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ABSTRACT

of the dissertation for the degree of Doctor of Philosophy

OPTIMIZATION OF THERAPY FOR PATIENTS WITH STABLE ANGINA USING EXTERNAL COUNTERPULSATION METHOD

Specialty: 3218.01 – Cardiology

Field of science: Medicine

Applicant: **Rovshan Huseyn Alakbarov**

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The work was performed at the Scientific Research Institute of Cardiology named after acad. J.M. Abdullayev and "Yaşam" Medical Center.

Scientific supervisor: Doctor of Medical Sciences, Professor
Tofig Shahmur Jahangirov

Official opponents: Doctor of Medical Sciences, Professor
Elman Zaur Alakbarov

Doctor of Medical Sciences, Associate Professor
Sona Mais Gahramanova

Doctor of Philosophy in Medicine
Ulvi Ahad Mirzoyev

Dissertation Council ED 2.27 of Supreme Attestation Comission under the President of the Republic of Azerbaijan operating at the Azerbaijan Medical University

Chairman of the Dissertation Council: Doctor of Medical Sciences, Professor
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Scientific Secretary of the Dissertation Council: Doctor of Philosophy, Associate Professor
Tora Akif Sadigova

Chairman of the Scientific Seminar: Doctor of Medical Sciences, Associate Professor
Gulnaz Mahir Dadashova

İMZANI TƏSDİQ EDİRƏM
Azərbaycan Tibb Universitetinin
ELMİ KATİBİ
Tibb elmləri doktoru, professor
Nazim Adil oğlu Pənahov
10.05.24

GENERAL DESCRIPTION OF THE WORK

Relevance and degree of development of the topic

Cardiovascular diseases are the leading cause of death worldwide. According to the American Heart Association, the prevalence of coronary heart disease (CHD) in the United States in 2018 was 7.2% (20.1 million Americans over 20 years of age), with the prevalence of CHD in men being 8.3% and in women 6.2%. The prevalence of stable angina in the United States in 2001 was 3.5%[1], and in 2018 this figure is already 4.1% (11 million patients)[2]. The increase from year to year in the number of patients with various forms of coronary heart disease is associated mainly with the aging of the population, improved survival of patients with acute coronary syndromes, as well as with the increasing number of patients with various risk factors for coronary heart disease. The mortality rate of patients with stable angina depends on a number of factors, such as: age, gender, nature of anginal pain, smoking, diabetes, resting heart rate and ECG changes. The 10-year mortality rate of patients with stable angina belonging to the high-risk group is 8.7%[3]. The presence of angina symptoms, including in patients with ischemic cardiomyopathy, as well as the degree of anatomical damage to the coronary bed are also independent predictors of mortality in patients with stable coronary artery disease[4]. Considering this, the problem of effective treatment of IHD remains relevant.

The variety of clinical forms of IHD, stages of the disease, variants of their course and complications are factors that often complicate the treatment process. Various treatment methods are used to treat coronary

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[3] Sekhri, N. A 10-year prognostic model for patients with suspected angina attending a chest pain clinic / N.Sekhri, P.Perel, T.Clayton [et al.] // Heart, – 2016. No. 102, – p. 869-875.

[4] Mentz, R.J. Persistent angina pectoris in ischemic cardiomyopathy: increased rehospitalization and major adverse cardiac events / R.J.Mentz, S.Broderick, L.K.Shaw [et al.] // European journal of heart failure, – 2014. No. 16, – p. 854-860.

artery disease. Drug treatment includes taking basic antianginal drugs, such as beta-blockers, calcium antagonists, nitrates, which are considered "first-line" therapy. Of no small importance is the use of drugs that improve the prognosis of the disease, which include: antiplatelet agents, statins and angiotensin-converting enzyme inhibitors (ACE inhibitors). Recently, in clinical practice, a number of other drugs with different mechanisms of action are increasingly used to treat stable angina: - ivabradine, nicorandil, ranolazine and a number of others[5]. However, despite the active use and a fairly large range of medications, quite often drug treatment is not effective enough for various reasons: low patient adherence to treatment (patient non-compliance with the drug treatment regimen); different individual sensitivity of patients to various drugs; development of treatment tolerance; development of side effects, etc. The progression of atherosclerosis of the coronary arteries is also of great importance, leading to the development of a more severe class of angina pectoris, despite active drug treatment[6].

In cases of insufficiently effective drug therapy, the use of myocardial revascularization methods leads to good results [7]. However, surgical interventions do not eliminate the cause of the disease, and the problem of treating IHD still remains relevant due to the accumulation of long-term observation data on patients who underwent invasive treatment[8]. The main problem is the development of recurrent angina pectoris, the cause of which is restenosis at the sites of stent implantation, stent thrombosis or occlusion of coronary

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[6] Papafaklis, M.I. Identifying the progression of coronary artery disease: prediction of cardiac events / M.I.Papafaklis, M.C.Mavrogiannis, P.H.Stone // Continuing Cardiology Education, – 2016. No. 2(2), – p. 105-114.

[7] Knuuti, J. 2019 ESC Guidelines for the diagnosis and management of chronic coronary syndromes: The Task Force for the diagnosis and management of chronic coronary syndromes of the European Society of Cardiology (ESC) / J.Knuuti, W.Wijns, A.Saraste [et al.] // European heart journal, – 2020. No. 41(3), – p. 407-477.

