Very long-term follow-up of patients with coronary bifurcation lesions treated with bioresorbable scaffolds

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ABSTRACT

Backgrounds: The data concerning the use of bioresorbable vascular scaffolds (BVS) in coronary bifurcation lesions are limited.

Aims: The objective of the study was to evaluate the early and very long-term clinical outcomes of bifurcation stenting with ABSORB BVS.

Methods: One hundred consecutive patients with coronary bifurcation lesions treated with BVS were included. A total of 124 BVS were implanted. Provisional side branch stenting was performed in 66 patients, distal main stenting in 14 patients, systematic T stenting in 2, and T with minimal protrusion (TAP) in 5 patients. Side branch ostial stenting was performed in additional 12 patients.

Results: The procedural success was achieved in 98% of patients. In long-term follow-up, the rate of cardiac death was 4.0%, target vessel myocardial infarction was 5.0%, and target vessel revascularization (TVR) was 11%. The cumulative incidence of definite/probable scaffold thrombosis (ST) was 2% at long-term follow-up. Comparison with the historical drug-eluting stents (DES) group revealed higher mortality and major adverse cardiac events rate in the ABSORB group.

Conclusions: Stenting of coronary bifurcation lesions of low-to-moderate complexity with BVS was feasible with good acute performance and acceptable results. However, the risk of death and major adverse cardiovascular events was higher as compared with DES.

Key words: bifurcation lesion, bioresorbable scaffolds, percutaneous coronary intervention

INTRODUCTION

Coronary artery bifurcation stenting has always been a challenging procedure in interventional cardiology. In the bare-metal stents era, the results were unsatisfactory, mainly due to the increased risk of periprocedural complications, high rate of restenosis, and repeat target lesion revascularization (TLR) [1–3]. Significant improvement has been observed with the advent of drug-eluting stents (DES), primarily because of the restenosis and TLR reduction [4, 5]. Nevertheless, even in the current era, bifurcation stenting, compared with percutaneous coronary interventions (PCI) for the non-bifurcation stenosis, is associated with a higher rate of periprocedural complications and stent thrombosis at follow-up [6–8].

Suboptimal treatment outcomes after implantation of metallic DES [9, 10] resulted in the development of the bioresorbable vascular scaffold (BVS) technology, with the potential long-term benefit after complete scaffold resorption [11, 12]. Although Abbott Vascular has withdrawn ABSORB BVS (Abbott Vascular, Santa Clara, CA, US) from commercial use, the idea of "leaving nothing behind" is still attractive. BVS could prevent permanent obstruction of a side branch (SB) in bifurcation lesions, reducing the risk of its closure and improving access if future treatment was needed.

WHAT'S NEW?

We report on very long-term clinical outcomes of bifurcation lesions stenting with everolimus-eluting bioresorbable vascular scaffolds (BVS). We have shown that stenting of coronary bifurcation lesions of low-to-moderate complexity with bioresorbable everolimus-eluting scaffolds was feasible with good acute performance and acceptable results. However, the risk of death and major adverse cardiovascular events was higher as compared with the second-generation drug-eluting stents. To our knowledge, this is the longest follow-up of patients after bifurcation stenting with everolimus-eluting BVS.

Since the benefits of BVS had been expected after scaffold disappearance, a very long-term observation time is necessary for the ultimate validation of this technology. The data concerning the use of BVS in coronary bifurcations are limited. Given the complexity of the procedure and the potential risk of struts' damage, it is imperative to evaluate the efficacy and long-term safety of BVS in such lesions.

METHODS

Study design, objectives, and patient selection

The study is a prospective, nonrandomized clinical registry of patients with coronary bifurcation lesions treated with everolimus-eluting BVS [16]. One hundred consecutive patients with stable coronary artery disease (SCAD) or acute coronary syndromes (ACS) were enrolled between October 2012 and December 2016. The study excluded patients with lesions deemed too complex to be treated with scaffolds (e.g., extreme tortuosity, severe calcifications, diffuse disease), concomitant serious, life-shortening illnesses, patients unable to receive prolonged dual antiplatelet therapy (DAPT), or requiring chronic oral anticoagulation therapy. Bifurcation lesion was defined and classified according to the European Bifurcation Club definition and Medina classification [13, 14].

