BRIEF REPORT

Complete Pulmonary Vein Isolation Using Balloon Cryoablation in Patients With Paroxysmal Atrial Fibrillation

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Electrical isolation of the pulmonary veins and disconnection of the left atrial musculature from their arrhythmogenic effects is the cornerstone of definitive and curative treatment in patients with symptomatic recurrent paroxysmal atrial fibrillation that is refractory to antiarrhythmic therapy.

The type of lesion produced by balloon cryoablation is such that the tissue architecture is preserved and thrombus formation and the risk of pulmonary vein stenosis are reduced.

We report on immediate outcomes in the first 5 patients who underwent treatment. These cases represent initial experience with the technique in Spain.

A total of 20 pulmonary veins were treated and complete acute electrical isolation was achieved in all cases (100%). Patients were discharged from hospital within 72 hours of the procedure, and there were no complications.

In conclusion, balloon cryoablation of the pulmonary veins is a practical, safe, and effective technique for achieving the electrophysiologic goal of acute pulmonary vein isolation in patients with paroxysmal atrial fibrillation.

Key words: *Balloon catheter. Freezing. Pulmonary vein isolation. Paroxysmal atrial fibrillation.*

Aislamiento circunferencial completo de venas pulmonares por crioablación con catéter-balón en pacientes con fibrilación auricular paroxística

El aislamiento de las venas pulmonares y la desconexión del músculo auricular izquierdo de la actividad arritmogénica de éstas son la piedra angular del tratamiento definitivo y curativo en pacientes con fibrilación auricular paroxística recurrente y sintomática refractaria a tratamiento antiarrítmico.

La lesión producida por frío con catéter-balón preserva la arquitectura tisular, disminuye la formación de trombos y el riesgo de estenosis venosa pulmonar.

Presentamos los resultados inmediatos conseguidos en los primeros 5 pacientes, que constituyen la experiencia inicial en España.

Se trataron un total de 20 venas pulmonares, y se demostró aislamiento eléctrico agudo completo en todas (100%). Los pacientes fueron dados de alta dentro de las primeras 72 h del procedimiento, sin complicaciones.

En conclusión, la crioablación con catéter-balón de las venas pulmonares es una técnica factible, segura y eficaz para conseguir el objetivo final electrofisiológico de aislamiento agudo de ellas en pacientes con fibrilación auricular paroxística.

Palabras clave: *Catéter-balón. Frío. Aislamiento de venas pulmonares. Fibrilación auricular paroxística.*

INTRODUCTION

The definitive treatment of patients with atrial fibrillation (AF) includes isolation of the potential triggering arrhythmogenic foci located predominantly in the pulmonary veins (PV),[1] as well as the abolition of nonpulmonary foci,[2,3] employing radiofrequancy (RF) as the source of energy. Individuals with paroxysmal atrial fibrillation (PAF) constitute the subgroup that most benefits in terms of efficacy, in comparison with chronic forms.[4]

The typically reported complications of RF include PV stenosis,[5] atrioesophageal fistula,[6] thromboembolism,[7] and postablation atrial arrhythmias.[8]

The lesion produced by cold, in contrast to that obtained by means of RF, preserves the tissue architecture and reduces the formation of thrombi.[9]

Declaration of conflict of interests: Dr Robert H. Hoyt is a USA researcher for the CryoCath system.

