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COMPARISON OF THE EFFICACY AND SAFETY OF PULMONARY VEIN CRYOBALLOON ABLATION ALONE AND WITH ADDITIONAL ISOLATION OF THE SUPERIOR VENA CAVA IN PATIENTS WITH PERSISTENT ATRIAL FIBRILLATION

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Aim. To study the impact and safety of cryoballoon ablation of the pulmonary vein (PV), supplemented by isolation of the superior vena cava in patients with persistent atrial fibrillation (AF).

Methods. The study is single-center, randomized, prospective. The total number of patients was 40. All of them underwent cryoballoon isolation of the PV for persistent AF. The patients were then divided into two groups: the first group included patients who underwent the standard procedure, and the second group included patients with the standard procedure supplemented by isolation of the superior vena cava. Patients in both groups had similar anatomical and clinical-anamnestic parameters. The duration of the surgical intervention was not statistically different.

Results. The average follow-up period was 354±19 days. In the group of classical cryoballoon PV isolation, after 12 months of observation without antiarrhythmic therapy, sinus rhythm was maintained in 40% of patients (8 people), in the group of extended cryoballoon PV isolation - in the same number of patients (40%, P=1). In the PV isolation group, persistent phrenic nerve palsy was observed in no patients, and in the extended ablation group, in eight patients (40%, P= 0.0016). At the end of the observation, no remote complications were registered.

Conclusions. In patients with persistent AF, cryoballoon PV isolation supplemented by superior vena cava isolation is a less safe technique than standard cryoballoon pulmonary vein isolation, with comparable efficacy.

Key words: persistent atrial fibrillation; superior vena cava; cryoballoon ablation; safety; pulmonary vein

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Atrial fibrillation (AF) is of particular interest in real clinical practice. The high prevalence of this arrhythmia, the severity of its symptoms, and the low effectiveness of drug treatment currently make interventional treatment of AF the top priority [1, 2]. The standard treatment for this arrhythmia is pulmonary vein isolation (PVI) [3]. Modern research results show similar effectiveness of two main technologies used for this purpose: radiofrequency ablation using contact force-sensing catheters and cryoballoon ablation with second- and third-generation balloon catheters [4, 5]. The effectiveness of interventional treatment for paroxysmal AF is reported to be 70-80% according to various authors and methods, while in the case of persistent AF, the effectiveness of interventions sharply decreases, with a wide range of results depending on the tools used, the criteria, and the methods of post-operative monitoring [6, 7].

One of the reasons for the failure of treatment in patients with persistent AF is the presence of non-pulmonary foci of arrhythmia, which can be localized in the posterior wall of the left atrium (PWLA), autonomic ganglionic plexuses, the border ridge, the Marshall ligament, the coronary sinus, and the superior vena cava (SVC), and participate in the arrhythmogenesis process, despite the previously achieved isolation of the pulmonary veins [8, 9].

Studies have shown that the SVC can act both as a trigger for AF and as a substrate supporting the fibrillation process [10]. Given the common origins of sinoatrial node cells and cardiomyocytes in the upper and lower parts of the vena cava, these areas may exhibit automaticity and participate in arrhythmogenic activity [11].

During embryogenesis, on the 7th-8th week, the right common cardiac vein, along with the right horn of the venous sinus, begins the formation of the superior vena cava. As development progresses, the openings of the SVC, inferior vena cava, and coronary sinus are formed. The venous sinus and part of the right horn also participate in the formation of the sinoatrial node. According to subsequent histological studies, on the 8th week, thickening is found in the intrapericardial sections of the SVC and inferior vena cava, represented by muscle-like cells that may serve as myocardial sphincters for the vena cava [12].

In the adult population, muscle-like cells are also found at the junction of the SVC and the right atrium

(RA), represented by the expansion of the atrial myocardium (myocardial sleeves) at the SVC opening, with sizes up to 14 mm, the maximum size of the "sleeves" reaching 47 mm. However, based on the conducted study, the relationship between the anatomical features of myocardial sleeves and the presence of AF in patients has not been proven [13]. Based on the above data, it can be assumed that isolating the SVC could increase the effectiveness of the intervention by eliminating non-pulmonary foci involved in the initiation and maintenance of AF.

