ORIGINAL ARTICLE

Bioresorbable vascular scaffolds in patients with acute coronary syndromes: the POLAR ACS study

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KEY WORDS

myocardial infarction, primary angioplasty, stent

ABSTRACT

INTRODUCTION The results of the ABSORB trial showed the efficacy and safety of bioresorbable vascular scaffolds (BVS) and their unique advantage, namely, the restoration of vasomotion after full biodegradation.

OBJECTIVES The aim of the registry was to evaluate procedural issues, angiographic results, and clinical outcomes of patients with acute coronary syndrome (ACS) treated with BVS implantation.

PATIENTS AND METHODS The study included 100 patients. Cohort 1 comprised 46 patients with unstable angina; cohort 2, 38 patients with non-ST-segment elevation myocardial infarction; and cohort 3, 16 patients with ST-segment elevation myocardial infarction.

RESULTS Predilation was performed in 93% of the patients. The final Thrombolysis In Myocardial Infarction (TIMI) 3 flow was achieved in 99% of the patients. In all patients, BVS was successfully implanted. In 81% of the patients, postdilation was performed with a balloon catheter with the same diameter as BVS; in 11%, with a balloon catheter with a diameter of 0.25 mm larger than BVS; and in 7%, with a balloon catheter with a diameter of 0.5 mm larger than BVS. We observed no no-reflow phenomenon, 1 distal embolization, and 2 slow-flow phenomena. Two major adverse cardiac events were reported, namely, periprocedural myocardial infarction in 2 patients. During 1-year follow-up, we observed only 1 additional myocardial infarction caused by stent thrombosis as well as 1 target lesion revascularization.

CONCLUSIONS In our study, BVS in patients with ACS showed to be a safe and effective procedure.

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INTRODUCTION Coronary revascularization with stent implantation has been the gold standard of interventional cardiology for almost 20 years. It has been strongly recommended in revascularization guidelines as a method leading not only to a reduction of repeated percutaneous interventions, but also a reduction of mortality due to myocardial infarction (MI).[1] Previously reported results of clinical trials and their meta-analyses showed a significant reduction in the need for subsequent or repeated target vessel revascularization, mortality rates, and MI with drug-eluting stents (DES) compared with bare metal stents (BMS).[2,3] Despite achieving very good results in the rate of restenosis with DES, it has been proved that DES implantation is associated with endothelial dysfunction both in the stented segment and distal edge.[4] The possibility of a higher risk of late stent thrombosis has been raised but not proved.[5]

In the first decade of the 21st century, the progress in biomedical technology made it possible to manufacture fully biodegradable scaffolds that allow vessel wall regeneration.[6] The new generation of stents is composed of a poly-(L)-lactic acid backbone and a biodegradable polymer that

elutes everolimus. The results of the ABSORB trial[7] showed the efficacy and safety of a bioresorbable vascular scaffold (BVS) as well as a unique advantage over the permanent metal prosthesis, namely, the restoration of vasomotion after full biodegradation. In 2012, BVS received the CE Mark approval for the world's first drug-eluting BVS for the treatment of coronary artery disease.[8]

The results of the ABSORB trial[7] were based on a clinically and angiographically selected group of patients. Since its introduction to the market, the numerous cases of BVS use in different clinical settings (complex lesions, chronic total occlusions, and MI) have been published showing good feasibility and safety of BVS implantation.[9-11] Recently, a nonrandomized clinical trial comparing BVS and DES implantation in patients with acute coronary syndrome (ACS) has shown that the use of BVS in this patient group is safe and has similar outcomes to that of metal DES.[12]

The aim of our study was to investigate the feasibility, angiographic and clinical outcomes, as well as short- and long-term safety of BVS implantation in patients with ACS.

PATIENTS AND METHODS

POLAR ACS was a 1-arm prospective observational registry study, which enrolled patients from 12 high-volume invasive cardiology centers in Poland from November 2012 to September 2013. The study protocol complied with the 1964 Declaration of Helsinki (with later amendments) and was approved by the bioethics committee of the Jagiellonian University in Kraków, Poland.

