

# The use of bioresorbable vascular scaffold Absorb BVS<sup>®</sup> in patients with stable coronary artery disease: one-year results with special focus on the hybrid bioresorbable vascular scaffolds and drug eluting stents treatment

Robert J. Gil<sup>1,2</sup>, Jacek Bil<sup>3</sup>, Tomasz Pawłowski<sup>1</sup>, Nabijon Yuldashev<sup>3</sup>, Leszek Kołakowski<sup>4</sup>, Jacek Jańczak<sup>5</sup>, Wojciech Jabłoński<sup>6</sup>, Piotr Paliński<sup>7</sup>

<sup>1</sup>Department of Invasive Cardiology, Central Clinical Hospital of the Ministry of the Interior, Warsaw, Poland

<sup>2</sup>Institute of Experimental and Clinical Medicine, Polish Academy of Science, Warsaw, Poland

<sup>3</sup>Republican Specialised Cardiology Centre, Tashkent, Uzbekistan

<sup>4</sup>Cardiology Clinic Allenort, Elk, Poland

<sup>5</sup>Cardiology Clinic Allenort, Ilawa, Poland

<sup>6</sup>Cardiology Clinic Allenort, Szczecinek, Poland

<sup>7</sup>Cardiology Clinic Allenort, Tomaszow Mazowiecki, Poland

## Abstract

**Background:** The number of percutaneous coronary interventions (PCI) with bioresorbable vascular scaffolds (BVS) is increasing because these procedures offer additional benefits compared to PCI with classical drug eluting stents (DES) made of permanent metallic prostheses.

**Aim:** To present the current experience of using BVS in a real life scenario in patients with stable coronary artery disease (CAD), with a special focus on the assessment of safety and effectiveness of the hybrid strategy (single stage BVS and DES implantation).

**Methods:** We performed a one-arm prospective registry, which enrolled patients with stable CAD in five interventional cardiology centres in Poland. All patients who met inclusion and exclusion criteria and had received at least one BVS stent during index PCI were included. The primary endpoint was the cumulative rate of major adverse cardiovascular events (MACE), consisting of cardiac death, myocardial infarction (MI), and clinically-driven target lesion revascularisation (TLR) at 12 months. The analysis was performed in the whole population as well as in the subgroup with the hybrid treatment (BVS + DES).

**Results:** Between August 2013 and April 2014 139 patients were enrolled. The mean age was  $59.5 \pm 5.5$  years, and 34.5% of the population were women. The target vessel was located in the left anterior descending artery in most cases (65.5%). The device success rate was 100%. At 12 months, in the whole population the cumulative MACE incidence was 7.2% ( $n = 10$ ), while the clinically-driven TLR rate was 5.0% ( $n = 7$ ). In further analysis, in the hybrid subgroup there was no death, MI, or stent thrombosis, and only one case of clinically-driven TLR (4.5%).

**Conclusions:** The obtained data enable us to say that in particular clinical scenarios the simultaneous use of BVS and DES might be safe and effective.

**Key words:** bioresorbable stent, Absorb, stable coronary artery disease, hybrid approach

Kardiol Pol 2016; 74, 7: 627–633

## Address for correspondence:

Jacek Bil, MD, PhD, Department of Invasive Cardiology, Central Clinical Hospital of the Ministry of the Interior, ul. Wołoska 137, 02–507 Warszawa, Poland, e-mail: biljacek@gmail.com

Received: 08.06.2015

Accepted: 23.11.2015

Available as AoP: 29.12.2015

Kardiologia Polska Copyright © Polskie Towarzystwo Kardiologiczne 2016

## INTRODUCTION

Drug-eluting stents (DES) have greatly improved outcomes of percutaneous coronary intervention (PCI) by managing the issue of excessive neointimal growth. However, the permanent presence of the metallic platform and the durable polymer might impair the natural healing process of the coronary vessel wall and lead to a prolonged inflammatory response as well as untoward clinical outcomes [1, 2].