There are three main approaches to isolating the SVC: 1) when an ectopic focus is proven in this localization using isoproterenol; 2) using electrophysiological studies to prove the earliest activation in this area or the shortest tachycardia cycle; 3) empirically, when there is confirmed complete isolation of the pulmonary veins [14].

The aim of our study was to assess the results of the effectiveness and safety of cryoballoon ablation of the pulmonary veins supplemented by isolation of the superior vena cava, compared with the standard pulmonary vein isolation procedure in patients with persistent atrial fibrillation.

METHODS

A randomized, prospective, single-center study included 40 patients with persistent AF aged 64.3±6.5 years, treated at the Department of Surgical Treatment of Complex Heart Rhythm Disorders and Cardiac Pacing at the Research Institute for Complex Issues of Cardiovascular Diseases from July 2022 to July 2023. The study was approved by the local ethics committee and conducted in accordance with the Helsinki Declaration. The 2020 ACC/AHA/ESC classification for AF was used during the study [3].

Inclusion criteria:

- At least two 12-lead electrocardiogram (ECG) recordings documenting AF.
- Results of 24-hour rhythm monitoring showing AF during the entire observation period.
- Objective medical documentation confirming the presence of persistent AF (initial examinations, discharge summaries).
- The patient showed clinical manifestations of arrhythmia and ineffectiveness of one or more antiarrhythmic drugs of class I or III in the history.
- All patients of both sexes over the age of 18 who provided written informed consent to participate in the study.

Exclusion criteria:

- Previous PVI.
- Ischemic heart disease with untreated hemodynamically significant coronary artery stenosis.
- Valvular disease requiring surgical treatment.
- Chronic heart failure of NYHA functional class IV.
- Previous cardiac surgery.
- Refusal to participate in the study or continuation of participation.
- Presence of a thrombus in the left atrial appendage.
- Left atrial anterior-posterior size >55 mm.
- Left ventricular ejection fraction <35% according to Simpson's method.
- Any other condition that would prevent surgery (e.g., thyroid diseases, musculoskeletal trauma, decompensated pulmonary diseases, etc.).
- Maximum diameter of one of the pulmonary veins >26 mm based on multidetector computed tomography (MDCT) of the heart or venous system developmental anomalies.

