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Potential risk factors of atrial fibrillation recurrence after cryoballoon ablation

Aim	To identify risk factors for recurrence of atrial fibrillation (AF) following cryoballoon ablation (CBA).
Material and methods	This prospective study included patients with paroxysmal AF who had undergone CBA (141 patients, median age 60 years, 3% men). The evaluation prior to CBA included clinical instrumental parameters (electrocardiography (ECG), 24-h ECG monitoring, echocardiography, contrast-enhanced cardiac multispiral computed tomography). Also, possible intraoperative indexes that could affect the CBA effectivity, were evaluated. The postoperative follow-up duration was 12 months. Effectivity was assessed during in-person visits at 3, 6, and 12 months, when questioning of patients and 24-h ECG monitoring were performed. CBA was considered ineffective if the patient had recurrences of any atrial tachyarrhythmia longer than 30 sec after the end of the 3-month "blind" period.
Results	During the 12-month follow-up, recurrences of atrial tachyarrhythmia were observed in 46 (32.6%) patients. Patients with ineffective CBA more frequently had AF during the first 3 months (71.7% vs. 11.6%; p<0.001). Such patients had a history of multiple ineffective treatments with antiarrhythmic drugs (AAD), common pulmonary venous (PV) collector (41.3% vs. 20.0%; p=0.008), and stroke/recurrent ischemic attacks (15.2% vs. 5.2%; p=0.047). Multifactorial regression analysis showed that the factors of AF recurrence included common PV collector (relative risk (RR) 2.35; 95% confidence interval (CI) 1.29–4.25; p=0.005), multiple ineffective AADs (RR 1.42; 95% CI 1.08–1.86; p=0.011), and early AF recurrence (RR 7.57; 95% CI 3.84–14.90; p<0.001).
Conclusion	Common PV collector and multiple ineffective AADs are risk factors of ineffective CBA. Early recurrences during the first 3 postoperative months are a significant risk factor of long-term AF recurrences.

Keywords	Atrial fibrillation; cryoballoon ablation; risk factors; early recurrence; common pulmonary venous collector; antiarrhythmic drugs
For citations	Novikov I.A., Novikov P.S., Mironov N.U., Laiovich L.Yu., Malkina T.A., Shariya M.A. et al. Potential risk factors of atrial fibrillation recurrence after cryoballoon ablation. Kardiologiia. 2022;62(6):23–29. [Russian: Новиков И.А., Новиков П.С., Миронов Н.Ю., Лайович Л.Ю., Малкина Т.А., Шария М.А. и др. Потенциальные факторы риска рецидива фибрилляции предсердий после катетерной баллонной криоабляции. Кардиология. 2022;62(6):23–29]

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There is increasing evidence of the benefits of choosing early rhythm control strategy for atrial fibrillation (AF). This approach significantly reduced the risk of adverse cardiovascular events or hospitalization compared to heart rate control strategy [1]. In the current clinical guidelines, rhythm control strategy in patients with paroxysmal AF include administering antiarrhythmic drugs (AADs) or performing catheter ablation with pulmonary vein isolation [2, 3]. Highly effective AADs are now available that allow restoring normal sinus rhythm in patients with persistent and long-long-standing persistent AF [4, 5]. However, drugs used for the prevention of recurrences are significantly inferior to catheter procedures. The results of a recent large trial show that, in patients, to whom AADs were first prescribed or cryoballoon ablation (CBA) was performed, the later was significantly more effective: 57.1% versus 32.2% of all AF recurrences and 89% versus 74% of symptomatic recurrences of AF with a comparable number of adverse events. Thus, CBA can be seen as a preferred treatment for AF [6]. At the same time, numerous clinical trials show that many patients have early and late recurrences of AF after CBA [7, 8]. The objective of our study in this regard was to identify risk factors (RFs) for recurrent AF after CBA

Material and methods

A single-site prospective study included 153 patients, 12 of whom were lost to follow-up (unable to personally visit the site). Inclusion criteria were: age over 18 years; symptomatic paroxysmal AF [2]. All patients were subjected to primary CBA.

Exclusion criteria were contraindications to interventions, untreated thyroid dysfunction, mitral heart disease.