[8] Sedlis, S.P. Effect of PCI on long-term survival in patients with stable ischemic heart disease / S.P.Sedlis, P.M.Hartigan, K.K.Teo [et al.] // The New England journal of medicine, – 2015. No. 373, – p. 1937-1946.

artery bypass grafts, further progression of atherosclerosis of the coronary arteries, incomplete revascularization of the myocardium, - diffuse coronary atherosclerosis, spontaneous dissection of the coronary artery, epicardial spasm coronary arteries, as well as microvascular dysfunction[9]. The results of some studies have shown that approximately 20-40% of patients after myocardial revascularization procedures experience symptoms of angina, so some patients require a repeat myocardial revascularization procedure. However, for one reason or another, these patients cannot undergo repeated myocardial revascularization. First of all, these are patients who refuse repeated interventions, have various contraindications to repeated surgery, patients with diffuse damage to the vascular bed, diseases of small vessels, as well as patients who have already undergone a myocardial revascularization procedure with a poor result. As a result, there is a need to search for new treatment methods for IHD.

External counterpulsation (ECP) is a non-invasive, safe and effective method for treating various forms of coronary artery disease. The main principle of operation of the ECP device is to increase perfusion coronary blood flow by increasing blood pressure in diastole, which is carried out through compression and decompression of special cuffs placed on the patient's legs and buttocks. Studies have shown the high safety and good tolerability of the ECP method, which has led to the active introduction of this treatment method in the USA and in a number of other countries[10].

However, despite the fairly active use of the ECP method in foreign clinical practice, this method of treating angina pectoris has never been used in the Republic of Azerbaijan. There is a need to study the clinical effectiveness, side effects and safety of this method in the complex treatment of patients with angina pectoris with additional research.

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[9] Crea F. Mechanisms and diagnostic evaluation of persistent or recurrent angina following percutaneous coronary revascularization / F.Crea, C.N.Bairey Merz, J.F.Beltrame [et al.] // European heart journal, – 2019. No. 40(29), – p. 2455-2462.

[10] Raza, A. Enhanced external counterpulsation therapy: past, present, and future / A.Raza, K.Steinberg, J.Tartaglia [et al.] // Cardiology in review, – 2017. No. 25(2), – p. 59-67.

Object and subject of the research. The study included 106 patients with stable angina pectoris. Subject of the research: external counterpulsation method.

Purpose of the study. To evaluate the effectiveness of complex treatment of patients with stable angina pectoris using the method of external counterpulsation.

Research objectives:

1. To evaluate the clinical effectiveness of the ECP method based on the results of a clinical examination and data from instrumental methods.
2. To conduct a comparative analysis of the effectiveness of the ECP method in patients with coronary artery disease, depending on the presence or absence of systolic heart failure, left ventricular diastolic dysfunction, arterial hypertension and diabetes mellitus.
3. To evaluate quality of life indicators in patients of the main group before and after the use of external counterpulsation and compare these indicators with the control group.
4. To compare adherence to drug treatment in patients treated with ECP with a control group.
5. To evaluate the tolerance, side effects and safety of using the ECP method in patients with coronary artery disease.

Research methods: Study and analysis of literature; complex methods of cardiological examination: clinical, functional-diagnostic, assessment of quality of life, invasive methods (coronary angiography); method of external counterpulsation and statistical processing of the material.

Key provisions submitted for defense:

1. External counterpulsation is an effective treatment method for patients with coronary heart disease. The good tolerability, accessibility, non-invasiveness and safety of the external counterpulsation method allows the use of this technique in an outpatient setting.

2. The use of external counterpulsation in patients with stable angina pectoris is associated with a decrease in the functional class of angina pectoris, a decrease in the use of nitroglycerin drugs, an increase in left ventricular ejection fraction, improved exercise tolerance, and an improved quality of life. as well as improving adherence to medications.

3. The use of the external counterpulsation method in patients with a moderately reduced left ventricular ejection fraction (EF 40-49%) leads to a significant improvement in this indicator, the stroke volume of the left ventricle, as well as a more pronounced decrease in the functional class of exertional angina.

4. The use of the external counterpulsation method in patients with diastolic dysfunction of the left ventricular myocardium leads to a decrease in the volume of the left atrium and the indicator of diastolic dysfunction (E/e' ratio).

Scientific novelty of the research:

This work is the first to summarize preliminary data on the effect of a course of treatment using the ECP method on the functional class of angina pectoris, the need for the use of nitroglycerin preparations, systolic and diastolic function of the left ventricular myocardium, exercise tolerance, quality of life indicators and adherence to drug therapy in patients with stable angina pectoris.

For the first time, the effect of the ECP method was studied on patients with moderately reduced left ventricular ejection fraction of ischemic origin (with LVEF 40-49%), with diastolic dysfunction of the left ventricle, as well as with diabetes mellitus and arterial hypertension.

Tolerance, safety and side effects of ECP procedures were analyzed. The issue of intolerance to ECP procedures was analyzed in detail.

Using univariate risk analysis, the issue of the effectiveness of the ECP method in different categories of patients was analyzed in detail.

The results of this work showed the clinical effectiveness, safety and good tolerability of the ECP method in patients with stable angina pectoris, with moderately reduced systolic and diastolic dysfunction

of the left ventricular myocardium, as well as in patients with arterial hypertension.

Theoretical and practical significance of the research:

The use of a course of ECP in patients with stable angina pectoris can reduce the functional class of angina pectoris, reduce the consumption of nitroglycerin preparations, increase exercise tolerance, improve the quality of life of patients, and also improve the objective manifestations of coronary artery disease.

