

Paroxysmal Atrial Fibrillation: Cryoballoon versus Radiofrequency Catheter Ablation

Fibrilación auricular paroxística: crioablación versus ablación por radiofrecuencia

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ABSTRACT

Background: There are few data about which is the best technique for the treatment of paroxysmal atrial fibrillation: radiofrequency catheter ablation or cryoballoon ablation.

Objective: The aim of this study was to compare immediate and long-term outcomes of irrigated radiofrequency ablation with second-generation cryoballoon ablation.

Methods: This retrospective, observational, single-center study evaluated 159 consecutive patients with paroxysmal atrial fibrillation undergoing pulmonary vein isolation using radiofrequency or cryoballoon ablation. Patient and procedure characteristics, the immediate success rate and the 12-month outcome were assessed.

Results: Among a total of 159 patients, 89 underwent cryoballoon ablation and 70 radiofrequency ablation. Mean follow-up was 12 months. There were no significant differences in the population characteristics. The immediate success rate was 97.8% with cryoballoon ablation versus 97.1% with radiofrequency ablation ($p=0.8$). Freedom from atrial fibrillation at 12 months after a single procedure was 77.5% with cryoballoon versus 71.4% with radiofrequency ($p=0.33$) ablation. Cryoballoon ablation was associated with shorter procedure duration compared with radiofrequency ablation (60.19 ± 15 minutes vs. 75.8 ± 31 minutes, respectively; $p < 0.00001$), with shorter left atrial dwell time (45 ± 14 minutes vs. 58 ± 26 minutes; $p < 0.00001$). Fluoroscopy time was significantly higher in the cryoballoon group (18 ± 3.76 minutes vs. 13 ± 2.23 minutes for radiofrequency; $p < 0.0001$). The rate of complications was similar with both procedures ($p=0.76$).

Conclusion: Compared with irrigated radiofrequency ablation, cryoballoon ablation was associated with shorter procedure time and similar rate of complications and freedom from atrial fibrillation at 12 months after a single procedure.

Key words: Atrial Fibrillation - Cryoablation - Radiofrequency

RESUMEN

Introducción: En la ablación de la fibrilación auricular paroxística por radiofrecuencia o crioablación existe poca información acerca de la superioridad de una técnica sobre la otra.

Objetivo: Comparar los resultados agudos y a largo plazo de las técnicas de ablación de la fibrilación auricular paroxística por catéter irrigado y mediante crioablación con balón de segunda generación.

Material y métodos: Estudio retrospectivo, observacional, unicéntrico, en el que se evaluaron 159 pacientes consecutivos con fibrilación auricular paroxística, a los cuales se les realizó aislamiento de venas pulmonares mediante radiofrecuencia o crioablación. Se examinaron las características de los pacientes y del procedimiento, así como el éxito inmediato y en el seguimiento a 12 meses.

Resultados: Sobre un total de 159 pacientes, 89 procedimientos se realizaron con crioablación y 70 mediante radiofrecuencia. El seguimiento promedio fue de 12 meses. No se encontraron diferencias significativas en las características de la población. La tasa de éxito inmediato fue del 97,8% con crioablación versus 97,1% con radiofrecuencia ($p = 0,8$). La tasa libre de fibrilación auricular a los 12 meses luego de un único procedimiento fue del 77,5% mediante crioablación versus 71,4% con radiofrecuencia ($p = 0,33$). La crioablación con balón se asoció con menor duración del procedimiento respecto de la radiofrecuencia ($60,19 \pm 15$ minutos frente a $75,8 \pm 31$ minutos, respectivamente; $p < 0,00001$), con menor tiempo en la aurícula izquierda (45 ± 14 minutos frente a 58 ± 26 minutos; $p < 0,00001$). Los tiempos de fluoroscopia fueron significativamente mayores para el grupo crioablación ($18 \pm 3,76$ minutos vs. $13 \pm 2,23$ minutos para radiofrecuencia; $p < 0,0001$). La tasa de complicaciones crioablación vs. radiofrecuencia fue similar ($p = 0,76$).