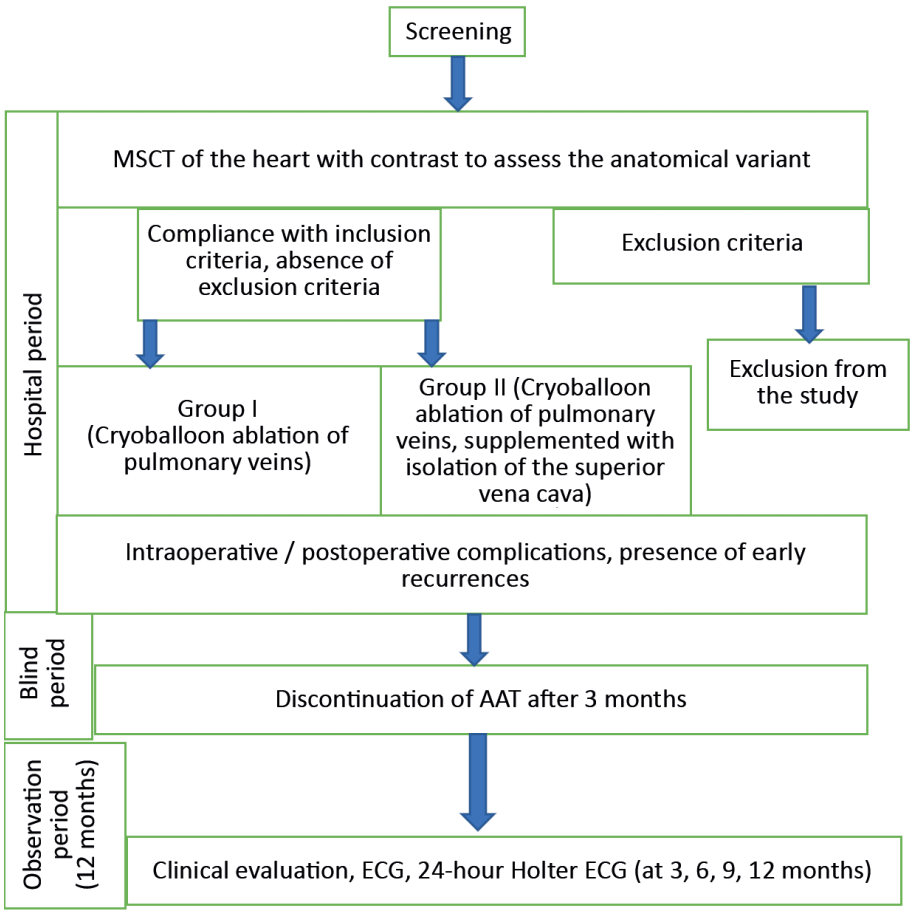

Fig. 1. Study Design.

The study included 40 patients, who were randomly divided into two groups: Group I (n=20) underwent cryoballoon PVI, and Group II (n=20) underwent cryoballoon pulmonary vein isolation supplemented with superior vena cava isolation. Randomization was performed using a random number generator in Excel (Microsoft, USA) with a 1:1 allocation. After cryoablation, all patients continued antiarrhythmic therapy for 3 months according to the current clinical guidelines. Class IC drugs were used for patients without structural heart disease, heart failure, or ischemic heart disease. For preventing AF recurrence in patients with ischemic heart disease but without structural damage, sotalol was prescribed. Amiodarone was

recommended for patients with structural heart damage, significant hypertrophy, heart failure, or ischemic heart disease. The observation period was 12 months, with follow-up visits at 3, 6, and 12 months after the catheter procedure. The procedure's efficacy was evaluated based on 12-lead ECG results and 24-hour ECG monitoring during in-person visits. Additional ECG recordings provided by patients, documenting the onset of arrhythmia symptoms, were also assessed. After the "blind period," at the first in-person visit, all patients discontinued antiarrhythmic therapy. A recurrence was defined as any documented episode of AF lasting more than 30 seconds. The study design is presented in Figure 1.

The average duration of AF history was 3.4±1.4 years. All patients were prescribed optimal antiarrhythmic and anticoagulant therapy with new oral anticoagulants during the outpatient stage. In the presented cohort of patients, 45% (18 patients) had ischemic heart disease, 100% (40 patients) had hypertension, and 40% (16 patients) had a history of acute cerebrovascular accidents or transient ischemic attacks.

All patients underwent a full preoperative protocol in accordance with the institution's internal orders, which included coronary angiography, transthoracic and transesophageal echocardiography on GE Vivid 7 Dimension and Philips iE33 equipment. If transesophageal echocardiography was not possible, cardiac and thoracic multislice CT with contrast enhancement was performed. Clinical-demographic characteristics of the patients are presented in Table 1.

Cryoballoon ablation was performed under local infiltrative anesthesia with a 5% levobupivacaine solution at the surgical access stage. Additional anesthesia during the ablation was achieved with intravenous infusion of fentanyl (5 μg/kg). Prior to starting the surgical procedure, all patients had an invasive arterial pressure monitoring system installed using radial access. Then, using the Seldinger method, both femoral veins were catheterized, and intracardiac catheters were placed: the right ventricle was accessed with the Polaris X catheter (Boston Scientific, USA), the right atrium with the Preface Multipurpose introducer (Biosense Webster, USA-Israel) with a Brockenbrough needle (Medtronic, USA), and the intracardiac ultrasound sensor AcuNav (Siemens, Germany) was also used. Heparinization was performed to achieve an activated clotting time of 300 seconds or more before performing the transseptal puncture.