All patients underwent various clinical examinations, including the evaluation of clinical and demographic

indicators, such as sex, age, co-morbidities, a number of previously administered ineffective AADs, the duration of the history of AF, the maximum duration of paroxysms. All patients underwent total blood count and biochemical blood tests, thyroid hormone analysis, 12 lead electrocardiography, 24-hour electrocardiogram (ECG) monitoring, echocardiography, contrast computed tomography (CT) (MSCT) of the heart to assess the anatomy of PV and the left atrial (LA) dimensions. The criterion of AADs inefficacy were AF recurrence during the administration of a minimum effective dose of class I and III AAD.

The study was designed following the Declaration of Helsinki and was approved by the local ethics committee. All patients signed the informed consent before being included in the study.

CBA protocol

CBA was performed using general endotracheal anesthesia. Venous access was performed through the right femoral vein. Decapolar catheter (EP-XT, Boston Scientific, MN, USA) was placed in contact with the

endocardium. Puncture of the interatrial septum (guided by transesophageal echocardiogram) was performed after LA thrombosis exclusion. Heparin was administered intravenously at the dose of 100 U/kg. Activated clotting time was subsequently maintained within 300–350 ms during ablation. A steerable sheath FlexCathAdvance (Medtronic, USA) and a 28 mm balloon catheter Arctic Front Advance (Medtronic, USA) were then placed into the LA cavity using the guidewire. A 20 mm circular catheter Achieve (Medtronic, USA) was used to evaluate PV isolation. For each PV, at least one 240 seconds application was employed. If PV was not isolated, one 180 seconds application was repeated. Right veins were ablated during the continuous stimulation of the phrenic nerve (15 mA) using an endocardial electrode catheter in the superior vena cava When signs of phrenic nerve paresis appeared (diaphragm movement became weak or stopped), cryoablation was immediately discontinued.

PV isolation was confirmed by the presence of a so-called pulse input/output module at the end of the 20 minutes waiting period after the last application. If patient with AF presented also with typical atrial flutter, radiofrequency ablation (RFA) of the cavotricuspid isthmus (CTI) was also performed. Direct oral anticoagulants resumed 3 hours after the end of ablation.

All patients underwent complete blood count test, duplex scan of the puncture site, 12-lead electrocardiography, and Holter ECG monitoring the next day after ablation.

AAD therapy was restarted after ablation, which was previously prescribed for a period of up to 3 months (blind period) followed by withdrawal. Anticoagulants was administered for at least 2 months. After this period, the decision to continue Anticoagulants was made taking into consideration the risk of adverse thromboembolic events based on the CHADS2 VASc score [2].

Patients were followed for 12 months after CBA. Patients were interviewed and an Holter ECG monitoring was performed to assess efficacy of the procedure in months 3, 6, and 12. CBA was considered ineffective if patients had recurrences of any atrial tachyarrhythmia (atrial tachycardia, atrial flutter, or AF) lasting for more than 30 seconds after the three-month blind period. Patients were divided into two groups based on the presence or absence of arrhythmia recurrences, and possible lack of efficacy of CBA was investigated.

Statistical analysis of the data obtained was performed using SPSS Statistics version 26.0 (USA). Verification of quantitative variables using the Kolmogorov-Smirnov test demonstrated the absence of normal distribution, thus, the data were expressed as the medians and interquartile ranges. The quantitative variables were compared between the groups using the Mann–Whitney U-test. The qualitative variables were expressed as the absolute values and percentages. The qualitative variables were compared between the groups using the chi-squared test. Kaplan-Meier curves were constructed to show the influence of various factors on the efficacy of CBA. Univariate and multivariate Cox regression analyses were carried out to detect independent RFs of AF recurrences after CBA. Only relevant parameters were included in the multivariate analysis. The differences were statistically significant at $p<0.05$.

Results

Analysis of the study results was carried out based on the follow-up data of 141 patients.

The efficacy of CBA was 85.1% at the end of the blind period (3 months after the intervention) and 67.4% after 12 months of follow-up (Figure 1). The median time to late recurrences of AF (i.e., beyond the blinded period) recurrence was 4 months. Completely clinically silent AF episodes were detected by Holter ECG monitoring in 4 patients during the follow-up period.

Clinical and demographic characteristics of patients are presented in Table 1.

During the follow-up period, 16 (11.3%) patients underwent PV RFA for symptomatic recurrences of AF.

