Research Article

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Immediate and Medium-Term (6 Months) Results of BVS Absorb Biodegradable Coronary Scaffolds Installation in Patients with Chronic Forms of Coronary Artery Disease

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AIM OF STUDY To evaluate the immediate and medium-term (6 months) results of BVS Absorb biodegradable stents implantation in patients with chronic forms of coronary artery disease, taking into account their location in coronary vessels, morphological nature of the initial lesion of the coronary arteries and technical features of implantation as well.

MATERIAL AND METHODS From June 2014 to December 2015, 199 biodegradable stents (Absorb Bioresorbable Vascular Scaffold — BVS; Abbott Vascular, CA, USA) were routinely installed in 114 patients treated at the Interventional Cardioangiology Center of I.M. Sechenov First Moscow State Medical University. The analysis of the obtained results was carried out depending on the type of coronary artery lesion, the length and diameter of the stents, and the details of the angioplasty procedure. To characterize the type of coronary artery lesion, the ACC/AHA classification was used: type A vascular lesion (95 coronary segments); type B vascular disease (68 coronary segments); type C vascular disease (36 coronary segments). The ultimate goal of the study was to study the frequency of thrombosis and in-stent stenosis of stented coronary arteries.

RESULTS The immediate success of scaffold implantation was 98.2%. Complications in the early hospital period were 1.8% (acute stent thrombosis was observed in 2 cases on the first day after implantation). In the medium-term (~6 months), 102 patients (89.5%) with 172 previously placed stents underwent comparison selective coronary angiography. The rest of the patients with stents refused to undergo coronary angiography due to good health and underwent a telephone survey.

The satisfactory result of stenting in the medium-term (6 months) was a completely preserved lumen of the stented area, or with less than 50% stenosis of this place, which comprised 94.3%. The frequency of in-stent stenosis (narrowing of the lumen of the stented area by 50% or more) was 5.7%. In-stent stenosis was detected in groups of patients with type B and C lesions, respectively, in 4% and 1.7%. In the group with type A coronary artery disease, in-stent stenosis was not detected in the medium-term period.

CONCLUSION The immediate and medium-term results of stenting with the biodegradable BVS Absorb stent were successful in the vast majority of cases (94.3%). Only in 2 cases (1.8%), acute thrombosis of the stent was observed immediately after stenting.

Keywords: coronary artery disease, biodegradable stents, immediate results of stenting, optical coherence tomography

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atm – atmosphere
BVS – bioabsorbable vascular stent
CAD – coronary artery disease
LAD – left anterior descending artery
LCA – left coronary artery
MI – myocardial infarction
OCT – optical coherence tomography
PD – post-dilation

INTRODUCTION

The history of coronary artery angioplasty in the treatment of coronary artery disease (CAD) dates back to 1977, when Andreas Gruntzig performed the first percutaneous balloon angioplasty of the coronary arteries [1]. However, further studies have shown that in 6 months, restenosis or complete occlusion of the angioplasty vessel occurs in about 30-40% of cases of balloon angioplasty.

Undesirable changes in the coronary artery, in all likelihood, occur, on the one hand, as a result of trauma to the endothelial layer, and on the other hand, the destruction of the plaque cap due to the inclusion of the von Willebrand phenomenon. This, in turn, leads to the activation of platelet aggregation, which triggers the mechanism of local thrombosis with all the ensuing consequences.

Certain negative consequences of balloon angioplasty such as high frequency of repeated narrowing and thrombosis led researchers to create a special frame (stent) to maintain the effect of angioplasty. The first stent was created in 1986, and at the same time Ulrich Sigvart installed it in the patient's coronary artery [2].

The introduction of stenting into clinical practice has led to significant improvement in the results of endovascular treatment of patients with coronary artery disease. The metal frame significantly reduced the causes of thrombosis and in-stent stenosis in the mid-term period. Nevertheless, the complications mentioned above, with a lower frequency, were still observed during stenting of the coronary arteries due to severe proliferation and neointimal hyperplasia after this procedure.