The POLAR ACS registry included 100 consecutive patients with a diagnosis of an ACS (ST-segment elevation MI [STEMI] or non-ST-segment elevation MI [NSTEMI]) who underwent the implantation with ABSORB™ (Absorb) BVS. All patients gave written informed consent to participate in the study and met the criteria for stent implantation with BVS (according to stent instruction). Postdilation was performed at an operator's discretion and dual antiplatelet therapy was prescribed for 12 months according to the current guidelines of the European Society of Cardiology (ESC).

The clinical endpoint for the study was the occurrence of a major adverse cardiovascular event (MACE) during a follow-up of 12 months. The MACE was defined as death, MI, and clinically driven target lesion revascularization. Periprocedural MI was defined according to the ESC guidelines.[13] For the purpose of this analysis, in-hospital and periprocedural efficacy was measured on the basis of angiographic (Thrombolysis In Myocardial Infarction [TIMI], stent deliverability) and clinical (death, recurrent MI, target lesion failure) features in all patients. Procedural success and device success were defined according to the Absorb II study protocol as described below. Additionally, 1-year follow-up data were collected on the basis of detailed telephone interviews and were available for 98% of the patients.

Procedural success was defined as the achievement of final in-scaffold/stent residual stenosis of less than 50% by quantitative coronary angiography (QCA) with a successful delivery and deployment of at least 1 study scaffold/stent at the intended target lesion and successful withdrawal of the delivery system for all target lesions without the occurrence of cardiac death, target vessel MI, or repeat target lesion revascularization during the hospital stay.

Device success was defined as the successful delivery and deployment of the first study scaffold in the intended target lesion and successful withdrawal of the delivery system with attainment of final in-scaffold residual stenosis of less than 50% by QCA.

Patients enrolled in the POLAR ACS study were independent from those enrolled in the Polish BVS Registry published elsewhere.[14]

Angiographic analysis

The QCA analysis was performed by an independent core laboratory (Krakow Cardiovascular Research Institute, Kraków, Poland) according to previously validated and published protocols. The analysis was performed by independent blinded analysts. All analyses were performed using an automatic vessel contour detection software (CAAS 5.7.0 Quantitative Coronary Angiography for Research, Pie Medical Imaging BV, Maastricht, The Netherlands).

The core laboratory was blinded to the clinical and procedural information. Measurements were performed on angiograms after maximum vasodilatation with nitroglycerin. An outer diameter contrast-filled, nontapered catheter tip was used for calibration (≥6 French guiding catheter). After the selection of the best projection depicting the most severe stenosis, the percentage of diameter stenosis at end-diastole was evaluated. The baseline reference vessel diameter, minimal lumen diameter, percent diameter stenosis, lesion length, and other parameters were measured. A distance between the proximal and distal references in the projection demonstrating the stenosis indicated lesion length. Coronary angiograms obtained at baseline and after predilation, stent implantation, and postdilation were analyzed.

Coronary blood flow on angiograms was graded using the TIMI flow grading system. According to the system, the TIMI flow is numbered from 0 to 3, where 0 denotes no perfusion and 3, complete perfusion. A thrombus grade was assessed using the TIMI thrombus grading system, wherein the thrombus is graded from 0 (no cineangiographic characteristics of a thrombus present) to 5 (total occlusion of the vessel by a thrombus).[15] The occurrence of distal embolization was also assessed, defined as the migration of a filling defect or thrombus to distally occlude the target vessel or one of its branches.[15]

Statistical methods

Data were analyzed using standard statistical methods. Categorical variables were presented as numbers and as percentages

TABLE 1 Demographic and clinical characteristics of the patients

Variable	STEMI (n = 16)	NSTEMI (n = 38)	UA (n = 46)	STEMI vs. NSTEMI vs. UA	Post hoc analysis		
					STEMI vs. NSTEMI	STEMI vs. UA	NSTEMI vs. UA
age, y	54.3 ±9.1	68.4 ±10.6	60.9 ±9.6	<0.001[c]	<0.001[c]	0.0602	0.002[c]
sex, male	81	61	80	0.089	–	–	–
GRACE score[a]	81.2 (59.6–95.3)	114 (96.8–132)	78 (61–102)	<0.001[c]	<0.001[c]	0.994	<0.001[c]
prior MI	0	21	18	0.162	–	–	–
prior stroke	0	3	3	0.810	–	–	–
prior CABG	0	5	14	0.192	–	–	–
prior PCI	0	29	26	0.065	–	–	–
family history of CAD	15	24	39	0.267	–	–	–
diabetes mellitus[b]	7	39	24	0.043[c]	0.019	0.154	0.139
dyslipidemia	62	68	78	0.454	–	–	–
hypertension	67	76	84	0.360	–	–	–
smoking[b]	64	29	50	0.045[c]	0.020	0.367	0.068
LVEF at discharge	50 (42.5–55.3)	50 (42.5–57)	55 (50–60)	0.028[c]	0.913	0.129	0.045[c]

