Pulmonary vein isolation as an index procedure for persistent atrial fibrillation: One-year clinical outcome after ablation using the second-generation cryoballoon

Giuseppe Ciconte, MD,[*] Luca Ottaviano, MD,[†] Carlo de Asmundis, MD, PhD,[*] Giannis Baltogiannis, MD,[*] Giulio Conte, MD,[*] Juan Sieira, MD,[*] Giacomo Di Giovanni, MD,[*] Yukio Saitoh, MD,[*] Ghazala Irfan, MD,[*] Giacomo Mugnai, MD,[*] Cesare Storti, MD,[‡] Annibale Sandro Montenero, MD, PhD,[†] Gian-Battista Chierchia, MD, PhD,[*] Pedro Brugada, MD, PhD[*]

From the [*]Heart Rhythm Management Centre, UZ Brussel-VUB, Brussels, Belgium, [†]Cardiovascular Department, IRCCS Multimedica, Sesto S. Giovanni, Milan, Italy, and [‡]Electrophisiology and Cardiac Pacing Unit, Istituto di Cura Città di Pavia, Pavia, Italy.

BACKGROUND No data are available about the clinical outcome of pulmonary vein isolation (PVI) as an index procedure for persistent atrial fibrillation (PersAF) ablation using the second-generation cryoballoon (CB-Adv).

OBJECTIVE The purpose of this study was to assess the 1-year efficacy of PVI as an index procedure for PersAF ablation using the novel CB-Adv.

METHODS Sixty-three consecutive patients (45 male [71.4%], mean age 62.7 ± 9.7 years) with drug-refractory PersAF undergoing PVI using the novel CB-Adv were enrolled. Follow-up was based on outpatient clinic visits including Holter ECGs. Recurrence of atrial tachyarrhythmias (ATs) was defined as a symptomatic or documented episode >30 seconds.

RESULTS A total of 247 PVs were identified and successfully isolated with a mean of 1.7 ± 0.4 freezes. Mean procedural and fluoroscopy times were 87.1 ± 38.2 minutes and 14.9 ± 6.1 minutes, respectively. Among 26 of 63 patients (41.3%) presenting with AF at the beginning of the procedure, 7 of 26 (26.9%) converted to sinus rhythm during ablation. Phrenic nerve palsy occurred in 4 of 63 patients (6.3%). At 1-year follow-up, after a 3-month blanking period (BP), 38 of 63 patients (60.3%) were in sinus rhythm. Because of AT recurrences, 9 patients underwent a second procedure with radiofrequency ablation showing a pulmonary vein reconnection in 4 right-sided PVs (44.4%) and 3 left-sided PVs (33.3%). Multivariate analysis demonstrated that PersAF duration ($P = .01$) and relapses during BP ($P = .04$) were independent predictors of AT recurrences.

CONCLUSION At 1-year follow-up, freedom from ATs following PersAF ablation with the novel CB-Adv is 60%. Phrenic nerve palsy is the most common complication. PersAF duration and relapses during the BP appear to be significant predictors of arrhythmic recurrences.

KEYWORDS Cryoballoon ablation; Second-generation cryoballoon; Persistent atrial fibrillation; Pulmonary vein isolation; One-year follow-up

ABBREVIATIONS **AAD** = antiarrhythmic drug; **AF** = atrial fibrillation; **AT** = atrial tachyarrhythmia; **LA** = left atrium; **PersAF** = persistent atrial fibrillation; **PV** = pulmonary vein; **PVI** = pulmonary vein isolation; **SR** = sinus rhythm

Introduction

The second-generation cryoballoon (CB-Adv; Arctic Front Advance, Medtronic Inc, Minneapolis, MN) is a safe and effective ablation device for pulmonary vein isolation (PVI).[1–4] Compared to the first generation, the CB-Adv has been designed with technical developments resulting in a larger and more homogeneous zone of freezing on its surface, which translates into significant improvements in procedural and clinical outcomes.[3,4]

Recently, acute and mid-term follow-up studies demonstrated the efficacy of this procedure, reporting a clinical success rate of approximately 80% in patients with paroxysmal and short-standing persistent atrial fibrillation (PersAF).[3–6]

To date, however, only sparse data are available about efficacy and 1-year clinical outcome after PVI for PersAF ablation using the cryoballoon. To the best of our knowledge,

Drs. Chierchia and Brugada contributed equally to this article as senior author. Drs. Chierchia and de Asmundis receive compensation for teaching and proctoring purposes from AF Solutions Medtronic. **Address reprint requests and correspondence:** Dr. Giuseppe Ciconte, Heart Rhythm Management Centre, Universitair Ziekenhuis Brussel, Vrije Universiteit Brussel, 101 Laarbeeklaan, 1090 Brussels, Belgium. E-mail address: g.ciconte@gmail.com.