The ECP technique is a valuable addition to standard drug therapy for patients with stable angina pectoris. The technique can be chosen in patients with clinically severe and refractory angina pectoris, especially in cases where it is impossible to perform invasive treatment for one reason or another, as well as in patients with angina pectoris after myocardial revascularization procedures. Previous myocardial revascularization procedures are not a contraindication to this treatment method.

The ECP technique can also be effectively used in patients with moderately reduced left ventricular ejection fraction of ischemic origin, with left ventricular diastolic dysfunction, as well as with arterial hypertension.

The peculiarities of this method are non-invasiveness, safety, ease of use, as well as good tolerability, which allows the use of this method in an outpatient setting.

Approbation of the research results: The materials and main results of the dissertation were discussed at the scientific council of the Scientific Research Institute of Cardiology named after acad. J.M. Abdullayev (July 23, 2021, protocol No. 1), and at the scientific seminar of the ED 2.27 Dissertation Council operating at the AMU (June 6, 2022, protocol No. 7). The results of the dissertation work were reported and discussed at foreign conferences of the European Society of Cardiology (ESC): HeartFailure 2019 (Athens, Greece) - Poster presentation, EuroEcho 2021 (Berlin, Germany).

Application of research results to practice: Scientific and practical results of research work have been introduced into the clinical practice of the "Yasham" Medical Center.

Name of the organization where the dissertation work was completed: The work was performed at the Scientific Research Institute of Cardiology named after acad. J.M. Abdullayev and "Yaşam" Medical Center.

Publication of the main results of the dissertation work: The main results of the research work were published in 5 journal articles, including 2 articles abroad (journals indexed in Scopus, Web of Science and other international indexing systems), and 3 articles in Azerbaijan. Articles were published in journals recommended by the Supreme Attestation Commission. 13 theses have been published on the topic of the dissertation.

Structure and total scope of the dissertation:

The dissertation is written on 186 pages, consisting of computer text in Russian. The total volume of the dissertation is 227,169 characters. The dissertation consists of the following chapters: Introduction (8 pages, 11566 characters); Literature review (27 pages, 38870 characters); Materials and methods (15 pages, 22016 characters); Results of our own research (88 pages, 118814 characters); Conclusion (19 pages, 30956 characters); Conclusions and Practical Recommendations (2 pages, 2763 characters); List of used literature (21 pages, 170 sources); List of conventional abbreviations (3 pages, 3443 characters). The dissertation uses 74 tables, 78 figures and 2 diagrams.

MATERIALS AND METHODS OF RESEARCH

A total of 106 patients were included in the study and were divided into 2 groups: the main group and the control group. The main group consisted of 71 patients who began treatment with the ECP method.

To assess the effectiveness of ECP therapy and assess the reliability of the study, a control group was formed for comparative analysis, which included 35 patients, in a ratio of 1:2 in relation to the main group.

The study was conducted at the "Yasham" Medical Center. The diagnosis of ischemic heart disease (IHD) was established on the basis of anamnesis, complaints, corresponding clinical picture, and confirmed by objective diagnostic methods.

Selection of patients for the ECP course

The selection of patients for the ECP course was based on known indications and contraindications for this treatment method.

Inclusion criteria for the study

1. Stable angina pectoris of class I-IV (according to the classification of the Canadian Heart Association (CCS));
2. Impossibility of performing invasive treatment of patients with stable angina pectoris for one reason or another;
3. Recurrence of angina after already performed invasive interventions.

Before starting the course of treatment with the ECP method, all patients received comprehensive information about this method of treatment, as well as about possible side effects.

Treatment with the ECP method was started in all patients of the primary main group. However, 14 patients (19.7%) from this group, for one reason or another, did not complete the entire course of treatment with ECP. These patients were excluded from the primary main group, and their data were used to analyze patient tolerance to the ECP method. Thus, the final main group consisted of 57 patients who received at least 20 hours of ECP.

In the main group, male patients predominated; out of 57 patients, 43 were male (75.4%), 14 were female (24.6%). The average age of the patients was 63.07 ± 7.44 years. The average value of the functional class of stable angina before treatment was

2.28 ± 0.73. Most patients had angina of functional classes 2 and 3 (84.2%). Analysis of coronary angiograms of patients in this group showed that mainly 3-vessel lesions of the coronary arteries prevail (in 33 patients, 57.9%), in 16 patients (28.1%) 2-vessel lesions, and in 8 (14.0%) 1-vascular lesion. In the main group, 27 patients suffered myocardial infarction, which accounted for 47.4% of the total number of patients. Arterial hypertension was observed in 27 patients (47.4%), and diabetes mellitus in 7 patients (12.3%). Revascularization procedures were performed before ECP treatment in 5 patients (8.8%). Patients received basic optimal drug therapy, including the following classes of drugs: nitrates, antiplatelet agents, calcium antagonists, ACE inhibitors, beta-blockers, ivabradine, statins and diuretics. Nitroglycerin preparations were used by 31 patients, which accounted for 54.4% of the total number of patients.

Just like in the main group, the control group was dominated by men - out of 35 patients, 26 were male (74.3%), 9 were female (25.7%, respectively). The average age of the patients was 61.09 ± 5.44 years. The average value of the functional class of angina was comparable to the class of angina in the main group and amounted to a total of 2.34 ± 0.73. Patients with angina of functional classes 2 and 3 predominated: out of 35 patients, 30 had class 2 or 3 angina (85.7%).

