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ТЕЧЕНИЕ ХРОНИЧЕСКОЙ СЕРДЕЧНОЙ НЕДОСТАТОЧНОСТИ В РАННЕМ ПЕРИОДЕ ПОСЛЕ КАТЕТЕРНОЙ КРИОБАЛЛОННОЙ АБЛАЦИИ ПРИ ПАРОКСИЗМАЛЬНОЙ И ПЕРСИСТИРУЮЩЕЙ ФИБРИЛЛЯЦИИ ПРЕДСЕРДИЙ

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Course of Chronic Heart Failure in the Early Period Following Catheter Cryoballoon Ablation in Paroxysmal and Persistent Atrial Fibrillation

Резюме

Цель. Изучить течение хронической сердечной недостаточности при пароксизмальной и персистирующей фибрилляции предсердий в раннем периоде после операции катетерной криобаллонной аблации устьев легочных вен. **Материал и методы.** Шестьдесят семь пациентов (средний возраст 65,07 ± 7,72 лет, 31(46,3 %) мужчин) с фибрилляцией предсердий и хронической сердечной недостаточностью разделены на 2 группы: I — пароксизмальная, II — персистирующая фибрилляция предсердий. Все пациенты получили первичную криобаллонную аблацию по стандартной методике. До и через 3 месяца после операции проводились тест 6-минутной ходьбы, оценка качества жизни по Миннесотскому опроснику, уровня N-терминального фрагмента прогормона мозгового натрийуретического пептида, эхокардиография. **Результаты.** Уровень N-терминального фрагмента прогормона мозгового натрийуретического пептида (NT-proBNP) был ниже в группе I — 151,00 [65,50; 249,00] против 513,00 [355,25; 948,00] нг/л (p <0,001) в группе II. Группа II отличалась большими размерами левого предсердия: передне-задний размер 40,00 [37,00; 43,00] мм (p=0,018), индекс объема левого предсердия 35,00 [31,00; 43,00 мл/м^2 (p=0,023), правого предсердия: 38,00 [36,00; 40,00] мм (p=0,001) и левого желудочка. Фракция выброса левого желудочка была ниже в группе II — 55,00 [50,50; 58,00] против 60,00 [57,00; 62,00] % (p <0,001). Внутригрупповой анализ изменений в динамике после КБА показал: в группе I улучшение качества жизни и увеличение дистанции 6-минутной ходьбы с 411,0 [377,0; 482,5] до 455,0[420,0 –515,0] метров (p=0,001). У пациентов группы II в динамике отмечено: увеличение расстояния 6-минутной ходьбы с 424,00 [390,00; 500,75] до 470,00 [410,00 — 551,50] метров (p < 0,001), значимое снижение уровня NT-proBNP с 513,00 [355,25; 948,00] до 153,00 [73,50 — 171,00] нг/л (p<0,001), уменьшение размеров левого предсердия, правого желудочка, систолическое давление в легочной артерии, увеличение фракция выброса левого желудочка с 55,0 [50,5; 58,0] до 60,0 [55,0 — 60,0] % (p=0,004). **Заключение.** У пациентов с персистирующей фибрилляцией предсердий, которые исходно имели более тяжелое течение хронической сердечной недостаточности, через 3 месяца после операции криобаллонной аблации устьев легочных вен отмечалось улучшение функционального статуса, повышение толерантности к ходьбе, уменьшение размеров левого предсердия, правого желудочка, систолического давления в легочной артерии, увеличение фракции выброса левого желудочка, снижение уровня

NT-proBNP в сыворотке крови. У пациентов с пароксизмальной фибрилляции предсердий проведенная катетерная криобаллонная аблация устьев легочных вен способствовала повышению толерантности к физической нагрузке и улучшению качества жизни.

Ключевые слова: *фибрилляция предсердий, сердечная недостаточность, качество жизни, криобаллонная аблация, эхокардиография, фракция выброса левого желудочка, NT-proBNP*

Конфликт интересов

Авторы заявляют, что данная работа, её тема, предмет и содержание не затрагивают конкурирующих интересов