Data are presented as mean ± standard deviation, percentage of patients, or median (interquartile range).

a Fox model for death between hospital admission and 6 months later (as used in the Palm Pilot software, maximum value equals 306); a missing value was treated as the possible minimum when calculating the Global Registry of Acute Coronary Events score
b owing to the introduction of the Šidák correction, a *P* value threshold for statistical significance is 0.017 for these variables
c statistically significant values

Abbreviations: CABG – coronary artery bypass graft, CAD – coronary artery disease, LVEF – left ventricular ejection fraction, MI – myocardial infarction, NSTEMI – non-ST-segment elevation myocardial infarction, PCI – percutaneous coronary intervention, STEMI – ST-segment elevation myocardial infarction, UA – unstable angina

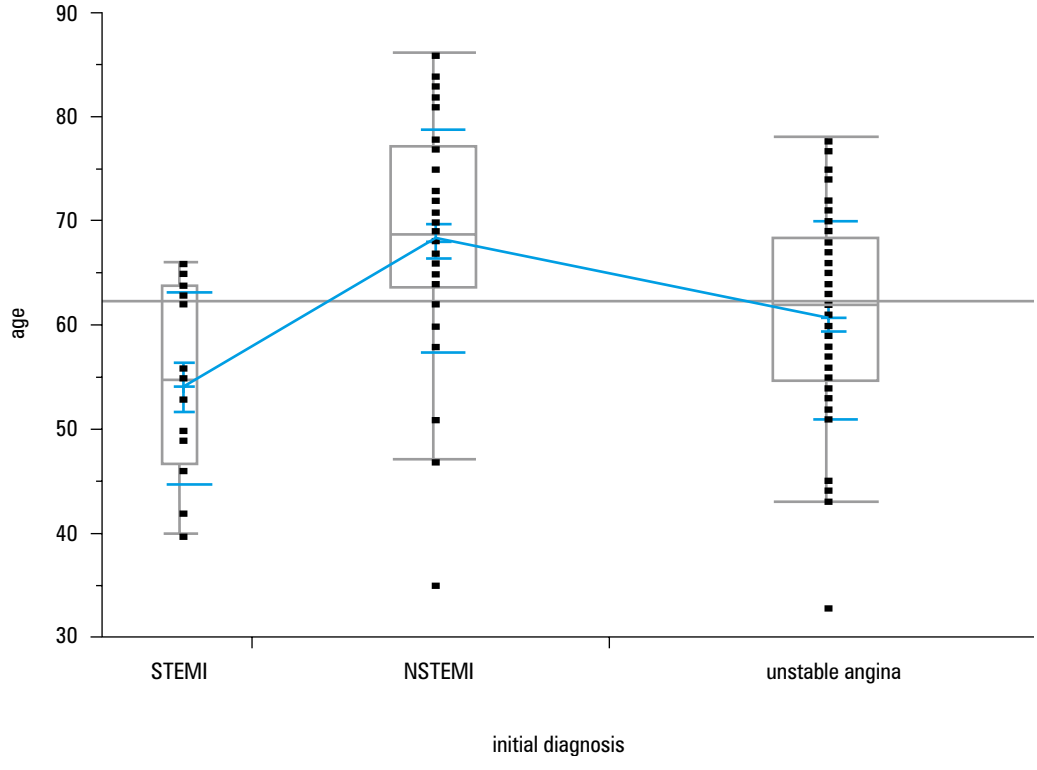

FIGURE 1 Age distribution in the study group
Abbreviations: see **TABLE 1**

and continuous variables as means ± standard deviation or median (interquartile range) if the data did not follow a normal distribution. To compare independent samples for continuous data, the 1-way analysis of variance was used if each sample followed a normal distribution, or the Kruskal–Wallis test for nonnormally distributed data. If the result was considered statistically significant, post hoc tests were conducted. Depending on the data distribution, the Tukey test or Steel–Dwass test was used. The χ^2 test was used for categorical data with the Šidák correction for post hoc comparisons. A *P* value of less than 0.05 was considered statistically significant. All calculations were