Conclusión: La crioablación con balón, en comparación con radiofrecuencia mediante catéter irrigado, se asoció con menor tiempo del procedimiento, similar tasa de complicaciones y tasa libre de fibrilación auricular a los 12 meses luego de un único procedimiento.

Palabras clave: Fibrilación auricular - Crioablación - Radiofrecuencia

Abbreviations

CB	Cryoballoon	LMWH	Low-molecular-weight heparin
AF	Atrial fibrillation	RF	Radiofrequency

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INTRODUCTION

According to a 2012 expert consensus, catheter ablation of paroxysmal atrial fibrillation (AF) refractory to antiarrhythmic therapy is a Class I, level of evidence A recommendation. (1)

Point-by-point radiofrequency (RF) ablation is the procedure most commonly used, leading to necrosis by tissue heating. As the method uses electroanatomic mapping, a limited use of fluoroscopy is required. However, as the complexity of the technique involves extensive training, it is restricted to specialized centers, thus limiting the availability of AF ablation. (2, 3)

Although RF is the source of energy most widely used, cryoballoon (CB) ablation offers certain advantages for the treatment of paroxysmal AF. These include reduced pain and discomfort during and after the procedure, improved catheter stability, diminished risk of thrombosis due to decreased activation of platelets and the coagulation cascade and, finally, the ability to rapidly create circumferential and contiguous lesions. In addition, the relative simplicity and the lower learning curve of the procedure, associated with the potential for enhanced efficiency, have led to the widespread adoption of this technique. (3-6)

The aim of this study was to compare the immediate and long-term outcomes of paroxysmal AF ablation using irrigated RF or second-generation CB in our setting.

METHODS

Study design, population and management before ablation

This retrospective, observational and single-center study, conducted at the *Instituto Cardiovascular de Buenos Aires* from August 2014 to August 2015, evaluated 159 consecutive patients with paroxysmal AF refractory to antiarrhythmic treatment undergoing pulmonary vein isolation using second-generation CB ablation (n=89) or irrigated RF ablation (n=70).

Exclusion criteria were: persistent AF, secondary AF, congestive heart failure, severe valve stenosis or regurgitation, congenital heart defects, contraindications for anticoagulation, left atrial thrombus, pregnancy or severe comorbidities.

The patients were treated with new oral anticoagulants, warfarin or acenocoumarol, the last two monitored using the international normalized ratio in the range between 2.0 and 3.0. Warfarin or acenocoumarol were discontinued 3 half-lives before the procedure and were substituted by low-molecular-weight heparin (LMWH). The new oral anticoagulants were discontinued 3 half-lives before the procedure without LMWH bridging. Prior to ablation, all the patients underwent high resolution 64-row computed tomography scan of the heart to determine left atrial anatomy and characterize pulmonary vein diameter and drainage. Of importance, the presence of a common pulmonary vein trunk was not an absolute contraindication to perform the procedure in our series.

Post-procedural and follow-up management

The patients remained hospitalized for 24 hours after the procedure in the intensive care unit and were discharged on the following day.

Anticoagulation with heparin as a continuous intra-

venous infusion was started 6 hours after the procedure, followed by oral anticoagulants for 3 months. All the antiarrhythmic therapies were resumed after the procedure and continued for the same period.

Follow-up consisted of visits to the Atrial Fibrillation Clinic at 1, 2, 3, 6, 9 and 12 months after the procedure, and included medical interview, physical examination, chest-X ray, 12-lead electrocardiography and 24-hour Holter monitoring.

Statistical analysis

Discrete variables are expressed as percentages and continuous variables as mean or median with their corresponding standard deviation or interquartile range, according to their distribution. The chi square test was used to compare discrete variables and continuous variables were analyzed using Student's t test or the Mann-Whitney test according to sampling distribution. A p value < 0.05 was considered statistically significant. The Kaplan-Meier method was used to evaluate freedom from AF. All the statistical calculations were performed using SPSS 21.0 software package.

