



LIFE QUALITY ASSESSMENT OF PATIENTS WITH STABLE CORONARY ARTERY DISEASE AFTER MYOCARDIAL REVASCULARIZATION

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The aim of this study is to assess the life quality of patients with stable coronary artery disease after angioplasty and stenting of coronary arteries at the post-hospital stage.

Materials and methods. Methods of the sociological analysis (questionnaire surveys) and methods of mathematical statistics (descriptive statistics, time series method, factor and variance analyses) were used at different stages of the prospective observational study. The research materials were as follows: 1458 electronic patient records with a stable coronary heart disease (SCHD) after angioplasty and stenting of coronary arteries (ASCA); 620 questionnaires filled in by patients before the surgery, 1, 6, 12 months after discharge. The statistical analysis was performed using the IBM SPSS Statistics software.

Results. The results of a comprehensive survey make it possible for us to assert that during the studied period, stable good healths of cardiac surgery patients with ASCA were maintained. Within the framework of the EQ-5D-5L questionnaire, it was revealed that more than 50% of patients have no physiological problems. The results of the SAQ analysis demonstrate that 58% of the patients feel better, and more than 34% of the patients do not have shortness of breath 1 year after the surgery. A statistically significant improvement in their healths was established according to a visual analogue scale relatively to the annual observation mark (62.82 ± 20.95), which corresponds to the high results assessment of the medical technology use. At the same time, 53% of the patients notify that the treatment results meet their own expectations.

Conclusion. The proposed calculation of the integrated index of patients' treatment efficiency demonstrated by the patients with stable coronary heart disease after angioplasty and stenting of the coronary arteries is based on the results of the factor analysis. This calculation can be used to assess the efficiency of pharmacotherapy in the framework of a value-oriented approach to the treatment of a number of other pathologies.

Keywords: life quality assessment; stable coronary heart disease; angioplasty and stenting of coronary arteries

Abbreviations: IHD – ischemic heart disease; SCHD – stable coronary heart disease; ASCA – angioplasty with and stenting of coronary arteries.

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ОЦЕНКА КАЧЕСТВА ЖИЗНИ ПАЦИЕНТОВ СО СТАБИЛЬНОЙ ИШЕМИЧЕСКОЙ БОЛЕЗНЬЮ СЕРДЦА ПОСЛЕ РЕВАСКУЛЯРИЗАЦИИ МИОКАРДА

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Цель. Оценка качества жизни пациентов со стабильной ишемической болезнью сердца после ангиопластики со стентированием коронарных артерий на постгоспитальном этапе.

Материалы и методы. На разных этапах проспективного обсервационного исследования использовались методы социологического анализа (анкетирование) и методы математической статистики (описательная статистика, метод динамических рядов, факторный и дисперсионный анализ). Материалами исследования служили: 165 электронных историй болезней пациентов со стабильной ишемической болезнью сердца после ангиопластики со стентированием коронарных артерий, а также 620 анкет, заполненных больными до операции, через 1, 6 и 12 месяцев после выписки. Статистическая обработка данных проводилась с использованием программного обеспечения IBM SPSS Statistics.

Результаты. Результаты комплексного опросника позволяют утверждать о сохранении стабильно хорошего самочувствия кардиохирургических пациентов после ангиопластики со стентированием коронарных артерий на протяжении исследуемого промежутка времени. В рамках опросника EQ-5D-5L выявлено, что более 50% пациентов не имеют физиологических проблем. Результаты анализа SAQ демонстрируют, что 58% пациентов отмечают улучшение самочувствия, а также более 34% больных не имеют одышки через 1 год после операции. Установлено статистически достоверное улучшение состояния здоровья по визуально-аналоговой шкале годовой отметки наблюдения ($62,82 \pm 20,95$), что соответствует высокой оценке результатов применения медицинской технологии. При этом 53% больных отмечают, что результаты лечения соответствуют личным ожиданиям.

Заключение. Предложенный расчет интегрированного индекса эффективности лечения пациента на примере больных со стабильной ишемической болезнью сердца после ангиопластики со стентированием коронарных артерий, базирующийся на результатах факторного анализа, может быть использован для оценки эффективности фармакотерапии в рамках ценностно-ориентированного подхода к лечению ряда других патологий.

Ключевые слова: оценка качества жизни; стабильная ишемическая болезнь сердца; ангиопластика со стентированием коронарных артерий

Сокращения: ИБС – ишемическая болезнь сердца; СИБС – стабильная ишемическая болезнь сердца; АСКА – ангиопластика со стентированием коронарных артерий.

INTRODUCTION

Despite the impressive progress achieved over the past decades in the prevention and treatment of cardiovascular diseases in general, coronary artery disease in particular, pathology still occupies a leading position in the structure of morbidity and mortality in the population of developed countries. According to the World

Health Organization data, coronary artery disease covers up to 15% of the total mortality structure worldwide [1].

In the Russian Federation, in 2018, the cause of the patients' primary disability was the pathology of the circulatory system in 30% of cases. At the same time, the mortality indicator due to coronary heart disease reaches 301.6 per 100 thousand population, which is 24% of

the total mortality. The losses of the Russian economy from the consequences of cardiovascular diseases were 3.2% of the gross domestic product. It determines the relevance of the search for effective and economical treatment strategies that correspond to the modern model of organizing medical care according to the principle of the 4P Medicine [2–4]. Thus, the implementation of the pilot projects aimed at improving the quality and life expectancy of the population in the rational use conditions of health care resources is the basis of the “Strategy for drug provision of the population of the Russian Federation for the period up to 2025” [5].