The transseptal access was performed under intracardiac echocardiographic guidance. After the transseptal puncture, a guided FlexCath Advance (Medtronic, USA) was inserted into the left atrium via a guidewire, through which the cryoablation catheter ArcticFront Advance 28 mm (Medtronic, USA) was inserted. A diagnostic catheter Achieve (Medtronic, USA) was introduced through its lumen. To monitor electrophysiological parameters, the Biotoc Unity electrophysiological system (Biotoc, Russia) was used. Left vein occlusion by the balloon was confirmed by injecting the contrast agent Omnipaque (GE Healthcare, Ireland) into the lumen of the left vein distal to the balloon and with intracardiac ultrasound. Then, cryoablation was performed.

One application was performed for each left PV for 240 seconds, with temperatures ranging from -35°C to -60°C inclusive [15-18]. The isolation of the pulmonary veins was confirmed by the disappearance of electrical activity in the PV with the diagnostic Achieve catheter and the presence of bidirectional conduction block. If residual electrical activity was observed, additional ablation was performed with the same parameters. After isolating the left upper and left lower pulmonary veins, the Polaris X catheter was repositioned on the lateral wall of the superior vena cava to achieve stimulation of the phrenic nerve. With continuous stimulation, the right pulmonary veins were isolated using the previously described parameters. The ablation procedure was stopped when effective phrenic nerve stimulation episodes ceased or when the muscle response amplitude to stimulation decreased.

In the group of patients with additional intervention in the superior vena cava after achieving the criteria for isolation of the pulmonary veins, the FlexCath Advance delivery system was positioned in the right atrium. Electrically active areas at the mouth of the superior vena cava were diagnosed using the Achieve catheter. To achieve contact of the catheter with the walls of the superior vena cava, the FlexCath Advance was used, adjusting the angle of the distal tip to achieve the maximum expressed amplitude of the endogram of the superior vena cava on the diagnostic electrode. Under angiographic control, using the Achieve catheter as a guide, the cryoballoon was positioned at the mouth of the superior vena cava (Fig. 2).

After balloon inflation, complete occlusion was confirmed by injecting contrast medium, after which continuous stimulation of the phrenic nerve was performed with distal pairs of the diagnostic electrode, with an amplitude of

Table 1.

Clinical and demographic characteristics of patients

Indicators	All patients (n=40)	CBI PV (n=20)	CBI PV + SVC (n=20)	P
Age, years	67.8±6.5	67.7±3.9	68.1±3.7	0.364
Gender, male, n (%)	18 (45%)	8 (40%)	10 (50%)	0.525
Duration of AF, months	8.7±1.2	8.5±2.1	8.8±1.7	0.271
History of AIS, n (%)	16 (40%)	10 (50%)	6 (30%)	0.197
LVEF (Simpson Biplane), %	50.8±5.1	50.4±5.4	51.1±4.7	0.403
Anteroposterior size of LA, mm	45±4	44±5	45±4	0.737
CHA_2DS_2-VASc, points	2.7±1.5	3±1.2	2.5±2	0.607
HASBLED, points	2.6±1.6	2.8±1.7	2.5±1.8	0.445

Note: here and below, CBI - cryoballoon isolation; PV - pulmonary veins; SVC - superior vena cava; AIS - acute ischemic stroke; LVEF - left ventricular ejection fraction; LA - left atrium.

16 V and a stimulation frequency of 50 pulses per minute. The next stage involved cryoablation for 180 seconds with temperature parameters ranging from -25°C to -40°C [15-18]. If there were changes in the phrenic nerve response to stimulation, the cryoablation procedure was stopped. The criterion for SVC isolation was the disappearance of electrical activity on the diagnostic Achieve electrode (Fig. 3, 4), followed by confirmation of exit block. The entry block in real-time was achieved in 65% (14) of patients. The exit block was confirmed in 80% (16) of patients after cessation of the procedure, with stimulation from the Achieve and Polaris X catheters. All patients underwent transthoracic echocardiography before catheter removal to monitor the pericardial leaflets. In cases of persistent AF, ECG-synchronized cardioversion was performed.