Recently, PCI with bioresorbable vascular scaffolds (BVS) has emerged as an interesting alternative because the presence of the prosthesis (the scaffold as well as the polymer with the drug) in the coronary artery is temporary. Moreover, this novel technology enables restoration of the normal vessel reactivity and facilitates positive remodelling. As a consequence, it reduces the trigger for persistent inflammation and enables further interventions by percutaneous or surgical means [3].

Also, the hybrid use of BVS and classical DES is a novel approach. This strategy can be applied to reduce the costs of PCI for very long lesions but also to avoid certain limitations of currently available Absorb BVS® stents. The customisation (sizes and lengths) of BVS at the time of the study was rather limited. The sole use of BVS in long lesions with significantly calcified segments may not be reasonable, especially if lesion preparation was not optimal and might result in significant residual stenosis even after balloon postdilatation. Also, the bifurcation lesion treatment seems to be an interesting indication for using this hybrid approach [4].

The aim of the study was to share our current experience in using single BVS in a real life scenario, with special focus on the assessment of safety and effectiveness of the hybrid approach, i.e. the simultaneous use of overlapping stents: BVS and classical DES.

## METHODS

### *Study population and study design*

It was a prospective, single-arm, open-label clinical study performed in five invasive cardiology centres in Poland (Warsaw, Elk, Szczecinek, Ilawa, Tomaszow Mazowiecki). It enrolled patients with one Absorb BVS® stent implanted between August 2013 and April 2014. To the hybrid group patients treated with BVS and classical DES (only when stents overlapped stents) were included. The blinded data were entered into the electronic case report form by collaborating physicians in these centres. The Institutional Review Board approved the study protocol.

The inclusion criteria were: stable coronary artery disease, age  $\geq 18$  years and  $\leq 65$  years, and *de novo* coronary lesions (excluding left main stem and arterial or saphenous vein grafts). The main exclusion criteria were: acute coronary syndrome, the inability to take the dual antiplatelet therapy for 12 months, left ventricular ejection fraction  $\leq 30\%$ , and lack of consent for personal data processing and telephone follow-up.

### *Study device*

The balloon-expandable Absorb BVS® (Abbott Vascular, Abbott Park, IL) consists of a poly-L-lactide (PLLA) backbone, the antiproliferative drug everolimus at the concentration of  $100 \mu\text{g}/\text{cm}^2$  (Novartis Pharmaceuticals Corporation, Basel, Switzerland), and poly-D, L-lactide polymer in a 1:1 ratio (PDLLA). Both PLLA and PDLLA are fully bioresorbable. PDLLA is thought to be totally resorbed in nine months and PLLA in approximately 36 months. A lactic acid is the final product of both PLLA and PDLLA degradation. At the time of the inclusion stent scaffolds were available in diameters of 2.5, 3.0, and 3.5 mm, and lengths of 18, 23, and 28 mm. If an additional DES was required, it was a Xience Pro® stent (Abbott Vascular) [5, 6].

### *Procedure*

Procedures were performed according to local standards via radial or femoral access using 6 Fr or 7 Fr guiding catheters. The pharmacological treatment was according to the most recent guidelines. All patients received acetylsalicylic acid (75 mg/24 h) and clopidogrel (75 mg/24 h) at least 72 h before PCI. This dual antiplatelet therapy was planned for one year. Troponin I (TnI), creatine kinase (CK), and CK-myocardial band (CK-MB) were measured pre-procedural and after 6 h and 24 h post-procedure in all patients. Periprocedural myocardial infarction (MI; type 4a) was defined according to the third universal definition [7].

Calcification was defined as readily apparent radiopacities within the vascular wall at the site of the stenosis and was graded as follows 1) none: calcifications not visible on angiograms, 2) mild calcifications: single spots; 3) moderate calcifications: plurality of single spots; or 4) severe calcifications: confluent number of calcifications. In order to reduce subjectivity of evaluation we combined 'none' with 'mild', and 'moderate' with 'severe'.