Currently, the combination of rational pharmacotherapy with myocardial revascularization is recognized as the most promising treatment of severe, rapidly progressive and drug-resistant coronary artery disease [6, 7]. It is important to emphasize that in this case the potential improvement of the life quality and prognosis of patients takes place in the post-surgery period.

In this regard, prospective studies of the outcomes and life quality of cardiac surgery patients at the stage of rehabilitation are of scientific and practical importance [8, 9].

THE AIM of this study is to assess the life quality of patients with stable coronary artery disease after angioplasty and stenting of coronary arteries at the post-hospital stage.

MATERIALS AND METHODS

Inclusion criteria

The patients aged 18 – 90; the patients who have ICD-10 diagnosis codes: I20.8, I25.0, I25.1, I25.2, I25.6, I25.8, I25.9; the patients who had undergone a planned myocardial revascularization surgery with the use of the ASCA method.

Exclusion criteria

The patients under 18 years of age, the patients who have all other ICD-10 diagnosis codes in the section “Ischemic heart disease” (codes I.20-I.25), with the exception of those mentioned in the inclusion criteria; the patients who underwent emergency ASCA surgery.

Design

An observational prospective study on the assessment of the outcomes of treatment of patients with stable coronary heart disease (SCHD) after ASCA, was carried out at the Federal State Budgetary Institution “V.A. Almazov National Medical Research Center” of the Ministry of Health of the Russian Federation. The study was conducted in accordance with the provisions of the 1975 Declaration of Helsinki (revised in 2000), as well as with the standards of the local ethics committee. All admitted patients were asked to read the information for the patient and sign an informed consent in duplicate. After signing the informed consent, the patients filled out a questionnaire without a doctor’s or third parties’

participation. After the discharge from the hospital, the questionnaires were sent to the patients by e-mail (if the patient indicated it) or the information was collected by phone. Additional methods of examination or the use of medication and non-medication methods of treatment, including the correction of the ongoing pharmacotherapy, had not been provided. After performing ASCA, the patients were discharged from the hospital on time and with the recommendations determined by the attending physician. If necessary, the patients were sent to medical organizations at their place of residence. The questionnaires were filled out by patients upon admission to a planned ASCA, as well as 1, 6 and 12 months after the discharge from the hospital.

For the most correct conduct of the study, a comprehensive questionnaire was developed. It includes the Russian-language validated versions of international questionnaires and consists of 6 blocks:

1. General questions necessary to form a patient’s profile;
2. Questions about the medication received, the doses and frequency of the drugs administration;
3. Questions characterizing the general self-assessment of the patients’ state of health at the moment, in comparison with their peers, as well as satisfaction with the operation;
4. Dyspnea scale of the Medical Research Council (to determine the degree of dyspnea);
5. Non-specific questionnaire of the life quality EQ-5D-5L with a visual analogue scale – VAS (to assess the health status);
6. Seattle Angina Questionnaire (SAQ), a specific questionnaire for patients with stable angina that has a sufficient reliability, validity and sensitivity in relation to the clinical symptoms of coronary artery disease [10–12].

For a polyhedral value-oriented results assessment of the studied medical technology, the patients were also asked to determine the importance degree of each life quality indicator included in the comprehensive questionnaire [13].

Statistical processing of research results

Statistical data processing was carried out using the IBM SPSS Statistics package. Descriptive statistical indicators were calculated on the basis of the data obtained. For continuous values. The mean value, the standard deviation, and the median were calculated for continuous values. The frequency of trait occurrence was calculated for categorical values. The one-sample Kolmogorov-Smirnov test was used to check the normal / abnormal distribution. In the comparative analysis, to test the hypothesis about the difference between two dependent samples, the Wilcoxon test was used, and the Mann-Whitney test was used for independent samples. The selection of generalized factors in the frame-

work of a two-stage factor analysis was carried out using the method of principal components and the method of rotation – varimax with Kaiser normalization. To assess the applicability of the factor analysis for the studied variables, the Kaiser-Mayer-Olkin (KMO) coefficient was used as a measure of the sample adequacy and the Bartlett coefficient, which determines the quality of the analyzed correlation matrix. To substantiate the homogeneity of the sample in the framework of the analysis of variance, the Livigne test and the R-squared value were used. The differences were considered significant at $p < 0.05$.

The data set was based on 165 electronic medical records of the patients with stable angina. The observational study included 165 patients (11.3% of the total number of patients with stable angina pectoris who had undergone the ASCA operation from 01.01.2017 to 31.12.2017). All patients signed informed consent to participate in the study. Since fewer than 1% of the patients use e-mail, oral telephone interviews had been the primary means of obtaining the primary data.

RESULTS

It has been established that in the study group, the share of men is 71.50%, of women – it is 28.50%. The age of the patients ranged from 36 to 89 years, the average age was 66.25 ± 9.52 years. The patient baseline characteristics are presented in Table 1.

Painless / newly diagnosed angina pectoris was detected in 26.67% of patients. Functional class (FC) 1 angina was registered in 0.61% of people, FC 2 angina – in 47.88% of patients, FC 3 angina – in 24.85% of patients. At the same time, 67.88% of patients had a history of myocardial infarction, 7.27% of patients had previously undergone coronary artery bypass grafting. The average period from myocardial revascularization to ASCA is 10.67 ± 5.40 years. The main concomitant cardiovascular and cerebrovascular diseases are presented in Table 2.

