapy was prescribed in 7 patients, of which one person used a novel anticoagulant.

Clinical implications

Despite the withdrawal of ABSORB BVS from clinical use, many patients treated with BVS require continuous evaluation in long-term follow-up. The presented outcomes indicate that in the STEMI population the use of bioresorbable scaffolding technology seems to be safe and effective in relation to EES. Nevertheless, further studies, especially with longer follow-up, are necessary. Observations in the STEMI population of patients may translate into better refinement of BVS technology in the future.

Limitations

Due to the retrospective design of the prospective registries data, potential selection biases could occur. We could not verify whether all the patients had been on DAPT for 1 year, as recommended, as there were no data in the registry on DAPT cessation or continuation. The low percentage of intravascular imaging techniques may have been caused by a lack of recommendations during primary PCI or by the gradual introduction of the optimal BVS implantation technique. Low frequencies of the analyzed groups cause that the results of the present study should be interpreted with caution.

Conclusions

In this hypothesis-generating single-center registry, outcomes of patients with STEMI treated with BVS or EES were similar. This finding comes from a limited population of patients, but it reflects real-world patients with a high-risk profile.

Conflict of interest

The authors declare no conflict of interest.

References

1. Freisinger E, Fuerstenberg T, Malyar NM, et al. German nationwide data on current trends and management of acute myocardial infarction: discrepancies between trials and real-life. Eur Heart J 2014; 35: 979-88.
2. Palmerini T, Biondi-Zoccai G, Della Riva D, et al. Stent thrombosis with drug-eluting and bare-metal stents: evidence from a comprehensive network meta-analysis. Lancet 2012; 379: 1393-402.
3. Nakazawa G, Otsuka F, Nakano M, et al. The pathology of neoatherosclerosis in human coronary implants bare-metal and drug-eluting stents. J Am Coll Cardiol 2011; 57: 1314-22.
4. Park SJ, Kang SJ, Virmani R, et al. In-stent neoatherosclerosis: a final common pathway of late stent failure. J Am Coll Cardiol 2012; 59: 2051-7.
5. Serruys PW, Garcia-Garcia HM, Onuma Y. From metallic cages to transient bioresorbable scaffolds: change in paradigm of coronary revascularization in the upcoming decade? Eur Heart J 2012; 33: 16-25.
6. Serruys PW, Ormiston J, van Geuns RJ, et al. A polylactide bioresorbable scaffold eluting everolimus for treatment of coronary stenosis: 5-year follow-up. J Am Coll Cardiol 2016; 67: 766-76.
7. Ellis SG, Kereiakes DJ, Metzger DC, et al. Everolimus-eluting bioresorbable scaffolds for coronary artery disease. N Engl J Med 2015; 373: 1905-15.
8. Puricel S, Arroyo D, Corpataux N, et al. Comparison of everolimus- and biolimus-eluting coronary stents with everolimus-eluting bioresorbable vascular scaffolds. J Am Coll Cardiol 2015; 65: 791-801.
9. Serruys PW, Chevalier B, Sotomi Y, et al. 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.
10. Brugaletta S, Radu MD, Garcia-Garcia HM, et al. Circumferential evaluation of the neointima by optical coherence tomography after ABSORB bioresorbable vascular scaffold implantation: can the scaffold cap the plaque? Atherosclerosis 2012; 221: 106-12.
11. Kochman J, Kołtowski Ł, Tomaniak M, et al. First serial optical coherence tomography assessment at baseline, 12 and 24 months in STEMI patients treated with the second-generation Absorb bioresorbable vascular scaffold. EuroIntervention 2018; 13: e2201-09.

12. Gomez-Lara J, Brugaletta S, Ortega-Paz L, et al. Long-term coronary functional assessment of the infarct-related artery treated with everolimus-eluting bioresorbable scaffolds or everolimus-eluting metallic stents: insights of the TROFI II trial. JACC Cardiovasc Interv 2018; 11: 1559-71.

13. Sabaté M, Windecker S, Iñiguez A, et al. Everolimus-eluting bioresorbable stent vs. durable polymer everolimus-eluting metallic stent in patients with ST-segment elevation myocardial infarction: results of the randomized ABSORB ST-segment elevation myocardial infarction-TROFI II trial. Eur Heart J 2016; 37: 229-40.

14. Kajiya T, Liang M, Sharma RK, et al. Everolimus-eluting bioresorbable vascular scaffold (BVS) implantation in patients with ST-segment elevation myocardial infarction (STEMI). EuroIntervention 2013; 9: 501-4.

15. Gori T, Schulz E, Hink U, et al. Early outcome after implantation of Absorb bioresorbable drug-eluting scaffolds in patients with acute coronary syndromes. EuroIntervention 2014; 9: 1036-41.

16. Dudek D, Rzeszutko Ł, Zasada W, et al. Bioresorbable vascular scaffolds in patients with acute coronary syndromes: the POLAR ACS study. Pol Arch Med Wewn 2014; 124: 669-77.

17. Kočka V, Malý M, Toušek P, et al. Bioresorbable vascular scaffolds in acute ST-segment elevation myocardial infarction: a prospective multicentre study 'Prague 19'. Eur Heart J 2014; 35: 787-94.

18. Diletti R, Karanasos A, Muramatsu T, et al. Everolimus-eluting bioresorbable vascular scaffolds for treatment of patients presenting with ST-segment elevation myocardial infarction: BVS STEMI first study. Eur Heart J 2014; 35: 777-86.