Moderate/severe tortuosity was defined as a finding of  $\geq 3$  bends (defined as  $\geq 45^\circ$  change in vessel direction) along the main trunk of at least one artery in systole and in diastole.

### *Follow-up*

The assessment of the anginal status, data collection of adverse events, details of any subsequent coronary interventions, and the use and changes in concomitant medications were collected at  $30 \pm 7$  days and  $12 \pm 0.5$  months.

### *Endpoints*

The primary endpoint was the cumulative rate of major adverse cardiovascular events (MACE) consisting of cardiac death, MI, and clinically-driven target lesion revascularisation (TLR). Secondary endpoints included cardiac death, all-cause death, MI, TLR, target vessel revascularisation (TVR), stent thrombosis, and device success rate. Cardiac death included death resulting from an acute MI, sudden cardiac death, death

due to heart failure, and death due to cardiac procedures. All deaths were deemed cardiac unless proven otherwise. MI was defined according to the third universal definition [7]. Clinically-driven TLR was defined as the reintervention of the target lesion due to the presence of a symptomatic  $\geq 50\%$  diameter stenosis during follow-up. TVR was defined as revascularisation of any segment of the index coronary artery. The device success was defined as successful deployment of the intended stent in the target site without a system failure.

### Statistical analysis

Continuous variables were presented as mean  $\pm$  standard deviation. Categorical data were presented as numbers (%). Continuous variables were compared using an unpaired student two-sided t test, and categorical data using the  $\chi^2$  test or Fisher exact test, as appropriate. If distribution was not normal (verified with the Shapiro-Wilk test), Wilcoxon signed-rank tests and Mann-Whitney U-tests were used. P values  $< 0.05$  were considered statistically significant. Statistical analyses were performed using R 3.0.2 for OS (R Foundation, Vienna, Austria).

## RESULTS

### Baseline clinical and angiographic characteristics.

Between August 2013 and April 2014 a total of 139 patients were enrolled to the registry. The mean age was  $59.5 \pm 5.5$  years, and 34.5% ( $n = 48$ ) of the population were women. The detailed clinical characteristics are presented in Table 1. In the studied group 80.6% of patients had arterial hypertension, 74.8% — hypercholesterolaemia, and 34.5% — a history of smoking (Table 1).

In the majority of cases there were patients with single vessel disease (61.9%) and lesions of moderate complexity (type A: 35.3%, type B1: 37.4%). Most lesions (65.5%) were

located in the left anterior descending artery (LAD). In 31.2% of cases lesions within coronary bifurcation were treated. More details are presented in Table 2.

### Procedural characteristics

The main procedural variables are presented in Table 3. The device success rate was 100%. Mean nominal Absorb BVS® stent parameters were  $3.02 \pm 0.41$  mm and  $21.13 \pm 6.39$  mm (diameter and length, respectively), while the mean maximal implantation pressure was  $15.9 \pm 4.3$  atm. On average 1.21 Absorb BVS® were implanted per artery. The predilatation rate was 87.1%, while the postdilatation rate was 52.3%. All procedures were performed via a 6 Fr guiding catheter, and radial access was preferred in 93.5%.

**Table 2.** Baseline angiographic characteristics of the study group ( $n = 1390$ )

One-vessel disease	86 (61.9%)
Two-vessel disease	37 (26.6%)
Three-vessel disease	16 (11.5%)
Lesion type:*	
A	49 (35.3%)
B1	52 (37.4%)
B2	32 (23%)
C	6 (4.3%)
Lesion location:	
LAD	91 (65.5%)
LCx	29 (20.9%)
RCA	19 (13.7%)
Bifurcation lesion:	
Side branch $< 2$ mm	24 (17.3%)
Side branch $> 2$ mm	18 (12.9%)
None	97 (69.8%)
Vessel tortuosity:	
None — mild	99 (71.2%)
Moderate — severe	40 (28.8%)
Calcification:	
None — mild	106 (76.3%)
Moderate — severe	33 (23.7%)
Vessel sizing method:	
Visual	113 (81.3%)
QCA	17 (12.2%)
IVUS	4 (2.9%)
OCT	5 (3.6%)