TABLE 2 Characteristics of the lesions

Variable	Value	STEMI	NSTEMI	UA	Total
localization	LAD	33	49	52	48 (46)
	RCA	50	20	27	27 (26)
	Cx	17	26	19	21 (20)
	IM	0	6	2	3 (3)
type	A	8	3	8	6 (6)
	B1	8	27	46	33 (31)
	B2	75	38	30	40 (38)
	C	8	32	16	21 (20)

Data are presented as percentage or percentage (number).

Abbreviations: Cx – circumflex artery, IM – intermediate artery, LAD – left anterior descending artery, RCA – right coronary artery, others – see TABLE 1

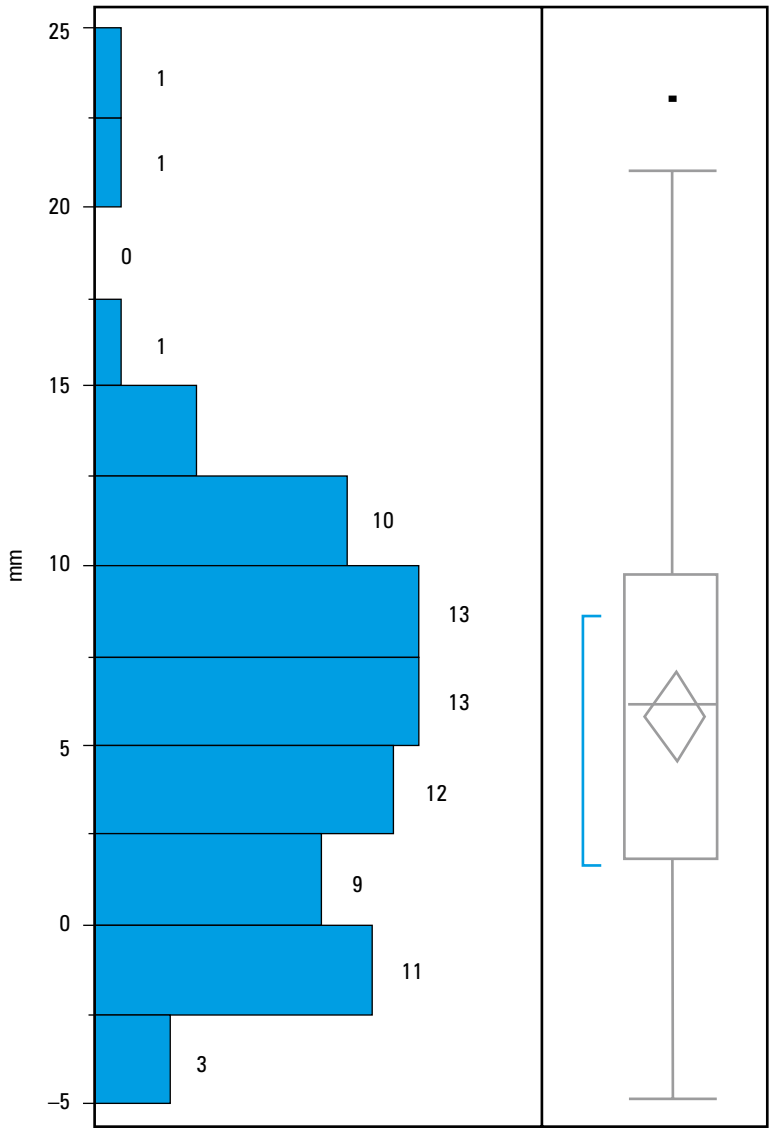

FIGURE 2 Difference between nominal stent length and lesion length

done with the JMP 9.0.0 software (SAS, Cary, North Carolina, United States). No formal sample size calculations were performed because this was a 1-arm observational study.

RESULTS Patients were classified into 3 groups according to clinical presentation: cohort 1, with unstable angina (n = 46); cohort 2, with NSTEMI (n = 38); and cohort 3, with STEMI (n = 16). Demographic and clinical characteristics of the patients are presented in TABLE 1.

