

**ASSESSMENT OF QUALITY OF LIFE IN PATIENTS WITH BIORESORBABLE VASCULAR SCAFFOLDS ABSORB (BVS) IN COMPARISON WITH MODERN DRUG-ELUTING STENTS (DES)**

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**ABSTRACT**

200 patients with CHD were examined. The study found that in the acute form of the disease, the indicators of quality of life (QOL) responsible for physical health were slightly worse than in chronic ischemic heart disease. In dynamics, an improvement in all grades of the SF-36 scale was noted. Depending on the type of implants are no significant differences in QoL scale was not detected (all  $p > 0.05$ ).

**KEYWORDS:** Acute and chronic forms of CHD, quality of life (QOL), various types of implants (BVS & DES).**INTRODUCTION**

The modern development of interventional technologies, the use of drug-eluting stents or bioresorbable vascular scaffolds, the development of highly effective disaggregants have become prerequisites for expanding the indications for the use of stenting in coronary artery disease. In this regard, it became necessary to compare the results of treatment of different methods with an emphasis on patients own opinion.<sup>[1]</sup>

Along with traditional methods of assessing the results of treatment, such as the clinical condition of patients, the presence of large and small cardiovascular complications, survival rates, instrumental assessment of the state of myocardium and coronary circulation, in recent years there has been another criterion for assessing the effectiveness of treatment-the quality of life (QOL), which is an integral indicator of overall health, but from the point of view of the patient.<sup>[2-4]</sup> And therefore can give additional selection criteria for a particular method of treatment. In this regard, the study of indicators of QOL in patients subjected to stenting is an extremely important and relevant direction of modern interventional cardiology.

The study of patients' QOL after intervention is an important component in assessing the effectiveness of surgical treatment and should include not only the study of biomedical parameters, but also the degree of activity of the patient and his ability to return to daily life after surgery.<sup>[5]</sup>

In connection with the above, the aim of our study was to assess the quality of life in patients with BVS in comparison with DES in hospital and long-term follow-up.

**Material and methods of research**

The study included 200 patients with coronary artery disease. All patients gave informed consent to participate in this study. All patients received recommendations for the correction of lifestyle, drug therapy according to the current standards for patients with coronary artery disease who have undergone PCI. All 200 patients underwent total endovascular treatment of intravascular stenting, of whom 133 (66,5%) patients had single-vascular lesions and 67 (33.5 percent) – bicon vascular lesions of the coronary bed.

**The criteria for inclusion in this study were**

- The diagnosis of coronary artery disease established by the results of clinical and instrumental examination, the signed informed consent.
- Patients with documented pain-free ischemia, stable and unstable angina, acute myocardial infarction and a history of myocardial infarction.
- Primary nature of the narrowing of the coronary arteries (**de novo native coronary artery**)
  - Presence of coronary artery lesion, allowing to perform stent implantation.
  - Hemodynamically significant ( $\geq 60\%$  in diameter) lesion of the coronary artery.
  - The diameter of the affected area of the vessel is 2,25 – 4 mm.

**The exclusion criteria were**

- Patients with a history of previous PCI with stenting or coronary artery bypass grafting (CABG).
- With severe concomitant pathology of the cardiovascular system (aortic aneurysm; valve pathology requiring surgical correction; severe left ventricular systolic dysfunction (LVF < 35%); decompensated heart failure).
- Patients are not tolerant of anticoagulants/disaggregants.
- Persons with the presence of bifurcation lesions, coronary stem lesion.
- \*Cardiogenic shock.
- Patients at medium and high risk for PCI on the SYNTAX score.

In the first 24-48 hours of hospitalization, control studies were conducted, including general clinical examination, ECG in 12 conventional leads, echocardiography, clinical and biochemical blood tests (including tests for syphilis, HIV and hepatitis), coagulation, analysis of platelet aggregation. In the presence of arrhythmia patients was conducted daily monitoring of ECG (DECG).