Источники финансирования

Авторы заявляют об отсутствии финансирования при проведении исследования

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Abstract

Aim. Study the course of chronic heart failure with paroxysmal and persistent atrial fibrillation (AF) during the early period after catheter cryoballoon ablation of pulmonary vein. **Material and Methods.** Sixty-seven patients (mean age 65.07 ± 7.72 years, 31 (46.3 %) men) with atrial fibrillation and heart failure were divided into two groups: Group I — paroxysmal AF and Group II — persistent AF. All patients underwent primary cryoballoon ablation using standard technique. Before operation and three months post-operation, tests included six-minute walk test, Minnesota Living with Heart Failure Questionnaire, measurement of N-terminal pro-brain natriuretic peptide, and echocardiography. **Results.** The NT-proBNP level was lower in Group I — 151.00 [65.50;249.00] ng/L versus 513,00 [355.25; 948.00] ng/L in Group II (p <0.001). Group II demonstrated larger left atrial dimensions: left atrial diameter 42.50[40.25;45.00] mm (p=0.018), indexed left atrial volume 40.00 [37.50;46.65] mL/m^2 (p=0.023), right atrial diameter 43.00 [40.25;45.75] mm (p=0.001) and left ventricular. Left ventricular ejection fraction was lower in Group II — 55.00 [50.50;58.00] % versus 60.00 [57.00;62.00] % (p <0.001). Within-group analysis showed that Group I improved the quality of life and an increased 6-minute walk test distance from 411.0 [377.0;482.5] meters to 455.0 [420.0–515.0] meters (p=0.001). For Group II, dynamic changes revealed an increase in 6-minute walk test distance from 424.00 [390.00;500.75] to 470.00 [410.00–551.50] meters (p<0.001), a significant drop in NT-proBNP level from 513.00 [355.25;948.00] to 153.00 [73.50–171.00] ng/L (p<0.001), reduction in left atrial dimensions, right ventricular size, systolic pulmonary artery pressure, and an increase in left ventricular ejection fraction from 55.00 [50.50;58.00] % to 60.00 [55.00–60.00] % (p=0.004). **Conclusion.** Patients with persistent atrial fibrillation, who initially had more severe chronic heart failure, experienced an improvement in their functional status, increased walking endurance, reduction in left atrial and right ventricular dimensions, as well as systolic pulmonary artery pressure, along with an increase in left ventricular ejection fraction and a decrease in NT-proBNP levels, 3 months after cryoballoon ablation. Patients with paroxysmal atrial fibrillation benefited from cryoballoon ablation through enhanced physical activity tolerance and improved quality of life.

Key words: *atrial fibrillation, heart failure, quality of life, cryoballoon ablation, echocardiography, left ventricular ejection fraction, NT-proBNP*

Conflict of Interest

The authors declare that this work, its topic, subject matter, and content do not affect any competing interests.

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Compliance with the principles of ethics

The study protocol was approved by the local ethics committee of Federal State Autonomous Educational Institution of Higher Education «N.I. Pirogov Russian National Research Medical University» of the Ministry of Health of the Russian Federation (Minutes No230 dated 28.06.2023). Approval and protocol procedure was obtained according to the principles of the Declaration of Helsinki. Written consent was obtained from the patients for publication of relevant medical information and all of accompanying images within the manuscript.

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AAT — antiarrhythmic therapy, LAVI — left atrial volume index, CBA — cryo-balloon ablation, EDV — end-diastolic volume, EDS — end-diastolic size, LA — left atrium, IVC — inferior vena cava, RV — right ventricle, LAAPS — left atrial anteroposterior size, SPAP — systolic pulmonary artery pressure, PVO — pulmonary vein ostia, LVEF — left ventricular ejection fraction, NYHA FC — functional class of congestive heart failure based on the New York Heart Association classification, AFib — atrial fibrillation, CHF — chronic (congestive) heart failure, CHFpEF — chronic heart failure with preserved ejection fraction, CHFmrEF — chronic heart failure with moderately reduced ejection fraction, CHFrEF — chronic heart failure with reduced ejection fraction, EchoCG — echocardiography, EHRA — European Heart Rhythm Association scale for the assessment of atrial fibrillation symptoms, MLHFQ — Minnesota Living with Heart Failure Questionnaire, NT-proBNP — N-terminal fragment of the brain natriuretic peptide hormone, TAPSE — tricuspid annular plane systolic excursion, 6MWT — 6-minute walking test

Introduction

Atrial fibrillation (AFib) and chronic (congestive) heart failure (CHF) are a serious burden for public health, causing high mortality and morbidity, negatively affecting the quality of life and prognosis in patients [1]. CHF is diagnosed in 22.5 % patients with paroxysmal AFib, 44 % patients with persistent AFib, and 56 % patients with permanent AFib. AFib prevalence increases in parallel with the CHF functional class (FC), reaching 45 % in FC III-IV [2, 3].

