

Long Term Follow-up of Pulmonary Vein Isolation Using Cryoballoon Ablation



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Background	Cryoballoon ablation is an established catheter-based approach to treating atrial fibrillation (AF). There is little data regarding the long-term efficacy of this approach.
Methods	We enrolled 200 consecutive patients with symptomatic AF who had failed therapy with at least one antiarrhythmic medication and followed them for five years. The primary efficacy endpoint was symptomatic recurrence of AF after a single cryoballoon ablation procedure.
Results	Two hundred patients formed the study group. Median follow-up was 56 months. Following a single procedure, 46.7% of patients with paroxysmal AF remained free of symptomatic recurrence of AF compared to 35.6% of patients with persistent AF. When allowing for repeat ablations, at the end of the follow-up period 53.3% of patients in the paroxysmal group remained free of symptomatic AF compared to 47.5% in the persistent group. The rate of complications was low.
Conclusions	Cryoballoon ablation is an effective catheter-based approach for treating symptomatic AF with a low risk of complications.
Keywords	Atrial fibrillation • Cryoballoon ablation

Introduction

Cryoballoon ablation is an established catheter-based approach used to isolate the pulmonary veins and has similar procedural success rates to radiofrequency catheter ablation [1–8]. To date, there is limited long-term data published evaluating the efficacy of cryoballoon ablation [9–11]. We have previously published medium-term results following cryoballoon ablation [12]. We present long-term results of cryoballoon ablation in terms of freedom from symptomatic recurrence in patients with both paroxysmal and persistent AF.

Methods

Two hundred consecutive patients who underwent cryoballoon ablation formed the study group. All patients had

symptomatic AF and had failed treatment with at least one antiarrhythmic drug. Patients with episodes of AF lasting longer than seven days were defined as persistent and those whose episodes self terminated within seven days were defined as paroxysmal. All procedures used the Cryocath® Arctic Front balloon (either 23mm or 28mm). Other aspects of the cryoballoon ablation procedure for this cohort of patients have been described previously [12]. Patients were routinely reviewed at three months with echocardiography and Holter monitoring and then at six, 12 and 24 months with clinic visits and electrocardiograms. Follow-up after 24 months was conducted at the discretion of the treating cardiologist. Every patient was contacted by telephone at the end of the study to enquire about symptomatic recurrence of AF. The local area health district electronic medical record was reviewed and correspondence was

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obtained from the patient's general practitioner and treating cardiologist.

Study End Points

The primary efficacy endpoint was freedom from symptomatic recurrence of AF after a single pulmonary vein isolation procedure using the cryoballoon. Secondary end points included freedom from symptomatic recurrence of AF after the last ablation attempt (including redo cryoballoon and radiofrequency ablation) and freedom from symptomatic recurrence after a single procedure according to balloon size. A trial fibrillation recurrence was documented on Holter monitoring or electrocardiogram in the majority of patients with a recurrence. If patients had symptoms suggestive of AF, they were considered to have had a recurrence. A three-month blanking period was applied after the first and subsequent ablation procedure to allow for transient exacerbations following cryoballoon ablation.

Statistical Analysis

Continuous variables are displayed as mean +/- standard deviation or median and interquartile range. Student t tests were used to compare normally distributed continuous variables and Mann-Whitney U test was used to compare variables that did not follow the normal distribution. Chi-square test or Fisher's exact test were used to compare categorical variables. Time to recurrence of AF was plotted using Kaplan-Meier survival curves. Data was collected and analysed using SPSS (IBM) version 22.

Results

Baseline Characteristics

The cohort of 200 patients was followed-up for a median of 56 (48-65) months. Baseline characteristics for the original 200 patients are shown in Table 1. Of the 200 patients, 146 were treated with the 28mm cryoballoon and 50 patients were treated with the 23mm cryoballoon. Both balloons were used in four patients. The median procedure time was 140 minutes

and the median fluoroscopy time was 31 minutes. Four patients were lost to follow-up. Long-term follow-up data was therefore available for 196 patients. Peri-procedural anti-coagulation and mid-term success rates have been reported previously [12].

Freedom from Symptomatic AF after a Single Procedure

Following a single procedure, 46.7% of patients with paroxysmal AF remained free of symptomatic recurrence of AF compared to 35.6% of patients with persistent AF (Figure 1). In those patients that had a recurrence, the median time to recurrence was 24 (9-51) months. There was no significant difference in time to recurrence in the paroxysmal and persistent groups ($p = 0.344$).

Freedom from Symptomatic AF after the last Procedure

A total of 47 repeat procedures were performed in 44 patients. These consisted of 28 radiofrequency ablations and 19 cryoballoon ablations. The choice of radiofrequency or cryoballoon ablation was at the discretion of the operator. The mean time interval between procedures was 17 months. The median follow-up time since last procedure in those patients who had repeat procedures was 41 (33-51) months. Overall, 53.3% of patients in the paroxysmal group remained free of symptomatic AF at last follow-up compared to 47.5% in the persistent group (Figure 2). There was no significant difference between the two groups ($p = 0.497$).

23mm vs 28mm Balloon

When comparing balloon sizes, patients were grouped into the largest balloon size used. Twenty-four out of 48 patients (50%) using the 23mm balloon had a recurrence compared to 87 out of 148 patients (57.1%) using the 28mm balloon (Figure 3) ($p = 0.508$). In those patients that had a recurrence, the median time to recurrence with the 23mm balloon was 31 months compared to 20 months with the 28mm balloon ($p = 0.346$).

Table 1 Baseline characteristics

Variable	Paroxysmal	Persistent	P value
Patients	139	61	
Age (mean +/- SE)	62.3	59.3	0.026
Sex (male)	93 (66%)	48 (78.7%)	0.093
Symptom duration (median + IQR)	60 (34-120)	48 (12-114)	0.07
LA diameter	41.0 +/- 0.6	45.8mm +/- 1.0	0.001
LVEF (%)	61.8 +/- 0.7	57.4 +/- 1.7	0.006
CCF	15 (10.8%)	17 (27.9%)	0.005
Diabetes	10 (7.2%)	5 (8.2%)	0.804
Stroke/TIA	15 (10.8%)	3 (4.9%)	0.282
Hypertension	73 (52.5%)	27 (45.9%)	0.282

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