Patients with the diagnosis of STEMI constitued the youngest group with the lowest prevalence of diabetes mellitus and the highest rate of smokers. Significant differences observed for the patients' age in all analyzed groups are presented in FIGURE 1.

During percutaneous coronary intervention (PCI) with BVS implantation, 48% of the lesions were localized in the left anterior descending artery; 27%, in the right coronary artery; 21%, in the circumflex artery; and 3%, in the intermediate artery. Details on the type and distribution of the lesions in the study group are presented in TABLE 2.

The ratio of a nominal stent length to lesion length was 1.5 ±0.7, and the difference between stent and lesion length was 5.9 ±5.5 mm (FIGURE 2).

The ratio of a nominal stent diameter to reference vessel diameter was 1.1 ±0.2, and the ratio of a stent diameter assessed by QCA during stent implantation to the reference vessel diameter was 0.9 ±0.2 (FIGURE 3).

Aspiration thrombectomy was performed in 13% of the patients, and predilation, in 93% of the patients. The ratio of a predilation balloon diameter to nominal diameter of BVS was 0.9 ±0.1, and in 62% of the patients, a semi-compliant balloon was used. In all patients, BVS was successfully implanted. In 60% of the patients, no additional postdilation was required. Treatment strategies are presented in detail in TABLE 3.

More than 75% of postdilations were performed by a balloon catheter with the same diameter as that of BVS. The differences in diameters between the balloon for postdilation and BVS and the results of QCA are presented in TABLE 4.

A TIMI score of 0 to 2 at baseline was observed in 30% of the patients and thrombus grade 5 in 15%. The final TIMI 3 flow was achieved in 99% of the patients (TIMI 2 in 1% of the patients). Detailed characteristics of the treated lesions are presented in TABLE 5.

Owing to edge dissection after BVS implantation, the second overlapping Absorb BVS was used in 4% of the patients and a regular metallic DES was used in 3%. In 1 patient, additional BVS and DES were implanted due to edge dissection. More details regarding bail-out stenting are presented in TABLE 3.

We observed no no-reflow phenomenon, 1 distal embolization (in the STEMI group), and 2 slow-flow phenomena (both in the NSTEMI group). No device failures were reported. Device success was achieved in 100% of the patients, and procedural success, in 98% of the cases.

Before or during the procedure, clopidogrel was used as part of dual antiplatelet therapy in all but 5 patients. In 3 of those patients, prasugrel was used during the procedure, and in 2, ticagrelor. However, only in 1 patient on prasugrel and 1 on ticagrelor, prasugrel and ticagrelor were reported as discharge medications. The mean hospital stay