Subsequent generations of stents with the addition of antiproliferative agents and polymer coatings led to even more significant reduction in the incidence of in-stent stenosis, which quickly made them the most used devices in the treatment of all forms of CAD [3]. But, unfortunately, it was not possible to completely avoid proliferation and neointimal hyperplasia during stenting with the most modern stents, since the degree of neointimal proliferation directly depends on the severity of endothelial damage during stenting, the intensity of the inflammatory response, and the biocompatibility of the implant itself.

The process of stent endothelization takes from 3 to 6 months, however, given that the stent remains in the lumen of the coronary artery forever, and, being a foreign substrate, has a constant irritating effect on the intima of the vessel, it can be a trigger for the occurrence of late thrombosis in the long term. This was the basis for the creation of fully biosoluble stents, which, having fulfilled their main function, must be disposed of without leaving a substrate for an inflammatory reaction [4, 5].

Biodegradable scaffolds had to retain all the advantages of stents, but be completely resorbed in the long term. According to the developers, the “leave nothing behind” strategy had a number of important advantages: it would allow to fully restore the vasomotor and endothelial functions of the coronary arteries; would neutralize the constant possibility of a local inflammatory process; would provide adequate visualization of the vessel; and what is very important, it would preserve the possibility of imposing the distal end of the shunt in this area of the vessel, if it is necessary for the patient to undergo direct myocardial revascularization.

Igaki-Tamai stent was the first idea of a biocompatible intravascular scaffold to be implemented. It was created from PLLA (Poly-L-lacticacid) [6, 7]. The most popular in the family of biodegradable scaffolds was BVS Absorb, developed by Abbotvasc. CA , USA. BVS Absorb has radiopaque markers made of platinum (for positioning), and a shell made of PDLLA containing Everolimus.

Xience drug-eluting stent. Characteristically, both the dosage and the release rate of the cytostatic drug in both stents are maximally identical [8–10]. Conducted large clinical studies comparing the efficacy and safety of the use of Xience and BVS stents with Absorb [11, 12] showed that the results of implantation of BVS Absorb and Xience in the first year of the study were comparable, however, 25 months after implantation, the frequency of adverse cardiovascular events in patients with BVS Absorb was significantly higher than that of Xience, 13.4% versus 10.4%, respectively (p=0.06) [13–15].

Thus, clinical trials of the fully biodegradable Absorb Bioresorbable Vascular Scaffold, BVS; Abbott Vascular, CA, USA have shown that they are significantly more prone to acute thrombosis leading to acute myocardial infarction (AMI) and other serious complications than with indwelling drug-eluting stents. As a result, these stents were banned in the United States in 2018 [16].

Nevertheless, given the continuing interest in biodegradable stents in general, as well as ongoing clinical and experimental studies in this direction, we considered it appropriate to analyze our experience with the use of BVS Absorb in clinical practice.

Thus, the aim of this study was a single-center retrospective analysis of the immediate and medium-term results of the use of BVS Absorb in patients with coronary artery disease, depending on such clinical and angiographic parameters as stent diameter; the nature of atheromatous damage (local, multiple or diffuse, the morphology of the plaque itself); strict adherence to the technical recommendations of the stent manufacturer for BVS implantation.

MATERIAL AND METHODS

In the Center for Cardioangiology, FSAEI HE I.M. Sechenov First Moscow State Medical University of the Ministry of Health of the Russian Federation, 199 Absorb intravascular scaffolds were implanted in 114 patients with chronic coronary artery disease from June, 2014 to December, 2015.

The indication for BVS implantation was a set of such clinical, laboratory and angiographic data as the presence of angina attacks or its equivalents, transient or permanent myocardial ischemia according to functional tests, and the presence of a stenosing lesion of at least one coronary artery.