Also, as in the main group, in patients of this group, when analyzing coronary angiograms, 3-vessel lesions of the coronary arteries more often prevailed, 2- and 1-vessel lesions were detected less frequently (respectively in: 51.4%, 28.6% and 20.0% of cases). In the control group, myocardial infarction was observed in 9 patients, which amounted to 25.7% of the total number. Arterial hypertension was observed in 15 patients (42.9%), and diabetes mellitus in 6 patients (17.1%). Revascularization procedures were performed in 3 patients (8.6%). Just like in the main group, in the control group all patients received basic optimal drug therapy. Nitroglycerin preparations were used by 22 patients, which accounted for 62.9% of the total number of patients.

All patients underwent a general clinical examination before and after treatment. In addition, adherence to medication treatment was assessed in all patients. Quality of life was assessed using the Seattle Angina Questionnaire.

To perform echocardiographic studies, an ultrasound scanner General Electric, model Vivid 4, using a 3S transthoracic probe was used. Echocardiographic examination was performed using all available modes. In the main group, the first examination was carried out before the start of ECP treatment, the second examination - after the end of treatment. In the control group, the first echocardiographic study was carried out before the start of drug treatment, and the second after 2 months.

Stress ECG tests were performed twice on all patients, both from the main group and from the control group. The first test was performed before the prescribed treatment, and the second after the end of treatment. To conduct the Stress ECG tests, a treadmill "Contec" was used.

Before treatment, all patients in both the main and control groups underwent selective coronary angiography in various clinics in the city of Baku, which was performed using angiographic units from various manufacturers, such as: Siemens (Germany) - "Axiom Artis"; GE (USA) – "Innova 2100", Philips (USA) – "Allura FD20".

Treatment with the ECP method was carried out using a Vasomedical device, model TS-4, as well as a PSK device (model PSK-ECP/TI). Before the start of the treatment session, all patients had their blood pressure measured and their clinical status assessed. After changing clothes, the patient lay down on the treatment couch of the ECP device. Special cuffs were placed on the patient's legs and buttocks. Using electrodes placed on the skin, an ECG was taken, which was transmitted to the control screen of the ECP device. A plethysmograph sensor was placed on the patient's finger, the signals from which were also transmitted to the screen of the ECP device, so that the patient's plethysmogram curve was displayed under his ECG signal. After turning on the device, air from the compressor was supplied to the cuffs strictly

during diastole, and before the next systole, the air from the cuffs was quickly released. The ECP pressure was in the range of 200-300 mmHg. Systole was determined based on the R wave of the patient's ECG. Compression and decompression times were adjusted by the physician based on the patient's plethysmogram in order to achieve optimal diastolic enhancement of blood flow.

Statistical data processing: Comparisons of two groups on quantitative scales were carried out based on the nonparametric Mann-Whitney test. Comparisons of three or more groups on quantitative scales were carried out based on the nonparametric Kruskal-Wallis test. To describe quantitative indicators, the average value and standard deviation in the "M ± S" format were used. The analysis of the dynamics of indicators in the case of comparing two periods was carried out on the basis of the nonparametric Wilcoxon test, in the case of comparing three or more periods - on the basis of the nonparametric Friedman test. Statistical significance of different values for binary and nominal indicators was determined using the Pearson's Chi-square test. Correlation analysis was carried out based on nonparametric Spearman's rank correlation. The level of statistical significance was fixed at a probability of error level of 0.05. Statistical data processing was performed using application packages Statistica 10 and SAS JMP 11.

RESEARCH RESULTS

Comparison of the main and control groups

Based on the results of the analysis comparing the main and control groups, it can be noted that the main (ECP) and control groups were equivalent in age, gender, angina class and a number of other parameters before treatment. After completion of treatment with the ECP method, a decrease in the class of angina pectoris was noted in both groups, but these changes were more significant in the ECP group. The use of nitroglycerin decreased sharply after treatment in the ECP group, and in the control group, despite a

slight decrease, the changes did not reach the level of statistical significance. Echocardiographic data show that the groups were also equivalent in almost all parameters, except for left ventricular end-diastolic volume and left ventricular stroke volume, which were greater in the control group. In the “After treatment” period, the differences in the groups became even smaller: the groups do not differ in terms of end-diastolic volume of the left ventricle and stroke volume of the left ventricle, but they differ in the absolute value of the E/e' ratio, which is higher in the control group. In the “Before treatment” period, all indicators of the stress ECG test data of the control and main groups were statistically the same, and in the “After treatment” period, significant differences appeared between the groups: the total time of the load, the load performed, as well as the time before the onset of ST segment depression by 1 mm, became significantly larger in the ECP group compared to the control group. When assessing the quality of life in the “Before treatment” period, the ECP group and the control group differed on the scale of physical activity limitations (higher score in the ECP group) and the scale of stability of angina attacks (higher score also in the ECP group). In the “After treatment” period, the differences turned out to be statistically significant on three of the five scales, the values of which were higher in the ECP group. Accordingly, the overall score for the quality of life assessment method was higher in the ECP group. Statistical analysis showed that overall medication adherence was significantly higher in the ECP group.

