

One-year clinical success of a ‘no-bonus’ freeze protocol using the second-generation 28 mm cryoballoon for pulmonary vein isolation

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Aims

Studies on the use of the second-generation 28 mm cryoballoon (CB) for the treatment of atrial fibrillation (AF) have reported superior 1-year clinical outcome. Customarily, a bonus freeze cycle is applied after pulmonary vein isolation (PVI). The purpose of the present study was to assess the 1-year clinical outcome following PVI foregoing a bonus freeze cycle.

Methods and results

Patients with drug-refractory paroxysmal AF (PAF) or persistent AF underwent PVI using the second-generation 28 mm CB. The freeze cycle duration was set at 240 s. No bonus freeze cycle was applied. Clinical follow-up (FU) included 12-lead ECGs and 24h-Holter ECGs at 3, 6, and 12 months. A total of 45 patients (age 60 ± 11 years, mean LA diameter 42.1 ± 8.6 mm, $n = 38$ [84%] PAF) underwent CB-based PVI. Of 177 pulmonary veins (PVs) identified, 176/177 (99%) PVs were successfully isolated. The mean number of CB applications was 1.2 ± 0.4 , 1.5 ± 0.8 , 1.4 ± 0.7 , 1.1 ± 0.3 and 1.7 ± 1.2 for the right superior PVs, right inferior PVs, left superior PVs, left inferior PVs, and left common PVs, respectively. Mean procedure and fluoroscopy times were 113 ± 32 and 19 ± 7 min, respectively. Phrenic nerve palsy occurred in 1/45 (2%) patients. One of 45 (2%) patients was lost to FU. After a mean FU period of 392 ± 58 (267–522) days including a 3-month blanking period, 36 of 44 (82%) patients remained in stable sinus rhythm. Five out of eight patients with arrhythmia recurrence underwent a second procedure. Only those PVs isolated with a single freeze cycle (5/11 PVs, 45%) demonstrated PV reconnection. In contrast, no PV reconnection was found in PVs initially treated with multiple freeze cycles.

Conclusions

A ‘no-bonus’-freeze protocol for PVI using the second-generation 28 mm CB resulted in an 82% 1-year clinical success rate. A bonus freeze cycle following successful PVI may not be essential to superior clinical outcome.

Keywords

Atrial fibrillation • Ablation • Pulmonary vein isolation • Cryoballoon • Outcome

Introduction

Pulmonary vein isolation (PVI) for the treatment of atrial fibrillation (AF) using the second-generation cryoballoon (CB, Artic Front Advance, Medtronic, Inc., Minneapolis, MN, USA) has demonstrated single-procedure success rates $\geq 80\%$ during the 1-year follow-up (FU).^{1–6}

Customarily a bonus freeze is applied after successful electrical isolation of the pulmonary veins (PVs). However, a strategy that limits the number of freeze cycles to a minimum might still result in an acceptable clinical outcome. The current study sought to assess the impact of a single-freeze protocol using the 28 mm CB; that is, foregoing a bonus freeze after successful PVI, on the freedom from AF after 1-year of FU.

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What's new?

- Pulmonary vein isolation utilizing the 28 mm cryoballoon and a 'no-bonus' freeze protocol resulted in an 82% 1-year freedom from atrial tachyarrhythmias
- Routine use of a bonus freeze cycle following successful pulmonary vein isolation may not be warranted in order to achieve durable 1-year success

Methods

Study population

The study population consisted of 45 subsequent patients with documented (12-lead ECG, Holter monitoring, or pacemaker/ICD) symptomatic, drug-refractory paroxysmal AF or persistent AF (duration of ≤ 3 months) who underwent catheter ablation for AF using the second-generation 28 mm CB. Exclusion criteria were prior PVI, a left atrial (LA) diameter > 60 mm, severe valvular heart disease or contraindications to post-interventional oral anticoagulation. To exclude intracardiac thrombi, a transoesophageal echocardiography was performed prior to each procedure. All patients provided written informed consent. The local ethics review committee approved the study.