Prior to coronary angiography (CAG), premedication with parenteral administration of sedative and antihistamines was performed. Re-stages the research was conducted in 3, 6, 12 and 24 months after the procedure of coronary angiography. Double antiplatelet therapy was administered to all patients at least 48 hours before the intervention: clopidogrel (plavix) at a daily dose of 75 mg (1 tablet), as well as aspirin at a daily dose of 150-325 mg. During the intervention, ECG and blood pressure were continuously monitored. Under local anesthesia (2.0 ml of 2% lidocaine solution), puncturing of the right/left radial/femoral artery was performed using the method of S. Seldinger with the installation of 5-7F. In the future, after the stenting procedure, aspirin was prescribed for continuous administration at a dose of 100 mg / day. Clopidogrel in a dose of 75 mg / day was prescribed for a period of 12 months. Under the disturbance regime of the receiving disaggregants was meant stopping early, recommended at discharge.

**Evaluation of the results of endovascular interventions**

The adequacy of endovascular intervention at the hospital and mid-remote stages was determined by angiographic and clinical criteria.

**a) Hospital-stage angiographic success.**

Satisfactory angioplasty-residual stenosis less than 20% after stent implantation, blood flow through dilated vessel not less than TIMI-III degree, no signs of dissection.

Unsatisfactory angioplasty - residual stenosis of more than 20% after stent implantation, blood flow through the dilated vessel TIMI-II and to a lesser extent,

development of artery dissections, any other disorders in the stented artery. Intervention was also considered unsuccessful if angiographic success was not achieved and complications were present.

**b) Clinical success in the hospital stage.**

Clinically effective angioplasty is the complete disappearance of angina (or reduction of at least two functional classes) and objective signs of myocardial ischemia, as well as the absence of acute cerebrovascular accident and myocardial infarction in the hospital period.

Clinically ineffective angioplasty in the absence of the above criteria.

In the study, all patients went through calculation of the SYNTAX-SCORE using on-line calculator on the website <http://www.syntaxscore.com>. The assessment of quality of life (QOL) was performed using the SF-36 questionnaire on the following scales:

1. Physical functioning (PF) – a scale that assesses physical activity, including self-care, walking, climbing stairs, carrying heavy loads, as well as performing significant physical activities.
2. Physical role functioning (RP) – a scale that shows the role of physical problems in limiting life.
3. Pain intensity - Body Pain (BP) - assesses the intensity of the pain syndrome and its effect on the ability to engage in normal activities.
4. General health (GH) - General Health, evaluates the condition at the moment, the prospects of treatment and resistance to disease.
5. Vitality scale or vital activity (VT) - means evaluation of the patient's feeling of full strength and energy.
6. Scale of social functioning (SF) - assesses satisfaction with the level of social activity (communication, spending time with friends, family, neighbors, in the team) and reflects the degree to which the physical or emotional state of the Respondent or patient limits them.
7. Emotional role functioning (RE) - involves assessing the extent to which the emotional state interferes with the performance of work or other normal daily activities.
8. Mental health (MH) - characterizes the mood, the presence of depression, anxiety, assesses the overall rate of positive emotions.

For all scales, with no restrictions or health problems, the maximum value should be 100 points. The higher the score on each scale, the better the QOL on this parameter.

**Statistical analysis of the results**

Statistical processing of the results was carried out on a personal computer Pentium-IV using the software package "STATISTICA 6". The arithmetic mean (M) and standard deviation (SD) were calculated. In order to avoid statistical discrepancies, the analysis is

accompanied by a proof of normality of the distribution of clinical signs. The student's *t* – test was used to compare arithmetic means of two groups (control and experimental). To assess the presence of links between the indicators, a correlation analysis was carried out with the calculation of the Pearson correlation coefficient. The  $\chi^2$  criterion was used to analyze the significance of differences between qualitative characteristics. In cases where the number of data in the compared groups was less than 30 and at least one group had less than 5, the results were verified by Fisher's exact method.

