


Cryoballoon ablation results and complications in mid-term follow-up of patients with atrial fibrillation

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Short Communication

Abstract

BACKGROUND: Atrial fibrillation (AF) is the most common cardiac arrhythmia, and its prevalence increases with advancing age. Pulmonary vein isolation is a standard approach in drug refractory paroxysmal AF which could be performed by cryoballoon ablation (CBA). We tried to evaluate its efficacy and safety in Iranian patients with AF.

METHODS: From 2015 to 2017, 97 patients with paroxysmal and persistent AF were enrolled in our observational historical cohort study. They were visited 1 and 6 months post-procedure in order to assess the efficacy (recurrence) and safety. Recurrence was defined as 30 seconds of arrhythmia on their 48-hours Holter monitoring.

RESULTS: Ninety-seven patients enrolled in the study, 64 (66.0%) of them were men, and their mean age was 55 ± 12 years. Hypertension was reported in 41 patients (42.3%), as the most common cardiac risk factor. 71 patients (73.2%) patients with paroxysmal AF and 15 patients (15.5%) with persistent AF underwent the procedure. After 6 months, recurrence was documented in only 17 patients (17.5%), and 82.5% of the patients were free from the recurrence. Post-procedural complication was detected only in 3 patients (3.1%).

CONCLUSION: In our study, the mid-term success and safety of CBA in patients with paroxysmal AF was showed. CBA is a safe and effective method in paroxysmal AF, and even in some cases with persistent AF.

Keywords: Catheter Ablation, Atrial Fibrillation, Follow-Up Studies

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Introduction

Atrial fibrillation (AF) is the most prevalent cardiac dysrhythmia, and its prevalence increases with advancing age. About 1% of patients with AF are less than 60 years old, but it is more common in patients older than 75 years of age.¹ AF is evidently more problematic in patients with structural heart disease, hypertension, coronary artery disease (CAD), and any other chronic condition.² The role of catheter ablation in the management of AF continues to evolve rapidly, with improvements in the efficacy and safety of the procedure.

Cryoballoon ablation (CBA) is an alternative to point-by-point radiofrequency ablation (RFA) to achieve pulmonary veins isolation.³

Long-term success of RFA in AF has been

constrained by the time consuming and unpredictable nature of point-by-point focal ablation and technical limitations.^{4,5} CBA has been showed to nonbeing inferior to RFA with respect to efficacy for the treatment of paroxysmal AF, and there was no significant difference between the two methods with regards to overall safety.⁶⁻⁹

As there is lack of evaluation of efficacy and complication of CBA in an Iranian population, we decided to conduct this study to assess its effectiveness, safety, and recurrence rate.

Materials and Methods

This was an observational historical cohort study that analyzed the result of CBA performed in patients with symptomatic paroxysmal or persistent

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AF, who were candidates for ablation according to the latest AF guideline.^{3,10} Patients with symptomatic paroxysmal or persistent AF that was refractory to antiarrhythmic drugs or beta-blockers were included. From all patients have been ablated by CBA from May 2015 to the March 2017, we could recruit 97 patients whom were reevaluated and revisited in 1 and 6 months after the procedure.

Patients were asked and assessed for their demographic measures, left ventricular ejection fraction (LVEF), and grade of mitral regurgitation (MR), if was present by echocardiography, the size of left atrium (LA), presence of cardiac risk factor as hypertension, CAD, or other structural heart diseases, past history of cerebrovascular accident (CVA) or transient ischemic attack (TIA), their medications before and after CBA including aspirin, rivaroxaban, dabigatran, warfarin, propafenone, sotalol, amiodarone, angiotensin-converting-enzyme (ACE) inhibitor, beta-blockers, angiotensin receptor blocker (ARB), and any other antiarrhythmic drug. Paroxysmal AF was defined as AF that terminated spontaneously or with intervention within 7 days.³

CHA₂DS₂-VASc score was calculated in office visits by the physician, but as some patients were just admitted for the procedure and due to the lack of fulfilled past history, we could not evaluate patients' CHA₂DS₂-VASc score; of course, all patients were anticoagulated based on the latest AF guideline, and it was withheld periprocedural time. After the procedure, patients all were visited 1 and 6 months later, after recruitment in the outpatient clinic. In 6-month follow up, to evaluate patients' recurrence, all patients underwent 48 hours of Holter monitoring to document any dysrhythmic abnormality or AF. Documented AF, atrial flutter, or atrial tachycardia, which lasted for more than 30 seconds, was defined as recurrence.

CBA procedure was performed according to the latest developed method; it induced necrosis by pumping N₂O through a balloon in a one-step mode, thereby freezing the tissue, and finally isolating bladed part of pulmonary vein (PV) to eradicate arrhythmia.^{8,11,12}

All patients were informed about the study, and the consent form was signed by all enrolled patients.

Statistical analyses were performed using SPSS software (version 22, IBM Corporation, Armonk, NY, USA). To describe numerical variables, mean \pm standard deviation (SD) was used, and categorical variables were presented as number and percentage. To explore the relationship between

categorical variables, chi-square test was applied.