Analysis of the dynamics of indicators in the main and control groups

After a course of treatment using the ECP method, based on the results of the analysis of the dynamics of indicators for the ECP and control groups, it can be concluded that more statistically significant changes occurred in the ECP group. Some indicators changed significantly in both the ECP group and the control group: the angina class decreased in both groups, all indicators of quality of life, except for limitation of physical activity, increased. When

comparing the dynamics of echocardiography indicators, the dynamics turned out to be approximately the same in both groups. Differences were obtained only for the dynamics of LVEF, which was greater in the ECP group, in which LVEF increased by 4.69%, while in the control group - only by 1.75%. The dynamics of all indicators of the stress ECG test differed in the main group. and control groups, and the dynamics in the ECP group are positive, and in the control group – negative. Thus, improvements were noted for: total time to perform the load (+103.19 ± 56.13 s versus –5.43 ± 38.68 s, $p<0.0001$); performed load in metabolic equivalents (METs) (+1.63 ± 0.89 versus –0.09 ± 0.59, $p<0.0001$); time until the onset of ST segment depression by 1 mm (+83.44 ± 57.78 s versus –4.29 ± 30.13 s, $p<0.0001$). When comparing indicators of quality of life data, we can conclude that on some scales the dynamics are insignificant and are the same for both groups, for example, on the scale of limiting physical activity. According to some scales (scales of stability of attacks and frequency of angina attacks), the dynamics in the ECP group are much higher than in the control group (respectively +30.18 ± 16.53 versus +12.00 ± 9.94, $p<0.0001$ and +36.67 ± 20.12 versus +12.86 ± 17.75; $p<0.0001$). The total score also improved much more in the ECP group than in the control group: +96.10 ± 40.73 and +45.31 ± 35.06, $p<0.0001$. A decrease in the functional class of angina by 1 FC is also observed much more in the ECP group than in the control group (78.9% versus 57.1%, $p=0.0258$). The use of nitroglycerin decreased sharply after treatment in the ECP group (51.6% decrease, $p=0.0002$), and in the control group, despite a slight decrease, the changes did not reach the level of statistical significance (22.7% decrease, $p=0.0736$). After completion of treatment, adherence to drug therapy in the ECP group was statistically significantly higher than in the control group (80 ± 20% and 57 ± 25 %, $p<0.0001$). A comparative analysis of the dynamics of changes in these parameters is presented in Table 1.

Table 1. Comparison of the dynamics of indicators between the periods: “Before treatment” and “After treatment” between the ECP and Control groups (negative dynamics are marked with a minus sign).

Index	Group		Level P
	ECP (N=57)	Control (N=35)	
Reducing the functional class of angina pectoris			
Reducing the functional class of angina by 1 class	45 (78.9%)	20 (57.1%)	**0.0258**
Echocardiography data, dynamics of indicators			
LV EDD, cm	-0.06 ± 0.28	-0.06 ± 0.14	0.3606
LV EDV, ml	-0.38 ± 13.84	-2.67 ± 36.82	0.3090
LV SV, ml	3.52 ± 9.64	0.42 ± 22.75	0.1336
LVEF, %	4.69 ± 5.56	1.75 ± 5.15	**0.0448**
Left atrium size, cm	-0.03 ± 0.23	-0.03 ± 0.15	0.8839
Left atrium volume, ml	-4.80 ± 15.02	-0.83 ± 7.40	0.1454
Degree of mitral regurgitation	-0.06 ± 0.27	-0.04 ± 0.14	0.4817
Early speed of mitral annulus movement (e'), cm/s	0.29 ± 1.30	0.17 ± 0.53	0.3956
Stress ECG test data, dynamics of indicators			
Total load time, s	103.19 ± 56.13	-5.43 ± 38.68	**<0.0001**
Load completed, METs	1.63 ± 0.89	-0.09 ± 0.59	**<0.0001**
Time to 1 mm ST segment depression	83.44 ± 57.78	-4.29 ± 30.13	**<0.0001**
Assessment of quality of life, dynamics of indicators			
Physical limitation scale, %	-2.40 ± 6.91	-0.72 ± 5.20	0.2884
Anginal stability scale, %	30.18 ± 16.53	12.00 ± 9.94	**<0.0001**
Anginal frequency scale, %	36.67 ± 20.12	12.86 ± 17.75	**<0.0001**
Treatment satisfaction scale, %	17.76 ± 19.18	12.11 ± 16.04	0.3165
Disease perception scale, %	13.89 ± 19.88	9.05 ± 26.83	0.5614
Changes in total score, points	96.10 ± 40.73	45.31 ± 35.06	**<0.0001**

Comparative analysis of the effectiveness of the ECP method in patients with systolic heart failure

To perform this analysis, all patients in the main group (ECP) were divided into 2 subgroups: 1) patients with left ventricular ejection fraction (LVEF) less than 50% (LV systolic dysfunction subgroup), and 2) patients with LVEF greater than 50% (subgroup control). The subgroup of LV systolic dysfunction included 15 patients, and the control subgroup consisted of 42 patients. The ejection fraction in patients of the LV systolic dysfunction subgroup before treatment averaged 44.23 ± 3.21%. A history of myocardial infarction was more common in the subgroup of patients with LVEF < 50%. Arterial hypertension, on the contrary, was more common in patients with LVEF > 50%. Patients of both subgroups did not differ from each other in the characteristics of ECP therapy.