All values are presented as arithmetic mean  $\pm$  standard deviation ( $M \pm SD$ ). Differences were considered significant at  $p < 0,05$ .

## RESEARCH RESULTS

During the study 200 patients with ischemic heart disease were examined, of which 169 (84.5%) were men and 31 (15.5%) were women. Clinical and demographic characteristics of patients are presented in the table 1. The mean age of patients was  $54.43 \pm 10.01$  years. The largest number of persons (35.5 per cent) were between 51 and 60 years of age.

Arterial hypertension (AH) occurred in 82.5%, obesity – in 44.0% and type 2 diabetes – in 26.0% of the subjects. The myocardial infarction in a history (HMI) recorded in 74 (37.0%) patients, 22 of whom had HMI less than 1 month ago. A more detailed nosological structure of the patients included in the study is presented in the table 1.

**Table 1: General clinical and demographic characteristics of patients.**

Sign	Absolute value	%
Age, years	54,57±10,10	
≤ 40 years	16	8,0
41-50 years	49	24,5
51-60 years	71	35,5
61-70 years	57	28,5
≥ 71 years	7	3,5
Men	169	84,5
Women	31	15,5
Angina of FC-II	13	6,5
Angina of FC-III-IV	77	38,5
ACS non ST-elevation and non STEMI	48	24,0
AMI with Q	62	31,0
AH	165	82,5
Diabetes mellitus type 2	52	26,0
Smoking	33	16,5
Obesity	88	44,0
HMI	52	26,0
AMI one month old	22	11,0
TOTAL PATIENTS	200	100%

*Notes: n and N – number of patients; FC-functional class; ACSnonSTEMI-acute coronary syndrome without ST-segment elevation; AMI-acute myocardial infarction without q wave; AH-arterial hypertension; MI-myocardial infarction; HMI - The myocardial infarction in a history*

Depending on the form of coronary artery disease, 2 groups of patients were identified: 1 group – 90 patients with chronic coronary artery disease (ChCAD), presented as stable angina (SA), mainly III FC; 2G. - 110 patients with acute coronary artery disease (ACAD), presented in the form of unstable progressive angina, acute myocardial infarction with or without ST-segment elevation.

Comparative analysis of clinical, functional and laboratory data of patients is presented in table.2, from which it can be seen that persons with ACAD were characterized by young age, male prevalence, a relatively large number of patients with concomitant carbohydrate metabolism disorders, while the lipid spectrum of the blood were practically comparable with similar data of

the group of patients with ChCAD. In addition, despite the smaller number of patients with a history of MI, the 2nd group of respondents was characterized by low systolic function of the heart muscle.

Table 2: Clinical characteristics of patients depending on the form of CAD.

Sign	1group, patients with ChCAD (n=90)	2 group, patients with ACAD (n=110)	p	x2
Age, years	57,14±8,94	52,45±10,55	<b>0,000</b>	
Number of men	72 (80,0%)	97 (88,2%)	0,163	1,944
Number of women	18 (20,0%)	13 (11,8%)		
Height, sm	169,76±7,49	171,00±7,01	0,229	
Weight, kg	86,95±13,87	86,12±13,17	0,665	
BMI, kg / m2	30,16±4,35	29,35±4,11	0,178	
Diabetes mellitus type 2	22 (24,4%)	30 (27,3%)	0,771	0,085
MI in anamnesis	37 (41,1%)	37 (33,6%)	0,346	0,887
Average number of RF	5,05±1,24	4,95±1,55	0,621	
Moderate score on the Syntax	9,29±4,75	9,85±5,02	0,422	
Hb, g/l	127,05±14,03	131,67±15,19	<b>0,028</b>	
ESR, mm	12,58±9,18	14,42±11,44	0,218	
TCh, mg/dl	186,69±46,24	184,90±58,41	0,813	
TG, mg/dl	216,24±153,07	208,88±133,11	0,717	
HDL, mg/dl	35,81±7,95	35,35±7,62	0,677	
VLDL, mg/dl	43,24±30,64	41,77±26,71	0,717	
LDL, мг/дл	108,60±38,62	107,51±42,64	0,851	
EDV, ml	143,36±32,62	150,17±36,73	0,172	
ESV, ml	56,89±22,51	67,12±27,07	<b>0,005</b>	
LVEF %	61,19±7,82	56,42±9,49	<b>0,000</b>	
IVS, mm	10,92±2,37	10,43±1,96	0,111	
LVPW, mm	10,48±1,57	10,15±1,54	0,137	