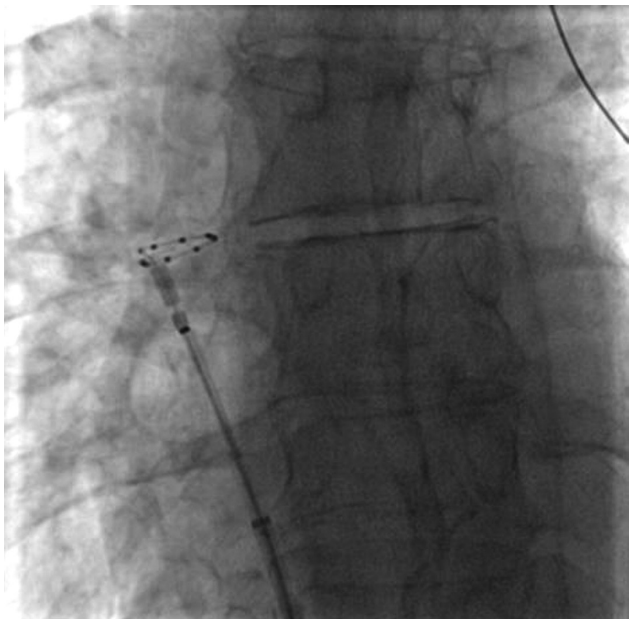

Fig. 2. Moment of cryoballoon inflation at the superior vena cava ostium.

Statistical analysis

Statistical data processing was performed using Statistica 12.0 (StatSoft, USA) and included descriptive statistics in the form of mean values of quantitative indicators, standard deviations, and absolute and percentage values of qualitative indicators. The normality of distribution was assessed through visual analysis of histograms and the Shapiro-Wilk test. To assess differences between groups, Student's t-test and χ^2 tests were used. Differences were considered statistically significant at a level of $p < 0.05$.

RESULTS

In the group of patients with classical PVI, one patient experienced a decrease in the amplitude of the diaphragmatic nerve response during cryoablation of the right inferior PV at the 90-second mark. After the procedure was stopped and a two-minute waiting period, the amplitude restored, the balloon was repositioned more anteriorly while maintaining the occlusion criteria, and a second 240-second ablation was performed. At the end of the procedure, isolation of all PVs was achieved, diaphragmatic nerve stimulation remained, and no radiological changes in the diaphragm dome position were noted.

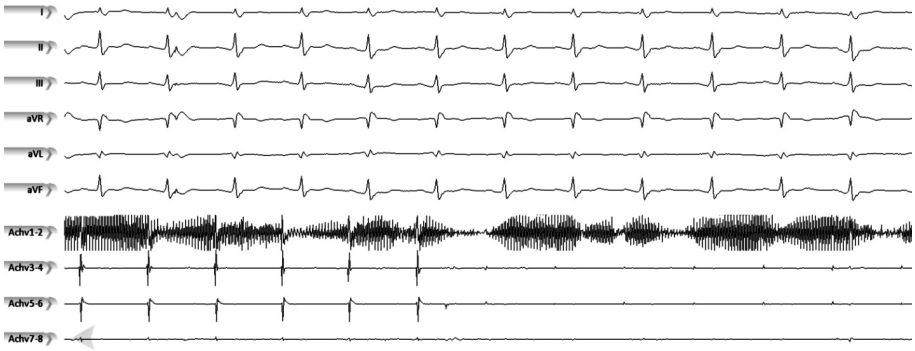

Fig. 3. Ablation during sinus rhythm. Onset of superior vena cava isolation - elimination of the muscle sleeve potentials at the superior vena cava, after which only low-amplitude atrial farfield potentials are recorded on the Achieve catheter.

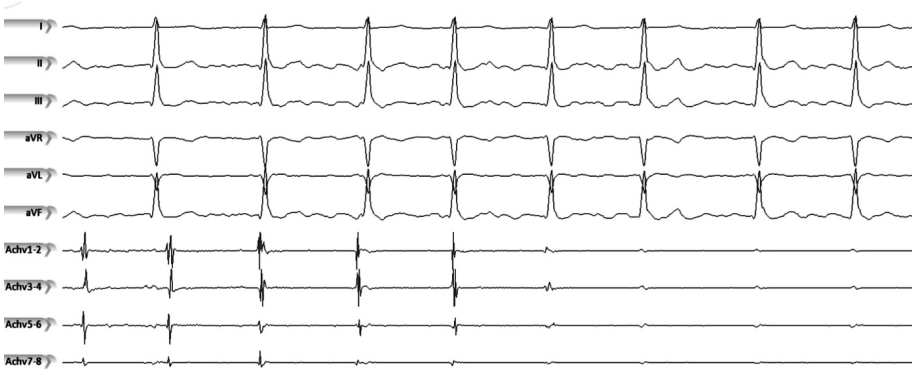

Fig. 4. Ablation during atrial fibrillation with already achieved superior vena cava isolation. Elimination of ectopic activity at the superior vena cava on the Achieve diagnostic catheter.