Periprocedural management

The procedure was performed with the patient being deeply sedated using midazolam, fentanyl, and a continuous infusion of propofol. Heparin was used targeting an activated clotting time of > 300 s. A 7F diagnostic catheter (Webster TM, Biosense Webster, Inc., Diamond Bar, CA, USA) was introduced via the right femoral vein and positioned in the coronary sinus (CS). Following transeptal puncture (TP), a single 8.5F sheath (SL1, St Jude Medical, Inc., St Paul, MN, USA) was advanced into the LA and selective PV angiographies were performed. An oesophageal temperature probe (Sensitherm, St Jude Medical, Inc.) was placed at the level of each CB position to monitor oesophageal temperatures during energy application. The intraluminal oesophageal temperature cut-off was set at 10°C .⁷ To monitor phrenic nerve (PN) function during cryoenergy delivery along the septal PVs, continuous PN pacing at maximum output and pulse width (12 mA, 2.9 ms) was performed via a diagnostic catheter positioned within the superior vena cava (7F, Webster TM, Biosense Webster, Inc.). If any weakening or loss of diaphragmatic movement was noted, the freeze cycle was stopped immediately. In addition, the compound motor action potential (CMAP) was recorded as described by Franceschi *et al.*⁸

Pulmonary vein isolation

The 8.5F transeptal sheath was exchanged over a guidewire for a 12F steerable sheath (FlexCath, Medtronic, Inc.). The 28 mm CB was advanced into the LA and guided into the target PV over a circular mapping catheter (20 mm Achieve, Medtronic, Inc.). The latter also served to verify electrical PVI. Contrast medium was injected through the central lumen of the inflated CB to verify complete occlusion of the PV ostium. A single freeze cycle of 240 s was applied per PV. If PVI was not achieved following a single freeze application, an additional freeze cycle was applied until electrical isolation was verified. Per protocol, no additional bonus freeze was utilized following successful PVI.

The acute procedural endpoint was defined as persistent PVI verified by spiral mapping catheter recordings 30 min after the last CB application.

Postprocedural management

Following the procedure, each patient underwent transthoracic echocardiography to exclude a pericardial effusion. Low-molecular-weight heparin was administered in patients on vitamin K antagonists and an INR of < 2.0 until a therapeutic INR of two to three was achieved. Novel oral anticoagulants were reinitiated at half the regular dose 6 h post ablation. Anticoagulation was continued for at least 3 months or longer depending on the individual CHA₂DS₂-VASC score. Previously ineffective antiarrhythmic drugs were continued for 3 months after ablation. All patients received proton-pump inhibitors for 6 weeks.

Follow-up

Patient FU was performed through visits in our outpatient department or via telephone interviews. The referring physician performed a 12-lead surface ECG as well as a 24 h-Holter ECG at 3, 6, and 12 months following ablation. Any documented episode of AF or atrial tachycardia longer than 30 s was considered a recurrence. In the case of symptoms suggestive of recurrent atrial tachyarrhythmia, an event monitor was provided to the patient.

Endpoints

The primary endpoint was defined as recurrent documented AF > 30 s in duration after a 3-month blanking period. Secondary endpoints were defined as procedure-related complications, including PN palsy, stroke, pericardial effusion, and tamponade, or atrioesophageal fistula.

Statistical methods

Continuous data were described as mean and standard deviation (SD) if variables were normally distributed, otherwise the median, minimum, first and third quartile, and maximum were reported. Categorical data were described with absolute and relative frequencies. Recurrence-free survival was estimated by the Kaplan–Meier method. Cox proportional-hazards models were applied to assess the effect of potential risk factors on AF recurrence. Associations between the covariates and survival were described with hazard ratios (HR) and 95% confidence intervals (CI). All *P*-values are two-sided and a *P*-value of ≤ 0.05 was considered significant. All calculations were performed using SAS (version 9.3, SAS Institute, Inc., Cary, NC, USA).

Results

Baseline characteristics

The patients' baseline characteristics are detailed in *Table 1*. Between January and August 2013, 45 patients (13 females [29%], mean age 60 ± 11 years) with a mean LA diameter of 42 ± 9 mm underwent 28 mm CB-based PVI according to the single-freeze protocol. A history of PAF was noted in 38 of 45 (84%) patients and persistent AF in 7 of 45 (16%) patients.

Pulmonary vein isolation using the 28 mm cryoballoon

In total, 177 PVs were identified in 45 patients [45 right superior PVs (RSPV), 45 right inferior PVs (RIPV), 42 left superior PVs (LSPV), 42 left inferior PVs (LIPV) and 3 left common PVs (LCPV)]. Of the 177 PVs targeted, 176 (99%) were successfully isolated. In 1 patient, PN palsy occurred during cryoenergy application targeting the RSPV 62 s into the freeze cycle. At that point the RSPV was already electrically isolated. Consequently, the RIPV was not targeted for ablation.