The questionnaire survey results of the patients on the general health status self-assessment and the assessment of health status in comparison with other people of the same age are presented in Table 3.

It has been established that the significant ($p < 0.05$) improvement in health was observed 1, 6, 12 months after the discharge from the hospital compared with the initial state of the patients. At all other times, the self-assessment of their health state did not change.

The analysis of the questionnaire results of a 100-point scale for assessing the patients' healths makes it possible to assert a significant increase in the indicator of the patients' life quality in comparison with the same indicator at the initial observation point (Table 4).

The responses of patients according to the European Quality of life five-dimension five-level questionnaire (EQ-5D-5L) indices indicate the presence of a positive dynamics of the patients' well-being by the one-year ob-

servation point, which is confirmed by statistically significant differences at individual points in comparison with the baseline values (Table 5).

The results obtained when processing the data of the SAQ questionnaire makes it possible to state that by the end of the 1-st year, the patients' physical activity, the stability of angina pectoris, the quality of their lives have increased, and there is a decrease in the severity of the underlying pathology (the differences are significant compared to the baseline) (Table 6).

The obtained data on the dyspnea severity assessment in patients demonstrate a decrease in the number of the respiratory system disorders, the pathogenesis of which are due to the cardiovascular pathology (Table 7).

It has been revealed that the majority of patients are satisfied with the operation results and evaluate the performed surgical intervention on a scale from “-10” to “+10” with a fairly high score (“+7” and above). However, at later points, the satisfaction with the operation results decreases slightly (Table 8). In addition, by the annual observation mark, the number of patients whose state of health from the performed surgical intervention does not meet expectations, increases in almost 1.5 times (Table 9).

As a tool for compressing the multidimensionality of the initial characteristics presented in a complex questionnaire, which takes into account the characteristics of each observation point, a two-stage factor analysis to the new generalized variables was used.

The 1st stage results of the factor analysis made it possible to identify 3 generalized components at each observation mark, i. e.: “Physiological status”, “Cardiological status”, “Rehabilitation status” (Table 10).

The factor scores for the studied variables were determined in a similar way by analyzing each generalized component at each observation point with specified statistical settings (Table 11).

The determination of the factor loading of the indicators in each component, made it possible to identify the most significant parameters, i. e.: usual activities, angina stability, visual analogue scale.

Based on the results obtained, a formula for calculating the integrated indicator of the pharmacotherapy effectiveness in patients after ASCA at the postoperative stage was proposed. Hereby, the value-based approach was taken into account:

$$I = \sum_{i=1}^n k_i * w_i * x_i \quad (1),$$

where: I – an integrated index of the patient's treatment efficiency; n – the number of performance indicators (generalized indicators); k_i – a weight coefficient of the performance indicator (based on the factor load); w_i – a coefficient of importance / significance of the indicator for a patient; x_i – a value of the patient's efficiency indicator.

Table 1 – Baseline characteristics of patients with stable angina pectoris who underwent ASCA

Indicators	Units of measurement	Mean value	Minimum	Maximum
Age	Year	66.25±9.52	36	89
Height	cm	169.76±9.41	146	192
Weight	Kg	85.72±16.51	48	135
Body mass index	kg/m ²	29.72±5.13	19.41	47.05
Systolic blood pressure	MmHg	133.36±15.36	90	190
Diastolic blood pressure	MmHg	80.35±8.80	60	110
Heart rate	Beats per minute	69.18±8.69	50	110

Table 2 – The structure of concomitant cardiovascular pathologies in patients who have undergone ASCA

Disease	Number of complications	Proportion of patients with concomitant diseases, %
Arterial hypertension	152	92.12%
Chronic heart failure	70, of them	42.42%, of them
Stage I	2	2.86%
Stage II	64	91.43%
stage III	4	5.71%
Diseases associated with irregular heart rhythm	36	21.82%
Diseases associated with impaired cerebral circulation	75	45.45%
Obliterating atherosclerosis of the lower extremities	10	6.06%
Pulmonary hypertension	13	7.88%
Diabetes mellitus	38, of them	23.03%, of them
Type 1	0	0.00%
Type 2 on oral hypoglycemic drugs	33	86.84%
Type 2 insulin-dependent	5	13.16%

Table 3 – Health status according to the patients' self-assessment

Indicators	Observation points			
	1 (n=165)	2 (n=160)	3 (n=148)	4 (n=147)
How do you assess your current state of health in general?				
Excellent, %	–	3.6*	2.4*	2.4*
Very good, %	1.8	2.4*	3.0*	4.2*
Good, %	12.1	35.8*	38.2*	37.0*
Satisfactory, %	60.6	40.0*	33.9*	31.0*
Bad, %	25.5	15.2*	12.1*	14.5*
Missing values, %	0	3.0	10.4	10.9
How do you currently assess your health status in comparison with other people of your age?				
Better, %	15.2	14.5*	10.9*	10.9
The same, %	33.9	44.2*	44.8*	41.2
Worse, %	50.9	38.2*	33.9*	37.0
Missing values, %	0	3.0	10.4	10.9

Note: * p < 0.05 in comparison with point 1; ** p < 0.05 in comparison with point 2