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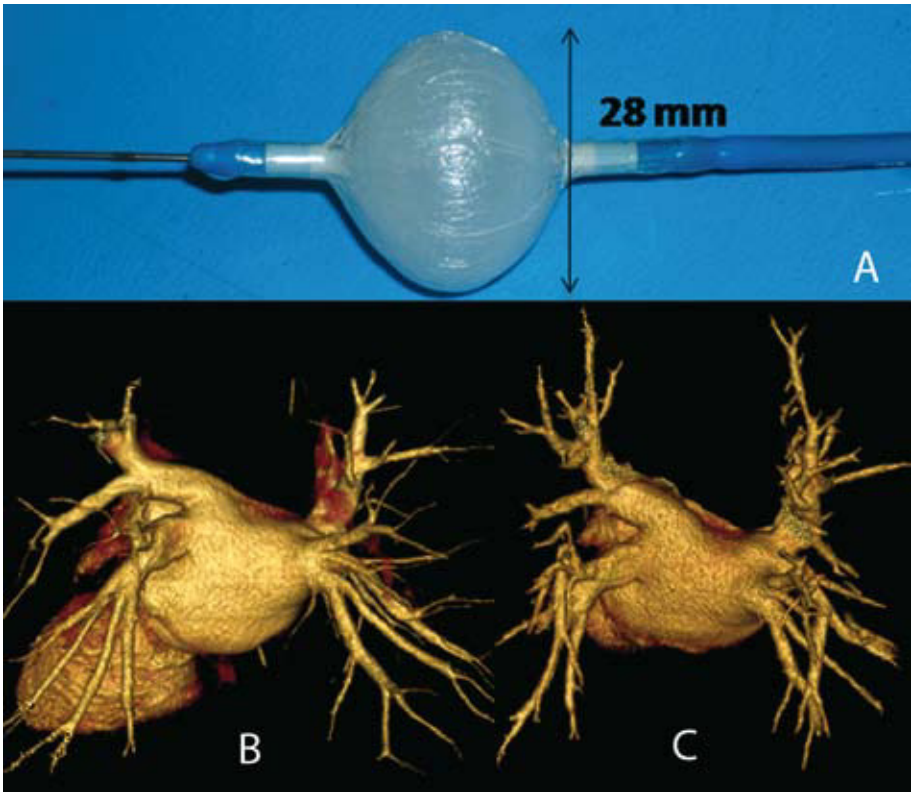

Figure 1. A: inflated balloon catheter. B: computed tomography (64 slices) of the pulmonary veins, case no. 5. C: computed tomography (64 slices) of the pulmonary veins, 3 months postablation, case no. 5.

Cryoablation using a catheter or a balloon catheter has been found to be safe in animals and humans as it enables the complete circumferential isolation of the veno-atrial junction in the pulmonary vein antrum.[9,10]

In this report, we present our initial experience with balloon catheter cryoablation, focusing on complete, acute circumferential isolation of the PV in patients with PAF; to the best of our knowledge, this is the first observation in Spain with this technique.

METHODS

Device

We used the 28-mm, 10.5 French (F) Artic Front double-lumen balloon catheter (CryoCath Technologies, Montreal, Quebec, Canada) (Figure 1) that allows the circulation of nitrous oxide at temperatures of –30ºC to –75ºC; the cooling vapor absorbs the heat of the surrounding tissue, thus resulting in its freezing. After each application, the gas is evacuated to the exterior of the system.

The cooling vapor is released by means of a console equipped with a monitor that provides data on the temperature reached and the duration of the application.

Patients

Five patients were included (4 men and 1 woman) with a mean age of 58.6 years (range, 53-72 years), with no structural heart disease and a documented history of 2 to 6 years of recurrent PAF refractory to antiarrhythmic therapy. The left ventricular ejection fraction (LVEF) was 58% or greater in every case (Table 1).

Studies Prior to the Procedure

All the patients underwent transthoracic and transesophageal echocardiogram at least 48 hours prior to the procedure and 64-slice computed tomography angiography (Figure 1) in order to define the anatomy of the left atrium and the PV (Table 2).

Procedure

The procedures were carried out with general anesthesia; intubation was achieved using cis-atracurium as the neuromuscular blocker.

TABLE 1. **Characteristics of the Patients**

Patient	Age, y	Sex	Arrhythmia			Antiarrhythmic Agents	Structural Heart Disease	LVEF
			Type	Duration, y	No. Episodes (Recurrences)			
1	53	M	PAF	2	1-2/day	Class IC, BB	No	65%
2	72	M	PAF	6	3-4/month	Class IC, III	No	60%
3	56	M	PAF	4	4-5/year	Class IC, III	No	58%
4	58	M	PAF	3	>1/month	Class IC, BB	No	65%
5	54	F	PAF	2	>1/week	Class IC, BB	No	64%

BB indicates beta-blockers; F, female; LVEF, left ventricular ejection fraction; M, male; PAF, paroxysmal atrial fibrillation.