Notes: ACAD and ChCAD – acute and chronic forms of CAD; BMI – body mass index; diabetes mellitus; MI – undergone myocardial infarction; FR – risk factors; HB – blood hemoglobin; ESR – erythrocyte sedimentation rate; TCh – total cholesterol; TG – triglycerides; HDL – high density lipoproteins; VLDL – very low density lipoproteins; LDL – low density lipoproteins; LDL – lipoproteins density; EDV and ESV – end-diastolic volume and end-systolic volume of the left ventricle; LVEF – left ventricular ejection fraction; IVS and LVPW – thickness of the interventricular septum and posterior wall of the left ventricle.

The angiographic characteristics of the compared groups of patients revealed that in ACAD, as well as in ChCAD, in most cases, the pool of the anterior descending (ADA) artery (85.6% and 82.7% of cases) is affected, but the degree of stenosis highly significantly prevailed in patients of the 2nd group. The second place in the incidence of atherosclerotic lesions belonged to the pool of the right coronary artery (RCA) (22.2% and 30.0% of patients, respectively, in the 1st and 2nd groups).

The degree of stenotic constrictions in the RCA basin in group 1 patients exceeded the similar index in group 2 patients, but the difference did not reach the level of reliability ( $p>0.05$ ). The occurrence of atherosclerotic lesions in the basins of the circumflex artery (Cx), obtuse marginal branch (OM) and the left ventricular branch (LVB) was practically the same, regardless of the form of coronary artery disease (table.3).

Table 3: X-ray morphological characteristics of patients with various forms of ischemic heart disease.

CAG characteristics		1gr., ChCAD (n=90)	2 gr., ACAD (n=110)	p	x2
<b>ADA</b>	% stenosis	82,63±13,04	90,13±8,45	<b>0,000</b>	
	Number of stenotic segments	80	104		
	Number of patients	77 (85,6%)	91 (82,7%)	0,670	0,181
<b>ACx</b>	Diametr arteries	3,41±0,36	3,46±0,34	0,357	
	% stenosis	71,95±20,56	86,50±10,28	<b>0,021</b>	
	Number of stenotic segments	18	15		
<b>RCA</b>	Number of patients	15 (16,7%)	15 (13,6%)	0,691	0,158
	Diametr arteries	3,23±0,48	3,31±0,56	0,678	
	% stenosis	83,84±15,89	79,12±16,42	0,309	
<b>LVB</b>	Number of stenotic segments	25	39		
	Number of patients	20 (22,2%)	33 (30,0%)	0,281	1,164
	Diametr arteries	3,41±0,53	3,40±0,61	0,952	

Notes: ChCAD – chronic coronary artery disease; ACAD – acute form of coronary heart disease; p/3, m/3 and d/3 – proximal, middle and distal third; LAD – left anterior descending artery; Cx – circumflex artery; OM – obtuse marginal branch; IA – intermediate artery; RCA – right coronary artery; PDA – posterior descending artery; LVB – left ventricular branch

Assessment of quality of life (QOL) showed that at the initial stage, patients had significant limitations not only on the physical component of health (PF, RP, BP and GH), but also psychological (VT, SF, RF and MH). At the same time, the median of all indicators, except for is, was below 60 points. On the contrary, the average scores on the BP was above 80 (average score for IS=82,73±14,05). (Fig.1).

