MEDIUM-TERM OUTCOMES AFTER CORRECTION OF LONG CORONARY ARTERY LESIONS WITH BIODEGRADABLE VASCULAR SCAFFOLDS

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Aim. To establish efficacy and safety of endovascular correction of long coronary lesion with biodegradable scaffolds in comparison with everolimus-eluting metallic coronary stents.

Materials and methods. From 2013 to 2018 in Republican Scientific and Practical Centre «Cardiology», Minsk, endovascular correction of long (more than 25 mm) coronary artery lesions was performed on 80 patients. Randomly patients were divided into 2 groups: group 1 (n = 40) – endovascular correction with the biodegradable everolimus-eluting vascular scaffold Absorb BVS, and group 2 (n = 40) – endovascular correction with the everolimus-eluting metallic stent Xience V/Xience Pro.

Results. In 12-month observational period there were no cases of death or myocardial infarction in both groups. One-year primary endpoint (death + myocardial infarction + target lesion failure) was 10% in group 1 (scaffolds BVS Absorb) and 8.75% in group 2 (Xience stents), 4 and 3 cases of target lesion failure accordingly ($p > 0.05$). As secondary endpoints there were 3 cases of target lesion revascularization registered and 4 cases of target vessel revascularization in each group, 5 cases of target vessel failure in group 1 and 4 cases in group 2 ($p > 0.05$). There was 1 case of confirmed and 1 case of probable scaffold thrombosis in group 1 (cumulative rate 5%), no cases of stent thrombosis in group 2 ($p = 0.49$).

Conclusion. Long lesion correction with biodegradable scaffolds shows similar one-year clinical and angiographic results in comparison with everolimus-eluting stents. Combined endpoint risk (all death cases + myocardial infarction + revascularization due to target lesion failure) statistically did not differ in one-year period in both groups.

Relevance

It is well known that cardiovascular diseases occupy a leading position in the structure of morbidity and mortality in developed countries. According to statistical reports, in the Republic of Belarus, 58.5% of deaths in 2019 occurred due to cardiovascular diseases (A. Mrochek, 2020).

Taking into account the increase in the life expectancy of the population of our country over the past 10 years from 68 to 74 years [1], it should be noted that increasing age of patients results in the increased frequency of complex lesions of the coronary arteries, which are characterized as multi-vessel and extended. According to the results of our studies, long lesions are detected in 19.1% of patients after coronary angiography, this being combined with occlusion of the coronary artery in 48.8% of cases and with areas of calcification of varying severity in 26.4% of cases [2].

The effectiveness of x-ray endovascular correction of long critical stenoses/occlusions continues to be the subject of scientific discussion. Thus, the use of bare-metal stents for the correction of long lesions was associated with an increase in the frequency of restenosis [3–4]. The use of first-generation drug-eluting stents also led to increased likelihood of myocardial infarction, stent thrombosis, and long-term patient death, especially in patients with a large length of stenting zone [5]. At the same time, in the medium-term period after successful percutaneous coronary intervention (PCI) in the area of chronic coronary occlusions, the frequency of intra-stent restenosis depended on the type of implant used [6].

The appearance of commercially available biodegradable vascular scaffolds (BVS) [7–8] makes it possible to use them for the correction of long coronary artery lesions. The expediency of this approach may be due to the fact that within 3–5 years after implantation, the implant is completely degraded, which allows not only restoring the normal vasomotor function of the vessel in this area, but also increasing the accessibility of these sections of the coronary arteries for repeated PCI and coronary bypass surgery [9–10]. At the same time, none of the completed large multicenter studies [11–15] were devoted to the effectiveness and safety of the use of BVS for the correction of long coronary artery lesions.

Thus, the above mentioned problem proves challenging, though unsolved, and requires further research in this direction.

Aim of research

To study medium-term results after correction of long coronary artery lesions using biodegradable vascular scaffolds.

Materials and methods

This work was carried out on the Basis of the Republican Scientific and Practical Center "Cardiology" and is a prospective single-center randomized study. From 2013 to 2018, endovascular correction of long coronary artery lesions was performed on 80 patients suffering from coronary heart disease (CHD) and having stable angina of various functional classes or silent myocardial ischemia.

The criteria for inclusion of patients in the study were as follows:

1) The patient's age > 18 years.

2) The presence of angina or silent myocardial ischemia.

3) The presence of a critical lesion of the native coronary artery more than 25 mm long.

4) SYNTAX score < 23 points.

5) The diameter of the native artery in the affected area according to optical coherence tomography and intravascular ultrasound in the range of 2.0–3.8 mm.