For a long time, the issue of the preferable management for patients with AFib remained debatable. The latest trials, i.e. EAST-AFNET 4 [4], RAAFT-2 [5], EARLY-AF [6], have demonstrated the advantages of a sinus rhythm (SR) recovery and maintenance strategy, including with the use of ablation methods. Catheter ablation as a first-line therapy in persistent AFib has a smaller evidence class (IIb) than that for the paroxysmal one (I) [7]. In 2024, a Consensus was published by the European Heart Rhythm Association concerning the catheter and surgical ablation in AFib. This document contains the systematic review of 11 randomized clinical trials (RCTs) devoted to the selection of the AFib treatment method in patients with chronic heart failure with reduced ejection fraction (CHFrEF), which has demonstrated the benefits of interventional procedures over the antiarrhythmic therapy (AAT), concerning the improved quality of life, decreased hospitalization and mortality rate, decreased AFib burden, increased ejection fraction (EF), prevention of CHF progression [8].

The study was aimed at analyzing the CHF course in paroxysmal and persistent AFib in the early period after the cryo-balloon ablation (CBA) of pulmonary vein ostia (PVO).

Materials and Methods

A total of 67 patients with paroxysmal and persistent AFib and CHF were included into the single-center prospective study. Subjects were aged 41 to 76 years (65.15±7.76), including 36 (53.7 %) females.

Study inclusion criteria:

Symptomatic paroxysmal or persistent AFib.

Confirmed heart failure.

Primary catheter ablation.

Patient's informed consent.

Study exclusion criteria:

Left atrial anteroposterior size (LAAPS) exceeding 5.0 cm based on echocardiography (EchoCG) criteria. LA appendage thrombosis based on contrast-enhanced cardiac computed tomography or transesophageal EchoCG; implanted devices (permanent pacemaker, implantable cardioverter-defibrillator [ICD], cardiac resynchronization therapy [CRT]); moderate and severe mitral and aortic heart diseases (or those requiring surgical correction); uncorrected thyroid dysfunction; current malignancy, end-stage renal disease, moderate or severe anemia or thrombocytopenia; acute infectious diseases; acute heart failure or decompensated CHF; myocardial infarction and/or coronary revascularization within the prior 3 months; infectious endocarditis, myocarditis, pericarditis, pulmonary embolism; acute cerebrovascular accident within the prior 6 months.

Before the surgical intervention, all patients underwent the assessment of the functional status using the 6-minute walking test (6MWT), the quality of life using the Minnesota Living with Heart Failure Questionnaire (MLHFQ), as well as the test for levels of N-terminal fragment of the brain natriuretic peptide hormone (NT-proBNP) and echocardiography (EchoCG). Linear and volumetric parameters, LVEF, tissue Doppler parameters, diastolic dysfunction degree were assessed during EchoCG. 24-hour ECG monitoring (Miocard-Holter-2 24-hour ECG Monitoring System; manufacturer: Scientific Research Institute of Medical Device Construction ESN LLC) was provided to all patients 3 months after the intervention to assess arrhythmias and heart blocks. In patients with ejection fraction ≥50 %, H2FPEF, HFA-PEFF scales, and (if indicated) the diastolic stress-test was used to verify chronic heart failure with preserved ejection fraction (CHFpEF). CHF was diagnosed based on Clinical Guidelines on the Management of Patients with Chronic Heart Failure (2024) [9]. All patients underwent the catheter cryo-balloon ablation (CBA) based on the procedure adopted in the hospital, with the achievement of the isolation of pulmonary vein ostia and without any additional occlusive interventions. Under local anesthesia with novocaine and total intravenous anesthesia (fentanyl, midazolam, propofol), the right internal jugular vein and the right femoral vein were punctured with subsequent insertion of hemostatic introducers. Multipolar diagnostic electrophysiological catheters were installed in the coronary sinus and the right ventricle. Under fluoroscopy guidance, the interatrial septum was punctured; heparin was administered intravenously for the prevention of intraoperative thromboembolic complications (target values of activated partial thromboplastin time: 300–350 seconds). The transseptal introducer was inserted into the left atrial cavity. The transseptal introducer was switched for the Polar Sheath 12F delivery system (Boston Scientific, USA) on a diagnostic guidewire 150–270 cm long. After inserting the PolarX cryo-balloon catheter (Boston Scientific, USA) into the left atrial cavity, cryo-interventions were sequentially arranged in the left superior, left inferior, right inferior, and right superior pulmonary veins (240 seconds long). Before each exposure, the pulmonary vein occlusion with the balloon catheter was confirmed by the fluoroscopic injection of

the contrast drug into it. The electric isolation of pulmonary veins was confirmed by the disappearance of the electrical activity in the muscle cuff of each pulmonary vein recorded using a PolarMap diagnostic circular catheter (Boston Scientific, USA) Additional non-occlusive interventions outside of pulmonary veins were not conducted. If atrial fibrillation was preserved after all interventions, electrical cardioversion was applied to restore the sinus rhythm. After completing the surgical intervention, patients were routed into the intensive care unit. After hemopericardium exclusion, anticoagulant therapy was resumed 4 hours after the surgery. Regardless of the CHA2DS2-VASC score, all patients were administered direct oral anticoagulants for at least 3 weeks before and 8 weeks after the surgery based on the Clinical Guidelines for the Treatment of Atrial Fibrillation and Flutter (2020) [10]. Vitamin K antagonists were not used.