The study group was compared with a historical control group of 107 patients undergoing coronary bifurcation stenting with a new generation DES (Xience™, Promus™, Endeavor™) between October 2006 and January 2009. Patients were selected from another prospective, nonrandomized clinical registry of patients treated with second-generation DES [15].

The main objective of the present study was to evaluate the long-term efficacy and safety of ABSORB BVS in coronary bifurcation lesions. The secondary outcome of interest was to compare the long-term performance of BVS with the second-generation DES.

The follow-up was calculated as the period from the procedure to the last contact with the patient, by phone or in-person during planned or urgent hospitalization.

The study was performed according to the provisions of the Declaration of Helsinki and good clinical practice and was approved by the local Ethics Committee (protocol no. 1015/13). All patients gave written informed consent to participate.

Procedure description

One day before planned PCI, all aspirin-, and clopidogrel-naive patients received a loading dose of both drugs, 300 mg each. Patients with ACS were loaded with 600 mg clopidogrel and 300 mg aspirin on admission. The PCI procedure was performed via the radial or femoral approach, according to the operator's preference. After vessel puncture, patients were given a bolus of unfractionated heparin in a dose of 100 U per kilogram. Intravascular ultrasound (IVUS) or optical coherence tomography (OCT) imaging were used at the operator's discretion but are strongly recommended in all complex cases. The procedure was regarded successful if the final thrombolysis in myocardial infarction (TIMI) 3 flow was obtained both in the main vessel (MV) and the side branch (SB), and the final MV diameter stenosis was below 30%. On discharge, all patients were advised to remain on DAPT for 12 months and then lifelong on aspirin alone. Clopidogrel was the only P2Y12 inhibitor used until March 2014 (66 patients) when the drug was replaced with ticagrelor after a few cases of BVS failures in other patients.

Bifurcation treatment strategy and techniques

The provisional approach was strongly recommended. In the first few months, we sized the MV scaffold according to distal reference diameter with high-pressure deployment (≥14 atm) and proximal optimization technique (POT) with a balloon diameter of 0.25–0.5 mm larger than the size of the scaffold (16 patients). In the later period, a proximal vessel maximum diameter (Dmax) was used to size the scaffold, with implantation pressure below 14 atm. Pre-dilatation and POT were also strongly recommended for all cases. Only T or T with minimal protrusion (TAP) techniques were allowed if a two-stent strategy was needed. All operators were strongly discouraged from using any complex techniques that might result in scaffold damage, e.g. culotte, crush, or simultaneous kissing stenting. If the final kissing-balloon post-dilatation (FKB) was required, low-pressure inflation (8 atm) was performed with a minimal protrusion of SB balloon into MV lumen (the mini kissing or snuggle technique). As no data were available on using BVS in this indication, all patients were scheduled for planned coronary angiography after 12 months post procedure. Quantitative coronary analysis (QCA) was performed after the procedure by two independent oper-

ators. Measurements were performed in three segments: the proximal and distal MV segment and SB.

Study endpoint and definitions

The primary clinical study endpoint was a device-oriented target vessel failure (TVF), defined as the combination of cardiac death, target vessel myocardial infarction (MI), or clinically driven target vessel revascularization (TVR). The primary procedural outcomes were device success, defined as successful delivery and deployment of the scaffold at the intended target lesion, and procedure success, defined as <30% residual stenosis in MB and TIMI 3 flow in both vessels, with no major periprocedural complications.

The secondary outcome of interest was the frequency of major adverse cardiac events (MACE), composed of death, myocardial infarction, ST, and target lesion revascularization (TLR), as well as the incidence of ST, classified according to the Academic Research Consortium criteria [17]. Both periprocedural and spontaneous MIs were defined according to the universal definition [18].

To compare BVS with DES II, we assessed the following endpoints: death and the composite endpoint of death, MI, and TLR.