Intraoperative parameters of the interventions did not differ statistically significantly between the groups (Table 2). Thrombosis (n=3), hematomas (n=1), or arteriovenous fistula (n=1) were the most common complications at the

ISSN 0022-9040. Kardiologiia. 2022;62(6). DOI: 10.18087/cardio.2022.6.n1667

Figure 1. Absence of recurrence of atrial fibrillation after cryoballoon ablation (Kaplan–Meier curve)

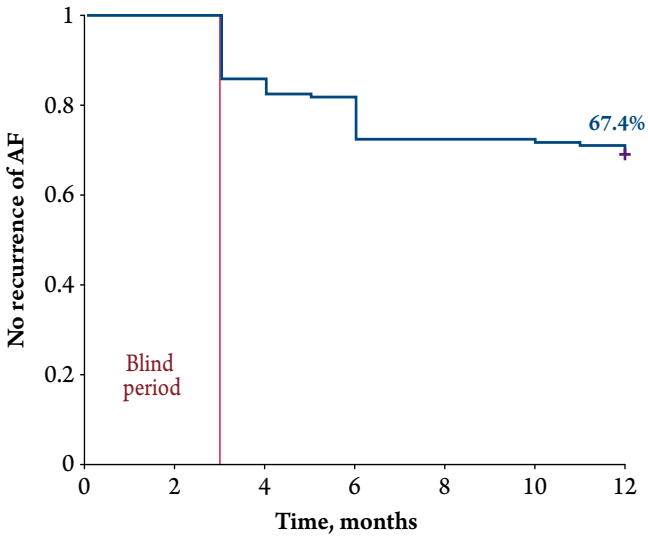


Table 1. Demographic and clinical characteristics of patients of the comparison groups

Parameter	All patients (n = 141)	AF recurrence (n = 46)	No AF recurrence (n = 95)	p
Age, years	60 [14]	59.5 [17.25]	60 [13]	0.787
Male, n (%)	85 (60.3)	23 (50)	62 (65.2)	0.082
BMI, kg/m^2	28 [5]	29 [6]	28 [5]	0.262
CHA2DS2-VASc score	2 [2]	2 [2]	1 [1]	0.07
History of AF, months	72 [96]	84 [96]	72 [90]	0.282
History of ineffective AADs, n	2 [2]	2 [2]	1 [1]	0.014
Cardioversion, n (%)	21 (14.9)	9 (19.6)	12 (12.6)	0.278
Essential hypertension, n (%)	96 (68.1)	33 (71.7)	63 (66.3)	0.517
DM, n (%)	12 (8.5)	6 (13.0)	6 (6.3)	0.180
CAD, n (%)	7 (5.0)	4 (8.6)	3 (3.1)	0.156
MI, n (%)	2 (1.4)	1 (2.1)	1 (1.0)	0.598
Stroke/TIA, n (%)	12 (8.5)	7 (15.2)	5 (5.2)	0.047
CKD, n (%)	3 (2.1)	2 (4.3)	1 (1.0.0)	0.204
LA volume, ml	60 [70]	62 [22]	58 [15]	0.127
LA diameter, cm	3.9 [1.8]	4 [0.4]	3.8 [0.5]	0.479
Common PV collector, n (%)	38 (27.0)	19 (41.3)	19 (20.0)	0.008
ACE inhibitors/ ARB, n (%)	90 (63.8)	31 (67.4)	59 (62.1)	0.540
Anticoagulants, n (%)	120 (85.1)	41 (89.1)	79 (83.2)	0.350
Beta-blockers, n (%)	58 (41.1)	20 (43.5)	38 (40.0)	0.694

The data are presented as the medians [interquartile range] or absolute values (%). AAD, antiarrhythmic drug; PV, pulmonary vein; LA – Left atrium, ACE – Angiotensin convertising Enzyme; ARB – angiotensin receptors blockers; TIA, transient ischemic attack.

puncture site. Transient phrenic nerve palsy was reported in 3 cases, its function recovered by the time of discharge. There was one case of clinically apparent esophageal erosion detected on day 1 after CBA. It should be noted that patients who experienced ineffective CBA were significantly more likely to have recurrent arrhythmias during hospital stay and in the first 3 months after ablation (blind period).

Patients with a history of ineffective CBA (recurrences after the blind period) had a greater number of ineffective AADs of class I or class III (p=0.014) administered for rhythm control. The criterion for the lack of efficacy of AADs was the persistence of AF attacks during the administration of a minimum effective dose of drugs of class I and class III by patients without recurrent AF. A history of transient ischemic attacks (TIA) or strokes was significantly more common in those patients (p=0.047). Common PV ostia

was also more common (p=0.008) in the recurrent AF group according to MSCT findings. There were no significant differences in the remaining indicators of interest. Changes in the frequency of AF recurrences are reflected using the Kaplan-Meier curves depending on factors that statistically significantly differed between groups depending on outcomes of CBA and shown in Figure 2 and Figure 3.