The study was arranged in accordance with the Good Clinical Practice standards and the Declaration of Helsinki principles. The study was approved by the Local Ethics Committee of the N.A. Pirogov Russian National Research Medical University, Protocol No. 230 dated June 28, 2023. The written informed consent was obtained from all subjects before the study enrollment.

The statistical analysis was conducted using the StatTech v. 4.8.0 software (StatTech LLC, Russia). Quantitative parameters were evaluated for the compliance with normal distribution using the Shapiro-Wilk test. Quantitative parameters, which selective distribution corresponded to the normal one, were described using the mean arithmetics (M) and standard deviations (SD). 95 % confidence interval (95 % CI) limits were defined for the mean values for representativeness. In the absence of normal distribution, quantitative data were described using the median (Me) and lower/upper quartiles [Q1 — Q3]. For the comparison of two groups in the quantitative parameter, which distribution in each group corresponded to the normal one, the Student's t-test was used provided the dispersions were equal. For the comparison of two groups in the quantitative parameter, which distribution was abnormal, the Mann-Whitney U-test was used. When comparing normally distributed quantitative parameters calculated for two linked samples, the paired Student's t-test was used. When comparing quantitative parameters with abnormal distribution in two linked groups, the Wilcoxon test was used. The Pearson's x2 test was used to compare qualitative parameters. Differences were considered statistically significant with $p<0.05$.

Results

Based on the study design, before CBA patients were divided into two groups depending on the AFib form: Group I — paroxysmal, n=45 (67.2 %), mean age 67.0 years, 16 males (35.6 %); Group II — persistent, n=22 (32.8 %), mean age 65.0 years, 15 males (68.2 %). No patients with long-standing persistent AFib (>1 year) were included into the study. Patients in groups differed by gender: Group I had 16 (35.6 %) males and 29 (64.4 %) females, Group II had 15 (68.2 %) males and 7 (31.8 %) females (p=0.012). Groups were similar in the age (p=0.505), body mass index (BMI) — 29.89 and 30.84 kg/m2 (p=0.372), comorbidities: essential hypertension (EH) — in 45 (100 %) patients from Group I and in 21 (95.5 %) from Group II (p=0.328); coronary artery disease (CAD) — 4 (8.9 %) in Group I, 5 (22.7 %) in Group II (p=0.160), type 2 diabetes mellitus — 3 (6.7 %) in Group I, 1 (4.5 %) in Group II (p=1.000), hypertrophic cardiomyopathy (HCM) — 1 (2.9 %) in Group I, 1 (7.1 %) in Group II (p=0.503), estimated glomerular filtration rate (eGFR) — 67.00 [60.00–75.00] mL/min/1.73 m2 in Group I, 71.00 [61.75–79.75] mL/min/1.73 m2 — in Group II (p=0.224).

All patients with essential hypertension were administered hypotensive therapy and achieved target blood pressure values. CHF medications were similar in both groups. Patients with CHFrEF were on quadruple therapy in maximum tolerated doses for at least 3 months before the surgical intervention: sacubitril/valsartan 200 mg/day, spironolactone 25 mg/day, bisoprolol 5 mg/day, dapagliflozin 10 mg/day. Differences were detected in the antiarrhythmic therapy: patients in Group used Class IC drug and beta-blockers more often, while amiodarone prevailed in Group II (Table 1).

The majority of patients from both groups had CHF FC II (NYHA) (p=0.717). The EHRA class reflecting the degree of AFib symptom severity was higher in Group I patients, but no significant differences between groups were observed (p=0.441) (Table 2).

Patients with preserved EF were predominant in both groups. In Group II, 5 (22.7 %) patients demonstrated reduced or moderately reduced LVEF, while in Group I, 3 (6.7 %) patients had moderately reduced EF. When comparing detected CHF phenotypes by EF, no statistically significant differences were established between groups (p=0.070). Groups were not statistically different in the parameters describing quality of life and 6-minute walking distance test, as well as points in H2FPEF and HFA-PEFF scales. NT-proBNP levels were significantly lower in Group I (151.00 ng/L, $p<0.001$). Among EchoCG parameters, Group II had significantly larger cardiac chamber sizes, including the anteroposterior left atrial size, left atrial volume index, right atrial and left ventricular sizes. LVEF was significantly lower in Group II (55.00 %, $p<0.001$). Thus, more severe CHF course was observed in Group II patients, which manifested with significantly elevated levels of the myocardial stress biomarker (NT-proBNP) and severe structural-hemodynamic deviations based on EchoCG data (Table 2).