Statistical analysis

All continuous variables were presented as means (standard deviation [SD]) for normal distribution or medians (interquartile range [IQR]) for non-normal distribution. The normality of the distribution of variables was tested using the Kolmogorov-Smirnov test. Categorical variables were presented as counts and percentages or frequencies. The significance of differences between the mean values of the continuous data consistent with the normal distribution was assessed using the Student's t-test. The Mann–Whitney U test was used to compare the continuous data inconsistent with the normal distribution. Categorized variables were compared using the χ^2 test.

The Gehan-Breslow-Wilcoxon test was used for survival analysis. In addition, the analyses were repeated, stratifying patients by cardiovascular high-risk groups. The prognostic relevance of different variables regarding the prediction of endpoints was estimated using univariable logistic regression analysis. The multivariable logistic regression model included the variables with the value of P <0.1 in the univariable model. We used PQStat Software (PQStat v.1.8.0.476, Poland) for statistical analysis.

RESULTS

Patient population and lesion characteristics

Between October 2012 and December 2016, one hundred patients with bifurcation lesions were treated with the implantation of one or more ABSORB BVS. Two patients received additional metallic stents during PCI because of major dissection of the main vessel after BVS implantation. The clinical follow-up was available for all survivors, at a median (IQR) of 1434 (1126–1969) days, with the follow-up at one year available in all patients. The baseline demography and clinical characteristics are presented in Table 1. The mean age was 62 (10) years, 76 patients were males (76%), 30 had diabetes mellitus (30%), and 13 had chronic kidney disease (13%). The majority of subjects had stable angina (82%). Supplementary material, *Table S1* summarizes vessel and lesion characteristics. True bifurcation lesion (Medina 1,1,1 / 1,0,1 / 0,1,1) was found in 27 patients, and ostial side branch lesions (Medina 0,0,1) in 13. About 90% of lesions were classed as type B2 or C according to the American College of Cardiology and American Heart Association. In 10% of cases, the lesion was diagnosed as MV chronic total occlusion (CTO). Twenty-one lesions comprised the left main coronary artery (LMCA). On QCA, the median of proximal and distal MV reference diameters were 3.4 (3.1–3.7) mm and 3.0 (2.5–3.3) mm, respectively, whereas the median of lesion length and diameter stenosis was 10.5 (8.0–16.0) mm and 70 (30–80)%. The median of SB reference diameter was 2.3 (2.0–2.55) mm, SB lesion length 5.0 (3.0 – 10.5) mm, and lesion diameter stenosis 20 (10–70)%.

Table 1. Baseline demographics and clinical characteristics of the study group

Variable	Patient-based
Age, years, mean (SD)	62 (9.7)
Male sex, n (%)	76 (76.0)
Previous MI, n (%)	47 (47.0)
Hypertension, n (%)	78 (78.0)
Diabetes mellitus, n (%)	30 (30.0)
Insulin-treated diabetes mellitus, n (%)	8 (8.0)
Current smoker, n (%)	41 (41.0)
Chronic kidney disease (eGFR < 60 ml/min), n (%)	13 (13)
PVD, n (%)	8 (8.0)
History of PCI / CABG, n (%)	54 (54.0) / 4 (4.0)
Clinical presentation, n (%)	
Stable angina / silent ischemia	82 (82.0)
Unstable angina / non-ST-elevation MI	15 (15.0)
ST-elevation MI	3 (3.0)
Left ventricular ejection fraction, %, median (IQR)	60.0 (50–60)
Multivessel disease, n (%)	39 (39.0)

Abbreviations: CABG, coronary artery bypass grafting; eGFR, estimated glomerular filtration rate; IQR, interquartile range; MI, myocardial infarction; PCI, percutaneous coronary intervention; PVD, peripheral vessel disease; SD, standard deviation