Table 4 – Dynamics of the indicator of the life quality, determined by a visual analogue (100-point) scale

EQ VAS	Observation points			
	1 (n=165)	2 (n=160)	3 (n=148)	4 (n=147)
Mean value	52.52	64.94*	63.38*/**	62.82*/**
Standard deviation	19.72	19.61	19.31	20.95

Note: * p < 0.05 in comparison with point 1; ** p < 0.05 in comparison with point 2

Table 5 – Dynamics of indicators of the scales of the questionnaire EQ-5D-5L

EQ-5D dimension	The proportion of patients who have no problems on the scales of the questionnaire, %			
	1 (n=165)	2 (n=160)	3 (n=148)	4 (n=147)
Mobility	30.43	48.73*	50.68*	52.78*
Self-care	68.84	77.85*	80.82	81.25
Usual activities	35.51	67.09*	63.70*	64.58*
Pain / discomfort	42.03	72.78*	76.03*	79.86*
Anxiety / depression	49.28	70.25*	71.23*	71.53*

Note: * p < 0.05 in comparison with point 1; ** p < 0.05 in comparison with point 2

Table 6 – Dynamics of scales indicators of the SAQ questionnaire

Scales of the SAQ	Observation points			
	1 (n=165)	2 (n=160)	3 (n=148)	4 (n=147)
Physical loads limitation	63.38±20.20	75.71±15.12*	76.02±14.75*	76.07±14.45*
Stability of angina shoots	60.24±30.52	87.50±23.82*	86.76±27.36*	86.12±27.76*
Frequency of angina shoots	65.39±30.75	90.50±18.25*	90.54±21.18*	90.00±21.55*
Treatment satisfaction	67.14±21.03	72.00±19.08*	71.76±21.07*	71.58±21.11*
Disease perception	44.90±21.04	59.22±14.47*	59.35±15.30*	58.95±15.49*

Note: * p < 0.05 in comparison with point 1; ** p < 0.05 in comparison with point 2

Table 7 – Dynamics of dyspnea scoring (on the dyspnea scale)

Dyspnea / severity	Observation points			
	1 (n=165)	2 (n=160)	3 (n=148)	4 (n=147)
0/without, %	25.5	40.6*	33.3*/**	34.5*
1/light, %	23.6	28.5*	26.1*/**	24.8*
2/average, %	35.2	20.0*	22.4*/**	21.8*
3/heavy, %	14.5	6.7*	7.3*/**	6.7*
4/very heavy, %	1.2	1.2*	0.6*/**	1.2*

Note: * p < 0.05 in comparison with point 1; ** p < 0.05 in comparison with point 2

Table 8 – Patient satisfaction with the results of the operation

Satisfaction with the results of the operation	Observation points		
	2 (n=159)	3 (n=148)	4 (n=147)
Median	+8	+7*	+7*/**

Note: * p < 0.05 in comparison with point 2; ** p < 0.05 in comparison with point 3

Table 9 – Analysis of compliance of the operation results with the patients' expectations

Meeting expectations	Observation points		
	2 (n=159)	3 (n=148)	4 (n=147)
Satisfaction, %	71.5	58.2*	53.3*/**
No satisfaction, %	24.8	31.5*	35.8*/**
Missing values, %	3.7	10.3*	10.9*/**

Note: * p < 0.05 in comparison with point 2; ** p < 0.05 in comparison with point 3

Table 10 – Structuring of generalized factors

Components		
1	2	3
Physiological status	Cardiological status	Rehabilitation status
Usual activity	Scale of angina stability	Health status on a five-point health scale
Mobility	Scale of angina frequency	Health status compared to peers
Self-care	Scale of disease perception	Visual analogue scale
Pain / discomfort		Dyspnea scale
Anxiety / depression		Treatment satisfaction
Physical loads limitation		Satisfaction with the results of the operation
		Meeting patients' expectations of the result of surgery

Table 11 – Matrix of the factor coefficients component values

Factor	Indicators	Observation points			
		1	2	3	4
1	Usual activities	0.232	0.248	0.241	0.228
	Mobility	0.210	0.246	0.236	0.227
	Self-care	0.196	0.241	0.226	0.215
	Pain / discomfort	0.200	0.211	0.196	0.198
	Anxiety / depression	0.189	0.161	0.186	0.191
	Physical load limitation	–0.213	–0.173	–0.184	–0.186
2	Scale of angina stability	0.380	0.382	0.354	0.354
	Scale of angina frequency	0.386	0.376	0.353	0.354
	Disease perception	0.382	0.354	0.344	0.352
3	Health status on a five-point health scale	0.293	–0.199	–0.195	–0.190
	Health status compared to peers	0.258	–0.152	–0.156	–0.159
	Visual analogue scale	–0.302	0.218	0.206	0.203
	Dyspnea scale	0.240	–0.164	–0.155	–0.161
	Treatment satisfaction	–0.239	0.191	0.183	0.173
	Satisfaction with the results of the operation	–	0.208	0.194	0.188
	Meeting patients' expectations of the surgery result	–	0.194	0.179	0.180

Note: Factor extraction method: principal component analysis; Rotation method: Varimax with Kaiser normalization.