Table 1. *Drug therapy before CBA*

Drug therapy n (%)	Group I (Paroxysmal AF) n=45	Group II (Persistent AF) n=22	p
Class I C antiarrhythmic drugs (propafenone, lappaconitine hydrobromide)	19 (42,2)	1 (4,8)	0,002*
Amiodarone	9 (20,0)	14 (63,6)	<0,001*
Sotalol	9 (20,0)	7 (31,8)	0,363
Beta-adrenergic blockers	27 (60,0)	7 (31,8)	0,030*
ACE inhibitors	22 (48,9)	10 (45,5)	0,792
Angiotensin II receptor antagonists	19 (42,2)	6 (27,3)	0,289
ARNI	1 (2,3)	3 (13,6)	0,100
SGLT-2	12 (26,7)	9 (40,9)	0,271
Mineralocorticoid receptor antagonists	18 (40,0)	10 (45,5)	0,793
Loop diuretics	1 (2,2)	0 (0,0)	1,000

Abbreviations: AAD — antiarrhythmic therapy, ACE — angiotensin-converting enzyme, ARNI — angiotensin receptor and neprilysin inhibitors, SGLT-2 — sodium-glucose cotransporter type 2 inhibitors

Table 2. *Data of patients with paroxysmal and persistent AF before CBA*

Indicator	Group I (Paroxysmal AF) n=45	Group II (Persistent AF) n=22	p
Men, %	35,6	68,2	0,012*
Age, years	67,00 [61,75; 72,00]	64,00 [61,00; 70,00]	0,505
NYHA FC CHF, n (%) Class I Class II Class III	 19 (48,2) 24 (53,3) 2 (4,4)	 8 (36,4) 12 (54,5) 2 (9,1)	0,717
Phenotype of CHF, n (%) CHFrEF CHFmrEF CHFpEF	 0 (0,0) 3 (6,7) 42 (93,3)	 2 (9,1) 3 (13,6) 17 (77,3)	0,070
MLHFQ, points	30,3 (±15,65)	23,52 (±13,81)	0,100
6MWT,	411,00 [377,00; 482,50]	424,00 [390,00; 500,75]	0,962
NT-proBNP, ng/l	151,00 [65,50; 249,00]	513,00 [355,25; 948,00]	<0,001*
EHRA класс, n (%) I IIa IIb III	 4 (8,9) 14 (31,1) 26 (57,8) 1 (2,2)	 1 (4,5) 11 (50,0) 10 (45,5) 0 (0,0)	0,441
LV EF , %	60,00 [57,00; 62,00]	55,00 [50,50; 58,00]	<0,001*
LA AP diameter, mm	40,00 [37,00; 43,00]	42,50 [40,25; 45,00]	0,018*
LAVI, ml/m²	35,00 [31,00; 43,00]	40,00 [37,5; 46,65]	0,023*
EDV, ml	87,00 [78,00; 109,00]	98,00 [89,25; 121,00]	0,008*
EDD, cm	4,5 [4,30 — 4,90]	4,91 [4,60 — 5,10]	0,033*
RV, mm	29,0 [26,0 — 31,0]	30,6 [29,0 — 31,0]	0,069
IVC, mm	17,0 [14,0; 19,0]	18,0 [15,0; 22,0]	0,187
TAPSE, cm	2,20 [2,00; 2,30]	2,00 [1,82; 2,20]	0,299
sPAP, mmHg	30,00 [25,00 — 34,00]	31,00 [25,00 — 38,00]	0,581
E/e’	9,50 ± 2,36 (8,67 — 10,32)	9,64 ± 2,79 (8,29 — 10,98)	0,847

Note: Data are presented as M ± SD or Me [Q1; Q3] depending on the type of distribution. * — $p < 0.05$ was considered statistically significant.
Abbreviations: AF — atrial fibrillation, NYHA FC CHF — functional class of chronic heart failure according to the New York Heart Association, EHRA — European Heart Rhythm Association Atrial Fibrillation Symptom Rating Scale, CHFrEF — heart failure with reduced ejection fraction, CHFmrEF — heart failure with moderately reduced ejection fraction, CHFpEF — heart failure with preserved ejection fraction, MLHFQ — Minnesota Living with Heart Failure Questionnaire , 6MWT -Six-minute walk test, NT-proBNP — N-terminal pro-brain natriuretic peptide , LV EF — left ventricular ejection fraction, LA AP diameter — Left atrial anteroposterior diameter, LAVI — Left atrial volume index, EDV — End-diastolic volume, EDD — End-diastolic diameter, RV — Right ventricular diameter, IVC — Inferior vena cava diamete, TAPSE — Tricuspid annular plane systolic excursion, sPAP — Systolic pulmonary artery pressure, E/e’ — the ratio of the transmitral E peak to the tissue myocardial Doppler e’.