6) The patient's consent and willingness to comply with the requirements of the study and subsequent medical prescriptions.

The following criteria were used to exclude patients from the study:

1) Lack of patient consent.

2) The presence of acute coronary syndrome.

3) Absolute indications for coronary bypass surgery.

4) Massive calcification of the coronary artery in the affected area.

5) Restenosis of the artery in the area of previous stenting.

6) Severe renal failure (glomerular filtration rate (GFR) less than 25 ml/min).

7) Life expectancy of less than 36 months.

Diagnostic and therapeutic x-ray endovascular interventions were performed using angiographic devices GE Innova 3100 (GE Healthcare, USA) and Siemens Artiszee (Siemens Healthcare GmbH, Germany). Initially, a coronary angiography was performed, after which the received data were processed on the Advantage Workstation 4.3 angiographic station (GE, USA). The length of the artery lesion, the degree of vascular obstruction, and the diameter of the vessel (proximal, in the affected area, and distal) were analyzed. Additionally, the transstenotic pressure gradient (QFR) was evaluated using the Medis Suite 3.0 computer package (Medis Medical Imaging Systems, the Netherlands).

Subsequent therapeutic x-ray endovascular intervention was performed in accordance with the principles generally accepted in interventional cardiology. It should be noted that the patients included in the study were randomly divided into two groups: the main study group (SG, n = 40) –biodegradable vascular scaffolds were implanted in the area of long lesion according to the original method developed by us [16–17], and the control group (CG, n = 40) – correction of lesions was performed using metal stents with a drug coating. The performed PCI was considered successful in the presence of residual angiographically detectable stenosis of less than 20%, the area of the lumen in the intervention zone of more than 4 mm^2, adequate fit of the implant frame fragments to the vascular wall, and the absence of angiographically detectable complications (thrombosis, D-F dissection, vascular wall perforation, refractory spasm of the treated vessel, no-reflow phenomenon).

After discharge from the hospital, the patients included in the study were transferred to outpatient treatment, during which we performed regular monitoring of them. During the follow-up, the clinical status was evaluated, and the development of cardiovascular outcomes was recorded (the need for hospitalization and emergency revascularization, the appearance of unstable angina, acute cerebrovascular accident, death, myocardial infarction, and other cardiovascular diseases). The regularity of taking prescribed medications was also noted.

12 months after PCI in the area of long lesion, all the above-mentioned patients were readmitted on the basis of planned hospitalization, during which we performed a follow-up angiography, intravascular ultrasound (IVUS) and optical coherence tomography (OCT). In case of the development of urgent cardiac conditions, the patients were hospitalized urgently and diagnostic tests from the above list were performed. During the control examination, the following indicators were evaluated: the development of patency failure of the target lesion and target vessel, cases of thrombosis and restenosis, the need for repeat revascularization of the target lesion and target vessel.

All patients were prescribed medication both during inpatient and outpatient care, in accordance with the protocols and standards of treatment for coronary heart disease adopted in the Republic of Belarus. In the presence of clinical indications, both the dosage and the duration of drug prescription were optimized, in accordance with the nature of the course of CHD and taking into account comorbid pathology.

Statistical analysis of the obtained data was performed using the computer software package STATISTICA (StatSoftInc., USA, version 6.5). For parametrically distributed values, a two-sample Student's test was used to confirm the hypothesis of differences between 2 independent groups; a paired Student's test was performed to study differences between several indicators in dynamics within the same group. If the distribution of values did not correspond to the normal law, the Mann-Whitney test was used to confirm the hypothesis of differences between 2 independent groups.

At the first stage of statistical processing of qualitative features, the studied data were com-

bined into 2×2 conjugacy tables (crosstabulations). The analysis of the obtained tables was carried out taking into account the recommendations of Cochran, according to which a two-tailed Fisher's exact test was performed to refute the null hypothesis.

Quantitative indicators are presented as the arithmetic mean ± standard deviation (M±σ). Nonparametric quantities are represented as the median, upper bound of the first quartile of the sample, and upper bound of the third quartile of the sample (Me (Q1; Q3)). When describing qualitative values, their absolute values are given, as well as percentages (n (%)).

Results and discussion

Table 1 features the demographic and clinical characteristics of the patients included in this study.