Procedural details

Complete procedural data are presented in Table 2. Lesion pre-dilatation was performed in 90% of procedures, whereas a high-pressure post-dilatation only in 59 patients (59%). A simple approach with single scaffold implantation was applied in 92, whereas the technique with two scaffolds in eight patients: systematic T stenting in two, TAP in five, and crush in one of them. Among 66 patients treated with provisional stenting, scaffold struts were crossed with a balloon towards SB in 20 cases. A potential scaffold deformation was then corrected with FKB (or mini-KB) and POT in eleven cases, whereas in the remaining nine, only POT was applied. All complex procedures were finished

Table 2. Procedure characteristics

Variable	Patient-based
Radial approach, n (%)	78 (78.0)
Guiding catheter 6 F, n (%)	98 (98.0)
Simple technique (single stent used), n (%)	92 (92.0)
Provisional SB stenting	66 (66.0)
Side branch ostial stenting	12 (12.0)
Distal main stenting	14 (14.0)
Systematic T stenting, n (%)	2 (2.0)
TAP, n (%)	5 (5.0)
Crush, n (%)	1 (1.0)
Pre-dilatation, n (%)	90 (90.0)
High-pressure post-dilatation, n (%)	59 (59.0)
POT, n (%)	59 (59.0)
SB post-dilatation, n (%)	20 (20.0)
Ballon diameter, mm, median (IQR)	2.5 (2.0–2.5)
Balloon pressure, atm, median (IQR)	10 (10–15)
MB Scaffold diameter, mm, median (IQR)	3.0 (3.0–3.5)
MB Scaffold length, mm, median (IQR)	18 (18–28)
MB Scaffold implantation pressure, atm, median (IQR)	16 (14–16)
SB Scaffold diameter, mm, median (IQR)	2.5 (2.5–3.0)
SB Scaffold length, mm, median (IQR)	18 (18–28)
SB Scaffold implantation pressure, atm, median (IQR)	16 (14–16)
Final kissing/snuggle, n (%)	19 (19.0)
IVUS / OCT, n (%)	38 (38.0)
Device (scaffold) success (lesion based), n (%)	100 (100)
Procedure success, n (%)	98 (98.0)
Fluoroscopy time, min, mean (SD)	12.2 (8.0)
Contrast use, ml, mean (SD)	157.7 (75.2)

Abbreviations: IVUS, intravascular ultrasound; LAD, left anterior descending; LCX, left circumflex; LMCA, left main coronary artery; OCT, optical coherence tomography; OM, obtuse marginal branch; POT, proximal optimization technique; RCA, right coronary artery; TAP, T, and protrusion; other — see Table 1

with FKB and POT. The median MV scaffold diameter and length were 3.0 (3.0–3.5) mm and 18 (18–28) mm, respectively, with the median implantation pressure of 16 (14––16) atm. In SB, the median scaffold diameter and length were 2.5 (2.5–3.0) mm, 18 (18–28) mm, and the median implantation pressure was 16 (14–16) atm. IVUS was used in six, whereas OCT in thirty-two patients. The device and procedure success rates were 100% and 98%, respectively.

Clinical outcomes

The in-hospital stay was clinically uneventful in all patients. Periprocedural MI was diagnosed in two subjects: as a consequence of SB occlusion in one case and in the course of a septal branch closure in another. An isolated, asymptomatic elevation of troponins more than five times above the limit was observed in one more patient, without any ECG changes. At 30 days, two deaths were observed: one sudden and unexplained death in a 53-year-old male, nine days after ostial LCX stenting (Medina 0,0,1) with a 3.5 × 18 mm scaffold. The second patient died during an ischemic stroke. In another patient, target-vessel MI occurred due to a scaffold thrombosis five days after stenting of the ostial lesion (Medina 0,0,1) in an obtuse marginal branch with a 2.5 × 18 mm scaffold (Figure 1). Final OCT examination during baseline procedure revealed scaffold protrusion into MV, with no signs of any strut fracture (Figure 1C). All three patients remained on aspirin and clopidogrel during the events. In a long-term follow up three more cases of cardiac death and four MI were observed. Target vessel failure was finally diagnosed in 5 patients