Statistically significant differences were detected between groups in the antiarrhythmic therapy administered after the surgery: in Group II 16 (72.7 %) patients were administered amiodarone, 6 (27.3 %) — sotalol, while in Group I 17 (37.8 %) used propaphenone, 9 (20.0 %) — amiodarone, 9 (20.0 %) — sotalol, 6 (13.3 %) — metoprolol, 4 (8.9 %) — lappaconitine hydrobromide (Table 3).

Patients were re-examined 3 months after CBA. The intra-group follow-up analysis of parameters before and after the CBA intervention demonstrated the following significant changes: in Group I MLHFQ points decreased, which reflected the improvement in the patient's quality of life; the distance in the 6-minute walking test increased as well. Among EchoCG parameters, only the diameter of the inferior vena cava (IVC) decreased from 17.0 [14.0; 19.0] to 15.0 [13.0–17.5] mm (p=0.047). No changes were observed in LVEF — 60.0 [57.0; 62.0] and 59.0 [56.0–61.0] % (p=0.831); left atrial anteroposterior size (LAAPS) — 40.00 [37.0; 43.0] and 39.0 [36.0–42.0] mm (p=0.948); left atrial volume index (LAVI) — 35.00 [31.00–43.00] and 34.50 [27.0–38,8] mL/m^2 (p=0,274); RV 29.1 [26.0–31.0] and 29.0 [27.0–30.0] mm (p=0.460); SPAP — 30.16 [25.0–34.0] and 30.0 [26.5–33.5] mm Hg (p=0.557).

The following statistically significant changes were detected among Group II patients: increased distance during the 6-minute walking test, significantly decreased NT-proBNP levels (Table 4). When evaluating EchoCG parameters, the statistically significant LVEF increase was verified, along with the significant decrease in linear and volumetric parameters of the left atrium and right ventricle, SPAP, IVC diameter (Figure 1).

Table 3. *Antiarrhythmic therapy in patients with paroxysmal and persistent AF after CBA*

Drug therapy	Group I (Paroxysmal AF) n=45	Group II (Persistent AF) n=22	p
Amiodarone	9 (20,0 %)	16 (72,7 %)	p<0,001
Sotalol	9(20,0 %)	6 (27,3 %)	p=0,542
Metoprolol	6 (13,3 %)	0	p=0,167
Propaphenone	17 (37,8 %)	0	p<0,001
Lappaconitine hydrobromide	4 (8,9 %)	0	p=0,249

