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Original article

Cryoballoon Ablation in Young Patients With Lone Paroxysmal Atrial Fibrillation

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ABSTRACT

Introduction and objectives: Long-term efficacy following cryoballoon ablation of lone paroxysmal atrial fibrillation remains unknown. We describe long-term follow-up results of the single cryoballoon ablation procedure.

Methods: Pulmonary vein isolation was performed in 103 patients (72 male; median age 52 years) with symptomatic lone paroxysmal atrial fibrillation. The end-point of this observational cohort study was first electrocardiogram-documented recurrence of arrhythmia (atrial fibrillation, atrial tachycardia, or atrial flutter) during the 5-year follow-up, in the absence of anti-arrhythmic treatment.

Results: Acute complete pulmonary vein isolation was achieved in 86% of the patients with a single cryoballoon. The 6-month, 1-year, and 5-year success rate after a single procedure was 94%, 91%, and 77%, respectively. Arrhythmia recurrence was observed in 24 cases at a median of 14.8 months [range, 8.0-16.8 months]. Thirteen symptomatic patients were well controlled on beta-blockers only. Seven symptomatic patients had anti-arrhythmic treatment (class IC in 5 patients; dronedarone in 2 patients) introduced during the blanking period. Two of them had early arrhythmia recurrence within the blanking period only; they were arrhythmia-free in further follow-up on dronedarone. The rate of complications was relatively low and included a 4.8% incidence of transient phrenic nerve palsy.

Conclusions: A single cryoballoon ablation procedure for lone paroxysmal atrial fibrillation resulted in high rates of acute, medium-term, and long-term efficacy. The rate of complications is relatively low and includes a 4.8% incidence of transient phrenic nerve palsy.

Ablación con criobalón en pacientes jóvenes con fibrilación auricular paroxística aislada

Palabras clave:
Fibrilación auricular
Fibrilación auricular paroxística
Ablación con criobalón
Resultados a largo plazo

RESUMEN

Introducción y objetivos: Todavía no se conoce la eficacia a largo plazo de la ablación con criobalón de la fibrilación auricular paroxística aislada. Se presentan los resultados de un seguimiento a largo plazo de la intervención de ablación con un solo criobalón.

Métodos: Se llevó a cabo el aislamiento de la vena pulmonar en 103 pacientes (72 varones; mediana de edad, 52 años) con fibrilación auricular paroxística aislada sintomática. El objetivo de este estudio observacional de cohorte era la primera recurrencia de la arritmia (fibrilación auricular, taquicardia auricular o aleteo auricular) documentada mediante electrocardiograma en un seguimiento de 5 años, en ausencia de tratamiento antiarrítmico.

Resultados: Se estableció aislamiento completo agudo de la vena pulmonar en el 86% de los pacientes con un solo criobalón. Las tasas de éxito a los 6 meses, 1 año y 5 años tras una sola intervención fueron del 94, el 91 y el 77% respectivamente. Se observó recurrencia de la arritmia en 24 casos, tras una mediana de 14,8 [intervalo, 8,0-16,8] meses. Se controló bien solo con bloqueadores beta a 13 pacientes sintomáticos; 7 pacientes sintomáticos recibieron tratamiento antiarrítmico (de clase IC en 5 pacientes; dronedarona en 2) que se introdujo durante el periodo de aclaramiento. Dos de ellos presentaron una recurrencia temprana de la arritmia solamente durante el periodo de aclaramiento; se mantuvieron sin arritmia en el seguimiento posterior durante el tratamiento con dronedarona. La tasa de complicaciones fue relativamente baja e incluyó una incidencia del 4,8% de parálisis transitoria del nervio frénico.

Conclusiones: Una intervención de ablación con un solo criobalón para la fibrilación auricular paroxística aislada produjo tasas altas de eficacia aguda y a medio y largo plazo. La tasa de complicaciones fue relativamente baja e incluyó una incidencia del 4,8% de parálisis transitoria del nervio frénico.

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Abbreviations

AAD: antiarrhythmic drugs
AF: atrial fibrillation
AFLAT: atrial fibrillation, atrial flutter, atrial tachycardia
CBA: cryoballoon ablation
LA: left atrium/atrial
PVI: pulmonary vein isolation

INTRODUCTION

The limited efficacy of drug treatment in patients with atrial fibrillation (AF) is known.[1] Catheter ablation of AF is an important therapeutic modality for such patients and the cornerstone of most procedures is pulmonary vein isolation (PVI).[2]