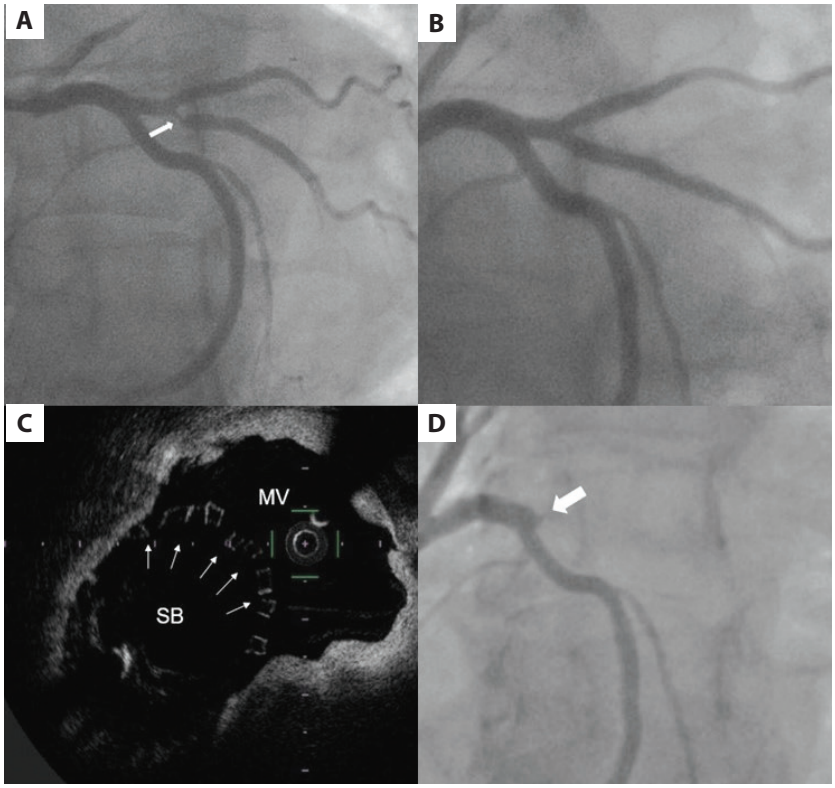

Figure 1. A case of side branch ostial stenting with BVS. **A.** Medina 0,0,1 lesion in the obtuse marginal branch. **B.** Final result after BVS 2.5 × 18 mm implantation and FKB with two 2.5 balloons. **C.** OCT image showing scaffold protrusion into MV. **D.** MV thrombosis five days after the procedure

Abbreviations: BVS, bioresorbable vascular scaffold; FKB, final kissing balloon; MV, main vessel; OCT, optical coherence tomography