Table 12 – Results of life quality assessment using integrated index

Indicators	Observation points			
	1	2	3	4
Mean value	35.065	47.742*	44.511 ^{*/**}	43.945 ^{*/**/**}
Standard deviation	13.776	15.444*	15.566 ^{*/**}	14.586 ^{*/**/**}

Note: * p < 0.05 in comparison with point 1; ** p < 0.05 in comparison with point 2; *** p < 0.05 in comparison with point 3

Table 13 – Variance analysis of qualitative factors influence on the integrated indicator of patients' with SBS after ASCA life quality

Factors	Number of degrees of freedom	Observation points					
		2		3		4	
		F	P	F	P	F	P
Sex	1	2.096	0.150	0.268	0.606	0.004	0.952
Age	5	0.558	0.732	0.156	0.978	0.317	0.902
Body mass index	4	0.728	0.574	0.034	0.998	0.504	0.733
Stent type *	1	0.461	0.498	0.463	0.498	0.198	0.657
History of myocardial infarction	1	0.288	0.592	0.002	0.966	0.037	0.849
Arterial hypertension	1	1.232	0.269	0.195	0.660	0.134	0.715
Chronic heart failure	1	0.945	0.333	0.250	0.618	0.890	0.347
Diseases associated with irregular heart rhythm	1	0.454	0.502	0.031	0.861	0.289	0.592
Diseases associated with impaired cerebral blood formation	1	0.343	0.559	1.982	0.162	0.076	0.783
Pulmonary hypertension	1	0.932	0.336	2.895	0.091	1.945	0.166
Diabetes mellitus	1	0.002	0.967	0.044	0.834	0.177	0.674
Obliterating atherosclerosis of the lower extremities	1	0.050	0.823	0.229	0.633	0.002	0.964
R-squared value	–	0.092		0.068		0.063	

Note: * – accepted division into uncoated stent / stents and stent / stents with drug-induced antiproliferative coating; F – Fisher's criterion, p – significance level

As a result of transformation, with the results of the factor analysis taken into account, formula (1) took the following form (Table 12):

$$I = k_{UA} * w_{UA} * x_{UA} + k_{AS} * w_{AS} * x_{AS} + k_{VAS} * w_{VAS} * x_{VAS} \quad (2),$$

where: I – an integrated index of treatment efficiency of patients with SCHD after ASCA; k – a-weight coefficient of the indicator “Usual activities”; w_{UA} – a coefficient of importance / significance of the indicator “Usual activities”; x_{UA} – a value of the patient’s indicator “Usual activities”; k_{AS} – a-weight coefficient of the indicator “Angina stability”; w_{AS} – a coefficient of importance / significance of the indicator “Angina stability”; x_{AS} – a value of the patient’s indicator “Angina stability”; k_{VAS} – a weight coefficient of the indicator “Visual analogue scale”; w_{VAS} – a coefficient of importance / significance of the indicator “Visual analogue scale”; x_{VAS} – a value of the indicator “Visual analogue scale”.

Thus, patients’ quality of life assessment after ASCA, based on the dynamics of indicators of the complex questionnaire, includes the data of the non-specific questionnaire EQ-5D-5L, the scales of the specific SAQ questionnaire, the scale of dyspnea, the general self-assessment of the patients’ health state and the analysis of the integrated index at every point. These factors make it possible to assert the certainty improvement of health before and after the surgery at all observation points, i. e.: 1, 6, 12 months after the hospital discharge. Attention is drawn to the fact that in 53% of patients, the results of treatment meet their expectations.

Taking into account the clinical pathology features and the approaches to the pharmacotherapy of patients, it seemed expedient to assess the influence of the qualitative factors on the value of the integrated indicator of the patients’ life quality of with SCHD after ASCA at the outpatient stage. Sex, age, type of stent, and the presence of concomitant cardiovascular pathologies were analyzed as independent variables. The results of a multifactorial univariate analysis of the qualitative factors variance in the studied sample, make it possible to assert that there is no statistically significant influence of the qualitative factors on the integrated indicator (Table 13).

It has been established that the value of the Livigne criterion (the criterion for the homogeneity of samples) at the points under study, shows the equality of variances, i.e. the combination of factors does not affect the dependent variable. At the same time, the value of the R-squared is low at all points, i.e., it confirms the statistical insignificance of the influence of independent variables. Therefore, for subsequent studies, the homogeneity of the study group was justified, which, in turn, mediated its assessment without dividing patients into groups.

DISCUSSION

All patients with stable coronary artery disease admitted for planned percutaneous coronary intervention,

i.e. for angioplasty and stenting of coronary arteries, had standard indications (a burdened anamnesis, a functional class of the underlying disease) for performing a surgery for myocardial revascularization. The incidence of cardiovascular and major cerebrovascular pathologies was typical for the patients with stable angina pectoris [14–17].

It is worth emphasizing a high importance of the rehabilitation stage after a surgical intervention on the coronary arteries, which is indicated in the works by national and foreign scientists [18–25]. The results of the study indicate an improvement in the patients’ health status after ASCA by the annual follow-up point compared to the baseline, including an increase in mobility, no problems associated with personal care, habitual daily activities, a decrease in pain and discomfort, a decrease in anxiety and depression. A decrease in frequency and stability of angina attacks. Such conclusions about the improvement in the patients’ life quality after myocardial revascularization, are consistent with the literature data [26–28].