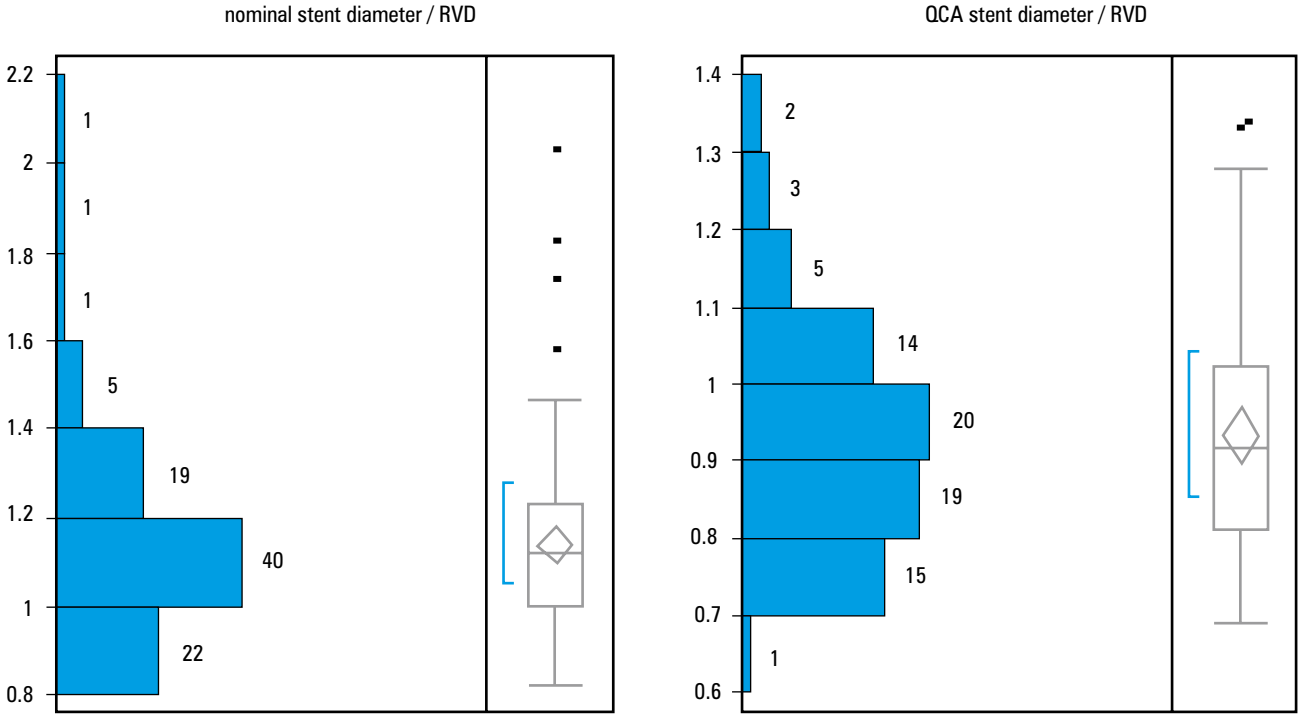

FIGURE 3 Ratios of stent to vessel diameters Abbreviations: RVD – reference vessel diameter, QCA – qualitative and quantitative analysis

was 4.2 ±4.1 days, and the shortest stay was reported in patients with unstable angina and the longest in those with NSTEMI (2.0 ±1.84 days vs. 5.4 ±5.4 days, $P = 0.028$),

There were 2 MACEs reported during hospital stay. In both cases, they were periprocedural MIs in patients with NSTEMI. Additionally, 1 patient with unstable angina had nontarget vessel revascularization (non-MACE). There was no stent thrombosis (definite, probable, or possible) reported during hospitalization in any of the patients.

A total of 98 eligible patients underwent 1-year follow-up, which revealed 1 additional MI caused by definite stent thrombosis (confirmed by angiography) in a patient who discontinued dual antiplatelet therapy immediately after index PCI. PCI with a new DES was performed in the target lesion with a good result. In addition, another patient underwent target lesion revascularization 11 months after index PCI owing to the occlusion of the artery at the site of the previously implanted BVS.

DISCUSSION To our knowledge, our study is the first multicenter registry to evaluate the implantation of bioresorbable everolimus-eluting scaffold in patients with a wide variety of ACSs.

The rationale for the use of BVS in patients with ACS has been provided by the results of the Absorb Cohort A&B studies suggesting plaque stabilization by changes in the morphology of the intraluminal tissue layers with a decrease in the areas of necrotic core and increase in the fibrofatty tissue near the lumen.[16] The promising clinical results as well as intravascular ultrasound findings with late lumen enlargement and recovery of vasomotion accompanying scaffold resorption have also been reported; however, in these trials, patients in the acute phase of ACS were excluded.[17]

There have been 2 reports of a single-center experience with Absorb BVS implantation in patients with ACS.[11,12] In our center, we had an opportunity to use this technology from the very beginning. Because of a different protocol in comparison with standard PCI, the technique requires some experience. Therefore, we considered it challenging to conduct a multicenter registry study involving centers without previous experience with the device. Before inviting the participating centers, we circulated the information containing the description of the procedure and useful tips based on the available literature and our own experience.[18]

The challenges of the scaffold implantation in ACS are associated with proper vessel sizing. This may be particularly difficult in this patient group because of the changes in the diameters of the vessel, which may collapse when flow is diminished or constricted by adrenergic stimulation. Adequate lesion preparation with proper predilations before scaffold implantation can potentially increase the risk of distal embolization if the lesion contains a thrombus. Finally, the deployment technique with prolonged inflation time (stepwise inflation of 2 atmospheres every 5 seconds up to the assumed pressure while maintaining the inflated balloon for 30 seconds) differs from the current approach with metallic stents.