\*According to ACC/AHA lesion classification. Data are presented as number and percentage (in brackets). LAD — left anterior descending; LCx — left circumflex; RCA — right coronary artery; QCA — quantitative coronary angiography; IVUS — intravascular ultrasound; OCT — optical coherent tomography

**Table 1.** Baseline characteristics of the study group ( $n = 1300$ )

Age [years]	$59.5 \pm 5.5$
Women [%]	48 (34.5%)
Hypertension	112 (80.6%)
Hypercholesterolaemia	104 (74.8%)
Diabetes type 2	41 (29.5%)
Prior MI	30 (21.6%)
Prior PCI	45 (32.4%)
Coronary artery bypass graft	0 (0%)
Peripheral artery disease	5 (3.6%)
Chronic kidney disease	11 (7.9%)
History of smoking	48 (34.5%)

Data are presented as number of patients and percentage (in brackets) or mean  $\pm$  standard deviation. MI — myocardial infarction; PCI — percutaneous coronary intervention

**Table 3.** Procedural characteristics

Successful implantation	139 (100%)
Predilatation	121 (87.1%)
Nominal stent diameter [mm]	3.02 ± 0.41
Nominal stent length [mm]	21.13 ± 6.39
Pressure implantation [atm]	15.9 ± 4.3
No of BVS per vessel	1.21
Additional DES implantation	22 (15.8%)
Postdilatation	73 (52.3%)
Edge dissection	5 (3.6%)
Side branch occlusion	2 (1.4%)
Vascular access femoral/radial	6.5%/93.5%
Guiding catheter 6 Fr/7 Fr	100%/0%

Data are presented as number of patients and percentage (in brackets) or mean ± standard deviation. BVS — bioresorbable vascular scaffold; DES — drug-eluting stent

**Figure 1.** Clinical outcomes at 12 months. The major adverse cardiovascular events (MACE) and clinically-driven target lesion revascularisation (TLR) rates at 12 months in the whole study group, in the subgroup treated only with bioresorbable vascular scaffold (BVS), and in the hybrid strategy subgroup

**Table 4.** Clinical outcomes

Parameter	30 days (n = 139)	12 months (n = 139)	12 months	
			Only BVS (n = 117)	Hybrid therapy (n = 22)
MACE	2 (1.4%)	10 (7.2%)	9 (7.7%)	1 (4.5%)
Death	1 (0.7%)	1 (0.7%)	1 (0.9%)	0 (0%)
Cardiac death	1 (0.7%)	1 (0.7%)	1 (0.9%)	0 (0%)
Myocardial infarction	1 (0.7%)	2 (1.4%)	2 (1.8%)	0 (0%)
Stroke	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Definite stent thrombosis	1 (0.7%)	2 (1.4%)	2 (1.8%)	0 (0%)
Clinically-driven TLR	1 (0.7%)	7 (5.0%)	6 (5.1%)	1 (4.5%)
TVR	0 (0%)	9 (6.5%)	8 (6.8%)	1 (4.5%)
PCI in another vessel	0 (0%)	4 (2.9%)	4 (3.4%)	0 (0%)

Data are presented as number of patients and percentage (in brackets). MACE — major adverse cardiovascular event; TLR — target lesion revascularisation; TVR — target vessel revascularisation; PCI — percutaneous coronary intervention

### Hybrid BVS-DES strategy

In 22 (15.8%) cases it was necessary to implant classical DES, i.e. Xience Pro<sup>®</sup>. The nominal Xience Pro<sup>®</sup> stent parameters were 2.85 ± 0.51 mm × 16.93 ± 5.42 mm (diameter and length, respectively). The main reasons for using the hybrid strategy were the lack of the proper Absorb BVS<sup>®</sup> size (n = 6; 4.3%) and the difficulties in delivering the BVS stent (due to the vessel anatomy: n = 6 [4.3%] and due to location distally to first BVS: n = 3 [2.2%]). Among others there were highly calcified lesions (n = 2; 1.4%) and lesions within true bifurcations (n = 5; 3.6%).