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this is the first study uniquely focusing on PersAF ablation using the second-generation cryoballoon. The purpose of this study was to assess the single procedural outcome in a 1-year follow-up period of a series of consecutive patients undergoing PVI for PersAF using the CB-Adv. Potential predictors of arrhythmia recurrence and procedure-related complications are also considered as secondary end-points.

Methods

Study population

From July 2012, patients who had undergone PVI as an index procedure for symptomatic PersAF (>7 days or requiring electrical or pharmacologic cardioversion, or <1 year when decision was made to adopt a rhythm control strategy)[1,2] refractory to at least 1 class I or class III antiarrhythmic drug (AAD) were consecutively included in our analysis and followed in prospective fashion. Exclusion criteria were long-standing PersAF,[7,8] presence of an intracavitary thrombus, uncontrolled heart failure, severe valvular disease, previous PVI procedure, left atrial (LA) diameter >60 mm, and contraindications to general anesthesia.

Patients provided written informed consent for participation in the study. The study design was approved by the ethics committee of our institution according to the principles of the Declaration of Helsinki.

Preprocedural management

All patients provided written informed consent to the ablation procedure. Structural heart disease was defined as coronary artery disease, impaired left ventricular ejection fraction <40%, left ventricular hypertrophy >15 mm, valvular insufficiency greater than grade 2/4, significant valvular stenosis, and prior valve replacements. Transthoracic echocardiography was performed within 1 week before ablation, enabling assessment of left ventricular ejection fraction and intracavitary dimensions. To exclude the presence of thrombi in the LA appendage, all patients underwent transesophageal echocardiography the day before the procedure. All patients underwent a preprocedural computed tomographic scan to assess detailed LA and pulmonary vein (PV) anatomy.

Cryoballoon ablation procedure

Our standard ablation procedure has been previously reported in detail.[9] In brief, after obtaining LA access through a steerable 15Fr sheath (FlexCath Advance, Medtronic), an inner lumen mapping catheter (Achieve, Medtronic) was advanced in each PV ostium to obtain baseline electrical information. A 28-mm CB-Adv (Arctic Front Advance, Medtronic) was advanced inflated and positioned in each PV ostium. Optimal vessel occlusion was considered to have been achieved when selective contrast injection showed total contrast retention with no backflow to the atrium. Once occlusion was documented, cryothermal energy was started with a freeze–thaw cycle of 240 seconds. After 1 application, an additional bonus freeze of 240-second duration was applied. The latter was avoided in case of (1) early occurrence (between 60 and 120 seconds) and low nadir temperature achievement during the first cycle (–60°C or below); (2) occurrence of phrenic nerve palsy (PNP) during the first cycle, forcing the operator to abort the freeze; or (3) weakening of diaphragmatic capture monitored by intermittent fluoroscopy and tactile feedback (ie, placing the operator's hand on the patient's abdomen).

PV activity was recorded with the mapping catheter at a proximal site in the ostium before ablation in each vein. During ablation, if PVPs were visible during energy delivery, time to isolation was recorded when PVPs completely disappeared or were dissociated from LA activity. If PVPs were not visible during ablation because of distal positioning of the mapping catheter, the latter was immediately retracted after completion of the freeze–thaw cycle to a more proximal position in which PVPs had been recorded before ablation. In order to avoid PNP, a decapolar catheter was inserted in the superior vena cava, and diaphragmatic stimulation was achieved by pacing the ipsilateral phrenic nerve with a 1200-ms cycle and 20-mA output. The reason for pacing at such a slow rate was to prevent catheter displacement, due to diaphragmatic contraction, in the early phases of application. Phrenic nerve capture was monitored via tactile feedback by placing the operator's hand on the patient's abdomen. Refrigerant delivery was immediately stopped if weakening or loss of diaphragmatic movement was noted. If at the end of the entire procedure AF did not convert to sinus rhythm (SR), external electrical cardioversion was performed. During the whole procedure, activated clotting time was maintained over 250 seconds by supplementing heparin infusion as required.

Postablation management

Patients were discharged the day after ablation if their clinical status was stable. After the intervention, patients were continuously monitored with ECG telemetry for at least 18 hours. Before hospital discharge, all patients underwent chest radiography and transthoracic echocardiography in order to exclude pericardial effusion. Oral anticoagulation was started the same evening of ablation and continued for at least 3 months. Previously ineffective AADs were continued for 3 months, and after that time their discontinuation was recommended. The decision to restart AADs after the blanking period (BP) usually was made in the case of a first episode of atrial tachyarrhythmia (AT) recurrence.

Follow-up

After discharge, patients were scheduled for follow-up visits at 1, 3, 6, and 12 months, during which baseline ECG and 24-hour Holter recordings were obtained. All reports of Holter or ECG recordings performed in referring centers were sent to our center for confirmation of the diagnosis of recurrent atrial arrhythmias. In addition, telephone calls were made during the follow-up. All documented AT episodes >30 seconds after the index procedure, with standard ECG