TABLE 2. **Anatomy of the Pulmonary Veins (Lumen in mm)**

Patient	RSPV	RIPV	LSPV	LIPV
1	20	19	20	19
2	14	13	23	12
3	17	16	23	14
4	28	16	21	17
5	19	17	20	18

LIPV indicates left inferior pulmonary vein; LSPV, left superior pulmonary vein; RIPV, right inferior pulmonary vein; RSPV, right superior pulmonary vein.

A 6-F decapolar electro catheter was introduced up to the coronary sinus and a 6-F quadripolar catheter up to the veno-atrial junction for the proximal bipolar recording of the His bundle potential.

Following transseptal puncture, anticoagulation was maintained with an activated coagulation time (ACT) longer than 300 ms. Once the SL0 or SL1 sheath was introduced into the left atrium, a St. Jude 404878 260-cm 0.32 guidewire with J tip was passed selectively into each of the PV, and phlebography was performed with injection of 50% contrast medium. After angiography, the 15-F Flex-Cath guide catheter was passed through the guidewire with its dilator (CryoCath Technologies), and was positioned with the distal portion in the atrial cavity, in 40º left anterior oblique projection, and the 7-F dodecapolar circular catheter with adjustable diameter (St. Jude Reflexion Spiral) was introduced for cartography; each and every PV was mapped, starting systematically with left superior PV, followed by left inferior, right superior and right inferior PV.

After mapping, each of the veins was catheterized selectively with the 28 mm diameter balloon catheter, which was adjusted to the antrum until occlusion was achieved, with retention of 50% contrast medium in the interior of the vein and absence of drainage into the atrial cavity (Figure 2). Once this was confirmed, the lumen of the catheter was rinsed with 3 to 5 mL of heparinized saline solution in order to prevent crystallization of the contrast medium due to the cold, and the freezing process was initiated, keeping pressure of the balloon against the vein for 90 seconds; after this time, the balloon was completely adhered to the PV antrum, and the freezing process was continued for a total of 300 seconds.

Cold was applied between 2 and 3 times to each vein (mean, 2.75 times) individually, and the quadripolar Hisian catheter was introduced up to the superior vena cava for continuous phrenic nerve stimulation at low frequencies (3000 ms of cycle length), for the purpose of monitoring its integrity during cryoablation of the right PV, especially the superior veins.

Once the procedure was over, and after the sheaths had been removed from the transseptal catheter anticoagulation was reversed using protamine and low-molecular-weight heparin was introduced. Four hours later, a loading dose of oral dicumarol and 300 mg of acetylsalicylic acid (ASA) was initiated.

RESULTS

Thirty minutes after the applications of cold had been completed, the PV were again mapped with the circular catheter, and their complete isolation (100%) was demonstrated (Figures 3C and 3D), with mapping of the antrum anterior to the ostium and inside the PV itself (Figures 3A and 3B). The entry and exit blocks were demonstrated with stimulation.

The mean temperature reached in all the applications was higher than –40ºC (range, –32ºC to –70ºC).

The mean total duration of the procedure was 5.4 hours (329 minutes), with a mean fluoroscopy time of 81.6 minutes.