### Clinical outcomes

There was one (1%) periprocedural MI due to distal dissection and debris embolisation. Additionally, in-hospital increased TnI levels (max 1.4 ng/mL; N: < 0.3 ng/mL) were observed in 10 (7.2%) patients. These were all asymptomatic, without electrocardiogram changes, and did not require repeat coronary angiography (i.e. they did not meet the criteria of MI type 4a). After six days one (0.7%) case of subacute Absorb BVS<sup>®</sup> thrombosis was observed. It led to MI and cardiac death.

The clinical follow-up at 12 months was available in all alive patients (Fig. 1 Table 4). The cumulative incidence of MACE was 7.2% (n = 10). In the observation period between one and 12 months there was no death, but one case of MI (0.7%) caused by late stent thrombosis at three months was registered. The clinically-driven TLR rate was 5.0% (n = 7). In these cases the restenosis pattern was rather diffuse. All cases were treated by PCI (POBA: three cases, classical DES: four cases).

In further analysis, in the hybrid BVS-DES subgroup there was no death, MI, or stent thrombosis, and only one case of clinically-driven TLR (4.5%).

### DISCUSSION

Our registry has shown that Absorb BVS<sup>®</sup> implantation is a safe and effective procedure in a wide range of cases, with an

MACE rate of 7.2% and a TLR rate of 5.1% at 12 months. Additionally, it suggests that the hybrid strategy with BVS and DES in certain cases might be a supplementary approach, which enables us to obtain a high device success rate, and a low rate of complications. To our knowledge this is the first study focusing on the safety and feasibility of hybrid treatment in clinical practice.

BVS release has provided an interesting strategy to treat coronary atherosclerotic lesions with temporary scaffolds that enable coronary anatomy and vessel reactivity restoration, as well as facilitate future procedures [8]. As mentioned earlier, this strategy might be used to reduce the cost of the procedure and to reduce the length of the metallic scaffold, and it might be a helpful option in challenging anatomy with a lot of tortuosity and heavy calcification. It is crucial since suboptimal BVS deployment and expansion may result in scaffold collapse, scaffold recoil, or scaffold thrombosis [9].

In our population, in 24 (17.3%) cases a second Absorb BVS® stent was deployed, and in 22 (15.8%) cases a classical DES was used as the additional stent. The implantation of the second Absorb BVS® was associated with one case of distal dissection, and in the remaining cases the reason was the length of the lesions. In the hybrid subgroup classical DES was chosen by the operator on the basis of the angiographic view and the experience with prior BVS implantation and balloon catheter passages during lesion preparation. As mentioned earlier, the main reasons for using the hybrid strategy were the lack of the proper Absorb BVS® size ( $n = 6$ ; 4.3%) and difficulties in delivering the BVS stent (due to the vessel anatomy:  $n = 6$  [4.3%] and due to location distally to first BVS:  $n = 3$  [2.2%]). Among others there were highly calcified lesions ( $n = 2$ , 1.4%) and lesions within true bifurcations ( $n = 5$ , 3.6%).

In our population the low rate of complications might have been related to various factors, but the lesion selection and the procedural technique are among the most important ones. The small number of patients with moderate-severe vessel tortuosity as well as moderate-heavy calcifications at the culprit lesion and adequate lesion preparation enabled us to obtain a 100% device success rate. In our study most frequently patients with lesions of type A or B1 (72.7%) were treated, while more complex lesions (B2/C) were only found in 27.3% of cases. Also, proper lesion preparation (predilatations with high pressure inflations and postdilatations with non-complaint balloons) might play a crucial role in the Absorb BVS® performance [10]. It is worth emphasising that when the programme with BVS started postdilatations with a non-complaint balloon were not clearly recommended, so the percentage of that step in our study was relatively low (52.3%). Despite this, the obtained results are comparable with other studies regarding short-term clinical [11] as well as long-term outcomes [5, 12].