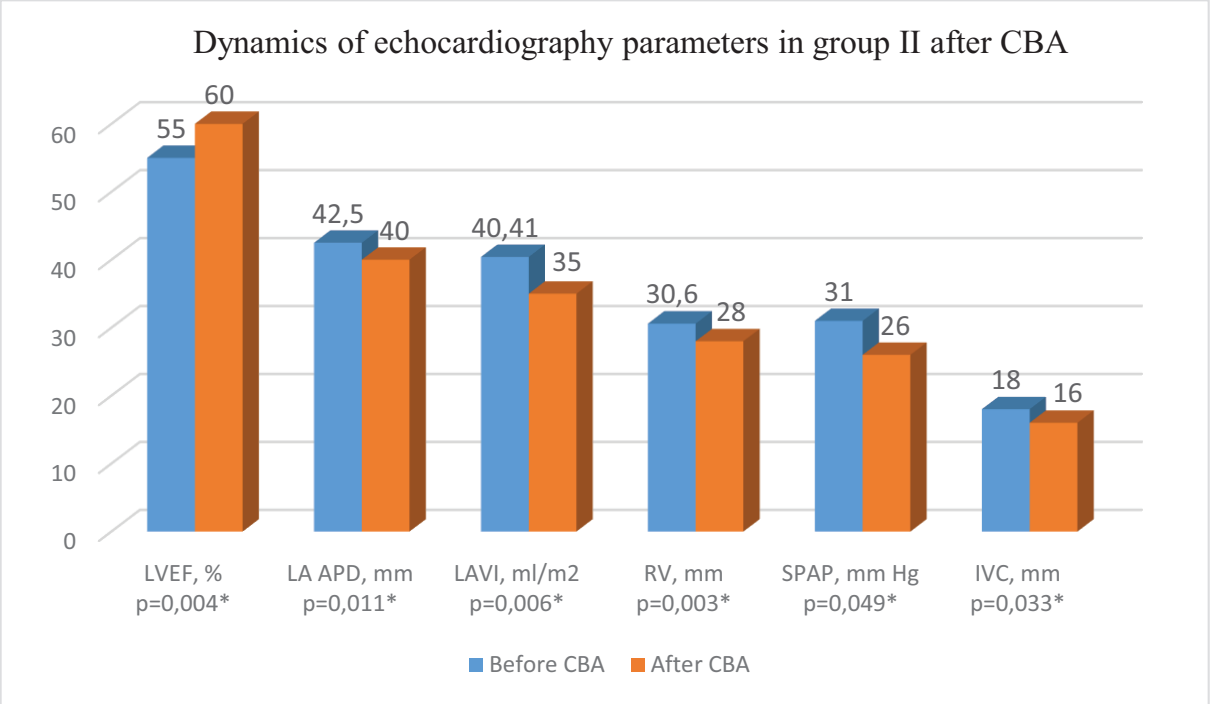

Figure 1. *Dynamics of echocardiography parameters in group II 3 months after CBA*

Abbreviations: LVEF — left ventricular ejection fraction, LA APD — left atrial anterior-posterior dimension, LAVI — left atrial volume index, RV — right ventricle, IVC — inferior vena cava, TAPSE — tricuspid annular systolic excursion, SPAP — pulmonary artery systolic pressure

Table 4. Data from patients with paroxysmal and persistent AF 3 months after CBA

	Group I			Group II		
Indicator	Before CBA	After CBA	p	Before CBA	After CBA	p
MLHFQ, points	30,3 (±15,65)	19,50 [6,25–41,0]	0,032*	23,52 (±13,81)	15,00 [6,50-23,00]	0,168
6MWT, meter	411,0 [377,0; 482,5]	455,0[420,0 –515,0]	<0,001*	424,00 [390,00; 500,75]	470,00 [410,00 — 551,50]	<0,001*
NT-proBNP, ng/l	151[65,5;249]	91,50 [46,30 — 219,75]	0,216	513,00 [355,25; 948,00]	153,00 [73,50 — 171,00]	<0,001*
EDV, ml	87,0 [78,0; 109,00]	85,00 [75,5–97]	0,122	98,00 [89,25; 121,00]	105,00 [94,00 — 120,00]	0,258
EDD, cm	4,64 (±0,41)	4,50 [4,3 — 4,9]	0,171	4,91 (±0,52)	4,80 [4,65 — 5,05]	0,529
TAPSE, cm	2,20 [2,0; 2,30]	2,11 ± 0,25 (2,03–2,19)	0,344	2,00 [1,82; 2,20]	2,19 ± 0,36 (2,01 — 2,37)	0,409
E/e’	9,50 ± 2,36	8,80 ± 2,48	0,078	9,64 ± 2,79	8,96 ± 3,44	0,358

Note: Data are presented as M ± SD or Me [Q1; Q3] depending on the type of distribution. * — p < 0.05 was considered statistically significant.
Abbreviations: MLHFQ — Minnesota Living with Heart Failure Questionnaire, 6MWT -Six-minute walk test, NT-proBNP — N-terminal pro-brain natriuretic peptide, LV EF — left ventricular ejection fraction, LA AP diameter — Left atrial anteroposterior diameter, LAVI — Left atrial volume index, EDV — End-diastolic volume, EDD — End-diastolic diameter, TAPSE — Tricuspid annular plane systolic excursion, E/e’ — the ratio of the transmitral E peak to the tissue myocardial Doppler e’

AFib paroxysms were observed in 6 (13.3 %) patients in Group I and 1 (4.5 %) patients in Group 2 (p=0.412) within the first 90 days during the blinded period after the CBA. Based on the 24-hour ECG monitoring, 3 months later AFib paroxysms were reported in 4 (8.9 %) patients only in Group I; accounting for a small number of patients with relapsing AFib, no statistically significant differences were confirmed between groups (p=0.294).

Thus, increased exercise tolerance was reported both in the paroxysmal and persistent AFib groups 3 months after the catheter cryo-balloon ablation. The quality of life gradually significantly improved in patients with paroxysmal AFib. Patients with persistent AFib had significantly decreased NT-proBNP and improved structural-hemodynamic EchoCG parameters: decreased linear and volumetric parameters of the left atrium and right ventricle, systolic pulmonary artery pressure, inferior vena cava, with the increasing left ventricular ejection fraction, thus reflecting the improved CHF course.