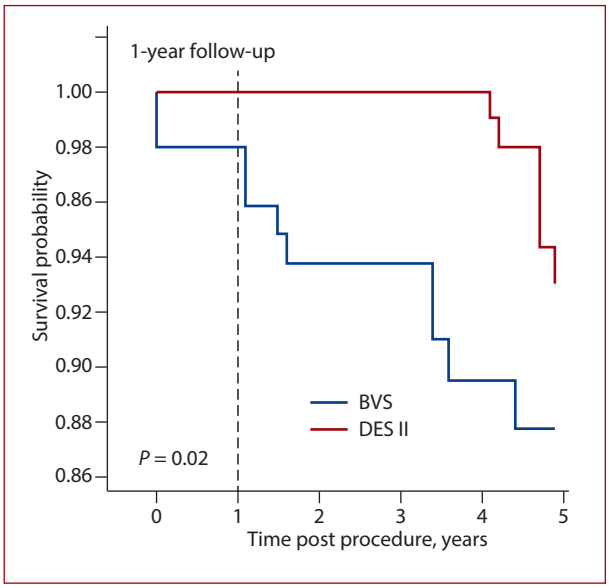

Figure 2. Kaplan-Meier curves for overall survival

Abbreviations: DES, drug-eluting stent; other — see Figure 1

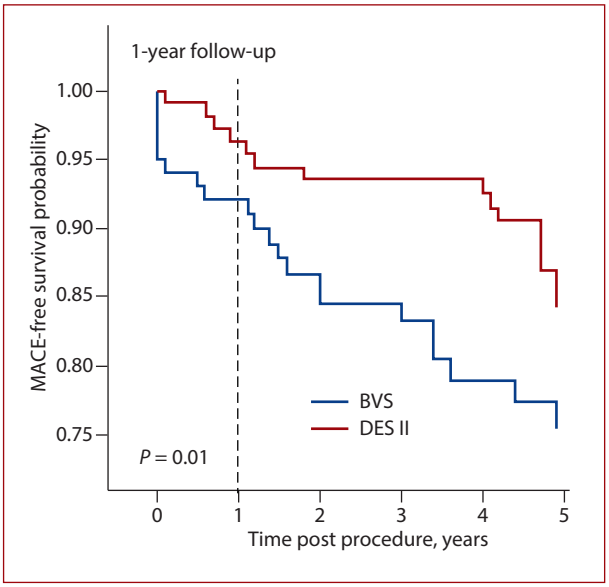

Figure 3. Kaplan-Meier curves for MACE

Abbreviations: MACE, major adverse cardiac events; other — see Figure 1

within 30 days after the procedure and 15 patients in the long-term follow-up. Data on 30-day and long-term clinical outcomes are presented in Table 3.

Angiographic follow-up

The angiographic follow-up, 12 months post the index procedure, was scheduled for all patients. Ultimately, the examination was performed in only 68 of them, mainly due to patients withdrawing their consent. The median time of coronary angiography was 372 (183–412) days. Among patients who underwent coronary angiography, the incidence of scaffold restenosis was 11.8% (8 patients), of which 7 occurred in the main vessel (treated with provisional stenting technique) and one in the side branch (treated with SB ostial stenting technique). There was no vessel occlusion in the implanted BVS. In 26 patients, OCT was performed, which showed the average main vessel diameter stenosis of 15 (10–22.7)% and late lumen loss (LLL) of 0.68 (0.18) mm.

Table 3. Clinical outcomes

Variable	30 days	Long-term
Death, n (%)	2 (2.0)	11 (11.0)
Cardiac death	1 (1.0)	4 (4.0)
Non-cardiac death	1 (1.0)	7 (7.0)
Any MI, n (%)	2 (2.0)	5 (5.0)
Target vessel MI, n (%)	1 (1.0)	5 (5.0)
TVR, n (%)	1 (1.0)	11 (11.0)
TVF, n (%)	5 (5.0)	15 (15.0)
MACE, n (%)	7 (7.0)	26 (26.0)
Scaffold thrombosis, n (%)	2 (2.0)	2 (2.0)
Definite	1 (1.0)	1 (1.0)
Probable	1 (1.0)	1 (1.0)
Ischemic stroke, n (%)	2 (2.0%)	4 (4.0%)

Abbreviations: MACE, major adverse cardiac events; TVF – target vessel failure; TVR, target vessel revascularization; other — see Table 1

Comparison with patients having bifurcation lesions treated with the second-generation DES (historical group)

The baseline demography and clinical characteristics of both study groups are presented in Supplementary material, *Table S2*. There was no significant difference in age, sex, and major cardiovascular risk factors. The Gehan-Breslow-Wilcoxon test revealed that bifurcation treatment with BVS was associated with significantly higher 5-year mortality compared to DES II ($P = 0.02$) (Figure 2). Moreover, the stratified analysis showed significantly higher mortality in the BVS group compared to the DES II group in patients with arterial hypertension ($P = 0.02$), diabetes mellitus ($P = 0.03$), after myocardial infarction ($P = 0.01$), with multivessel coronary artery disease ($P = 0.004$) and left main disease ($P = 0.01$).

Moreover, MACE was also observed significantly more often in the ABSORB BVS group compared to DES II in the long-term follow-up (26.0% vs. 14.0%; $P = 0.03$) (Figure 3). The stratified analysis revealed a significantly higher rate of MACE in the BVS group compared to the DES II group in patients with hypertension ($P = 0.01$), previous myocardial infarction ($P < 0.001$) and a history of PCI ($P = 0.01$), multi-vessel coronary disease ($P = 0.009$), left main disease ($P < 0.001$), and moderate/severe calcifications ($P = 0.02$). In addition, a multivariable logistic regression analysis was included in the supplement to identify independent risk factors for death and MACE (Supplementary material, *Tables S3, S4*).