Table 1. Characteristics of patients included in the study

Parameter	Study Group (n = 40)	Control Group (n = 40)
Male, n (%)	34 (85)	29 (72.5)
Female, n (%)	6 (15)	11 (27.5)
Age (years), M±σ	56.1±10.1	57.4±7.6
Current smokers, n (%)	8 (20)	6 (15)
Ex-smokers, n (%)	15 (37.5)	17 (42.5)
Arterial hypertension, n (%)	36 (90)	37 (92.5)
BMI, kg/m^2	30.2±4.5	30.9±4.4
Diabetes mellitus, n (%)	5 (12.5)	9 (22.5)
Previous myocardial infarction, n (%)	28 (70)	26 (65)
Previous PCI, n (%)	9 (22.5)	6 (15)
Previous CABG, n (%)	2 (5)	3 (7.5)
LVEF, %	54.8±8.5	53.8±8.1

* BMI: body mass index; CABG: coronary artery bypass grafting; PCI: percutaneous coronary intervention; LVEF: left ventricular ejection fraction

As can be seen from Table 1, patients in both groups were comparable in gender, age, and the number of people who continued to smoke and had previously smoked ($p > 0.05$ in all cases). Analysis of concomitant diseases (incidence of arterial hypertension, diabetes mellitus, and myocardial infarction) showed no significant differences in these indicators ($p > 0.05$ in all cases). Body mass index and baseline left ventricular ejection fraction were comparable in both groups. Despite the fact that patients in the study and control groups had previously undergone PCI or cardiac surgery, there were no statistically significant intergroup differences in these indicators ($p > 0.05$ in all cases).

Thus, the groups of patients included in the study were fairly homogeneous in terms of the main clinical and anamnestic indicators.

Table 2 shows an analysis of the detected long lesions of the coronary bed in patients of the studied groups.

Table 2. Characteristics of coronary artery lesions

Variable		Study Group (n = 40)	Control Group (n = 40)
Lesion localization	LAD, n (%)	28 (70)	22 (55)
	CX, n (%)	5 (12.5)	7 (17.5)
	RCA, n (%)	7 (17.5)	11 (27.5)
SYNTAX score		14.5±5.2	13.7±5.4
Initial lesion diameter stenosis, %		86.8±12.4	91.9±12.9
Quantitative flow ratio (QFR)		0.36±0.29	0.25±0.33
Chronic total occlusions, n (%)		13 (32.5)	24 (60)
Lesion length, QCA, mm		39.6±12.6	36.5±13.0
Lesion calcification	no	34 (85)	33 (82.5)
	moderate	6 (15)	7 (17.5)

It should be noted that the included patients were characterized by a rather complex nature of coronary lesions, as evidenced by the high frequency of chronic occlusive lesions (32.5% in SG versus 60.0% in CG, $p = 0.0243$). At the same time, calcification was not a common change in the affected area: for example, moderate calcification (according to angiographic manifestations) was detected in 15% of SG patients versus 17.5% in CG ($p > 0.05$). The degree of vascular obstruction was almost identical (86.8±12.4% in SG versus 91.9±12.9% in CG, $p > 0.05$), while the tendency to have more extensive lesions was typical for SG patients (39.6±12.6 mm versus 36.5±13.0 mm, $p > 0.05$). The hemodynamic significance of these lesions is indicated by the QFR values of 0.36±0.29 in SG and 0.25±0.33 in CG, which is significantly less than the minimum allowable value of 0.75.

As follows from Table 3, all patients in both groups underwent IVUS approximately in the same proportion (90% vs. 97.5%, $p > 0.05$), the frequency of OCT was 85% in SG and 70% in CG ($p > 0.05$).

As for the number of implanted devices, it was slightly higher in SG patients (2.00±0.70 pieces

Table 3.
PCI characteristics

Variables			Study Group (n = 40)	Control Group (n = 40)
Invasive examinations	Angiography, n (%)		40 (100)	40 (100)
	IVUS, n (%)		36 (90)	39 (97.5)
	OCT, n (%)		34 (85)	28 (70)
Lesion predilatation, n (%)			40 (100)	38 (95)
Postdilatation, n (%)	Postdilatation, total,n (%)		31 (77.5)	17 (42.5)
	The same balloon diameter		13 (32.5)	8 (24.0)
	Bigger balloon	0.25 mm bigger	5 (12.5)	0 (0)
		0.5 mm bigger	12 (30)	7 (20)
		0.75 mm bigger	1 (2.5)	1 (3.0)
		1.5 mm bigger	0 (0)	1 (3.0)
Implanted devices, number			2.00±0.70	1.90±0.75
Stented zone length, mm			44.9±13.5	41.6±15.3
Implantation pressure, atm			16.9±1.8	17.3±2.6
Residual stenosis, %			9.8±4.7	9.2±4.7

IVUS – intravascular ultrasound investigation, OCT – optical coherence tomography.

versus 1.90±0.75 pieces, p > 0.05), which was due to the greater length of the affected area in patients of this group (see table 3). Accordingly, there was a tendency to a longer stenting zone in SG (44.9±13.5 mm vs. 41.6±15.3 mm), but no significant differences were found (p > 0.05).