The study did not include patients with intolerance to antiplatelet and anticoagulant therapy; intolerance to everolimus and poly L-lactide; with a left ventricular ejection fraction of less than 30%; with acute coronary syndrome; who have undergone acute cerebrovascular accident within the next 6 months; with damage to the trunk of the left coronary artery (LCA) or ostial lesions of the coronary arteries (within 3 mm from the aorta or bifurcation of the trunk of the LCA); with excessive tortuosity of the target vessels and severe calcification.

Most of the patients were male — 73 (64%). The age of the patients averaged 66.3±8.7 years. 91.2% of patients had arterial hypertension, 80.7% smoked, 34.2% of patients had diabetes mellitus. The clinical and anamnestic data is represented in Table 1.

Table 1

Clinical and anamnestic characteristics of the studied patients

Number of patients, n	114
Gender, m/f	73 (64%)/41 (36%)
Age, years	66.3±8.7 (58–74)
Body mass index, kg / m ^{2}	26.0±3.1
Diabetes mellitus, n	39 (34.2%)
Smoking, n	92 (80.7%)
Arterial hypertension, n	104 (91.2%)
Low density lipoproteins over 4.0, n	78 (68.4%)
CAD lasting more than 10 years, n	69 (60.5%)
MI in history, n	18 (15.8%)
Multivessel lesion, n	31 (27.2%)

Notes: CAD — coronary artery disease; MI — myocardial infarction

The coronary artery stenting procedure BVS Absorb was performed in a planned manner. Due to the fact that the minimum diameter of these scaffolds is 2.5 mm, and this size is more often intended for the middle segments of the coronary arteries, as a rule, the proximal and middle segments of the vessels were stented, only very rarely performing procedures on the distal segments of the coronary arteries.

BVS Absorb stent was implanted according to the method recommended by the manufacturers. Following this instruction, in all cases before stent implantation, balloon angioplasty was performed with catheters of at least 2.5 mm with a nominal pressure of at least 10 atmospheres (atm) to facilitate the delivery of BVS to the implantation site. Also, according to the manufacturer's instructions, when inflating the stent, different pressure levels were used depending on the stent diameter: the pressure was 7 atm for a stent diameter of 2.5 mm and 3.5 mm, and 6 atm for a stent diameter of 3 mm.

The time of inflating the stent took an average of ~ 3–5 minutes, while for every 1 atm. inflation required at least 30 seconds. Optical coherence tomography (OCT) or intravascular ultrasound was performed to

optimize the different stages of the procedure. In order to achieve adequate deployment of the stent, in certain cases, it was post-dilated with a high-pressure balloon catheter.

Fig. 1 shows the frequency of BVS implantation in individual coronary arteries and their segments. In about half of all cases (44.2%), stenting of the anterior interventricular branch (LAD) of the LCA was performed. It should also be noted that in one case, stenting of the anastomosis of the mammary coronary bypass graft to the LAD was performed, and in 3 cases, venous aortocoronary bypass grafts were performed.

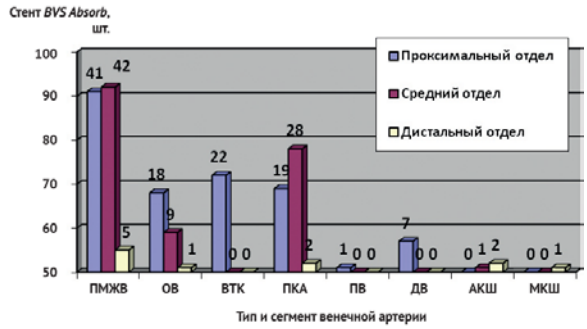

Fig. 1. The frequency of implantation of biodegradable stents in individual coronary arteries and their segments

Notes: CABG — coronary artery bypass grafting; OMB — obtuse marginal branch; DB — diagonal branch; MCB — mammary coronary bypass; CB — circumflex branch; IB — intermediate branch; RCA — right coronary artery; LADA — left anterior descending artery