In everyday clinical practice operators deploy stents with a variable length of the overlapping part. Some authors suggest that treatment with proximal BVS with distal DES should be called the hybrid BVS-DES overlapping technique, and that proximal DES with distal BVS should conversely be named the hybrid DES-BVS approach. This differentiation might be crucial since there are some variations in the sequence of BVS and DES deployment [13].

In the hybrid DES-BVS technique, BVS lies on top of the metallic scaffold at the overlapped segment. If the BVS was positioned first proximally and then overlapped distally with a DES, the thinner metallic struts lay on top of the thicker BVS scaffold at the overlapped segment. Once the BVS scaffold under the metallic strut resorbs, it leaves an overhanging metallic strut segment that is not apposed to the vessel wall. The longer the overlapped segment, the longer the potentially malapposed stent segment is. Also, the expansive remodelling property of the BVS may contribute to the malapposition at the DES-BVS overlap junction. Therefore, overlapping DES-BVS during PCI must be done adequately to minimise the potential risk of in-stent thrombosis [9]. Standard overlapping technique is also prone to potential complications, such as geographical miss or an overlapped segment. Therefore, hybrid DES-BVS or BVS-DES PCI can pose a potential risk for stent/scaffold thrombosis if it is not performed reasonably and meticulously. However, this was not proven in our registry. In our study two cases of definite stent thrombosis were registered (after six days and after three months). The former case was probably the consequence of poor lesion preparation and Absorb BVS® underexpansion in the distal LAD, and the latter one was caused by the poor compliance of the patient regarding dual antiplatelet therapy. Nevertheless, no case of stent thrombosis appeared in the hybrid subgroup.

As the concept of coronary artery reparative therapy with Absorb BVS® appears to be very appealing, the use of this device is expected to increase in the foreseeable future. However, due to its limitations (strut thickness, difficulties in the optimal stent apposition in the vessel with “hard plaques”, and the limited range of sizes) there is still a need to support BVS treatment with classical everolimus-eluting stents. This suggests that in particular clinical scenarios BVS and DES are complementary devices. However, better BVS customisation, proper patient selection, and lesion preparation might reduce the percentage of hybrid strategies with BVS and DES.

### *Limitations of the study*

This registry has several limitations that should be acknowledged. First of all, the sample size was relatively small. Another limitation of this study is its non-randomised manner and all of the known drawbacks of registry studies. Also, no follow-up angiographic analysis was performed.



## CONCLUSIONS

The obtained data enable us to say that in particular clinical scenarios the simultaneous use of BVS and DES is safe and effective.