After 7-10 days after the PCI, the average values of the components of the QOL questionnaire improved slightly. Namely, the level of PF increased by 6.1 points; RP – by 5.9 points; GH – by 18.0 points; VT – by 6.3 points and

SF – by 0.8 points (all  $p > 0.05$ ). The indicator of IS decreased by 50.5 points ( $p = 0.000$ ). After 6 months indicators of QOL also revealed positive changes in general in all subjects, but drew attention to the tendency to stabilize the emotional and social status of patients. Dynamics of QOL in 12 months after stenting, patients established a statistically significant recovery not only of the physical component of the QOL, but also of the psychological component, which persisted after 24 months observations, with the level of is, practically came to naught, in comparison with the original data (Fig.1).

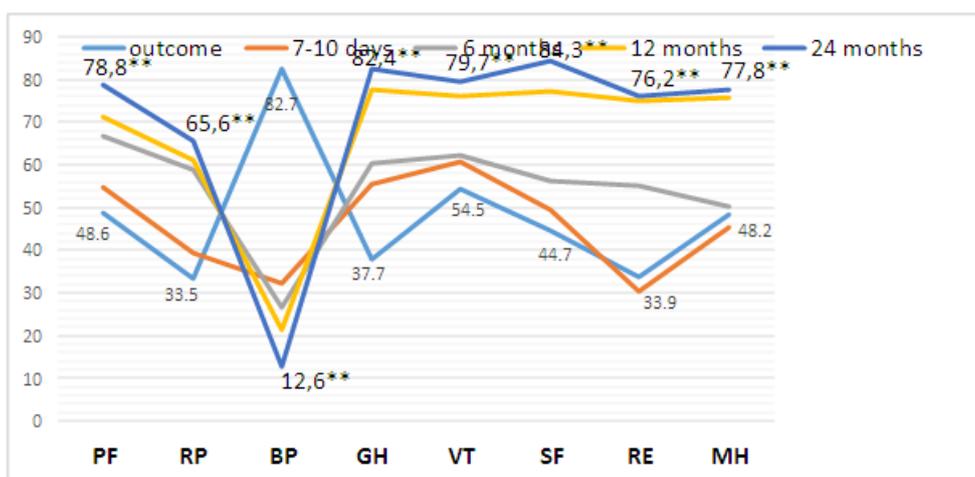


Figure 1: Dynamics of quality of life indicators according to SF-36 questionnaire.

Notes: PF - physical functioning; RP — Physical Role Functioning; BP –is the intensity of the pain; GH - general health; VT - life activity; SF - social functioning; RE - emotional and role functioning and MH - mental health; \*\* - the significance of differences when compared with the original data at  $p < 0,001$ .

Thus, in general, in all patients, after the PCI there was an improvement in the indicators of QOL. But a more detailed analysis of some of them revealed the following (Fig.2). The pain intensity dropped sharply in the first

week after PCI, general health recovered gradually, but the mental (mental) health, as seen in Fig.2, recovered a "step-like". I. e. in the first six months, the mental component of health has not changed, probably, it was due to the fact that patients had not quite a positive attitude, many of them had a feeling of inferiority or disability on the background of intervention. However, as the general state of health improved, the mood changed and recovery of the mental health component was noted.