In the group of patients with extended PVI, during cryoablation in SVC, diaphragmatic nerve paresis symptoms were observed in 12 patients (60%), with the average time from the start of ablation being 65 ± 8 seconds. Further diaphragmatic nerve stimulation was ineffective in 10 (50%) patients. Radiography performed 25 hours after the ablation procedure showed no movement of the right diaphragm dome in 8 (40%) patients. During the hospital phase, 4 (20%) of them showed recovery of the diaphragmatic nerve function according to chest radiography, accompanied by complete regression of symptoms. Two patients were discharged without recovery of diaphragmatic nerve paresis in stable condition for dynamic monitoring. At the follow-up examination three months later, diaphragmatic nerve paresis regression was observed in one patient. In one patient, symptomatic diaphragmatic nerve paresis persisted for 6 months, after which it also regressed.

Thus, in the PVI group, no patient had sustained diaphragmatic nerve paresis, whereas in the extended ablation group, 8 (40%, P = 0.0016) patients had symptomatic paresis, leading to the early termination of the study. No cases of sinus node injury were recorded in either group. PV isolation was achieved in 100% of patients in both groups by the end of the procedure. Isolation of the SVC was achieved in 80% of cases (16 patients). The mean cryoablation time until the disappearance of electrical activity in the SVC was 44 ± 8 seconds. Intra-procedural efficacy and safety parameters are presented in Table 2.

The mean follow-up period was 354 ± 19 days. In the classical cryoballoon PV isolation group, after 12 months of observation without antiarrhythmic therapy, sinus rhythm was maintained in 40% of patients (8 people), and in the extended cryoballoon PV isolation group, sinus rhythm was maintained in the same proportion of patients (40%, P = 1). No long-term complications were registered at the end of the observation period.

DISCUSSION

The method of performing superior vena cava (SVC) isolation remains an open question. The use of second-generation cryoballoons allows for more uniform damage to the myocardial sleeves of the SVC with a lower probability of perforating the walls of the right atrium at the junction area, thanks to the larger area of simultaneous impact. In a study conducted by W. Hui-Qiang et al. (2020) involving 26 patients with paroxysmal AF associated with the SVC, isolation was achieved in 80% of cases using a second-generation cryoballoon. Transient diaphragmatic nerve damage was observed in 19.2% of cases, and sinus node injury occurred in 7.7% of cases [19]. Possible reasons for the differences in complication rates during the procedure compared to the global literature may be the anatomical features of the spatial arrangement of diaphragmatic nerve fibers and sinus node cells.

It should be noted that there are significant limitations to the aforementioned technology. To achieve SVC isolation, its occlusion is required, accompanied by pronounced symptoms of obstruction. To achieve circulatory transmural impact, the area of the diaphragmatic nerve is subjected to permanent contact, which is why its damage rate remains extremely high even in highly specialized centers. Moreover, continuous monitoring of the sinus node is required, as it is also localized near the impact zone. Radiofrequency energy allows for more precise interventions and helps avoid diaphragmatic nerve damage using stimulation mapping and its subsequent visualization on a three-dimensional model. Meanwhile, contact force-sensing catheters allow for stable, controlled contact with the tissue. The use of navigation systems offers the possibility of mapping the sinus node, as well as the morphological and electrophysiological assessment of myocardial sleeves' distribution in the SVC.

The C-shaped method of SVC isolation stands out, with the advantage of a smaller area of impact required to achieve isolation, as well as a reduced risk of complications such as stenosis of the SVC and damage to nearby structures [20]. A limitation of these methods is the documented cases of sinus branch damage to the right coronary artery during the use of radiofrequency energy [21].