Univariate and multivariate analyses of recurrences in the first 3 months after CBA showed that the number of ineffective AADs and Common PV ostia were RFs of ineffective intervention (Table 3). Univariate analysis identified features that were subsequently investigated in the multivariate analysis. Multivariate analysis was conducted in two stages: the evaluation of baseline parameters (model A) and the subsequent introduction of the «Early recurrence of AF» parameter into the model (model B).

Discussion

Efficacy of CBA was 67.4% in our study. Efficacy in terms of symptomatic recurrences of AF paroxysms was slightly higher at 70.4%. Various devices for long-term record of the heart rhythm are used more and more commonly for more objective assessment of various recurrent arrhythmias after catheter ablation (including analysis of the total burden of AF). Among such devices, special attention should be paid to implantable loop recorders [9]. The study by Davtyan et al., in which loop recorders were used, showed a marked difference in efficacy depending on an endpoint. In our study, absolute efficacy and efficacy for symptomatic recurrences of AF was 65.9% and 81.8%, respectively (p<0.01) in the RFA group in 12 months, and the difference was not significant in the CBA group [10]. In the CIRCA-DOSE study, the frequencies of recurrences were assessed using long-term ECG record devices. The standard follow-up after CBA (survey, periodic Holter ECG monitoring or ECG in symptomatic paroxysms) detected recurrences in 22.8%

Table 2. Intraoperative parameters, incidence of adverse events and early recurrences

Parameter	All patients (n = 141)	AF recurrence (n = 46)	No AF recurrence (n = 95)	p
PVI, %	96.9	95	97.8	0.054
PVI + CTI RFA, n (%)	32 (22.7)	8 (17.4)	24 (25.2)	0.295
Adverse events, n (%)	10 (7.0)	5 (10.8)	5 (5.2)	0.454
Transient phrenic nerve palsy, n (%)	3 (2.1)	2 (4.3)	1 (0.7)	0.454
Complications at the puncture site, n (%)	6 (4.2)	3 (6.5)	3 (3.1)	0.355
Esophagus damage, n (%)	1 (0.7)	0	1 (0.7)	0.487
Recurrences during hospital stay, n (%)	32 (22.6)	24 (52.2)	8 (8.4)	<0.001
Recurrences in the first 3 months, n (%)	44 (31.2)	33 (71.7)	11 (11.6)	<0.001

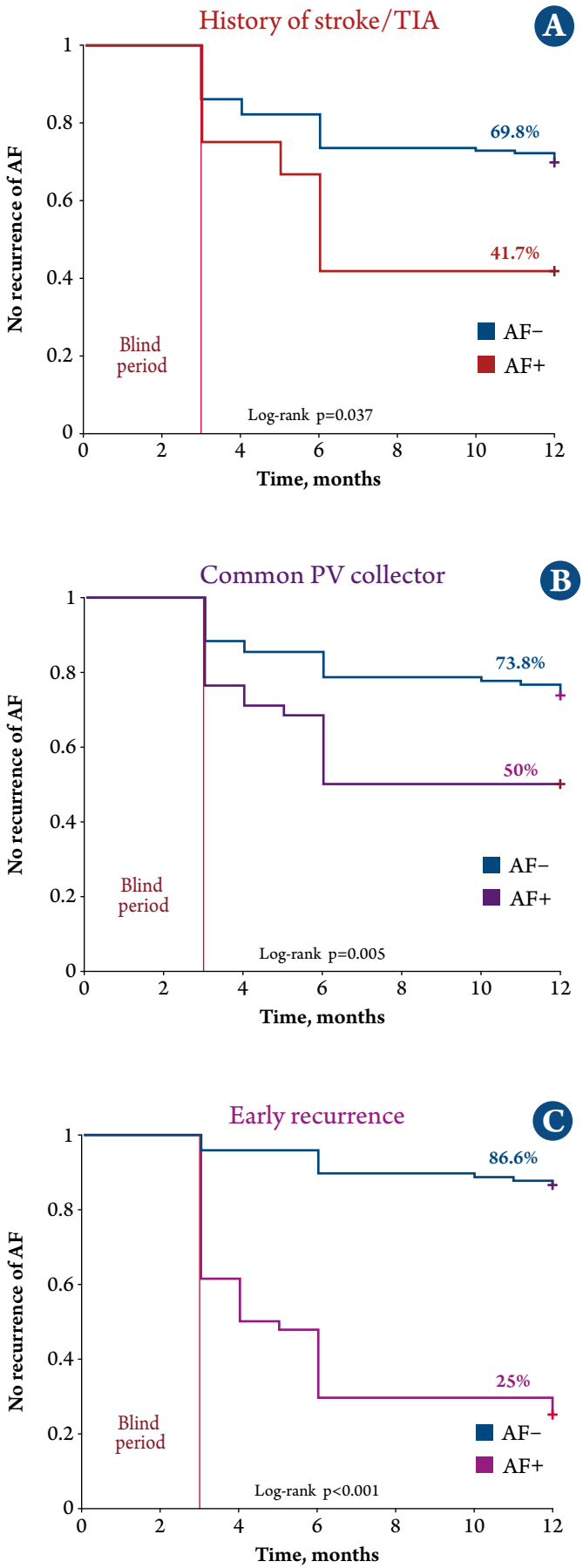
The data are presented in absolute values (%).
PV, pulmonary vein; PVI, pulmonary vein isolation;
CTI RFA, radiofrequency ablation of the cavotricuspid isthmus.