In the present study, the majority of subjects included in the study underwent postdilatation after stent/BVS implantation (77.5% in SG versus 42.5% in CG, p < 0.05). For this purpose, both balloons of the same diameter as the implant and balloons exceeding the implant diameter were used with the same frequency in SG and CG. Among the latter, the most frequently used balloons were those with a diameter 0.5 mm larger than that of the implant (p > 0.05 for inter-group comparison). It should be noted that our methods of appositioning the implanted products proved to be quite effective, as evidenced by the low rate of residual stenosis verified after the completion of PCI (9.8±4.7% in SG versus 9.2±4.7% in CG, p > 0.05).

Analysis of medium-term results showed that there were no cases of patient death or myocardial infarction during the 12-month period. Table 4 summarizes the main mid-term outcomes recorded after endovascular correction of long coronary artery lesions.

As can be seen from Table 4, during the 12-month follow-up period, we identified 4 cases of target lesion failure in SG patients. The cause of these adverse outcomes in one case was non-occlusive parietal thrombosis of the implant, in another case it was reocclusion in the scaffold, and in two cases intra-stent restenosis in the area of the performed intervention occurred. The total number of major coronary events (death + development of myocardial infarction + development of patency failure of the target lesion) in SG was 10%.

In the control group, the failure of the target lesion at the 12-month control was registered in 3 patients, and the cause of it in 100% of cases was the development of intra-stent restenosis. The total number of major coronary events was 7.5% and did not significantly differ (p > 0.05) from similar indicators in SG.

Analysis of thrombotic outcomes in SG showed that the patient with occlusion in the area of the previously implanted scaffold did not manifest changes in the nature of clinical manifestations (asymptomatic clinical presentation). At the same time, the presence of non-occlusive parietal thrombosis in the BVS zone was associated with the development of progressive angina. Despite the difference in absolute numbers, the difference in the frequency of thrombotic complications between SG and CG was statistically insignificant (p = 0.49).

As for the correction of the restenotic and thrombotic lesions described above, 3 SG patients (75% of the total number of patients with these outcomes) and 3 patients in CG (100% of the total number of patients with these outcomes) successfully underwent repeated PCI. A conservative treatment strategy was chosen for the SG patient with detected non-occlusive parietal thrombosis in the area of previously implanted BVS, which included a revision of the antithrombotic therapy regimen. It should also be noted that 2 patients (one from SG and one from CG) additionally underwent repeated revascularization of the target vessel, the indication for which was the formation of de novo stenoses in previously unstented areas. As for negative outcomes in the form of intra-stent restenosis, in both groups they were successfully corrected by means of repeated PCI.

Thus, in the present study, the development of negative outcomes during the medium-term period after endovascular correction of long coronary artery lesions was observed in a relatively small number of patients and did not statistically differ in the groups of bioresorbed scaffolds and drug-coated metal stents.

It should be noted that our data correlate with the majority of international studies devoted to the effectiveness and safety of BVS in clinical practice [18–24]. Thus, in the ABSORB China Trial, which included 480 patients, one year after PCI, there were no statistically significant differences between the groups of BVS and everolimus-eluting stents, both in terms of achieving the primary endpoint (3.4% vs. 4.2%, p = 0.62) and in the development of thrombosis at the sites of intervention (0.4% and 0%, p = 1.0) [18, 21]. In the comparable ABSORB III Trial (n = 2008), the risk of reaching the primary endpoint 3 years after surgery was 13.4% in the scaffold group and 10.4% in the metal stent group (p = 0.06) [15].

Another independent study (GHOST-EU Registry) [24], which included data on 1,468 patients, showed a relationship between the length of the initial lesion area and the frequency

Table 4.
12-month clinical and angiographic outcomes after x-ray endovascular correction of long coronary artery lesions