In 1 patient, the oesophageal temperature reached 5.5°C during ablation along the LIPV after aborting energy delivery at a predefined temperature cut-off of 10°C 211 s into the freeze cycle. At that point the LIPV had already been successfully isolated.

Electrical PVI with the first CB application occurred in 34 of 45 (76%) RSPVs, 26 of 45 (58%) RIPVs, 28 of 42 (67%) LSPVs, 40 of 42 (89%) LIPVs, and 2 of 3 (67%) LCPVs, respectively (Table 2). In 16/45 (36%) patients, all 4 PVs were isolated during the initial freeze cycle. The mean number of CB applications per PV was 1.2 ± 0.4 for the RSPV, 1.5 ± 0.8 for the RIPV, 1.4 ± 0.7 for the LSPV, 1.1 ± 0.3 for the LIPV, and 1.7 ± 1.2 for the LCPV, respectively. The mean procedure duration was 113 ± 32 min including a 30-min waiting period and the average fluoroscopy time 19 ± 7 min. In 3 of 45 (7%) patients additional ablation of the cavotricuspid isthmus was performed for the treatment of typical atrial flutter.

Procedure-related complications

Targeting the RSPV for ablation, PN palsy developed abruptly in 1 in 45 (2%) patients during the second freeze-cycle after 205 s and a balloon temperature of -50°C . Loss of pace capture and decrease of CMAP amplitude occurred nearly simultaneously and despite

immediate interruption of energy delivery, PN palsy persisted beyond 12 months. Upon the next FU at 18 months, PN function had fully recovered as verified by fluoroscopy, while patients' symptoms had abated at 12-month FU. In 1 in 45 (2%) patients, a pericardial tamponade was noted on transthoracic echocardiography following isolation all PVs. Likely cause was a failed transeptal puncture attempt at the outset of the procedure. Following pericardiocentesis and aspiration of 370 mL blood, the patient was discharged home on hospital day 3. No other procedure-related complications were noted.

Clinical follow-up

Clinical FU was available for 44 of 45 (98%) patients. One patient was lost to FU. During a mean FU of 392 ± 58 (range 267–522) days, 36 of 44 (82%) patients [32 of 38 (84%) with PAF, 4 of 6 (67%) with persistent AF] remained in stable sinus rhythm (SR) without symptomatic and/or documented episodes of atrial tachyarrhythmias (Figure 1). Of 44 patients who completed the 6-month

Table 1 Patients' baseline characteristics

Patients (n)	45
Age (years)	60 ± 11
Female gender, n (%)	13 (29)
Paroxysmal AF, n (%)	38 (84)
Persistent AF, n (%)	7 (16)
LA size (mm)	42.1 ± 8.6
Hypertension, n (%)	29 (64)
Type II diabetes, n (%)	2 (4)
Coronary artery disease, n (%)	7 (16)
Medication prior to ablation	
β-Blockers, n (%)	41 (91)
Flecainide, n (%)	16 (36)
Amiodarone, n (%)	3 (7)
Dronedarone, n (%)	3 (7)
Warfarin, n (%)	30 (67)
New oral anticoagulants, n (%)	8 (18)

AF, atrial fibrillation; LA, left atrial.

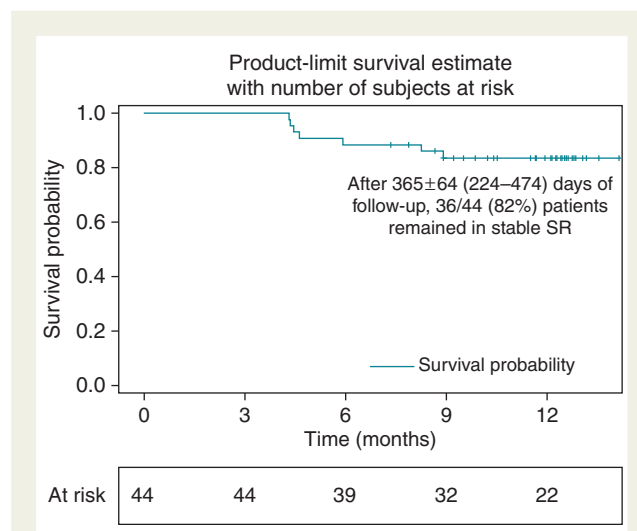


Figure 1 Kaplan–Meier curve. The Kaplan–Meier curve reflects the relative proportion of patients in stable SR following initial pulmonary vein isolation using the second-generation 28 mm cryoballoon during a mean FU period of 392 ± 58 (range 267–522) days including a 3-month blanking period. SR, sinus rhythm.