19. Kochman J, Tomaniak M, Kołtowski Ł, et al. A 12-month angiographic and optical coherence tomography follow-up after bioresorbable vascular scaffold implantation in patients with ST-segment elevation myocardial infarction. Catheter Cardiovasc Interv 2015; 86: E180-9.

20. Ielasi A, Cortese B, Varriccio A, et al. Immediate and midterm outcomes following primary PCI with bioresorbable vascular scaffold implantation in patients with ST-segment myocardial infarction: insights from the multicentre "Registro ABSORB Italiano" (RAI registry). EuroIntervention 2015; 11: 157-62.

21. Cortese B, Ielasi A, Romagnoli E, et al. Clinical comparison with short-term follow-up of bioresorbable vascular scaffold versus everolimus-eluting stent in primary percutaneous coronary interventions. Am J Cardiol 2015; 116: 705-10.

22. Brugaletta S, Gori T, Low AF, et al. ABSORB bioresorbable vascular scaffold vs. everolimus-eluting metallic stent in ST-segment elevation myocardial infarction (BVS EXAMINATION study): 2-year results from a propensity score matched comparison. Int J Cardiol 2016; 214: 483-4.

23. Chakraborty R, Patra S, Banerjee S, et al. Outcome of everolimus eluting bioabsorbable vascular scaffold (BVS) compared to non BVS drug eluting stent in the management of ST-segment elevation myocardial infarction (STEMI) – a comparative study. Cardiovasc Revasc Med 2016; 17: 151-4.

24. Schnorbus B, Wiebe J, Capodanno D, et al. Twelve-month outcomes after bioresorbable vascular scaffold implantation in patients with acute coronary syndromes. Data from the European Multicenter GHOST-EU Extended Registry. EuroIntervention 2017; 13: e1104-11.

25. Hellenkamp K, Becker A, Gabriel YD, et al. Mid- to long-term outcome of patients treated with everolimus-eluting bioresorbable vascular scaffolds: data of the BVS registry Göttingen predominantly from ACS patients. Int J Cardiol 2017; 234: 58-63.

26. Iwańczyk S, Hiczkiewicz J, Araszkiewicz A, et al. Evaluation of bioresorbable vascular scaffolds in acute coronary syndrome: a two-center, one-year follow-up analysis. Cardiol J 2018; 25: 479-86.

27. Orlik B, Milewski K, Derbisz K, et al. Comparison of the Absorb bioresorbable vascular scaffold to the Xience durable polymer everolimus-eluting metallic stent in routine clinical practice: a propensity score-matched analysis from a multicenter registry. Adv Inter Cardiol 2018; 14: 149-56.

28. Ielasi A, Campo G, Cortese B, et al. One-year results following a pre-specified ABSORB implantation strategy in ST-elevation myocardial infarction (BVS STEMI STRATEGY-IT study). Cardiovasc Revasc Med 2019; 20: 700-4.

29. de Hemptinne Q, Picard F, Ly HQ, et al. Long-term outcomes of bioresorbable vascular scaffold in ST-elevation myocardial infarction. Acta Cardiol 2018; 73: 276-81.

30. Piegza J, Desperak P, Kowalczyk J, et al. Early and long-term outcomes of bioresorbable vascular scaffolds in the treatment of patients with coronary artery disease in real-world clinical practice – insights from the ZABRZE-BVS registry. Adv Interv Cardiol 2018; 14: 338-46.

31. Ibanez B, James S, Agewall S, et al. 2017 ESC Guidelines for the management of acute myocardial infarction in patients presenting with ST-segment elevation: the Task Force for the management of acute myocardial infarction in patients presenting with ST-segment elevation of the European Society of Cardiology (ESC). Eur Heart J 2017; 39: 119-77.

32. Cutlip DE, Windecker S, Mehran R, et al. Clinical end points in coronary stent trials a case for standardized definitions. Circulation 2007; 115: 2344-51.

33. Libby P. Mechanisms of acute coronary syndromes and their implications for therapy. N Engl J Med 2013; 368: 2004-13.

34. Harrison RW, Aggarwal A, Ou FS, et al. Incidence and outcomes of no-reflow phenomenon during percutaneous coronary intervention among patients with acute myocardial infarction. Am J Cardiol 2013; 111: 178-84.

35. Capodanno D, Joner M, Zimarino M. What about the risk of thrombosis with bioresorbable scaffolds? EuroIntervention 2015; Suppl V: V181-4.

36. Karanasos A, Van Mieghem N, van Ditzhuijzen N, et al. Angiographic and optical coherence tomography insights into bioresorbable scaffold thrombosis: single-center experience. Circ Cardiovasc Interv 2015; 8: e002369.

37. Lipinski MJ, Escarcega RO, Baker NC, et al. Scaffold thrombosis after percutaneous coronary intervention with ABSORB bioresorbable vascular scaffold: a systematic review and meta-analysis. JACC Cardiovasc Interv 2016; 9: 12-24.

38. Capodanno D, Angiolillo DJ. Antiplatelet therapy after implantation of bioresorbable vascular scaffolds: a review of the published data, practical recommendations, and future directions. JACC Cardiovasc Interv 2017; 10: 425-37.

39. Räber L, Brugaletta S, Yamaji K, et al. Very late scaffold thrombosis: intracoronary imaging and histopathological and spectroscopic findings. J Am Coll Cardiol 2015; 66: 1901-14.

40. Gorenek B, Kudaiberdieva G. Atrial fibrillation in acute ST-elevation myocardial infarction: clinical and prognostic features. Curr Cardiol Rev 2012; 8: 281-89.