Parameter	Study Group (n = 40)	Control Group (n = 40)
Primary endpoints		
Death, n (%)	0 (0)	0 (0)
Myocardial infarction, n (%)	0 (0)	0 (0)
Target lesion failure, n (%)	4 (10)	3 (7.5)
Total, n (%)	4 (10)	3 (7.5)
Secondary endpoints		
Confirmed stent/scaffold thrombosis, n (%)	1 (2.5)	0 (0)
Probable stent/scaffold thrombosis, n (%)	1 (2.5)	0 (0)
Total stent/scaffold thrombosis, n (%)	2 (5)	0 (0)
Target vessel failure, n (%)	5 (12.5)	4 (10)
Target lesion revascularization, n (%)	3 (7.5)	3 (7,5)
Target vessel revascularization, n (%)	4 (10)	4 (10)
Left ventricular ejection fraction, baseline, n (%)	54.8±8.5	53.8±8.1
Left ventricular ejection fraction, 12-month control, n (%)	56.3±8.7	54.8±7.7

of negative events 12 months after implantation of the BVS. In particular, the achievement of the primary endpoint was registered in 4.8% of cases after PCI in the areas of shorter lesions (< 30 mm), in 4.5% – in areas with a length of 30–60 mm, in 14.3% – after implantation in the affected areas with a length exceeding 60 mm (p = 0.001 compared to the previous 2 groups). Similar patterns were obtained for the indicator that characterizes the frequency of thrombosis: 3.0-3.8% after implantation of products in the locations of lesions > 60 mm long, 1.1% – 30–60 mm, 2.1% – < 30 mm, which once again demonstrates the influence of the length of the pathologically altered section of the coronary artery on the long-term results of PCI.

It should be noted that in all the above-mentioned studies, patients did not undergo control imaging (angiography, IVUS, OCT), which may explain a slightly lower frequency of reaching the primary endpoint compared to our work. In the present study, reaching the primary endpoint one year after implantation was primarily detected by angiography, and in the vast majority of cases, there were no significant clinical symptoms. Thus, if we used criteria for evaluating effectiveness and safety that are identical to the studies described above [11–15, 18–24], most of the verified events would simply be missed.

In order to assess the activity of neointimal proliferation in the PCI zone, the minimum size of the vascular lumen was compared in dynamics. The data obtained are shown in Table 5.

Table 5 shows that, despite the above-described trend towards more frequent postdilatation in the SG (see Table 3), the minimum diameter of the vascular lumen immediately after the completion of PCI was significantly higher in CG patients (2.5±0.5 mm vs. 2.2±0.3 mm, p = 0.0005). 12 months after the correction of long coronary artery lesions, there was a significant decrease in this indicator both in SG (from 2.2±0.3 mm to 2.0±0.5 mm, p = 0.0066) and in CG (from 2.5±0.5 mm to 2.3±0.5 mm, p = 0.0098). At the same time, the degree of decrease in the diameter of the vascular lumen, recorded 12 months after PCI, did not significantly differ in the study groups (0.1(0;0.3) mm in SG versus 0.1(0;0.2) in CG, p > 0.05).

Thus, in both groups, 12 months after successful endovascular intervention, there is a slight decrease in the diameter of the vascular lumen, apparently due to the development of fibroproliferative processes in the areas of stent/scaffold implantation. At the same time, the degree of vascular lumen reduction is identical regardless of the type of selected coronary implant (metal stent or polymer BVS).

Table 5.
Minimal vascular lumen diameter after x-ray endovascular treatment of long coronary artery lesions

Parameter	Study Group (n = 40)	Control Group (n = 40)
Minimal vessel lumen diameter after PCI, mm	2.2±0.3**	2.5±0.5
Minimal vessel lumen diameter 12 months after PCI, mm	2.0±0.5**^^	2.3±0.5^^
Late lumen loss (LLL), 12 months after PCI, mm	0.1(0;0.3)	0.1(0;0.2)

Legend: ** – p < 0.001 as compared with control group, ^^ – p < 0.01 inside the group, as compared with the results immediately after PCI.

The data obtained in the course of this study indicate equivalent immediate and medium-term results in patients of both study groups after correction of long coronary artery lesions. However, taking into account the possible progression of the atherosclerotic process in the area of PCI in the long-term period, it is important to provide conditions for repeated operations, including the possibility of re-implantation of the stent/BVS. In this regard, the use of a biodegradable vascular implant opens up wider therapeutic possibilities.

Conclusions

1) In the medium-term period of observation (12 months) frequency of reaching the primary endpoint (death + myocardial infarction+ target lesion failure) was equivalent in both study groups (10% in SG, 7.5% CG, p > 0.05).

2) Despite the difference in absolute numbers of thrombotic events between SG and CG, a statistically significant difference between groups by this indicator was not detected (p = 0.49).

3) The degree of reduction of the vascular lumen diameter registered in the 12 months after PCI, was not significantly different in the studied groups (0.1(0;0.3) mm in the SG versus 0.1(0;0.2) in CG, p > 0,05).

4) Biodegradable vascular scaffolds, with some restrictions, are a good alternative to metallic drug-eluting stents in endovascular correction of long coronary lesions.

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