Results

From 97 patients in this study, 64 patients (66.0%) were men and 33 (34.0%) were women. Patients' demographic data and some echocardiographic measures were summarized in table 1.

Table1. Demographic and echocardiographic data

Variable	Minimum	Maximum	Mean \pm SD
Age (year)	29.00	80.00	55.36 \pm 11.00
BMI (kg/m ²)	17.30	47.26	29.27 \pm 5.51
EF (%)	20.00	60.00	50.31 \pm 7.10
LA diameter (cm)	1.40	5.00	3.63 \pm 0.58
LA volume (ml)	17.00	67.20	37.23 \pm 17.47
Serum creatinine (mg/dl)	0.60	1.60	0.97 \pm 0.20

SD: Standard deviation; BMI: Body mass index; EF: Ejection fraction; LA: Left atrium

Hypertension was documented in 41 patients (42.3%), structural heart disease in 2 patients (2.1%), as the less number which means less inconvenience in our analysis, CAD in 10 patients (10.3%), and CVA or TIA in only 3 patients (3.1%). Echocardiography indicated 51 patients (52.6%) with mild MR, 29 (29.9%) with mild to moderate MR, 13 (13.4%) with moderate MR, and 4 patients (4.1%) with missing MR. Sixty-nine patients (71.1%) were categorized in paroxysmal AF, 15 patients in persistent type AF (15.5%), whose procedural success was considerable, and 1 patient (1.0%) was in the persistent group, but he intended to not take the antiarrhythmic drug because of its side effects.

Most patients (22 patients) who underwent CBA were taking sotalol, and 16 patients were on amiodarone, followed by flecainide and propafenone in the rest of patients. For rate control of the patients before ablation, most patients were prescribed metoprolol (in 53 patients), and bisoprolol, carvedilol, and propranolol were in the next places.

Based on the patients CHA₂DS₂-VASc score, 52 patients were taking anticoagulant drugs such as warfarin, rivaroxaban, or dabigatran.

Recurrent AF was detected in 17 patients, and 80 patients maintained their normal sinus rhythm (82.5%). In patients in whom recurrent dysrhythmia was documented, the most common type of recurrence was AF (11 patients), followed by atrial flutter (AFL) in 4 patients, and atrial tachycardia (AT) in 1 patient. Two patients underwent repeated ablation procedure due to recurrence.

CBA procedure was done by mean freeze time

of 184 seconds and mean balloon temperature of -45°C . In this regard, patients with recurrent AF had the same procedural parameters as patients with successful CBA.

Postprocedural examination of patients revealed complication in 3 patients (3.1%), 1 pericardial effusion, 1 vascular complication, and phrenic nerve palsy in only 1 patient which resolved within 3 months. We also had no report of CVA, TIA, hemorrhagic complication, or death.

Discussion

In this cross sectional study, patients underwent CBA, and then were reevaluated 1 and 6 months postprocedure. Patients' enrollment was based on the latest guideline of AF, and no patient had the contraindication to the CBA.^{3,13} Demographic measures of our patients were quietly similar to the studies have been conducted so far.^{6,14} In 2 studies reported in China,^{6,15} success rate was 76% with complication rate of 5% and 4% at 6- and 12-month follow-up, respectively; in our study, 82.5% of success rate and complication of 3% was achieved. In STOP AF trial study,⁶ success rate at 1 year was reported as 69.9% compared to our 82.5% at 6 months. Moreover, we had 3% of complication rate, which was reported as 2% in that study.⁶

The success rate and complications in our study proved CBA as a novel procedure to eradicate paroxysmal AF. Many studies so far compared these two methods,^{9,12,16-19} and FIRE and ICE randomized trial demonstrated their efficacy and safety.⁹

Nowadays, United States Food and Drug Administration (FDA) proves both methods for eradicating paroxysmal AF. Based on the results of the latest studies,²⁰⁻²³ pulmonary vein isolation might be a sufficient ablation strategy in persistent AF. Therefore, cryoablation of the PVs may also suffice not only in paroxysmal but also in persistent AF. This hypothesis has been evaluated in several studies.²⁰⁻²³ as we performed the procedure in 15 patients with persistent AF. In these studies success rate as freedom from AF was reported from 59% to 69%.²⁰⁻²³

Phrenic nerve palsy has been reported as the most common complication of the CBA with a prevalence of 2.7% in the FIRE and ICE trial,⁹ and it was reported 1% in our population. Safety of the CBA was assessed by latest studies, and has been reported even safer than RF ablation.^{12,24}

Procedural time and temperature of our study was comparable to other studies conducted so far.¹⁶⁻¹⁹

We need multicenter randomized studies to

empower our results, as there was no control group in our study. We measured the recurrence by 48-hour Holter monitoring, but we might have missed some asymptomatic recurrences.

Conclusion

CBA is a safe and effective method in paroxysmal AF, and even in some patients with persistent AF.

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None.

Conflict of Interests

Authors have no conflict of interests.

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