Table 2 Acute ablation results

	RSPV	RIPV	LSPV	LIPV	LCPV
Number of PVs, n	45	45	42	42	3
Isolated PVs, n (%)	45/45 (100%)	44/45 (98%)	42/42 (100%)	42/42 (100%)	3/3 (100%)
PVI during initial freeze cycle, n (%)	34/45 (76%)	26/45 (58%)	28/42 (67%)	40/42 (89%)	2/3 (67%)
Total number of CB applications, mean ± SD	1.2 ± 0.4	1.5 ± 0.8	1.4 ± 0.7	1.1 ± 0.3	1.7 ± 1.2

CB, cryoballoon; PV, pulmonary vein; PVI, PV isolation; RSPV, right superior PV; RIPV, right inferior PV; LSPV, left superior PV; LIPV, left inferior PV; LCPV, left common PV.

FU period, 39 (89%) were in stable SR, while 29 of 36 (81%) of patients completing the 12-month FU were free from recurrent atrial tachyarrhythmias.

One patient in the PAF group experienced recurrent AF during the blanking period 28 days after the index procedure and underwent successful electrical cardioversion. During an FU period of 473 days and respecting a 3-month blanking period, the patient remained in stable SR. Freedom from recurrent atrial tachyarrhythmias in 16 patients merely necessitating a single freeze cycle, that is, 4 freeze applications for a total of 4 PVs was 87.5% after a mean of 381 ± 70 (range 267–508) days. Following a 3-month blanking period, 15 of 44 (34%) patients remained on β -blockers, while 4 of 44 (9%) patients continued on flecainide, 1 of 44 patients (2%) on dronedarone, and 1 in 44 (2%) patients on amiodarone (2%), respectively.

Repeat procedures

A total of 5 of 8 (63%) patients (with $n = 19$ PVs) suffering from arrhythmia recurrence underwent a second procedure 250 ± 133 days after initial PVI using irrigated radiofrequency ablation in combination with an electroanatomical mapping system (Carto 3, Biosense Webster, Inc.). In those five patients with recurrence, during the initial procedure, 11 of 19 (58%) PVs were isolated applying a single freeze cycle, while 8 of 19 (42%) PVs necessitated multiple freeze applications (a mean of 2.1 freezes per PV). Only those PVs isolated with a single freeze cycle (5 of 11 PVs, 45%) demonstrated PV reconnection. In contrast, no PV reconnection was found in PVs initially treated with multiple freeze cycles. Right PV reconnection was observed in 4 of 5 (80%) patients. All lateral PVs were isolated. In 1 in 5 (20%) patients, both the left and right PVs were still isolated and ablation of complex fractionated atrial electrograms within the LA was performed leading to AF termination.

Discussion

In the present study, implementing a 'no-bonus' freeze protocol, 82% of patients treated with the second-generation 28 mm CB remained free from atrial tachyarrhythmias during a FU period of 1 year. Previous single-centre studies on the use of the second-generation CB demonstrated similar 1-year outcome with the notable difference that all studies deployed an extra freeze cycle once successful electrical isolation had been established.^{1–3} Considering the findings from the current study, the routine use of a bonus freeze application may not be essential to the 1-year freedom from recurrent tachyarrhythmias. In an earlier study on the utility of one vs. two bonus freeze cycles following successful PVI, a higher rate of PN palsy occurred during the second bonus freeze application.^{9,10} Hence, striving for optimal patient treatment, the operator should limit the number of freeze cycles to a minimum while securing superior clinical outcome. In this regard, a 'no-bonus' freeze protocol may enhance patient care.

