Rev Esp Cardiol. 2016;69(5):488–493

Original article

Electrical Isolation of Pulmonary Veins Using Laser Catheter in the Treatment of Paroxysmal and Persistent Atrial Fibrillation. One-year Results

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Article history:
Received 20 April 2015
Accepted 3 August 2015
Available online 10 December 2015

Keywords:
Atrial fibrillation
Ablation
Laser catheter

ABSTRACT

Introduction and objectives: A new laser balloon that allows visualization of atrial tissue has recently been introduced for pulmonary vein electrical isolation. The aim of this study was to evaluate the mid-term safety and efficacy of this catheter in the treatment of atrial fibrillation.
Methods: Laser balloon ablation was performed in 71 patients with paroxysmal (80%) or persistent (20%) atrial fibrillation. Arrhythmia recurrence was defined as any episode lasting longer than 30 seconds. During follow-up, regular visits were performed every 3 months with 24- to 48-hour Holter tests.
Results: Isolation was possible in 275 of 278 (99%) of pulmonary veins. Mean procedure and fluoroscopy times were 154 ± 25 and 34 ± 15 minutes, respectively. A total of 89% of veins were isolated during the first attempt. The most common complication was phrenic nerve paralysis (5.6%), which appeared in only the first 18 cases. A total of 59 patients received follow-up for a mean of 420 ± 193 days, with a rate of arrhythmia recurrence of 12% and 30%, respectively, in paroxysmal and persistent atrial fibrillation (P = .155).
Conclusions: The laser balloon is a safe and effective system for pulmonary vein electrical isolation. Its advantages include the capacity to adapt to pulmonary vein anatomy using a single catheter, the efficacy with which pulmonary vein electrical isolation is achieved, and the favorable mid-term clinical progress, even for patients with persistent atrial fibrillation.

Aislamiento eléctrico venoso pulmonar con catéter láser en el tratamiento de la fibrilación auricular paroxística y persistente. Resultados a un año

Palabras clave:
Fibrilación auricular
Ablación
Catéter láser

RESUMEN

Introducción y objetivos: Recientemente se ha introducido un nuevo catéter-balón láser para el aislamiento eléctrico venoso pulmonar que permite la visualización del tejido auricular. El objetivo del presente trabajo es evaluar la seguridad y la eficacia a medio plazo de este catéter en el tratamiento de la fibrilación auricular.
Métodos: Se realizó ablación con catéter-balón láser a 71 pacientes con fibrilación auricular paroxística (80%) y persistente (20%). Se consideró recurrencia arrítmica los episodios de duración > 30 s. Durante el seguimiento se realizaron visitas periódicas cada 3 meses con Holter 24-48 h.
Resultados: Se logró aislar 275 de 278 (99%) de las venas pulmonares. Los tiempos medios de procedimiento y de fluoroscopia fueron 154 ± 25 y 34 ± 15 min respectivamente. Un 89% de las venas se aislaron en el primer intento. La complicación más frecuente fue la parálisis del nervio frénico (5,6%), que apareció solo en los primeros 18 casos. Se siguió a 59 pacientes durante una media de 420 ± 193 días, con una tasa de recurrencia arrítmica del 12 y el 30% respectivamente en fibrilación auricular paroxística y persistente (p = 0,155).
Conclusiones: El catéter-balón láser es un sistema seguro y efectivo para lograr el aislamiento eléctrico de las venas pulmonares. Entre sus ventajas destaca la capacidad de adaptarse a la anatomía venosa pulmonar con un único catéter y la eficacia con que logra el aislamiento eléctrico de las venas pulmonares, con una evolución clínica favorable a medio plazo, incluso para los pacientes con fibrilación auricular persistente.

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http://dx.doi.org/10.1016/j.rec.2016.02.006, Rev Esp Cardiol. 2016;474–6.
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http://dx.doi.org/10.1016/j.rec.2015.08.022

Abbreviations

AF: atrial fibrillation
PV: pulmonary vein

INTRODUCTION

Atrial fibrillation (AF) ablation is the recommended treatment for patients with paroxysmal or persistent AF who remain symptomatic despite antiarrhythmic therapy.[1,2]

In AF ablation, the main purpose is to achieve complete electrical isolation of pulmonary veins (PVs).[3] This is usually accomplished by point-to-point radiofrequency ablation around the ostium of PVs using irrigated tip catheters and electroanatomical navigation systems. However, the procedure is complex and time-consuming and has a long learning curve, with outcomes highly dependent on the operator. These limitations have led to the development of catheters specially designed to achieve PV electrical isolation using other energy sources.[4,5] Balloon cryoablation is the alternative to radiofrequency used at most hospitals and for which there is more clinical experience and scientific evidence. At present, point-to-point radiofrequency ablation and cryoablation are the 2 most common methods used for AF ablation.[3]

In recent years, a new ablation system that uses laser energy as an ablation source has been added to the therapeutic armamentarium.[6–9] The catheter is fitted with an adaptable balloon and is the first system to allow direct visualization of the left atrium and PVs to guide the ablation. Early clinical results show a good safety and efficacy profile, as well as a greater durability of PV isolation.[8,9]

The aim of this study was to describe the experience at our facility, to evaluate the efficacy and safety of this laser catheter in a series of patients referred to our hospital for ablation of paroxysmal or persistent AF, and to report on clinical outcomes over a mean follow-up of 1 year.