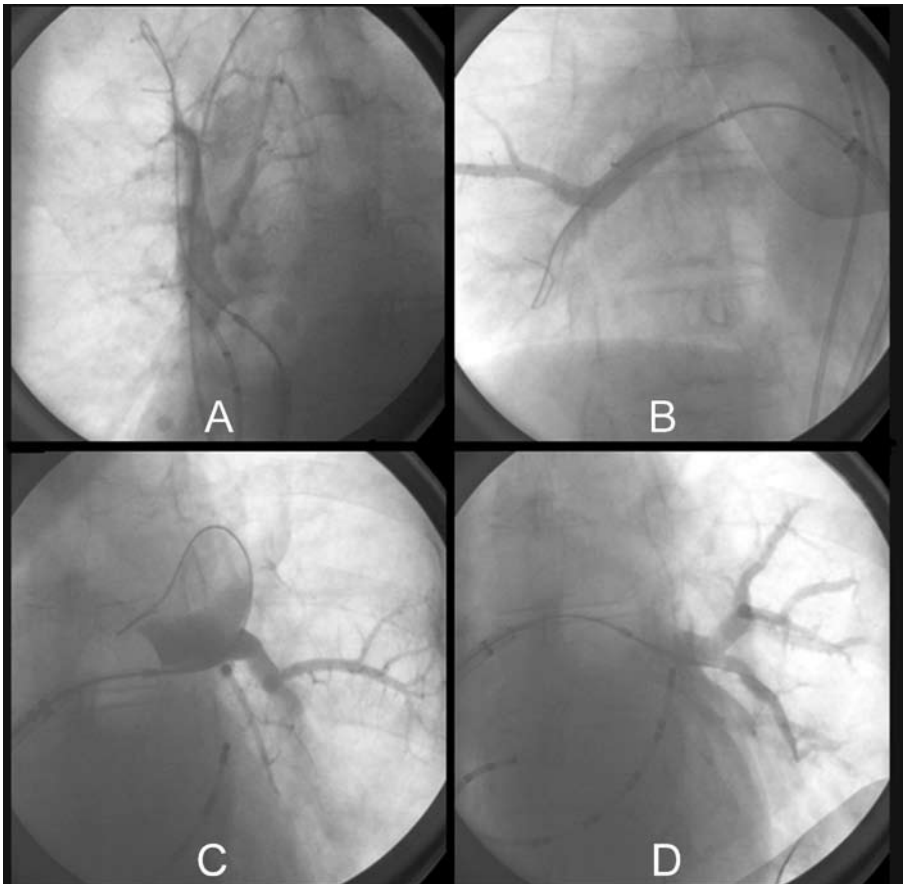

Figure 2. Ablation. Balloon catheter occlusion showing retention of the contrast medium with absence of atrial drainage due to complete occlusion, case no. 5. A: balloon catheter occlusion of right superior pulmonary vein. Note the quadripolar catheter in superior vena cava for phrenic nerve stimulation. B: balloon catheter occlusion of right inferior pulmonary vein. C: balloon catheter occlusion of left superior pulmonary vein. D: balloon catheter occlusion of left inferior pulmonary vein.

Course

The patients spent the first 24 hours post-procedure in the intensive care unit and were discharged from the hospital within 48 to 72 hours, with no complications, and with 300 mg flecainide, ASA and oral anticoagulation for the first three months post-ablation.

Three months post-ablation, non stenosis of the PV and non recurrence of arrythmia were documented, with follow-up involving Holter at 7, 15, 30, and 90 days and multislice computed tomography at 30 and 90 days.

DISCUSSION

Radiofrequency ablation in the area of the PV orifice is the most widely utilized method for the definitive treatment of AF.

This method, in all of its technical variants, requires technical skill and experience, since it necessitates prolonged procedures with considerable fluoroscopy times.

Moreover, RF applications in the ostium can produce the stenosis of one or more PV[5] and, due to the close anatomical relationship,[11] more lethal complications such as atrioesophageal fistula.[6]

The initial experiences reported in humans, involving the application of cold using a given catheter, suggest that cryoablation may be safer than RF ablation since it can reduce the risk of PV stenosis and other complications, such as atrioesophageal fistula, and achieves immediate acute isolation of 97% of the PV.[12]

The use of the novel Arctic Front balloon catheter[10] has been associated with the absence of PV non stenosis and absence of atrioesophageal fistula.

In short, we present here the immediate acute results for the first cases done in Spain with the cryoballoon catheter as a faster and safer method to achieve complete acute circumferential isolation of the arrhythmogenic focus in the PV in patients with PAF.