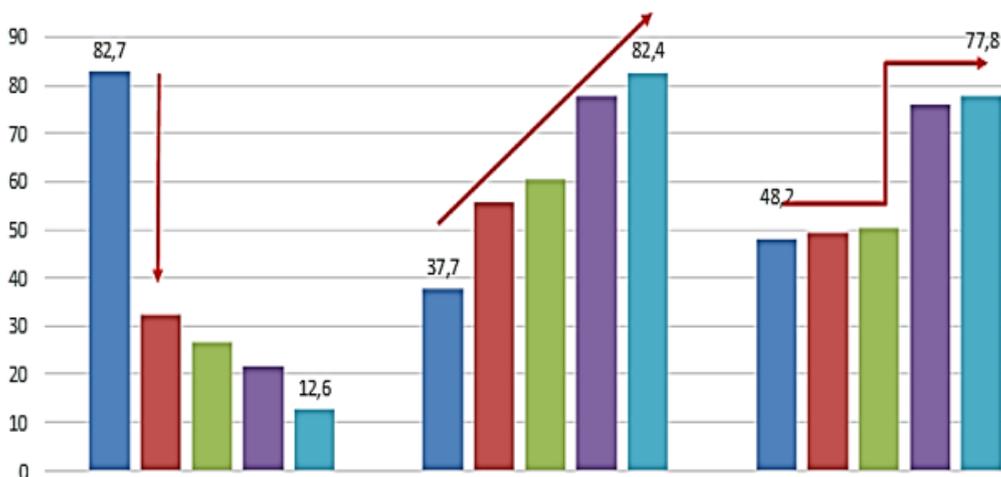


Figure 2: Some selected indicators of quality of life in the dynamics.

Explanation of the figure: The first column - BP; second column - GH; the third column - MH. The first bars are the original values; second bars - values in 7-10 days; third columns - values after 6 months; fourth bars - values after 12 months. and the fifth bars - values after 24 months.

A more detailed analysis depending on the form of ischemic heart disease revealed that at the initial stage in the ACAD components of the QOL were relatively worse than in the ChCAD, while the indicators of the physical component were particularly affected, which, in our opinion, was due to the sudden occurrence of cardialgia and a sharp restriction of physical activity. However, the revealed differences did not reach the level of reliability. Namely, when ACAD level PF average was  $44.9 \pm 8.6$  score; BP= $84.3 \pm 12.4$  points and GH= $35.6 \pm 11.2$  points. Similar indices in ChCAD were  $50.2 \pm 10.4$ ;  $81.6 \pm 10.9$  and  $38.8 \pm 11.5$  points (all  $p < 0.05$ ). Assessment of indicators in the dynamics also found that the components of QOL recovered somewhat faster in the ACAD, but the revealed trend was not statistically significant (all  $p < 0.05$ ).

Analysis of the dynamics of QOL depending on the type of implants did not reveal any significant differences, all  $p > 0.05$ . This, in turn, testified to the fact that QOL significantly improves after intervention with stenting regardless of the type of implants installed and in this aspect BVS were comparable with DES stents.

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## DISCUSSION

Currently, the effectiveness of minimally invasive interventions as methods of treatment of IHD is evaluated not only by survival and life expectancy criteria, but also by special indicators of QOL.<sup>[6,7]</sup> QOL becomes an independent criterion for evaluating the effectiveness of treatment, complementing the results of objective clinical and economic data.<sup>[8]</sup> K<sub>j</sub>, as defined by who, is a characteristic of physical, psychological, emotional and social functioning based on its subjective perception (1996). QOL is determined, first of all, by the patient's assessment of the degree of satisfaction with various or expected changes due to the disease and its consequences, as well as related to the process of medical supervision and treatment.<sup>[9]</sup>

The results described in the literature on the influence of interventions on the condition of QOL in patients with coronary artery disease are very versatile. Thus, in Poland, the influence of CABG and optimal drug therapy (ODT) on QOL in 107 patients with coronary artery

disease with multivessel lesions was compared. The study concluded that, according to the SF-36 questionnaire, patients at high risk for CABG had a higher physical, mental, and viability than patients receiving only ODT. But this provision was recognized in the short-term observation after ODT and CABG, however, in the long term this provision did not require clarification.<sup>[10]</sup>

The publication from Austria presents the results of a prospective multicenter study of QOL in 432 patients with coronary artery disease. He made PCI and CABG. Analysis of the dynamics of QOL was carried out in 1 and 3 months. It was found that the frequency of angina attacks decreased within 1 month, regardless of the method of treatment. However, the positive dynamics of QOL after PCI and CABG was observed only after 1 and 3 months, respectively. At a later date, this improvement was not so obvious. In the end, the authors concluded that QOL largely depends not on the method of revascularization, but on the patient's psycho-emotional state.<sup>[11]</sup>