Ethical considerations

The study protocol was approved by the institutional Ethics Committee. An informed consent was not required because the study was retrospective (Law 3101, CABA). The Argentine personal data protection law 25,326 ensures the confidentiality of all the information.

RESULTS

Among a total of 159 patients, 89 underwent CB ablation and 70 received RF ablation. Most patients were men (79.8% in the CB ablation group and 67.1% in RF ablation group, p=0.07) and mean age was 56.7±11 years in the CB ablation and 61.2±10.5 years in the RF ablation group (p=0.1). All the patients had a history of documented recurrent paroxysmal AF refractory to antiarrhythmic treatment lasting between 2 and 6 years. Average CHA₂DS₂-VASc score was 1 (1-3) in both groups. There were no significant differences in left atrial diameter (21.78±4.6 cm² in the CB ablation group and 22.55±3.71 cm² in the RF ablation group, p=0.14) and ejection fraction (61.38%±5.18% in the CB ablation group and 60.25%±8.37% in the RF ablation group, p=0.5) (Table 1).

Immediate success rate was 97.8% with CB ablation versus 97.1% with RF ablation (p=0.8). In the CB group, procedure duration was shorter compared with RF ablation (60.19±15 minutes versus 75.8±31 minutes, respectively; p<0.00001), with shorter left atrial dwell time (45±9.14 minutes versus 58±26 minutes; p<0.0001). Fluoroscopy time was 18±3.76 minutes in the CB ablation group and 13±2.23 minutes in the RF group (p=0.0001) (Table 2).

The rate of complications was 3.37% (3 patients) with CB ablation and 4.28% with RF ablation (p=0.76). In patients undergoing CB ablation, phrenic nerve injury was the most common complication (3.37%). Two of these patients recovered before ending the procedure, and only one patient (1.12%) was discharged with phrenic nerve palsy which recovered

within 3 months. In the RF ablation group, vascular related-complications were the most common: 2 patients (2.85%) had pseudoaneurysms, one of them requiring surgical intervention, and 1 patient (1.42%) presented cardiac tamponade needing drainage. None of the groups presented major complications, as stroke, atrioesophageal fistula or death. The incidence of proarrhythmias was 2.24% (2 patients) in the CB ablation group and 4.28% (3 patients) in the RF ablation group ($p=0.46$) (Table 3).

Early recurrence occurred in 19.01% (17 patients) of the patients undergoing CB ablation at an average of 17.18 ± 7.18 days and in 15.71% (11 patients) of those in the RF group at an average of 39.3 ± 11.46 days ($p=0.44$).

Late recurrence was analyzed in 152 patients followed-up at the Atrial Fibrillation Clinic and in 7 patients by telephone calls. Mean follow-up was 11.5 ± 3.5 months in the CB ablation group with a recurrence rate of 22.5%, and 11.7 ± 4.94 months in the RF ablation group, with a recurrence rate of 28.6%. ($p=0.33$) (Figure 1).

DISCUSSION

This study presents the immediate and long-term

outcomes of 159 patients undergoing paroxysmal AF ablation in Argentina (*Instituto Cardiovascular de Buenos Aires*) using CB in 89 patients and RF in 70.

In our initial experience with CB ablation, we have demonstrated that the technique has acceptable results after an adequate training. However, follow-up was short and there are no studies in our country comparing both techniques.

The characteristics of the patients in the present study were similar in both groups and did not differ from those published in other studies, representative of patients with paroxysmal AF (7-11)

We understand that CB ablation is more efficient than RF ablation, since despite both techniques achieved a similar rate of acute pulmonary vein isolation, CB ablation required fewer applications by vein and shorter time to achieve isolation.