A greater number of patients, with medium-term and long-term follow-up, and comparative studies

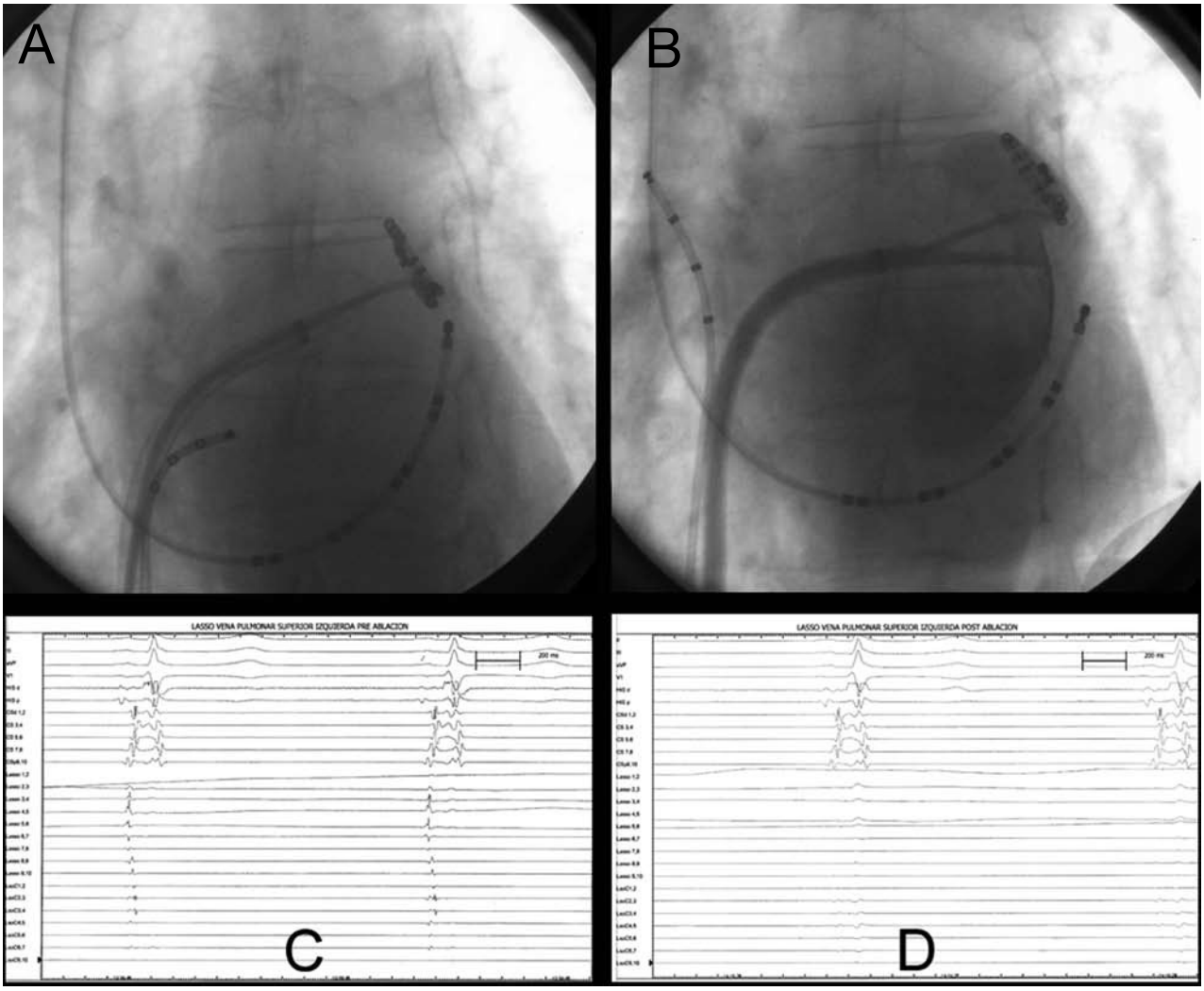

Figure 3. Case no. 5. A: catheter mapping in antrum of left superior pulmonary vein prior to ablation. B: catheter mapping in antrum of left superior pulmonary vein with injection of contrast medium following ablation. C: intracavitary recording prior to ablation obtained in Figure 3A with the circular catheter in the outer portion of the pulmonary vein ostium, with arrhythmogenic potentials of the pulmonary veins (PVAP). D: recording obtained in the same position as in Figure 3A following ablation, with absence of PVAP, showing complete circumferential isolation.

involving other methodologies will ultimately enable us to define the role of cryoablation in the curative treatment of PAF.

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