According to the nature and location of atherosclerotic lesions of the coronary arteries and in accordance with the classification of the American College of Cardiology and the American Heart Association (ACC/AHA), three groups were distinguished: Group 1, type A lesions of the coronary arteries, in which there are local concentric stenoses less than 10 mm with smooth contours; Group 2, type B lesions, when there are eccentric lesions, as well as stenoses with moderate calcification and uneven contours, and finally, Group 3 of type C lesions with stenoses more than 20 mm long, as well as having ulcerated surface diffuse lesions or chronic occlusion of the coronary vessels. The type A stenosis of coronary arteries was observed in 47.7% of cases, type B in 34.2%, and type C in 18.1% (Table 2).

Table 2

The frequency of in-stent stenosis depending on the type of initial lesion of the stented areas of the coronary arteries

Type of initial stenosis coronary artery	Restenosis	p
Stenosis type A, n (%) (n = 88)	0 (0)	<0.001*
Stenosis type B, n (%) (n = 57)	3 (5.3)	$P_{2\text{-}3}$=0.006*
Stenosis type C, n (%) (n = 27)	7 (25.9)	

Notes: * — statistically significant difference (p<0.05)

Before stenting, in all cases (100%), balloon pre-dilation of the stenotic area was performed, and post-dilation with a high-pressure balloon catheter was performed in 127 (63.8%) cases (see Fig. 2).

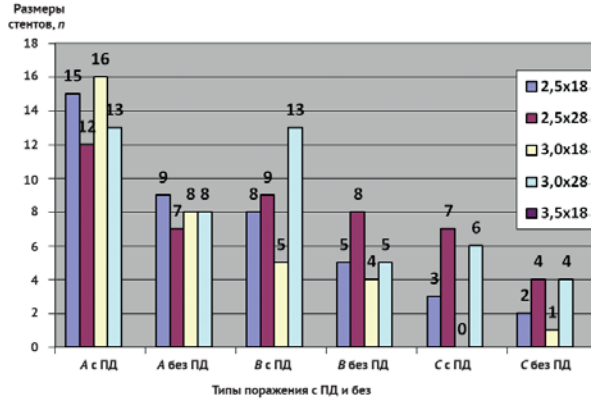

Fig. 2. The distribution of stents sizes depending on the type of lesion (according to ACC/AHA), as well as the presence or absence of post-dilation (PD)

Statistical analysis. The results were statistically processed using the IBM SPSS program Statistics 26.0 (USA). Comparative analysis of independent categorical variables was performed using χ^2 Pearson, as well as using post-hoc analysis. The first stage is Pearson's χ^2 criterion, which essence of which is to compare all lines with all, it answers the question: do the groups really differ; the second stage is post-hoc, where we compare groups in pairs. The prefix 2-3 denotes the difference between the compared lines 2 and 3 - stenosis type B and type C. The nominal indicator was represented by the absolute number of observations; the percentage of the trait in the subgroups is given. In all statistical analysis procedures, the critical level of significance was taken as $p<0.05$.

RESULTS

The immediate success of stenting was observed in 112 patients (194 stents), which amounted to 97.5%. Complications immediately after stenting were noted in 2 cases (1.8%). In both cases, patients had STEMI caused by stent thrombosis. In one observation, immediately after implantation of BVS Absorb, non-occlusive stent thrombosis developed in case of damage to the coronary artery type B and the size of the stent was 2.5 × 28 mm.

Given the unsatisfactory result of stenting, it was decided to immediately implant a drug-eluting stent (using the stent-in-stent technique) with a good result. In the second case, after successful implantation of BVS Absorb 3×18 mm into a vessel with a type B lesion, MI developed in 16 hours. Urgent coronary angiography revealed occlusive stent thrombosis. The patient immediately underwent mechanical recanalization, balloon angioplasty, and stenting with a drug-eluting stent in the occluded area. However, the patient died of acute heart failure. It should be noted that in these cases, during BVS implantation, PD with a high-pressure balloon was not performed.