Aspiration thrombectomy for the reduction of thrombus burden and the risk of distal embolization followed by direct stenting is a common technique for the treatment of ACS in patients with a thrombus in the culprit artery.[19] On the other hand, predilation is mandatory in the clinical trial setting before implanting the Absorb scaffold, and in addition, it is strongly recommended in the instructions for clinical use of this scaffold. The

TABLE 3 Types of treatment in the study group

Variable		STEMI	NSTEMI	UA	Total	STEMI vs. NSTEMI vs. UA	Post hoc analysis		
							STEMI vs. NSTEMI	STEMI vs. UA	NSTEMI vs. UA
aspiration thrombectomy[a]		58	11	2	13 (12)	<0.001[b]	0.002[b]	<0.001[b]	0.097
direct stenting		17	0	10	7 (7)	0.079	–	–	–
postdilation		50	46	33	40 (38)	0.394	–	–	–
absolute difference balloon for postdilation – BVS diameter, mm	0	64	76	91	81 (79)	–	–	–	–
	0.25	7	16	9	11 (11)				
	0.5	29	8	0	7 (7)				
bail-out stenting	BVS	0	2	2	4	–	–	–	–
	DES	0	2	1	3				
	BVS+DES	0	0	1	1				

Data are presented as percentage or percentage (number)

a owing to the introduction of the Šidák correction, a *P* value threshold for statistical significance is 0.017 for these variables
b statistically significant values

Abbreviations: BVS – bioresorbable vascular scaffolds, DES – drug-eluting stents, others – see **TABLE 1**

TABLE 4 Off-line quantitative coronary angiography report

Variable	STEMI	NSTEMI	UA	STEMI vs. NSTEMI vs. UA	Post hoc analysis		
					STEMI vs. NSTEMI	STEMI vs. UA	NSTEMI vs. UA
baseline							
RVD, mm	3.2 ±0.5	2.7 ±0.5	2.7 ±0.5	0.003[a]	0.009[a]	0.003[a]	0.899
MLD, mm	0 (0–1.06)	1.02 (0.73–1.28)	1.04 (0.78–1.36)	0.014[a]	0.040[a]	0.011[a]	0.868
DS, %	86.1 ±20.9	63.1 ±17.9	60.5 ±16.2	<0.001[a]	<0.001[a]	<0.001[a]	0.776
lesion length, mm	15.7 ±4.3	15.8 ±6.4	15.5 ±6.0	0.967	–	–	–
after stent implantation							
MLD, mm	2.3 ±0.5	2.1 ±0.4	2.2 ±0.3	0.437	–	–	–
DS, %	16.5 ±5.2	16.1 ±9.2	15.0 ±6.8	0.895	–	–	–
final result							
MLD, mm	2.6 ±0.4	2.3 ±0.5	2.3 ±0.4	0.203	–	–	–
DS, %	13.6 ±9.2	13.9 ±9.8	12.3 ±6.9	0.676	–	–	–

Data are presented as mean ± standard deviation or median (interquartile range).

a statistically significant values

Abbreviations: DS – diameter stenosis, MLD – minimal lumen diameter, others – see **TABLE 1** and **FIGURE 3**

predilations with balloons with a 1:1 ratio of the balloon diameter to the planned scaffold diameter are potentially at higher risk of distal embolization before scaffold implantation. In the current registry, only 1 distal embolization and 2 cases of the slow-flow phenomenon were observed on angiography at the end of follow-up. The risk of distal embolization could be also decreased by the use of thrombectomy in almost 60% of the patients with STEMI before predilation.

In 17% of the patients with STEMI and 10% of those with unstable angina, predilation was skipped at the discretion of the operator and direct stenting was used. In a study by Gori et al.,[12] predilations were done in all patients; however, the angiographic results were not reported. The unstable plaque morphology with the lipid core is most common in patients with ACS. The treatment of lesions with the soft plaque and without significant calcifications was possible with direct Absorb implantation in a selected cohort of patients, but this approach requires further research.

Gori et al.[12] reported definite acute stent thrombosis in 3 cases: the first one occurred 15 minutes after the procedure; the second one, after 3 days; and the third one, within 30 days of follow-up. In 2 of those patients, underdeployed scaffolds were found on optical coherence tomography. Interestingly, all patients with thrombosis were treated with ticagrelor as a second antiplatelet agent. In the present registry, no stent thrombosis was reported during hospital stay and only 2 patients were treated with ticagrelor in the acute in-hospital phase.