of patients, and this indicator increased to 48.8% with loop recorders [11]. However, it should be noted that using loop recorders and other devices for long-term ECG monitoring requires careful analysis of the data obtained as there are many false-positive results [12].

In our study, the differences in the frequency of clinically apparent and clinically silent recurrences were not significant, which may be indicative of a limited power of Holter ECG monitoring in detecting the latter. It is important to find reliable RFs of AF recurrence after CBA to understand the pathogenesis of AF and determine the strategy for interventional and drug treatment of patients with this type of arrhythmia. There many scores for assessing the risk of recurrence after catheter ablations. APPLE, ATLAS, CAAP-AF are the most common ones [13–15]. However, they are not routinely used in clinical practice [16]. It also should be noted that special attention is paid in the latest clinical guidelines to such modified RFs as uncontrolled hypertension, obesity, and obstructive sleep apnea [3].

Stable isolation may be difficult to achieve using CBA in certain venous abnormalities: large or slit-like common PV collectors. Such structural variants can make it more difficult to achieve reliable PV obstruction and close contact of the balloon with the endocardium. In our study, the frequency of Common PV ostia was 27% (n=38), which is consistent with the previous published data (8.2–37%) [17–19]. Moreover, multivariate analysis showed that common PS collector was an independent RF if the lack of efficacy of CBA. Similar results were demonstrated in the study by Beiert et al. [20], in which common PV collector, as well as chronic heart failure and mitral regurgitation, were RFs of late recurrences of AF.

Figure 2. Absence of recurrence depending on different factors (Kaplan-Meier curves)



TIA, transient ischemic attack; PV, pulmonary vein.

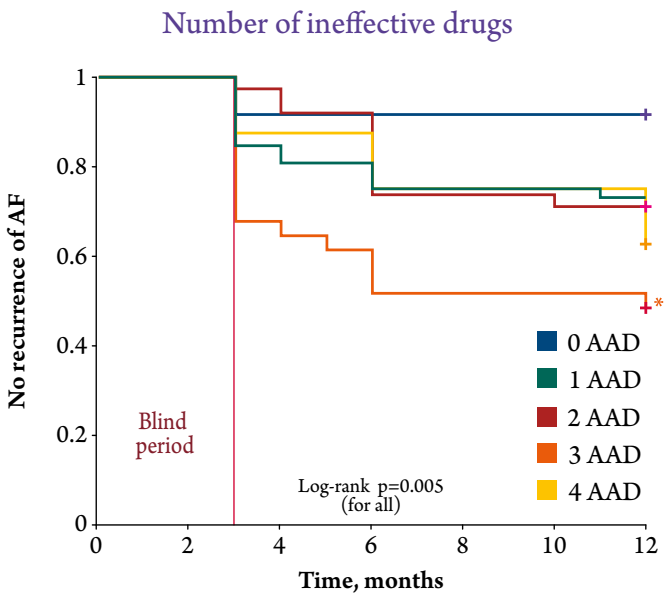
ISSN 0022-9040. Kardiologiia. 2022;62(6). DOI: 10.18087/cardio.2022.6.n1667