After a course of treatment using the ECP method, a decrease in the angina class (by at least 1 class) occurred in all patients with LVEF < 50%, and only in 71.4% of patients from the group with LVEF > 50%. When analyzing echocardiographic indicators, it was found that in the "Before treatment" period, the subgroups differed in four of the eight echocardiographic indicators: EDV and LV EDD were significantly lower in the subgroup of patients with LVEF > 50%, just like the absolute value of the E/e' ratio, and the early speed of movement of the mitral ring (e'), on the contrary, is greater. In a comparative analysis of the dynamics of ejection fraction between patients of the main (LVEF < 50%) and control (LVEF > 50%) subgroups, a statistically significant result was obtained, namely p = 0.0487 (the dynamics of the increase in LVEF was greater in the subgroup with LVEF < 50%). To assess the effect of the ECP method on patients with LVEF < 50%, a comparison was made with the control group, which in turn was also divided into two subgroups: with LVEF < 50% and with LVEF > 50%. When analyzing the dynamics of LVEF there were no statistically significant differences between patients with LVEF < 50% and LVEF > 50% within the control group (p=0.1948). When analyzing the dynamics of LVEF in patients with LVEF < 50% between the ECP group and the control group a statistically significant difference was obtained: p=0.0283, while when

analyzing the dynamics of LVEF in patients with LVEF > 50%, no statistically significant differences were obtained between the ECP group and the control group: p=0.4385. Thus, a statistically significant increase in LVEF occurred only in the subgroup of patients with EF < 50 % from the ECP group (Table 2).

Table 2. Comparative analysis of the dynamics of ejection fraction between the subgroups of patients with LVEF < 50% and LVEF > 50% between each group (ECP group and control group).

Index	Left ventricular ejection fraction	ECP Group	Control Group	Level P
Dynamics of LVEF, %	**LVEF < 50 %**	**+7.90 ± 7.44**	-1.57 ± 2.71	0.0283
Dynamics of LVEF, %	**LVEF > 50 %**	+3.55 ± 4.27	+2.06 ± 5.24	0.4385
		p=0.0487	p=0.1948	

The dynamics of changes in the Stress ECG test indicators turned out to be approximately the same in both the main and control subgroups. Only the change in time to onset of ST segment depression of 1 mm changed more in the subgroup of patients with LVEF > 50%. There were no differences between subgroups in the dynamics of changes in quality of life assessments.

Comparative analysis of the effectiveness of the ECP method in patients with left ventricular diastolic dysfunction

To perform this analysis, all patients in the main group (ECP) were divided into 2 subgroups: 1) patients with left ventricular diastolic dysfunction (LV diastolic dysfunction subgroup), and 2) control subgroup. The criterion for LV diastolic dysfunction was the ratio of the maximum speed of early filling of the transmitral blood flow of the left ventricle in pulsed wave Doppler mode (E) to the maximum speed of movement of the mitral valve annulus fibrosus in the phase of rapid filling of the left ventricle in tissue pulsed wave Doppler mode (e') exceeding the value of 14.0 (ratio E/e' > 14.0). The LV diastolic

dysfunction subgroup included 15 (26%) patients, and the control subgroup consisted of 42 (74%) patients. A history of myocardial infarction was more common in the subgroup of patients with left ventricular diastolic dysfunction “E/e' > 14”; the same subgroup was characterized by more frequent use of ACE inhibitors and diuretics. The subgroups did not differ in the characteristics of ECP therapy.

After the course of treatment using the ECP method, all differences that reached the level of statistical significance occurred in echocardiography parameters. Of all the echocardiography dynamics indicators, significant differences were obtained only for two indicators: the dynamics of the left atrium volume and the dynamics of the E/e' ratio, which were greater in the “E/e' > 14” subgroup. The volume of the left atrium in the subgroup “E/e' > 14” decreased by 12.41 ± 16.33 ml (in the control subgroup it decreased by 2.09 ± 13.72 ml, p=0.0124), and the E/e' ratio in the subgroup "E/e' > 14" decreased by 2.87 ± 3.94 units (in the control subgroup it increased by 0.39 ± 2.12 units, p=0.0003). The subgroups did not differ in stress-ECG test, and almost all indicators of assessing quality of life, as well as adherence to drug treatment. After the end of treatment, both subgroups experienced approximately the same decrease in the overall angina class.

Comparative analysis of the effectiveness of the ECP method in patients with diabetes mellitus

To perform this analysis, all patients of the main group (ECP) were divided into 2 subgroups: 1) patients with diabetes mellitus (diabetes mellitus subgroup), and 2) a subgroup of patients without diabetes mellitus (control subgroup). The diabetes mellitus subgroup included 7 patients (12%), and the control subgroup consisted of 50 patients (88%). Patients in these subgroups differed in the following clinical characteristics: CABG and a history of angioplasty were more common in the subgroup with diabetes mellitus; patients in this subgroup were also more likely to take ivabradine and diuretics. These subgroups were equivalent by gender. The subgroups did not differ in the characteristics of ECP therapy.

After completion of treatment using the ECP method, the results of the analysis comparing data from echocardiographic studies did not reveal statistically significant differences in patients with diabetes mellitus and without diabetes mellitus. It is especially worth paying attention to the fact that there were no significant differences in the dynamics of the main indicators of echocardiography, which can be interpreted as the fact that diabetes mellitus does not affect the effectiveness of treatment with the ECP method. The identified subgroups turned out to be equivalent in terms of quantitative variables of the category "Stress ECG test data" both in the "Before treatment" and in the "After treatment" periods: the dynamics for these indicators also turned out to be the same in both subgroups. According to assessments of quality of life in the "Before treatment" period, there were no differences between subgroups, but in the "After treatment" period, differences appeared between subgroups on the scale of attitude towards the disease: this indicator was higher in the subgroup of patients without diabetes mellitus. However, there were no differences between the subgroups in the dynamics of all indicators of quality of life, including the scale of attitude towards illness. The distribution of patients by angina class in both subgroups was uniform, both in the "Before treatment" period and in the "After treatment" period. Both subgroups experienced approximately the same reduction in overall angina class. There was also a similar reduction in nitroglycerin use in both subgroups. Adherence to drug treatment was similar in both subgroups.