In the light of these considerations, one cannot ignore the allocation of state quotas for performing surgical interventions on the vessels that nurse the heart. Thus, according to the data of the Federal Mandatory Medical Insurance Fund in 2019, the average standard of financial costs per unit of medical care in the territory of the Russian Federation within the framework of the program “Coronary myocardial revascularization with the use of angioplasty in combination with stenting for coronary heart disease” was 221,645 rubles. Depending on the stage of the disease, the pathophysiological characteristics of the organism, the patient’s previous anamnesis, modern technologies for myocardial revascularization make it possible to choose the most effective and safe method for the patient, taking into account his individual characteristics. An assessment of the spectrum of state quotas with a high prevalence of surgical interventions on the vessels supplying the heart, indicates a significant burden on the federal budget. In its turn, it justifies the feasibility of conducting rational rehabilitation measures aimed at improving the prognosis of patients, improving their life quality, as well as increasing life expectancy of the patients with stable angina pectoris in the context of limited funding for the health care system.

In a lot of countries, there is an improvement in the system of providing medical care to the population towards an emphasis on involving patients in making decisions about treatment, as well as evaluating the methods of prevention, diagnosis and therapy used. According to the creators of the value-based medicine system, the calculation should be based on the results of achieving a positive outcome of the disease from the patient’s point of view [29, 30]. Changes in the terms of contracts for payment of medical services in terms of expanding the choice of medical organizations will slightly reduce the

annually progressing budgetary funds for health care. These are due to the loss of benefits to organizations. They are caused by an increase in the number of services provided and their rise in costs. The achievement of a favorable outcome of the disease with the lowest costs of treatment will be commercially viable. According to experts, such an approach will reduce healthcare costs by 10% or more due to limiting / eliminating the use of unnecessary medical and diagnostic procedures, increasing the effectiveness of treatment, replacing ineffective and expensive medical technologies, as well as the widespread use of primary and secondary kinds of prevention [31]. For the first time in 2006, the FDA published Guideline for assessing patient reported outcomes (PRO). It indicates the value of assessing patient outcomes as any assessment of a patient's health status given by the patient himself without any interpretation by a doctor or third parties. At the same time, it is important to notify that the subjective opinion expressed by the patient is not questioned and is taken into account as it is. The use of PRO helps to assess all patient's symptoms; the general state of his health; his usual activity; psychological condition; the general life quality and the life quality associated with health. The study of health state indicators in dynamics, the satisfaction with the treatment process and its result are of no small importance. PRO is a tool that makes it possible to measure the effect of a medical intervention from a patient's point of view. The study of the evaluation of the patient's treatment results contributes to the achievement of three main goals of the patient's treatment: a patient satisfaction with the treatment, improving his health status and reducing the costs of treatment, which improves the patient's life quality

through the use of effective and affordable methods of diagnosis and treatment [32-34].

Currently, coronary heart disease still occupies a leading place in the structure of mortality in the population worldwide, which underlines the need to improve the provision of medical care to patients at every stage of treatment. Thus, summarizing all of the above, due to the wide variability of the disease and the significant influence of comorbidities, it is appropriate to apply a personalized approach in each clinical situation for the treatment of patients in conditions of rational use of budgetary funds [35]. The following studies will be devoted to the use of tools for optimizing health care resources in the treatment of coronary artery disease.

CONCLUSION

Evaluation of patient treatment outcomes after undergoing planned percutaneous coronary intervention demonstrates an improvement in health status according to the analyzed parameters of the complex questionnaire, which is confirmed by statistical analysis tools.

In the context of the value-oriented paradigm of health care development, the calculation of an integrated indicator of the treatment effectiveness of patients with stable coronary artery disease after angioplasty with stenting of coronary arteries has been proposed and scientifically substantiated. It is based on the results of a two-stage factor analysis, which will be further used in the framework of the pharmacoeconomic «cost-benefit» analysis of patients' therapy in the study group. In addition, the proposed calculation of the quality of life indicator can be used to assess the effectiveness of medical technologies in the treatment of a number of other pathologies.

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CONFLICT OF INTEREST

The authors declare no conflicts of interest.

AUTHORS' CONTRIBUTION

I.A. Narkevich – choice of the research direction, idea; O.D. Nemyatykh – formulation of research aims and objectives, development of the research algorithm, consultations at all research stages, article writing;

K.A. Kovaleva – literature analysis, article writing, conducting all research stages, processing the results;

L.G. Ratova – collection of primary data, consultations at separate research stages, article writing;

I.O. Trushnikova – consultations on mathematical and statistical data processing; E.N. Parizskaya – collection of the primary data; A.O. Konradi – consultations on carrying out separate stages of the study.

REFERENCES

1. WHO (World Health Organization). 2020. The top 10 causes of death. Geneva: WHO. Available from: <https://www.who.int/news-room/fact-sheets/detail/the-top-10-causes-of-death>.
2. Kontsevaya AN, Drapkina OM, Balanova YuA, Imaeva AE, Suvorova EI, Khudyakov MB. Economic burden of cardiovascular diseases in the Russian Federation in 2016. Rational Pharmacotherapy in Cardiology. 2018;14(2):156–166. DOI: 10.20996/1819-6446-2018-14-2-156-166.
3. Paltsev MA, Belushkina NN, Chaban EA. 4P-Medicine as a new model of healthcare in the Russian Federation. Healthcare management: news. Views. Education. Bulletin of Higher School of Organization and Health Management. 2015. 2:48–54. Russian
4. Osmanov EM, Manyakov RR, Osmanov RE, Zhabina UV, Konyaev DA, Agafonova YV, Peshkova AA. 4 "P" medicine as a basis of new system of public health. Tambov University Reports. Series: Natural and Technical Sciences