In recent years, technological improvement led to the implementation of faster and potentially safer "straight-forward" anatomically-oriented methods of PVI. Cryoballoon ablation (CBA) showed their superiority over antiarrhythmic drugs (AAD),[3] with a success rate comparable to radiofrequency-based PVI procedures in patients paroxysmal AF.[4,5] Recently, high efficacy of CBA as first-line therapy in a selected cohort has also been demonstrated in mid-term follow-up.[6]

The overall prevalence of AF is 0.4% to 1% in the general population.[7,8] Among that group, paroxysmal AF (LPAF)[9,10] occurs in 1% of all cases of AF.[11] While this population has a relatively low risk of mortality, heart failure, and thromboembolic complications, the risk of progression to persistent or permanent AF was estimated at 47%.[11,12] Moreover, the beneficial effects of early abolition of AF to prevent atrial remodeling and evolution to persistent/permanent AF was recently described.[13]

The latest guidelines[14,15] strongly recommend a focus on "low-risk" young patients (< 65 years of age) with AF. The latest consensus underlines the need for reporting long-term success, defined as "freedom from AF, atrial flutter, atrial tachycardia (AFLAT) recurrences, following the 3-month blanking period through a minimum of 36 months follow-up from the date of the ablation procedure in the absence of class I and III AAD therapy", especially in "newer ablation technologies" such as balloon techniques, and in specific patient populations, such as those with lone AF.[2] Following the recommendations,[2,14] we present the first very long-term safety and success outcome of CBA in patients with LPAF.

METHODS

Patients

Patients with lone AF were defined as young individuals (< 65 years of age) without clinical or echocardiographic evidence of cardiopulmonary disease, including hypertension.[9,10,16] Between January 1, 2005 and December 31, 2008, we enrolled 103 consecutive patients with recurrent and drug-refractory LPAF. In all patients, paroxysmal AF was documented by electrocardiogram (ECG) at least once within the last 3 months before ablation. Exclusion criteria were defined as non-paroxysmal AF, any structural heart disease, hypertension, chronic obstructive pulmonary disease treated with beta-sympathomimetic drugs, severe respiratory insufficiency, bleeding diathesis or intolerance of heparin or oral anticoagulation, previous attempted AF ablation, left atrial (LA) thrombus, pregnancy, and severe co-morbidity.

Our single-center study was performed at *Kerckoff Klinik*, Bad Nauheim, Germany.

Pre-ablation

Medical history was obtained during ambulatory visits with a thorough review of the medical records, including ECGs and Holter-ECG recordings showing episodes of AF. All patients gave written informed consent. The study was approved by the local institutional ethics committee. Oral anticoagulation was stopped 3 days before the intervention and replaced by subcutaneous low-molecular-weight heparin. AAD were discontinued at least 3 days before ablation. Beta-blockers were allowed according to the protocol.

All patients underwent echocardiography to determine LA diameter and exclude LA thrombus. The LA size was assessed by measurement of short and long axis in the apical four-chamber view.[17]

Intervention

The procedure was previously described.[18,19] After the transseptal punctures were performed, heparin was introduced with the aim of maintaining activation clotting time > 300 s throughout the whole procedure. Briefly, we used 23 mm and/or 28 mm cryoballoon (Arctic Front™, Medtronic Cryocath). The single application time was 240 s to 300 s. During CBA of the right-sided pulmonary veins (PVs), unaffected phrenic movement was assessed by continuous phrenic nerve stimulation and continuous monitoring of spontaneous breathing. After initial isolation, recurrence of PV conduction was checked during a 30-min observation period. If PVI could not be achieved with a first-choice cryoballoon size, an additional attempt used a different size. If PVI could not be confirmed after 5 consecutive applications per PV with any balloon, an 8-min tip cryoablation catheter (FreezorMAX™, Medtronic Cryocath) was used for touch-up ablation to complete PVI, which was verified as complete elimination of all PV signals at the antral or ostial level. Additionally, exit and entrance block of all PVs were confirmed by pacing maneuvers, as previously described.[18,19]

Post-ablation Management

After the procedure, intravenous heparin was continued to achieve a partial thromboplastin time of 60 s to 80 s, followed by oral anticoagulation with coumadin, for at least 3 months, targeting an international normalised ratio of 2-3. Antiarrhythmic treatment was stopped. Beta-blockers were allowed during the follow-up.

Follow-up

Our strict follow-up protocol follows the latest recommendations.[2] After discharge from the hospital, patients were scheduled for quarterly follow-up visits. Late follow-up (> 1 year post-intervention) was performed annually for 5 years. Seven-day Holter-ECG recordings were obtained at each follow-up visit. Each patient, in case of any palpitations, was instructed to have ECG performed to confirm or exclude AFLAT.

Statistical Analysis

The study used an observational cohort study design. The endpoint of the study was defined as first AFLAT-recurrence after the