DISCUSSION

We reported on the clinical outcomes of one hundred patients with bifurcation lesions treated with the implantation of the ABSORB BVS. Our population comprised medium-risk

patients, mostly with SCAD and preserved left ventricle function, with simple or moderately complex bifurcation lesions. Combined MV and SB involvement was found in only 27% of cases, and the majority of them were treated with single scaffold deployment. Given the nature of lesions, the early and long-term results were acceptable and comparable to previous studies [19, 20]. Overall mortality was 11% during the entire follow-up period. Four patients died of cardiovascular causes, all of them within a year of the procedure. The design of ABSORB BVS has been evaluated in multiple trials, mostly with a low number of patients and relatively simple lesions. None of them was dedicated to bifurcation lesions. On the contrary, most patients with such lesions were excluded. The only study reporting on "real world" patients treated with BVS was the GHOST-EU registry [21]. A total of 1189 patients were enrolled, including more than 300 subjects with bifurcation lesions. Although no distinct analysis for this lesion subset was performed, bifurcation lesion was not found to be an independent predictor of target lesion failure (TLF). At six months, the rate of cardiac death was 1.0%, target vessel myocardial infarction 2.0%, TLR 2.5%, and TVR 4.0%. The cumulative incidence of definite/probable ST was 1.5% at 30 days and 2.1% at six months. Importantly, 16 out of 23 cases of ST occurred within 30 days after index PCI. GHOST-EU was the first study, showing the higher rate of ST, mostly clustered within 30 days after the procedure. This observation was consistent with our results, where both cases of ST occurred within the first days after the procedure.

Two major issues should be addressed regarding scaffold thrombosis: the learning curve and appropriate antiplatelet therapy. The retrospective studies highlighted the importance of predilatation, proper sizing of the scaffold (optimally based on intracoronary imaging), and post-dilatation, summarizing all components as a pre-dilatation, sizing and post-dilatation (PSP) technique. In May 2015, a group of European experts published a consensus that contained recommendations on the PSP technique as the optimal technique of BVS implantation [22]. The effectiveness of the above strategy was confirmed in the MICAT registry (the Coronary Slow-flow and Microvascular Disease Registry), in which the optimization of BVS implantation was associated with a significant reduction of in-scaffold thrombosis [23]. Since 2015, we have modified our BVS implantation technique according to the PSP technique. In all subsequent patients, pre-dilation and the high-pressure scaffold post-dilatation with the use of a non-compliant balloon, 0.25–0.5 mm larger than the scaffold diameter, was performed. In none of such cases, did we find any signs of strut fractures on the intravascular examination. In line with the recommendations, we have also significantly increased the use of OCT to select the scaffold size and optimize the procedure.

Since thick struts malapposition increases stent thrombogenicity [24], we changed scaffold sizing according to proximal MV reference diameter, using lower inflation pressure (10–14 atm) to avoid major carina shift and SB flow compromise. In case of flow compromise, a scaffold strut could have been easily crossed with a balloon in the majority of patients. Careful FKB was safely performed, but required low inflation pressure and minimal protrusion of SB balloon. Most of the FKB cases in our group were controlled with OCT, and we found no signs of scaffold damage. If SB stenting was needed, a scaffold or metallic DES could be used. The T or TAP technique was preferable. In the whole analyzed group, only one patient required DES that was implanted into the side branch using the TAP technique. We did not observe any complications with such an approach. Importantly, in each case of the two-stent technique, the use of imaging (preferably optical frequency domain imaging, OFDI) was highly recommended, to optimize the outcomes of the procedure and, during the control coronary angiography, to confirm the bioresorption process [25].