Upon discharge from the hospital, all patients were recommended to strictly conduct dual antiplatelet and anticoagulant therapy. In accordance with existing recommendations, patients initially received a loading dose of clopidogrel 300 mg, followed by its maintenance dose (75 mg 1 time per day) for a year.

Upon discharge from the hospital, all patients were offered hospitalization 6 months after stenting for a follow-up examination.

After an average of 6.42±2.2 months (from 4 to 9 months) after implantation, 102 patients (89.5%) with 172 implanted BVS (86.4%) underwent a control inpatient examination, including selective coronary angiography. The remaining patients refused hospitalization due to good health, and they were interviewed via phone.

At control selective coronary angiography, a satisfactory result of stenting was observed in 94.3% (162 stents). In another 4% of cases (7 stents), hemodynamically significant in-stent stenosis was detected. The complete occlusion of the stent was detected in 1.7% of cases (3 stents). An unsatisfactory result of stenting in all cases was detected in lesions located either in the middle and distal segments of the target arteries, or in secondary arteries. It should be noted that there was no in-stent stenosis in stents implanted in vessels with type A stenosis. In stents placed for type B stenosis, in-stent stenosis was revealed in 1.7% (3 cases), while in stents placed for type C stenosis, an unsatisfactory result was noted statistically significantly more often (4.0%): In-stent stenosis occurred in 4 cases (2.3%), and occlusion of the stented site was observed in 3 cases (1.7%) ($p<0.05$). In all cases of in-stent stenosis, successful transluminal angioplasty with implantation of drug-eluting stents was performed (Fig. 3). At the same time, in case of occlusion of previously implanted BVS, attempts to mechanically recanalize it were unsuccessful in all cases.

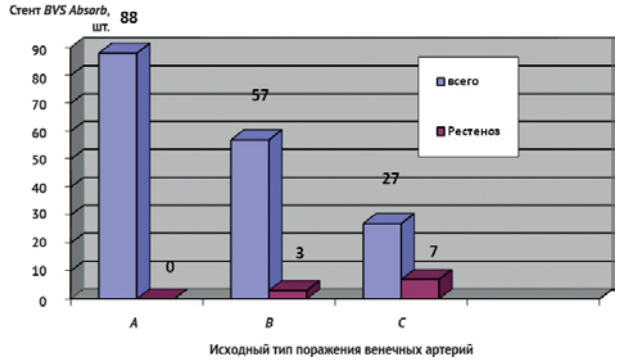

Fig. 3. The frequency of in-stent stenosis and occlusion of BVS Absorb depending on the type of lesion in the medium-term after stenting

The analysis of the obtained data showed that there is a statistically significant difference in the frequency of in-stent stenosis in different types of coronary artery lesions: with type C coronary artery stenosis, in-stent stenosis is statistically significantly more common than with type B vessel lesions (Table 2) .

It should also be noted that in the medium term, a statistically significant relationship was observed between the results of BVS stenting and whether or not balloon PD was performed. Out of 107 stents in which stenting was completed by the PD procedure, an unfavorable outcome in the form of in-stent stenosis was observed only in 2 cases (1.9%), while if this procedure was not performed (65 stents), in-stent stenosis was observed in 5 cases (7.7%). In another 3 cases (4.6%) the stent's occlusion was revealed (Table 3).

Table 3

The frequency of unsatisfactory results of BVS Absorb stenting in the medium-term in two groups in which the procedure of balloon post-dilation was performed or not performed

Characteristics of the control study	Post-dilation after implantation		R
	Performed (n =107)	Not performed (n =65)	
Restenosis, n (%)	2 (1.9)	5 (7.7)	0.106
Occlusion, n (%)	0 (0)	3 (4.6)	0.052
Unsatisfactory result on the test Coronary angiography, n (%)	2 (1.9)	8 (12.3)	0.007*

Note: * - statistically significant difference

However, there was no difference in the incidence of in-stent stenosis or occlusion in the mid-term period when using BVS Absorb of different sizes (Fig. 4).