The duration of the procedure was significantly shorter with CB ablation than with RF. In our experience, the mean duration of CB ablation was 60 ± 10.2 minutes, shorter than the one reported by other authors. (7-10, 12) Left atrial dwell time was also significantly shorter with CB ablation, while fluoroscopy time was significantly longer with CB than with RF ablation. (7, 10, 11)

Table 1. Population characteristics

	CBAb group	RF group	p
Male sex, %	79.8	67.1	0.07
Age, years	56.7 ± 11	61.2 ± 10.5	0.1
Paroxysmal AF, %	100	100	
Ejection fraction, %	61.38 ± 5.18	60.25 ± 8.37	0.5
Left atrial area, cm ²	21.78 ± 4.6	22.55 ± 3.71	0.14
CHA ₂ DS ₂ VASc	1 (1-3)	1 (1-3)	

CBAb: Cryoballoon ablation. RF: Radiofrequency. AF: Atrial fibrillation.

Table 2. Technical characteristics of the procedure

	CBAb	RF	p
Rate of acute PV isolation, %	97.8	97.1	0.8
Procedure duration, min	60.19 ± 15	75.8 ± 31	0.00001
Left atrial dwell time, min	45 ± 14	58 ± 26	0.00001
Fluoroscopy time, min	18 ± 3.76	13 ± 2.23	0.00001

CBAb: Cryoballoon ablation. RF: Radiofrequency. PV: Pulmonary veins.

Table 3. Procedure-related safety and adverse events

	CBAb %	RF %	p
Total complications	3.37	4.28	0.76
Phrenic palsy	3.37	0	0.12
Phrenic palsy at discharge	1.12	0	
Vascular complications	0	2.85	0.1
Cardiac tamponade	0	1.42	0.25
Stroke, atrioesophageal fistula and death	0	0	
Proarrhythmias	2.24	4.28	0.46

CBAb: Cryoballoon ablation. RF: Radiofrequency.

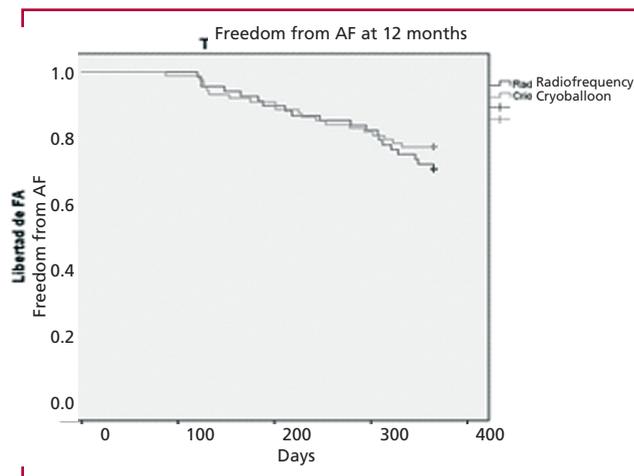


Fig. 1. Freedom from atrial fibrillation (AF) during follow-up.

Early recurrence was similar in both groups; however, mean time for recurrence was earlier with CB ablation compared with RF ablation. This difference could be explained by the fact that CB ablation produces a more homogeneous lesion with less endothelial disruption and greater vascular integrity.

Some studies have already demonstrated noninferiority of CB ablation versus RF ablation. (9, 11, 13) In our experience, and despite the absence of significant differences between both groups after 12 months of follow-up, we observed a trend in favor of CB ablation; larger studies might demonstrate this difference in the future.

Cryoballoon ablation is a safe procedure, as we have shown absence of differences between both groups in agreement with reports of large studies. (9, 11, 12, 14) Phrenic nerve palsy is still the most common complication of CB ablation; however, its incidence is lower than the one reported in the first studies and reverted in all the cases; in addition, vascular complications are more frequent with RF ablation.

CONCLUSION

Second-generation CB ablation of paroxysmal AF was associated with shorter procedure duration and similar rate of complications and of freedom from AF at 12 months after a single procedure, and with longer fluoroscopy time compared with irrigated radiofrequency ablation.

Conflicts of interest

None declared.

(See authors' conflicts of interest forms on the website/Supplementary material).

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