The rationale to forego the conventional bonus freeze cycle after successful PVI is based on previously published data demonstrating high isolation rates during the initial freeze application. Published results from our laboratory on the 1-year success rate following PVI using the second-generation CB demonstrated an overall 87% isolation rate during the initial freeze cycle. Similar

results were reported by Martins *et al.* and Frnkranz *et al.* with a PVI rate of 90 and 84%, respectively, during the initial freeze application.^{11,12}

In the present study, the procedure duration and fluoroscopy times were lower than reported previously from our laboratory utilizing a single bonus-freeze cycle per PV.³ An expected lower incidence in adverse events, procedure duration, or fluoroscopy time compared with studies utilizing one or two bonus freeze cycles would require larger studies to demonstrate statistical significance. An alternative strategy reported by Chierchia *et al.* demonstrated encouraging 6-month FU results applying a 3-min freeze cycle.¹³ In any event, shortening of the individual freeze cycle or foregoing a bonus freeze application will have to be measured against the rate of recurrence upon mid- and long-term FU.

The 'no-bonus' freeze protocol followed in the current study utilized a standardized 240-s freeze cycle, irrespective of the time to actual PVI. In the majority of patients the time to isolation can readily be verified monitoring the PV signals recorded on the Achieve (Medtronic, Inc.) catheter. If isolation ensues promptly, continuing energy delivery for a total of 240 s may be overly ambitious. In contrast, a 240-s freeze cycle may prove too short if PVI occurred late during energy delivery. Consequently, a tailored approach to the individual patient taking into account the time to PVI may improve clinical outcome and will have to be assessed in future studies. In this context, the ongoing ICE-T study uses a protocol where PVI within 75 s precludes the use of a bonus freeze application, while isolation after 75 s will necessitate a second freeze-cycle 240 s in duration (German clinical trials registry ID: DRKS00004937).

Furthermore, device modifications may enhance acute and chronic outcome. An updated version of the currently available second-generation CB incorporates a shorter tip to facilitate close positioning of the Achieve (Medtronic, Inc.) catheter to the CB surface. This in turn may increase the rate of real-time verification of PVI during the freeze cycle.

Limitations

The presented findings are based on a single-centre experience enrolling a limited number of patients. Although the 1-year success rate reported is 82%, only 36 of 44 (82%) patients completed the 1-year cut-off period. The remaining 8 of 44 (18%) patients were followed for <1 year with the shortest follow-period spanning 267 days. Reducing the number of freeze cycles per PV should result in a lower incidence of complications, which to confirm would necessitate a larger patient cohort. Follow-up was limited to 24 h-Holter ECGs at 3, 6, and 12 months post ablation. This likely overestimates the success rate as higher intensity FU may have detected a greater number of recurrences.

Conclusions

Foregoing a bonus freeze after successful PVI using the second-generation 28 mm CB resulted in an 82% freedom from recurrent atrial tachyarrhythmias at 1-year FU. These findings suggest that a bonus freeze application may not be essential to achieve stable SR over 1-year.

Conflict of interest: E.W. received speaker's honoraria from and serves as consultant to Medtronic and is member of Medtronic's advisory board. K.H.K. received research grants and speaker's honoraria from Medtronic and is a consultant to Medtronic. A.M. received speaker's honoraria from and serves as consultant to Medtronic.

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Haemoptysis and pulmonary haemorrhage associated with cryoballoon ablation

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A 55-year-old male patient was referred to our hospital for pulmonary vein isolation (PVI) by cryoballoon of drug-resistant paroxysmal atrial fibrillation. Pulmonary vein isolation was performed with a 28 mm cryoballoon. The patient was anti-coagulated with iv heparin and the activated clotting time was kept ~350 s after a transseptal puncture.

Firstly, the left superior pulmonary vein (LSPV) was targeted. After inflation of the cryoballoon within the ostium of LSPV, -48°C temperatures were reached during the first application. During the second cryoablation application at -50°C , sudden haemoptysis was developed (~100 ml in 15 s). Cryoablation was stopped and the balloon was deflated. Activated clotting time was checked and was 400 s. Patient desaturated to 85% and fluoroscopy demonstrated wedge-shaped consolidation of the left middle zone that may be consistent with pulmonary infarction (Hampton hump-like image) (Figure, left panel). Nasal oxygen therapy increased the saturation and haemoptysis was discontinued. The consolidation area did not enlarge on fluoroscopic examination. Other pulmonary veins were isolated successfully. The computed tomography scan of the chest (Figure, right panel) confirmed the consolidation in the left lower lobe at the superior boundary suggestive of a pulmonary haemorrhage. Warfarin was started at the third day after the procedure and haemoptysis did not re-occur.

The full-length version of this report can be viewed at: <http://www.escardio.org/communities/EHRA/publications/ep-case-reports/Documents/Haemoptysis-and-pulmonary.pdf>.