- 22(6):1680–1685. DOI: 10.20310/1810-0198-2017-22-6-1680-1685. Russian
5. Nemyatyh OD., Kovaleva K.A. Social'no-ekonomicheskie aspekty lekarstvennogo obespecheniya pacientov s serdechno-sosudistymi patologiyami v postoperacionnm periode / O.D. Nemyatyh, // Sbornik materialov IV Vserossijskoj nauchno-prakticheskoy konferencii s mezhdunarodnym uchastiem «Innovacii v zdorov'e nacji»: Sankt-Peterburg, 9-10 noyabrya 2016 g. – S. 445–447. Russian
 6. Kovaleva KA, Nemyatykh OD, Narkevich IA, Ratova LG, Parizhskaya EN, Konradi AO, Basakina II. analysis of the medicines' range for therapy of patients with stable angina in the Russian Federation. Bashkortostan Medical Journal. 2019;14(5):43–47. Russian
 7. Kovaleva KA, Nemyatyh OD, Narkevich IA, Ratova LG, Parizhskaya EN, Konradi AO, Basakina II. Analysis of state purchases in the area of preferential provision of medicines for the patients with stable angina (evidence from Saint Petersburg) VestnikRoszdraznadzora. 2020;1:83–88. DOI: 10.35576/2070-7940-2020-1-83-88. Russian
 8. Ratova LG, Parizhskaya EN, Kovaleva KA, Nedoshivin AO, Nemyatykh OD, Pulit VV, Konradi AO. An observational study to assess the outcomes of treatment of patients with stable angina after planned percutaneous coronary intervention: baseline patient characteristics. Russian Journal of Cardiology. 2018;(12):52–56. DOI: 10.15829/1560-4071-2018-12-52-56. Russian
 9. Ratova LG, Parizhskaya EN, Kovaleva KA, Zvartau NE, Ionov MV, Semenov AP, Fedorenko AA., Nedoshivin AO, Nemyatykh OD, Konradi AO. Evaluation of the outcomes of stable angina management after selective percutaneous coronary intervention (Pilot Results). Russian Journal of Cardiology. 2017;(12):8–13. DOI: 10.15829/1560-4071-2017-12-8-13. Russian
 10. Chuchalin AG, Avdeev SN, Aysanov ZR, Belevskiy AS, Leshchenko IV, Meshcheryakova NN, Ovcharenko SI, Shmelev EI. Russian respiratory society. Federal guidelines on diagnosis and treatment of chronic obstructive pulmonary disease. Pulmonologiya. 2014;(3):15–54. DOI: 10.18093/0869-0189-2014-0-3-15-54. Russian
 11. Amirdjanova VN, Erdes SF. Validation of general questionnaire EuroQol-5D (EQ-5D) Russian version. Rheumatology Science and Practice. 2007;45(3):69–76. DOI: 10.14412/1995-4484-2007-691. Russian
 12. Syrkin AL, Pechorina EA, Drinitsina SI. Validation of methods for assessing the quality of life in patients with stable angina pectoris Clinical Medicine. 2001;79(11): 22–25. Russian
 13. Balackij EV. Faktory udovletvorennosti zhizn'yu: izmerenie i integral'nye pokazateli. Monitoring obshchestvennogo mneniya. 2005;4:42–52. Russian
 14. Sumin AN, Korok EV, Shcheglova AV, Barbarash OL. Comorbidities in patients with ischemic heart disease: gender differences. Rational Pharmacotherapy in Cardiology. 2017;13(5):622–629. DOI: 10.20996/1819-6446-2017-13-5-622-629. Russian
 15. Mirzakhanova L.R. Efficacy of coronary stenting and basic pharmacotherapy in elderly and senile patients: the results of long-term prospective follow-up. Rational Pharmacotherapy in Cardiology. 2011;7(6):708–712. Russian
 16. Manzella D, Paolisso G. Cardiac autonomic activity and Type II diabetes mellitus. Clin Sci (Lond). 2005;108(2):93–9. DOI: 10.1042/CS20040223.
 17. DeLuca AJ, Saulle LN, Aronow WS, Ravipati G, Weiss MB. Prevalence of silent myocardial ischemia in persons with diabetes mellitus or impaired glucose tolerance and association of hemoglobin A1c with prevalence of silent myocardial ischemia. Am J Cardiol. 2005;95(12):1472–4. DOI: 10.1016/j.amjcard.2005.02.016.
 18. Lo KY, Chan CK. Characteristics and outcomes of patients with percutaneous coronary intervention for unprotected left main coronary artery disease: a Hong Kong experience. Hong Kong Med J. 2014 Jun;20(3):187–93. DOI: 10.12809/hkmj134069.
 19. Hilliard AA, From AM, Lennon RJ, Singh M, Lerman A, Gersh BJ, Holmes DR Jr, Rihal CS, Prasad A. Percutaneous revascularization for stable coronary artery disease temporal trends and impact of drug-eluting stents. JACC Cardiovasc Interv. 2010 Feb;3(2):172–9. DOI: 10.1016/j.jcin.2009.11.013.
 20. Averin EE, Apuhtin AF, Delaryu VV. Reabilitaciya pacientov kardiohirurgicheskogo profilya: kriticheskaya ocenka social'no-pravovoj bazy. YUrist – Pravoved". 2010;4:42–44. Russian
 21. Clinical guidelines. Stable ischemic heart disease. (Cited: 28 Aug 2020). 2020:114. Available from: <http://cr.rosminzdrav.ru/#/schema/>. Russian
 22. Karpova ES, Kotelnikova EV, Lyamina NP. Ischemic preconditioning and its cardioprotective effect in post-intervention cardiac rehabilitation programmes for patients with coronary heart disease. Russian Journal of Cardiology. 2012;(4):104–108. Russian
 23. Neumann FJ, Sousa-Uva M, Ahlsson A, Alfonso F, Banning AP, Benedetto U, Byrne RA, Collet JP, Falk V, Head SJ, Juni P, Kastrati A, Koller A, Kristensen SD, Niebauer J, Richter DJ, Seferovic PM, Sibbing D, Stefanini GG, Windecker S, Yadav R, Zembala MO; ESC Scientific Document Group. 2018 ESC/EACTS Guidelines on myocardial revascularization. Eur Heart J. 2019;40(2):87-165. DOI: 10.1093/eurheartj/ehy394.
 24. Martynova VV, Andreev DA, Doletskii AA, Abugov SA, Saakian IuM. Safety and efficacy of early physical rehabilitation after planned percutaneous coronary interventions. Kardiologiya i Serdechno-Sosudistaya Khirurgiya. 2013;6(5):11–16.
 25. Kuznetsov VA, Samoylova EP, Bessonov IS, Gulyaeva EP, Zyryanov IP, Berdinskikh SG, Gorbatenko EA, Kolunin GV. Long term results of percutaneous coronary interventions comparing with conservative management in treatment of stable ischemic heart disease patients under real circumstances. Russian Journal of Cardiology. 2016;(2):7–11. DOI: 10.15829/1560-4071-2016-2-7-11. Russian
 26. Baron SJ, Chinnakondapalli K, Magnuson EA, Kandzari DE, Puskas JD, Ben-Yehuda O, van Es GA, Taggart DP, Morice MC, Lembo NJ, Brown WM 3rd, Banning A, Simonton CA, Kappetein AP, Sabik JF, Serruys PW, Stone GW, Cohen DJ; EXCEL Investigators. Quality-of-Life After Everolimus-Eluting Stents or Bypass Surgery for Left-Main Disease: Results From the EXCEL Trial. J Am Coll Cardiol. 2017;70(25):3113–3122. DOI: 10.1016/j.jacc.2017.10.036.
 27. Baron SJ, Chinnakondapalli K, Magnuson EA, Kandzari DE, Puskas JD, Ben-Yehuda O, van Es GA, Taggart DP, Morice MC, Lembo NJ, Brown WM 3rd, Banning A, Simonton CA, Kappetein AP, Sabik JF, Serruys PW, Stone GW, Cohen DJ; EXCEL Investigators. Quality-of-Life After Everolimus-Eluting Stents or Bypass Surgery for Left-Main Disease: Results From the EXCEL Trial. J Am Coll Cardiol. 2017;70(25):3113–