Table 3. Univariate and multivariate analyses of risk factors of AF recurrence

Parameter	RR (95 % CI)	p
Univariate analysis		
Age	1.01 (0.97–1.03)	0.936
Male	0.59 (0.33–1.05)	0.075
BMI	1.02 (0.95–1.09)	0.503
Duration of AF:	1.00 (0.99–1.00)	0.148
Number of ineffective AADs	1.36 (1.04–1.77)	0.023
Common PV collector	2.69 (1.20–3.97)	0.01
LA diameter	1.14 (0.49–2.62)	0.751
AH	0.83 (0.43–1.58)	0.579
DM	0.52 (0.22–1.22)	0.135
CAD	0.49 (0.17–1.37)	0.178
History of stroke/TIA	0.45 (0.20–1.01)	0.055
Early recurrence of AF	8.64 (4.50–16.58)	<0.001
Multivariate analysis (model A#)		
Number of ineffective AADs	1.42 (1.08–1.86)	0.011
Common PV collector	2.35 (1.29–4.25)	0.005
Multivariate analysis (model B§)		
Number of ineffective AADs	1.14 (0.84–1.55)	0.374
Common PV collector	1.58 (0.87–2.88)	0.132
Early recurrence of AF	7.57 (3.84–14.90)	<0.001

AAD, antiarrhythmic drug; PV, pulmonary vein; LA, left atrium; AH – arterial hypertension; TIA, transient ischemic attack. § Model A for multivariate analysis, in which only baseline characteristics were used; # Model B for multivariate analysis, in which the presence of recurrences in the first 3 months was included.

Figure 3. Absence of recurrence depending on the number of ineffective antiarrhythmic drugs (Kaplan-Meier curves)



AAD, antiarrhythmic drug.
* statistically significant differences were achieved only between the groups of patients with three ineffective AADs and patients who administered none, 1, or 2 ineffective AADs.

According to our findings, the lack of efficacy of previously administered AADs was also a predictor of AF recurrence after CBA. At the same time, the highest recurrence was observed in the subgroup of patients with three ineffective drugs (see Figure 3). This may reflect the degree of atrial remodeling and, thus, the lack of efficacy of most available AADs [21].

History of TIA or stroke was also, according to our data, associated with a higher risk of late recurrences of AF after CBA. In the study by Bavishi et al. [22], a history of stroke or TIA, the lack of efficacy of AADs before interventional treatment were significant predictors of efficacy, which is also consistent with our findings. This may be due to severe fibrotic atrial remodeling (atriopathy), which may increase the risk of adverse thromboembolic events and reduce the efficacy of CBA due to an additional substrate, other than PV, for the initiation and maintenance of AF [23, 24].

The presence of early recurrence in the first 3 months also was a RF of AF recurrence after CBA in our study. It should be noted that this is one of the most common RFs of AF recurrence after CBA, according to the literature [8, 25–29]. This may indicate the benefit of the strategy of early repeated ablation in the case of recurrences in the first 3 months after CBA, since, according to several studies, repeated ablation in the blind period resulted in a significant reduction of the risk of late recurrences of AF [28, 29]. However, almost 60% of patients with early recurrences will not have recurrent atrial tachyarrhythmias in the distant period, which is indicative of a transient nature of this phenomenon [30, 31]. According to the current guidelines for catheter ablation in AF, performing an intervention in the first month is an overaggressive strategy [30]. In this regard, additional research is necessary to assess the efficacy of repeated ablation later in the blind period.

Such RFs as diabetes mellitus, volume of LA according to echocardiogram, the duration of the history of AF did not increase the risk of late recurrences of AF, which is also consistent with other studies [22, 31].

Conclusion

Recurrent atrial fibrillation after cryoballoon ablation is clinically silent in some patients. Due to the high likelihood of false negative results, the use of 24-hour electrocardiogram monitoring to detect silent episodes of atrial fibrillation is of limited value.

According to our findings, the presence of common pulmonary vein collector, the lack of efficacy of previously administered antiarrhythmic drugs, and the recurrence of atrial fibrillation in the first 3 months are risk factors of atrial fibrillation recurrence after cryoballoon ablation.

No conflict of interest is reported.

The article was received on 03/06/2021

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