Comparative analysis of the effectiveness of the ECP method in patients with arterial hypertension

To perform this analysis, all patients of the main group (ECP) were divided into 2 subgroups: 1) patients with arterial hypertension (main subgroup), and 2) a subgroup of patients without arterial hypertension (control subgroup). The subgroup of patients with arterial hypertension included 27 patients (47%), and the control subgroup consisted of 30 patients (53%). The subgroups of patients with and without hypertension differed in only three indicators: patients with hypertension were more likely to take calcium antagonists, ACE

inhibitors, and diuretics. The subgroups were equivalent in gender: in both subgroups the majority were men. The subgroups did not differ in the characteristics of ECP therapy.

After completion of treatment with the ECP method, the results of the analysis comparing the subgroup with arterial hypertension and the control subgroup can be concluded that in terms of the clinical characteristics of patients, the differences between the subgroups are minimal. Neither in the “Before treatment” nor in the “After treatment” period did these subgroups differ in terms of echocardiography indicators. Accordingly, no statistically significant differences in the dynamics of indicators in the category “Echocardiography” were found between the subgroups. Neither in the “Before treatment” period, nor in the “After treatment” period were any statistically significant differences found in the quantitative variables of the category “Stress ECG test data”. However, despite the absence of differences in these indicators both before and after treatment, their dynamics still differ in the subgroups with and without hypertension. Total exercise time and time to 1 mm ST segment depression increased to a greater extent in the hypertensive subgroup compared with the non-hypertensive subgroup. The subgroups of patients with and without hypertension had similar quality of life scores both before and after treatment. Analysis of the dynamics of these indicators indicates that the changes occurring in these two subgroups are also approximately the same. The distribution of patients by angina class in both subgroups was uniform, both in the “Before treatment” period and in the “After treatment” period. Both subgroups experienced approximately the same reduction in overall angina class. There was also a similar reduction in nitroglycerin use in both subgroups.

Univariate risk analysis

This section presents the results of a statistical univariate risk analysis of the following indicators:

1. “Dynamics of LVEF, % > = 5%”,
2. “Dynamics of completed load, METs >= 2.0”,
3. "Reducing the class of angina pectoris"

4. “Change in quality of life, total score > = 80”,

5. “Adherence to drug treatment > = 70%.”

Based on the results of the single-factor risk analysis, the following conclusions can be drawn:

1. For the indicator “Dynamics of LVEF, % >= 5%” the leading factors with an increase in risk levels from 24.8% to 38.0% are: “Total number of sessions ≥ 35.0”, “Total treatment time, h ≥ 29.7”, “angina class before treatment ECP ≥ 3.0” and “LV ejection fraction before treatment < 50%”;

2. For the indicator “Dynamics of performed load, METs >= 2.0” the leading statistically significant factors with an increase in risk levels from 26.1% to 36.8% are “Group (ECP)”, “Left ventricular ejection fraction (LVEF)”, % ≥ 59.2" and "Total treatment time, h ≥ 30.8";

3. For the indicator “Reduction of angina class”, the leading - statistically significant factors with an increase in risk levels from 64.4% to 80.4% are “Total treatment time, h ≥ 20.7”, “Group (ECP)” and “Angina class” ≥ 2.0";

4. For the indicator “Change in quality of life > = 80”, the leading statistically significant factors with an increase in risk levels from 53.0% to 64.3% are “Group (ECP)”, “Total treatment time, h ≥ 20.7” and “General number of sessions ≥ 21.0";

5. For the indicator “General adherence to drug treatment >= 70%”, the leading statistically significant factors with increasing risk levels from 34.0% to 72.2% are “Total number of sessions ≥ 23.0”, “Group (ECP)” and “Change in quality of life >= 80.”

Assessment of tolerance, safety and side effects of the ECP method

To assess patient tolerance to the ECP method, a group of patients was analyzed who, for one reason or another, did not complete the recommended 35-hour course of treatment. A total of 71 patients were included in the study in the primary main group of ECP. The criterion for completion of the course of ECP treatment was the receipt of at least 20 hours of ECP. Of the 71 patients, 57 patients met this criterion. 14 patients, for one reason or another, did not complete the course of

treatment with ECP and were excluded from the primary main group. On average, they received 8.29 ± 4.23 ECP sessions (range 3 to 17 sessions). When analyzing the total time of ECP therapy, on average these patients received 7.27 ± 3.66 hours of ECP therapy (range 1.75 to 11.33 hours). To analyze tolerance to the ECP method, a comparative analysis was carried out. To perform this analysis, all patients of the primary main group (ECP) were divided into 2 subgroups: 1) patients who did not complete the course of treatment with ECP (interrupted treatment subgroup), and 2) a subgroup of patients who completed the course of treatment with ECP (control subgroup). The interrupted treatment subgroup included 14 patients (19.7%), and the control subgroup consisted of 57 patients (80.3%). Thus, tolerance to the ECP method was approximately 80%.