Table 2.

Intraprocedural measures of efficacy and safety

Indicators	All patients (n=40)	CBI PV (n=20)	CBI PV + SVC (n=20)	P
Procedure duration, min	85±12	80±10	90±15	0.081
Fluoroscopy time, min	19±4	17±3	21±4	0.078
Absorbed dose, mGy	163±25	160±28	166±23	0.090
Confirmed isolation of SVC, n (%)	-	-	16 (80%)	-
All complications, n (%)	16 (40%)	2 (10%)	14 (70%)	0.0001
Phrenic nerve palsy, n (%)	12 (30%)	0 (0%)	12 (60%)	<0.0001
Sustained phrenic nerve palsy, n (%)	8 (20%)	0 (0%)	8 (40%)	0.0016
Hematomas at puncture site, n (%)	4 (10%)	2 (10%)	2 (10%)	1
Achieved activated clotting time, s	315±21	317±19	314±22	0.674
No. of cryoapplications in LSPV	1.25±0.1	1.2±0.1	1.3±0.1	0.608
No. of cryoapplications in LIPV	1.1±0.1	1.1±0.1	1.1±0.1	1
No. of cryoapplications in RSPV	1.1±0.1	1.1±0.1	1.1±0.1	1
No. of cryoapplications in RIPV	1.2±0.1	1.3±0.1	1.2±0.1	0.608
No. of cryoapplications in SVC	1.1±0.1	-	1.1±0.1	-
AD of cryoapplications in LSPV, s	260±15	250±10	270±15	0.334
AD of cryoapplications in LIPV, s	265±13	266±14	257±15	0.457
AD of cryoapplications in RSPV, s	251±10	252±11	250±10	0.898
AD of cryoapplications in RIPV, s	270±20	273±20	265±15	0.566
AD of cryoapplications in SVC, s	65±6	-	65±6	-

Note: AD - average duration.

According to the literature, the incidence of diaphragmatic nerve injury during SVC isolation using cryotechnology or radiofrequency energy is 2.1-9.2%. These rates are lower than those obtained in our study. However, it is worth noting that in a significant number of studies conducted by our colleagues, only permanent diaphragmatic nerve damage is considered. Transient diaphragmatic nerve damage, most often without pronounced symptoms of respiratory insufficiency, is not included in complications and is not considered in statistical data. Also, in comparison to literature data, the symptoms of transient diaphragmatic nerve damage are notable [19, 22].

An alternative method of SVC isolation may be the use of the rapidly developing pulse field technology, which is currently actively applied in PVI procedures. The main advantage of this method is selective tissue impact, which reduces the risks of damage to surrounding structures. High efficacy in using this method was noted in the study by P. Ollitrault et al. (2024) [23]. In their study, the procedure of PV isolation, supplemented by SVC isolation using pulse field energy, was performed in 105 patients. It was noted that in 80% of cases, the myocardial sleeves of the SVC exhibited electrical activity. SVC isolation was achieved in 100% of cases, and no permanent damage to the diaphragmatic nerve or sinus node was observed during the study.

The question of the impact of SVC isolation on the effectiveness of AF procedures remains open. A limiting factor of our study is the small number of observations. However, first, we were unable to recruit more patients because the safety indicators in the extended cryoablation group were so low that it forced us to terminate the study early. Secondly, despite this, a statistically significant difference was obtained even with such a small sample. Thus, currently, the routine performance of SVC isolation using cryoballoons carries extremely high risks of complications without a positive impact on procedure efficacy and should only be performed in patients with proven ectopic foci in this location. Using alternative methods of impact and careful monitoring of safety parameters would be more advisable.

CONCLUSION

In patients with persistent atrial fibrillation, cryoballoon pulmonary vein isolation supplemented by superior vena cava isolation is a less safe technique compared to standard cryoballoon pulmonary vein isolation, with the frequency of intraoperative complications in the extended ablation group reaching 40% (p=0.0016). No statistically significant differences in the procedural efficacy indicators were observed.

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