Concerning adverse events in the early post-CBA period, transient phrenic nerve paralysis was reported in 1 patient from Group I (2.9 %), non-fatal ACVA developed 36 days after the surgery in 1 patient from Group I (2.9 %), with further complete compensation of neurological deficit. A post-puncture hematoma not requiring additional interventions was observed in 1 patient from Group I (2.9 %).

Discussion

Catheter ablation (CA) as a rhythm control strategy significantly improves survival, decreases the rate of repeated hospitalizations, promotes the sinus rhythm maintenance, preserved cardiac function, and improves the quality of life in patients with AFib and CHF [11]. Optimal CA strategy for patients with persistent atrial fibrillation (persAFib) and heart failure (HF) remains unclear. In the CRYO4PERSISTENT AF study [12] enrolling 101 patients with persistent AFib without CHF after the cryo-balloon ablation, the quality of life improved: mean standardized SF-36 Physical Health parameter improved by 7.1 points (from 46.9 to 53.9 points; p<0.0001), while the Psychic Health parameter improved by 3.3 points (from 47.3 to 50.6 points; p=0.008). In our study the quality of life improvement was demonstrated in patients with paroxysmal AFib, while no significant changes were detected in patients with persistent AFib.

CA benefits in patients with AFib and CHF were demonstrated by S.A. Virk et al. [13]: the meta-analysis of 6 RCTs compared the results of CA and drug therapy in 772 AFib patients with the mean LVEF parameter 30±9 % and a predominantly persistent AFib. CA vs. drug therapy was accompanied by a larger improvement in LVEF (mean difference in absolute parameter increment between groups 5.67 %; p<0.001), larger mortality decrease by 48 % (p=0.001), increased distance in the 6-minute walking test (MD 25.12 m; 95 % CI, 0.59–49.65; p=0.04), and an improved quality of life with a larger MLHFQ score decrease (MD 9.03; 95 % CI, 2.48–15.59; p=0.007). In our study patients with persistent AFib after CBA also demonstrated improved LVEF, improved exercise tolerance, although no significant quality of life improvement was confirmed.

In the RAFT-AF trial [14], 411 patients with CHF with preserved or reduced EF, with over 90 % patients suffering from persistent AFib, were distributed into the ablation-based rhythm control group (n=214) and the rate control group (n=197). LVEF increased in the ablation group by 10.1±1.2 % vs. 3.8±1.2 %, p=0.017; the distance in the 6-minute walking test increased by 44.9±9.1 m vs. 27.5±9.7 m, p=0.025; meanwhile,

NT-proBNP levels decreased by 77.1 % vs. 39.2 %, p<0.0001. The MLHFQ questionnaire demonstrated a more significant improvement in the quality of life in the ablation-based rhythm control group (p=0.0036). Data from our study also demonstrate positive changes of LVEF, cardiac cavity remodeling, NT-proBNP levels, distance in the 6-minute walking test in patients with persistent AFib after CBA.

The trial of A. Pott [15] that enrolled 414 patients with AFib after the primary cryo-balloon ablation, with 137 (33 %) diagnosed with persistent atrial fibrillation, 113 (27.3 %) had CHFrEF (mean LVEF 38.4±10.8 %), while 301 (72.7 %) had preserved left ventricular ejection fraction; LVEF increased from 38.4±10.8 % to 52.5±17.2 % (p<0.001), symptoms associated with HF regressed, and NYHA FC of CHF decreased within the first 12 months after CBA, while the hospitalization rate decreased. In our study the group of patients with persistent AFib had more patients with LVEF <50 % than in the paroxysmal AFib group, and the former one demonstrated significantly increased ejection fraction with the improvement of the functional patient status.

Conclusion

The presented study demonstrates that patients with persistent atrial fibrillation and a more significant pathological myocardial remodeling along with the high myocardial stress level marker at baseline had significantly positive changes in parameters characterizing chronic heart failure 3 months after the catheter cryo-balloon ablation: improved functional status, increased exercise tolerance, decreased left atrial and right ventricular sizes, SPAP, increased left ventricular ejection fraction, decreased NT-proBNP levels. CBA promoted increased exercise tolerance and improved quality of life in patients with paroxysmal atrial fibrillation.

It is scheduled to continue patient follow-up and evaluate the parameters analyzed 12 months after the surgery, which can provide the assessment of long-term alterations in the heart failure course.

Limitations of this study include a small sample size and a short follow-up period (3 months).

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