METHODS

Patients

The laser balloon ablation system first became available for use in our hospital in February 2013. As of that date, patients referred for AF ablation were alternatively assigned to treatment by radiofrequency ablation or laser ablation if they met either of the following criteria: *a)* patients with symptomatic paroxysmal AF who were refractory to at least 1 antiarrhythmic drug, and *b)* as of September 2013, patients with persistent AF from < 1 year previously who were symptomatic and refractory to at least 1 antiarrhythmic drug.

Patients with any of the following characteristics were excluded: *a)* left ventricular ejection fraction < 50%; *b)* age < 18 years or > 75 years; *c)* concomitant significant structural heart disease, and *d)* left atrial diameter > 50 mm. The study obtained results from 71 patients with AF who had been treated by laser-catheter ablation, from among a total of 137 patients referred for AF ablation.

Description of the Laser Balloon

The ablation system (CardioFocus, Inc.; Marlborough, Maryland, United States) includes a deflectable sheath (inner and outer diameters, 12 Fr and 15 Fr), balloon catheter with an inflatable diameter, endoscope, and console.

At its distal end, the balloon has a soft, nontraumatic tip to ease insertion of the balloon catheter into each PV and to reduce the risk of traumatic injury. The balloon diameter is adaptable and can progressively inflate up to a maximum of 38 mm, in order to maximize PV-to-balloon contact. The catheter shaft is multi-lumen for D_2O circulation to cool the balloon, for real-time visualization of the outer balloon surface via a 2-Fr endoscope, and for an optical fiber used to generate a movable light beam that covers 30°. Laser energy (980-nm diode laser) is administered through the same optical fiber. Endoscopic vision is partially obstructed in the area behind the central shaft of the balloon. Once ablation is completed in the visible tissue around the PV, the balloon is ruptured to complete the ablation circumference.

The console controls several parameters, among them, the energy administered (5.5-12 W), application time (20 or 30 s), and balloon diameter. The console has 2 images: a real-time image and a side-by-side image of previous and current applications to ensure continuity of the ablation line.

Ablation Procedure

Two operators (J. Osca and O. Cano) handled all cases simultaneously. All cases were treated by cannulation of the coronary sinus with a decapolar catheter (reference for transseptal puncture and right diaphragmatic stimulation) and use of an esophageal thermometer (SensiTherm™, St. Jude Medical; Minnesota, United States). Double transseptal puncture was performed by a modified Brockenbrough technique using 2 sheaths of 8.5 Fr (SL1; St. Jude Medical). A decapolar circular catheter was inserted through 1 of the sheaths to map the PVs (Lasso™, Biosense Webster; Diamond Bar, California, United States), whereas the free SL1 sheath was switched to a deflectable sheath (CardioFocus), always infused with heparinized solution. After transseptal puncture and throughout the rest of the procedure, heparin was administered to achieve an activated coagulation time > 300 s.

Selective angiography was then performed on the PVs, and after venography, the laser balloon was introduced through the deflectable sheath and advanced to the PV to start ablation. The purpose of ablation was to focus the laser beam on the area closest to the antrum, to the extent possible. Each application was overlapped with the preceding application by 30% to 50% to achieve a continuous ablation line. The energy administered was adjusted according to the anterior or posterior position of the application (8.5 W in the posterior wall; 10–12 W in the anterior wall), according to the width of the tissue visualized (higher power for wider tissues), and by reducing the power in the case of blood retained or trapped by the balloon. Once ablation was completed around each PV, the presence of bidirectional conduction block was confirmed.

Due to persistent conduction between the PV and the left atrium, additional laser applications were performed according to the records obtained with the Lasso™ catheter.

Once the persistence of PV electrical isolation in the next 20 minutes was confirmed, the procedure was finished. Adenosine was not used in any patients to confirm reconnection.

Postablation Follow-up

After ablation, patients received follow-up in the arrhythmia outpatient clinic every 3 months. The information obtained during follow-up included an electrocardiogram and a 24- to 48-hour Holter at each visit. Recurrence was not considered to include arrhythmias that appeared within the first 3 months after ablation