There is another point of view. Thus, QOL was studied in 2287 patients with stable ischemic heart disease from the USA.<sup>[12]</sup> Positive dynamics of QOL parameters in patients after PCI lasted for 24 months. However, after 3 years the differences between PCI and DMT could not be identified, and even with longer periods of observation the results of the effectiveness of PCI and ODT were comparable.<sup>[13]</sup> Thus, despite the seemingly proven benefits of coronary interventions in the short term, their impact on QOL during long-term follow-up was controversial. So in Brazil.<sup>[14]</sup> was conducted a study of QOL in 480 patients with coronary artery disease; 3 groups were formed: 1G. - 161 patients who underwent surgical revascularization; 2G. - 166 examined, which performed PCI and 3G. - 153 patients who received only ODT. The follow-up period was 4 years. The study found that in 1G. mental and physical condition improved in 72.7% and 82.6% of cases, respectively; in 2G. - mental and physical component of QOL increased in 66.9% and 77.1% of cases and in 3G. - improvement of mental and physical well-being was observed in 64.1% and 70.1% of patients, respectively. The authors conclude that with 4-year follow-up period, patients who underwent surgical revascularization, compared to other methods of treatment of CHD, have higher QOL.<sup>[14]</sup> In our study, the mental and physical components of QOL after six months were 53.9% and 61.9%, after 12 months. - 76.1% and 70.1% and after 24 months. - 79.4% and 75.6%, respectively.

In some publications, a different view is expressed. The authors from Slovakia admit that, of course, CABG and PTCA improve QOL. However, some patients note its decrease after interventions. It is concluded that, in many ways, QL patients are associated with a change in their psychosocial status in the postoperative period.<sup>[15]</sup> However, Denmark and Australia conducted a

prospective study of QOL after CABG and PCI.<sup>[16]</sup> The survey was conducted at the beginning of treatment and after 6 months. It was found that most of the surveyed noted a significant improvement in their QOL, but 27% of patients had a decrease in QOL compared to the original. In the last decade, drug-coated stents have been widely used in PCI.<sup>[17-19]</sup> The authors from the Netherlands give the results of comparing QL with different types of implants.<sup>[20]</sup> During the study, it was found that, in general, a decrease in the frequency of ischemic heart attacks and improvement of QOL were observed regardless of the type of device installed. Though, scientists from the USA Express a different point of view.<sup>[21]</sup> They note that after 6 and 12 months, the proportion of patients without cardiac events after CABG is higher than after PCI using paclitaxel-covered stents. This substance is completely absorbed within 8 weeks. Due to the natural endothelialization of the stent reduces the likelihood of coronary thrombosis. In the end, this allows you to limit the period of DATES to 6 months. In another article, the authors emphasize,<sup>[22]</sup> that the use of drug-coated stents makes it possible to significantly reduce the risk of restenosis.

Thus, it can be clearly argued that in General, minimally invasive interventions can improve the long-term results of interventional treatment of patients with coronary artery disease. However, the study of QOL in these patients require additional study. At the same time, it is necessary to evaluate its individual parameters. A more detailed study of QOL and the creation of clinically relevant standards will help doctors to determine the most appropriate tactics for the treatment of patients with coronary artery disease on an individual basis.

## SUMMARY

1. Assessment of QOL showed that at the initial stage patients had significant limitations not only on the physical component of health, but also psychological. In the acute form of the disease, the components of the QOL responsible for physical health were slightly worse than in chronic coronary artery disease, which was probably due to the sudden onset of cardialgia and a sharp restriction of physical activity.
2. Assessment of the dynamics of QOL found improvement of all gradations of the scale SF-36, with the intensity of pain decreased sharply in the first week after PCI, overall health was restored gradually, and mental (mental) health was restored "stepwise".
3. Depending on the type of implants installed, no significant differences in the QOL scale were found (all  $p > 0.05$ ). This showed that the quality of life is significantly improved after interventions with stenting, regardless of the type of implants installed.

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