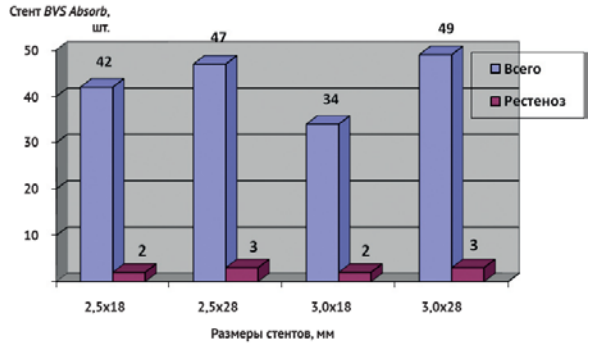

Fig. 4. The frequency of in-stent stenosis and occlusion after stenting when using stents of different sizes

When analyzing BVS stenting, it is extremely important to study the dynamics of endothelialization of the area of stent installation and resorption of the scaffold. For this purpose, an intravascular OCT study was performed in 123 stents (71.5%) in the medium-term. In 6 months, complete endothelialization was observed in 68 stents (55.3%), in the remaining 53 cases it was partial (Fig. 5). It should be especially noted that during the control examination, none of the implanted scaffolds showed signs of resorption at this time.

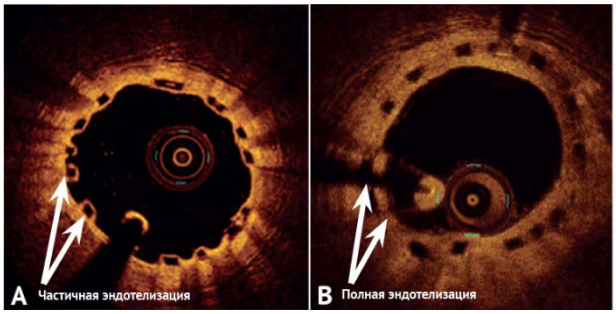

Fig. Fig. 5. Optical-coherent tomographic image of biodegradable BVS Absorb stents 6 months after implantation: A — partial endothelialization of a stent; B — complete endothelization

DISCUSSION OF THE RESULTS

The study showed that the vast majority of patients (97.6%) may successfully have BVS Absorb with good immediate and mid-term results (~6 months). At the same time, it should be noted that acute stent thrombosis occurred in 2 patients (1.8%), despite the fact that all the manufacturer's recommendations were followed during the implantation procedure.

In both cases, the stented site was successfully recanalized with drug-eluting stents. It should be noted that acute stent thrombosis in the next few hours after stenting in 1.7% of patients is a somewhat alarming circumstance, since acute stent thrombosis is extremely rare during stenting with conventional modern stents in the short term after the procedure.

It should also be noted that in both cases PD was not performed. In the remaining patients, the hospital period proceeded without complications, and all of them were discharged from the hospital in the next few days under the supervision of polyclinic physicians at the place of residence with a recommendation to take dual antiplatelet therapy.

Six months after the stenting procedure, a telephone survey of all patients was conducted with the collection of the necessary data. All patients were offered hospitalization for a follow-up examination. 102 patients (89.5%) agreed and were hospitalized. It should be noted that all 112 patients were alive and doing well. None of them had an MI. Seven patients (6.9%) had angina attacks. All hospitalized patients underwent a complete inpatient examination, including control selective coronary angiography.