**Conflict of interest:** none declared

## References

1. Stettler C, Wandel S, Allemann S et al. Outcomes associated with drug-eluting and bare-metal stents: a collaborative network meta-analysis. *Lancet*, 2007; 370: 937–948. doi: [10.1016/S0140-6736\(07\)61444-5](https://doi.org/10.1016/S0140-6736(07)61444-5).
2. Kandzari DE, Leon MB, Meredith I et al. Final 5-year outcomes from the Endeavor zotarolimus-eluting stent clinical trial program: comparison of safety and efficacy with first-generation drug-eluting and bare-metal stents. *J Am Coll Cardiol Cardiovasc Interv*, 2013; 6: 504–512. doi: [10.1016/j.jcin.2012.12.125](https://doi.org/10.1016/j.jcin.2012.12.125).
3. Rzeszutko L, Depukat R, Dudek D. Biodegradable vascular scaffold ABSORB BVS: scientific evidence and methods of implantation. *Post Kardiol Interw*, 2013; 9: 22–30. doi: [10.5114/pwki.2013.34026](https://doi.org/10.5114/pwki.2013.34026).
4. Yew KL. Hybrid ABSORB bioresorbable vascular scaffold and drug eluting stent or hybrid BVS-DES percutaneous coronary intervention: method and rationale for hybrid overlapping PCI. *Int J Cardiol*, 2015; 186: 74–76. doi: [10.1016/j.ijcard.2015.02.092](https://doi.org/10.1016/j.ijcard.2015.02.092).
5. Abizaid A, Ribamar Costa J, Jr., Bartorelli AL et al. The ABSORB EXTEND study: preliminary report of the twelve-month clinical outcomes in the first 512 patients enrolled. *EuroIntervention*, 2015; 10: 1396–1401. doi: [10.4244/EIJV10I12A243](https://doi.org/10.4244/EIJV10I12A243).
6. Bezenek S, Hermiller J, Lansky A et al. Low stent thrombosis risk with the XIENCE V(R) Everolimus-Eluting Coronary Stent: evidence from randomized and single-arm clinical trials. *J Interv Cardiol*, 2011; 24: 326–341. doi: [10.1111/j.1540-8183.2011.00628.x](https://doi.org/10.1111/j.1540-8183.2011.00628.x).
7. Thygesen K, Alpert JS, Jaffe AS et al. Third universal definition of myocardial infarction. *Circulation*, 2012; 126: 2020–2035. doi: [10.1161/CIR.0b013e31826e1058](https://doi.org/10.1161/CIR.0b013e31826e1058).
8. 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: 16–25b. doi: [10.1093/eurheartj/ehr384](https://doi.org/10.1093/eurheartj/ehr384).
9. Capodanno D, Gori T, Nef H et al. Percutaneous coronary intervention with everolimus-eluting bioresorbable vascular scaffolds in routine clinical practice: early and midterm outcomes from the European multicentre GHOST-EU registry. *EuroIntervention*, 2015; 10: 1144–1153. doi: [10.4244/EIJY14M07\\_11](https://doi.org/10.4244/EIJY14M07_11).
10. De Ribamar Costa J, Jr., Abizaid A, Bartorelli AL et al. Impact of post-dilation on the acute and one-year clinical outcomes of a large cohort of patients treated solely with the Absorb Bioresorbable Vascular Scaffold. *EuroIntervention*, 2015; 11: 141–148. doi: [10.4244/EIJY15M05\\_06](https://doi.org/10.4244/EIJY15M05_06).
11. Rzeszutko L, Siudak Z, Włodarczyk A et al. Use of bioresorbable vascular scaffolds in patients with stable angina and acute coronary syndromes. Polish National Registry. *Kardiol Pol*, 2014; 72: 1394–1399. doi: [10.5603/KP.a2014.0147](https://doi.org/10.5603/KP.a2014.0147).
12. Ormiston JA, Serruys PW, Regar E et al. A bioabsorbable everolimus-eluting coronary stent system for patients with single de-novo coronary artery lesions (ABSORB): a prospective open-label trial. *Lancet*, 2008; 371: 899–907. doi: [10.1016/S0140-6736\(08\)60415-8](https://doi.org/10.1016/S0140-6736(08)60415-8).
13. Yew KL. Overlapping technique for hybrid percutaneous coronary intervention strategy utilising drug eluting stent and ABSORB bioresorbable vascular scaffold. *Int J Cardiol*, 2015; 178: e8–e10. doi: [10.1016/j.ijcard.2014.08.085](https://doi.org/10.1016/j.ijcard.2014.08.085).

**Cite this article as:** Gil RJ, Bil J, Pawłowski T et al. The use of bioresorbable vascular scaffold Absorb BVS® in patients with stable coronary artery disease: one-year results with special focus on the hybrid bioresorbable vascular scaffolds and drug eluting stents treatment. *Kardiol Pol*, 2016; 74: 627–633. doi: [1056.03/KP.a2015.0250](https://doi.org/10.5603/KP.a2015.0250).