Based on the results of the analysis comparing the subgroup of patients who did not complete treatment and the control subgroup, it can be concluded that in terms of the clinical characteristics of patients, the differences between the subgroups are minimal: patients are equivalent in age, gender, average angina class (as well as distribution by angina class), and history of myocardial infarction, revascularization procedures, arterial hypertension and taking medications. Differences between subgroups included the presence of diabetes mellitus. In the subgroup of patients who did not complete ECP treatment, diabetes mellitus was significantly more common than in the control subgroup, and only in male patients. Of the 12 patients with diabetes mellitus (9 men and 3 women) included in the study, only 58.4% were able to complete the standard 35-hour course of ECP treatment (4 men and 3 women). Thus, based on the results of this analysis, we can conclude that diabetes mellitus in male patients has a negative impact on patients' tolerance to ECP.

The main side effect of ECP procedures was the psychological discomfort of the procedure, which was observed in 35.2% of cases, and was the main reason for patients' refusal of further treatment. Of the 14 patients who refused to undergo ECP treatment, 12 (85.7%) refused precisely because of this reason. Side effects also included: maceration of the skin in the area of cuffing (in 28.2% of patients, one patient refused further treatment for this reason); the urge to urinate

frequently (in 23.9% of patients, one patient refused further treatment for this reason); pain in the lumbar region (in 14.1% of patients).

When analyzing the safety and side effects, we can conclude that the ECP technique is quite safe for patients with coronary artery disease, and the main side effect that reduces tolerance to this treatment method is the patient's psychological discomfort during the ECP session.

CONCLUSIONS

1. The use of the ECP method in patients with stable angina pectoris compared with the control group leads to a more pronounced decrease in the functional class of angina (decrease in average FC from 2.28 ± 0.73 to 0.93 ± 0.80, $p<0.05$ vs from 2.34 ± 0.73 to 1.83 ± 0.71, $p<0.05$), decrease in consumption of nitroglycerin drugs (by -51.6%, $p=0.002$ versus -22.7%, $p=0.0736$), increase in left ventricular ejection fraction (+4.69 ± 5.56% vs +1.75 ± 5.15%, $p=0.0448$), improved performance of the stress ECG test [4, 5, 9].

2. In patients with moderately reduced ejection fraction of the left ventricle, the use of the ECP method compared with the control subgroup leads to an increase in the ejection fraction (increase by 7.90 ± 7.44% versus 3.55 ± 4.27% ($p=0.0487$)) and left ventricular stroke volume (increase by 6.35 ± 13.08 ml versus 2.51 ± 8.03 ml ($p=0.0176$)). In this subgroup, the angina class decreases to a more pronounced extent. In patients with diastolic dysfunction of the left ventricular myocardium, the use of the ECP method, compared with the control subgroup, was associated with a decrease in E/e' (-2.87 ± 3.94 versus +0.39 ± 2.12, $p=0.0003$) and left atrium volume (-12.41 ± 16.33 ml versus -2.09 ± 13.72 ml, $p = 0.0124$) [10, 12, 13, 14, 15, 16].

3. In patients with arterial hypertension, the use of the ECP method compared with the control subgroup leads to an improvement in the stress ECG test indicators: total time to complete the load (+118.96 ± 60.64 s versus +89.00 ± 48.45 s, $p=0.0229$) and time to the onset of ST segment depression by 1 mm (+97.63 ± 37.98 s versus +70.67 ± 69.27 s, $p = 0.0090$). In patients with diabetes

mellitus who received a course of treatment with ECP, compared with the control subgroup, no differences were found in the studied parameters [17].

4. When comparing quality of life indicators, the dynamics of some indicators are the same for both groups, for example, the degree of limitation of physical activity, the degree of satisfaction with treatment and attitude towards the disease. According to other indicators (stability of angina attacks and frequency of angina attacks), the positive dynamics in the ECP group are significantly higher than in the control group (30.18 ± 16.53 and 12.00 ± 9.94, respectively, $p < 0.0001$; 36. 67 ± 20.12 and 12.86 ± 17.75, $p < 0.0001$). The total quality of life score improved to a greater extent in the ECP group than in the control group (96.10 ± 40.73 versus 45.31 ± 35.06, $p < 0.0001$) [4, 5, 7, 9, 11].

5. Adherence to medication treatment was statistically significantly higher in the ECP group compared to the control group ($80 \pm 20\%$ vs. $57 \pm 25\%$ $p < 0.0001$) [5].

6. The use of the ECP method is not accompanied by serious side effects; patient tolerance to the ECP method is approximately 80%. Diabetes mellitus in male patients significantly reduces tolerance to ECP [18].

PRACTICAL RECOMMENDATIONS

1. The ECP method can be used in patients with stable angina pectoris.

2. The ECP method can be used in patients with moderately reduced left ventricular ejection fraction.

3. The ECP method can be used in patients with diastolic dysfunction of the left ventricular myocardium.

4. The ECP method is safe for patients with coronary artery disease and is not associated with serious side effects, which makes it possible to use this technique in an outpatient setting.

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List of abbreviations:

ACEI – angiotensin-converting enzyme inhibitor
AMU – Azerbaijan Medical University
CABG – coronary artery bypass grafting
CHD – coronary heart disease
ECG – electrocardiogram
ECP – External Counterpulsation
EDD – end-diastolic diameter
EDV – end-diastolic volume
FC – functional class
IHD – ischemic heart disease
LV – left ventricle
LVEF – left ventricle ejection fraction
METs (Metabolic Equivalent of Task) – metabolic equivalent of load
SV – stroke volume

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