Interestingly enough, both cases of scaffold thrombosis occurred in patients with Medina 0,0,1 lesions after ostial SB stenting. This technique implies some scaffold overhang into the MV lumen. Due to scaffold elastic recoil, such protrusion may not be fully corrected with FKB. Hence, we cannot recommend using a scaffold for such lesions.

Based on our experience, at some point in the study, we decided to modify antiplatelet treatment after BVS implantations [26]. Since December 2014, we have recommended ticagrelor instead of clopidogrel for at least three months after the procedure. Following that change, we have not observed any more scaffold thrombosis in patients treated with BVS in our institution. It seems, therefore, that both the implantation technique and optimal DAPT significantly contribute to improving the safety of PCI with the use of BVS.

Comparing ABSORB BVS with the historical DES II group using the Gehan-Breslow-Wilcoxon test showed significantly higher mortality in the ABSORB group. The data also showed a significantly more frequent occurrence of MACE in the ABSORB BVS group compared to DES II. The presence of comorbidities increased both the risk of death and MACE.

The ABSORB II study compared ABSORB BVS with its everolimus-eluting metallic counterpart, Xience, but also excluded complex lesions such as bifurcation, CTO, and LMCA [27]. In a 3-year observation, device-orientated composite endpoint (DoCE) occurred significantly more often in the ABSORB BVS group, mainly due to the increased frequency of myocardial infarction associated with the treated vessel. Moreover, the expected improvement in vasomotor function was not demonstrated, and the late vascular lumen loss was significantly greater in the ABSORB group. The end of the ABSORB BVS technology was brought by the results of a 3-year follow-up of the randomized multicenter ABSORB III study, which compared ABSORB with Xience stents [28]. A 3-year follow-up revealed a higher incidence of the primary endpoint (cardiac death, target

vessel myocardial infarction, repeat revascularization due to ischemia) in the BVS group compared to the EES (13.4% vs. 10.4%; $P = 0.06$). However, the greatest concern was the significantly higher risk of stent thrombosis after BVS implantation compared to the EES (2.3% vs. 0.7%; $P = 0.01$).

The unfavorable results of studies with ABSORB BVS ™ prompted the European Society of Cardiology to change the recommendations for using bioresorbable scaffolds to class III, which was associated with their withdrawal from everyday clinical practice and allowing implantation only as part of research [29]. However, due to the potential benefits of BVS, the development of this technology is still ongoing. The current direction of research is focused mainly on the reduction of biodegradation time and struts thickness, which largely determines the healing process. Undoubtedly, all bioresorbable technologies require further intensive research, and the experience gained from very long observations of the use of ABSORB BVS ™ is a very valuable source of knowledge, setting the direction for the improvement of the future platforms.

A major limitation of the study is a nonrandomized, observational, single-center design with a small number of patients. The angiograms were not reviewed by the central angiographic core lab. Patients' selection might also play a role, with less complex lesions having been favored for enrolment. Clinical results were compared with a historical group of patients treated with second-generation DES.

CONCLUSIONS

Stenting of coronary bifurcation lesions of low-to-moderate complexity with bioresorbable everolimus-eluting scaffolds was feasible with good acute performance and acceptable results. However, the risk of death and major adverse cardiovascular events was higher as compared with the second-generation drug-eluting stents, especially in patients with comorbidities and multivessel or left main disease. In the future, the possible widespread use of new generation bioresorbable scaffolds will require careful clinical evaluation also in complex coronary lesions.

Supplementary material

Supplementary material is available at https://journals.viamedica.pl/kardiologia_polska.

Article information

Conflict of interest: Maciej Lesiak has received payments as an individual for advisory board and speaker's honoraria from Abbott Vascular, AstraZeneca, Biotronik, Boston Scientific, and Tryton Medical. Stefan Grajek has received payments as an individual on the advisory board and speaker's honoraria from Astra-Zeneca, Servier, Pfizer, Sandoz, Adamed, and Polpharma. Aleksander Araszkiewicz has received payments as an individual for the advisory board and speaker's honoraria from Abbott Vascular. None of the other authors has any conflicts of interest to declare.

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