# Wykorzystanie stentów bioresorbowalnych Absorb BVS<sup>®</sup> u pacjentów ze stabilną chorobą wieńcową: ocena skuteczności i bezpieczeństwa leczenia hybrydowego stentów bioresorbowalnych i stentów uwalniających lek

Robert J. Gil<sup>1,2</sup>, Jacek Bil<sup>3</sup>, Tomasz Pawłowski<sup>1</sup>, Nabijon Yuldashev<sup>3</sup>, Leszek Kołakowski<sup>4</sup>, Jacek Jańczak<sup>5</sup>, Wojciech Jabłoński<sup>6</sup>, Piotr Paliński<sup>7</sup>

<sup>1</sup>Klinika Kardiologii Inwazyjnej, Centralny Szpital Kliniczny MSW, Warszawa

<sup>2</sup>Instytut Medycyny Doświadczalnej i Klinicznej, Polska Akademia Nauk, Warszawa

<sup>3</sup>Republican Specialised Cardiology Centre, Tashkent, Uzbekistan

<sup>4</sup>Centrum Kardiologii, Allenort, EtK

<sup>5</sup>Centrum Kardiologii, Allenort, Itawa

<sup>6</sup>Centrum Kardiologii, Allenort, Szczecinek

<sup>7</sup>Centrum Kardiologii, Allenort, Tomaszów Mazowiecki

## Streszczenie

**Wstęp:** Zabiegi angioplastyk wieńcowych (PCI) z wykorzystaniem stentów bioresorbowalnych (BVS) stają się coraz bardziej popularne, gdyż poza pierwszym okresem pozbawione są wad związanych z metalową platformą, jak ma to miejsce w przypadku klasycznych stentów uwalniających lek (DES).

**Cel:** Celem niniejszej pracy było przedstawienie zebranego doświadczenia w stosowaniu BVS w codziennej praktyce klinicznej, ze szczególnym uwzględnieniem oceny bezpieczeństwa i skuteczności podejścia hybrydowego, tzn. jednoczesnego stosowania BVS i DES.

**Metody:** Do prospektywnego rejestru włączano pacjentów ze stabilną chorobą wieńcową w 5 ośrodkach kardiologii interwencyjnej w Polsce. Wszyscy chorzy spełniający kryteria włączenia i wyłączenia, u których implantowano co najmniej jeden BVS w trakcie PCI, byli włączani do badania. Pierwszorzędowym punktem końcowym był odsetek poważnych zdarzeń sercowo-naczyniowych (MACE) definiowany jako łączny odsetek zgonu sercowego, zawału serca (MI) i ponownej rewaskularyzacji leczonej zmiany warunkowanej objawami klinicznymi (TLR).

**Wyniki:** Pomiędzy sierpniem 2013 r. a kwietniem 2014 r. do badania włączono 139 chorych. Średnia wieku wynosiła  $59,5 \pm 5,5$  roku, a kobiety stanowiły 34,5%. W 2/3 przypadków zabieg angioplastyki wykonywano w tętnicy przedniej zstępującej. Odsetek skuteczności urządzenia wyniósł 100%. Po 12 miesiącach odsetek MACE wyniósł 7,2% (n = 10), podczas gdy wartość klinicznego TLR była równa 5,1% (n = 7). Warto podkreślić, że w podgrupie chorych leczonych hybrydowo nie stwierdzono żadnego zgonu, MI, zakrzepicy w stencie, jak również zarejestrowano tylko 1 przypadek TLR uwarunkowany objawami klinicznymi (4,5%).

**Wnioski:** Uzyskane wyniki pozwalają stwierdzić, że w pewnych sytuacjach klinicznych BVS i klasyczne DES są uzupełniającymi się wyrobami. Jednak lepsze dostosowanie BVS, właściwy dobór chorych i poprawne przygotowanie leczonych zmian może zmniejszyć odsetek przypadków leczenia hybrydowego (BVS + DES).

**Słowa kluczowe:** stent bioresorbowalny, Absorb, stabilna choroba wieńcowa, podejście hybrydowe

Kardiol Pol 2016; 74, 7: 627–633

## Adres do korespondencji:

dr n. med. Jacek Bil, Klinika Kardiologii Inwazyjnej CSK MSW, ul. Wołoska 137, 02-507 Warszawa, e-mail: biljacek@gmail.com

Praca wpłynęła: 08.06.2015 r.

Zaakceptowana do druku: 23.11.2015 r.

Data publikacji AoP: 29.12.2015 r.