22. DOI: 10.1016/j.jacc.2017.10.036.
28. Jensen LO, Thayssen P, Maeng M, Christiansen EH, Ravkilde J, Hansen KN, Kalso A, Tilsted HH, Madsen M, Lassen JF; Scandinavian Organization for Randomized Trials With Clinical Outcome SORT OUT IV Investigators. Three-year outcomes after revascularization with everolimus- and sirolimus-eluting stents from the SORT OUT IV trial. *JACC Cardiovasc Interv.* 2014 Aug;7(8):840–8. DOI: 10.1016/j.jcin.2014.02.014.
29. Contracting for Outcomes A Value-Based Approach. 2014. [Cited: 10 Aug 2020]. Available from: http://outcomes-basedhealthcare.com/Contracting_for_Outcomes.pdf. Subscription required.
30. Outcomes based approaches to healthcare. Outcomes based approaches to healthcare Ltd. 2014. [Cited: 10 Aug 2020]. Available from: http://outcomesbasedhealthcare.com/OBH_Outcomes_Myths_2014.pdf. Subscription required.
31. Latkovic T. The Trillion Dollar Prize. Using outcomes-based payment to address the US healthcare financing crisis. McKinsey and Company. 2013. [Cited: 10 Aug 2020].: 40. Available from: <http://healthcare.mckinsey.com/sites/default/files/the-trillion-dollar-prize.pdf>. Subscription required.
32. Bae JM. Value-based medicine: concepts and application. *Epidemiol Health.* 2015 Mar 4;37:e2015014. DOI: 10.4178/epih/e2015014.
33. Kelly MP, Heath I, Howick J, Greenhalgh T. The importance of values in evidence-based medicine. *BMC Med Ethics.* 2015 Oct 12;16(1):69. DOI: 10.1186/s12910-015-0063-3.
34. Shlyakhto EV, Vasilievich Yul. Outcome-based healthcare. *Translational Medicine.* 2017;4(1):6–10. Russian
35. Shlyakhto EV, Konradi AO. Medicina, osnovannaya na cennosti, – novaya paradigma v zdravoohraneni. *Remedium Privolzh'e.* 2018;3(163):4–8.

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