TABLE 5 Angiographic characteristics of the lesions

Data	Value	STEMI	NSTEMI	UA	Total	*P* value
TIMI flow						
baseline	0	67	11	4	15	<0.001
	1	8	0	0	1	
	2	17	11	15	14	
	3	8	78	81	71	
final result	2	0	3	0	1	0.441
	3	100	97	100	99	
thrombus grade						
baseline	0	25	70	87	73	<0.001
	1	0	11	2	5	
	2	8	5	0	3	
	3	0	0	4	2	
	4	8	3	0	2	
	5	58	11	7	15	
final result	0	100	97	100	99	0.441
	1	0	3	0	1	

Data are presented as percentage of patients.

Abbreviations: TIMI – Thrombolysis in Myocardial Infarction, others – see TABLE 1

Postdilations were necessary in 40% of the patients, with a higher rate of up to 60% observed in the STEMI cohort. It is much higher compared with a rate of 14% reported by Gori et al.[12] However, we did not observe an increase in the incidence of flow deterioration after postdilations in this group of patients.

Edge dissections, which occurred in 10 patients, were covered by the second BVS or metallic everolimus-eluting stent implantation.

The rate of angiographic complications was low; we observed only 1 distal embolization and 1 case of compromised side-branch flow. However, it was reported earlier that small side branches, especially those below 0.5 mm, are at higher risk of acute closure after implantation of the scaffold, which has to be considered during implantation.[20]

A high device success rate and no complications or device handling problems reported in our study confirm good performance of BVS also during acute coronary procedures.

The major limitation of this study is a single arm, open-label registry without comparison to the metallic stent, and a small number of patients with STEMI. Only clinical follow-up was provided. Optical coherence tomography and intravascular ultrasonography were not required for the assessment of the vessel size before BVS implantation in our study and the decision was left at the discretion of the operator.

In conclusion, BVS implantation in patients with ACS proved to be a safe and effective procedure resulting in an optimal TIMI 3 flow. Procedural success was achieved in all but 1 patient and device success—in all patients. In-hospital MACEs were observed only in 2% of the patients during index hospitalization, and only 1 stent thrombosis occurred during the 1-year follow-up.

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ARTYKUŁ ORYGINALNY

Stenty bioresrobowalne w leczeniu chorych z ostrymi zespołami wieńcowymi: badanie POLAR ACS

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SŁOWA KLUCZOWE

pierwotna angioplastyka wieńcowa, stent, zawał serca

STRESZCZENIE

WPROWADZENIE Badanie ABSORB wykazało skuteczność i bezpieczeństwo stosowania stentów bioresorbowalnych (*bioresorbable vascular scaffolds* – BVS) oraz pokazało ich unikalną cechę – powrót wazomotoryki po pełnej biodegradacji.

CELE Celem rejestru była ocena okołozabiegowa, angiograficzna i kliniczna pacjentów z ostrym zespołem wieńcowym (*acute coronary syndrome* – ACS) leczonych implantacją BVS.

PACJENCI I METODY Do badania włączono 100 pacjentów. Kohortę 1 stanowiło 46 chorych z niestabilną dławicą piersiową, kohortę 2 – 38 pacjentów z ACS bez uniesienia odcinka ST, a kohortę 3 – 16 pacjentów z ACS z uniesieniem odcinka ST.

WYNIKI Predylatację wykonano u 93% chorych. Końcowy przepływ TIMI 3 (Thrombolysis In Myocardial Infarction) uzyskano u 99% pacjentów. U wszystkich chorych udało się z powodzeniem implantować BVS. U 81% chorych postdylatację wykonano cewnikiem balonowym o średnicy BVS, u 11% chorych – cewnikiem większym o 0.25 mm, a u 7% chorych – cewnikiem większym o 0.5 mm niż BVS. Nie zaobserwowano zjawiska *no-reflow*, zanotowano 1 dystalną embolizację i 2 zespoły *slow-flow*. Zaobserwowano 2 duże zdarzenia niepożądane – okołozabiegowy zawał serca u 2 pacjentów. W okresie rocznej obserwacji wystąpił dodatkowo tylko 1 zawał serca spowodowany zakrzepicą w stencie oraz 1 angioplastyka wieńcowa zmiany docelowej.

WNIOSKI Nasze badanie wykazało, że implantacja BVS u pacjentów z ACS jest bezpieczna i skuteczna.

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