During control coronary angiography, the state of 172 scaffolds was studied, which accounted for 86.4% of all implanted stents. Six months after the implantation of BVS Absorb stents, we observed a satisfactory result of stenting in the vast majority of patients (94.3%), and only 4% of cases had in-stent stenosis and 1.7% of cases had stent occlusion. Therefore, it can be confidently stated that, according to the results of successful stenting in the medium-term, the biodegradable BVS Absorb stents are not inferior to most drug-eluting stents with one exception that the frequency of complete scaffold occlusions is slightly increased (3.4%).

The study also showed that there is a certain inverse relationship between good mid-term results of Absorb stenting and plaque morphology [14, 16]. So, when stenting coronary arteries with plaques of simple morphology (type A) in the medium-term period, there was not a single unsatisfactory result, while when stenting vessels with type C lesions, the frequency of in-stent stenosis was already 2.3% and another 1.7% of cases had complete occlusion of the stent.

The study also showed that in the mid-term stenting for the morphological and functional state of the implanted BVS, it was important whether the balloon PD of the scaffold was performed immediately after implantation or it was not performed. Thus, in patients who underwent balloon PD after stent implantation, in-stent stenosis was observed only in 1.9% of cases, while in cases where PD was not performed, in-stent stenosis developed in 7.7% of cases, and stent occlusion occurred in another 4.6% of cases. In 1 more case (0.9%), stent malposition was observed. It was installed in a vessel with a type B lesion.

It should also be noted that PD was not performed in this observation. A similar view on the importance of PD for optimal results is expressed by Boeder et al. In their study, stent malposition was significantly more frequently observed in cases where PD of the scaffold was not performed. The authors believe that non-fulfillment of AP is one of the causes of thrombosis at different times after stent implantation [15].

Our study also showed that mid -term results largely depend on the initial diameter of the vessel at the site of stent implantation, namely, the wider the diameter of the vessel, the higher the likelihood of a good result in the future. It is known that the most successful results of implantation of such scaffolds occur in coronary arteries, in which the plaques are located in the proximal or middle segments, and the diameter of the vessels is 2.5 mm or more.

Considering that the study concerned bioresorbable stents, during the control study, special attention was paid to studying the state of the structure and morphology of the BVS Absorb stent. For this purpose, OCT was used, which showed that at this observation period (~6 months) no significant scaffold resorption was observed in any of the scaffolds. Good visualization of the bars of almost all stents without any significant deformation was noted. Based on the data obtained, it can be said that the process of elimination of resorbable stents begins later than a six-month period after implantation, and, according to our data, reaches complete elimination by five years [17].

Meanwhile, the study showed an active process of endothelialization of the stented area. Approximately half of the cases (55.3%) showed complete endothelialization of the stent walls. The remaining stents showed only partial endothelialization.

CONCLUSION

A retrospective study has shown that in the vast majority of cases, BVS Absorb can be implanted without much difficulty if all the manufacturer's recommendations are followed. In particular, this applies to stenosing changes in the proximal and middle sections of the coronary arteries.

Immediately after the implantation of scaffolds, acute stent occlusion was observed in 2 cases (1.7%), which, in our opinion, was the result of failure to perform the post-dilation procedure after implantation of the scaffolds. The mortality at the inpatient stage was 0.85% (1 patient). In 6 months, all patients were alive. None of them had myocardial infarction, 7 patients (6.9%) had angina attacks.

In the vast majority (87.7%), selective coronary angiography revealed a good condition of the stents. In other cases, in-stent stenosis (7.7%) or occlusion (4.6%) was observed. It should be noted that the results obtained are not significantly inferior to those obtained by different authors in the study of conventional drug-eluting stents in similar follow-up periods [13].

The best results of BVS Absorb stenting were obtained in type A lesions of the coronary arteries, the worst ones were in type C lesions. It should be especially noted that 6 months after the implantation of the scaffolds, in no case was any significant resorption of the stents observed. The obtained results allow us to express the opinion that it is necessary to continue the search in this direction. Our study, having entered into conflict with some publications on the same topic, did not reveal any grounds for a negative attitude towards this category of stents.

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