# Reduced incidence of esophageal lesions by luminal esophageal temperature–guided second-generation cryoballoon ablation

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**BACKGROUND** An increased incidence of esophageal lesions (EL) after pulmonary vein isolation (PVI) using the second-generation cryoballoon (CB2) has been described. We hypothesized that luminal esophageal temperature (LET)–guided PVI reduces the incidence of EL.

**OBJECTIVE** The aim of this study was to investigate the incidence of EL after LET-guided PVI using the CB2.

**METHODS** Ninety-four consecutive patients underwent CB2-PVI for paroxysmal or persistent atrial fibrillation. Target freezing time was 2 × 240 seconds. LET was continuously measured by a probe with 3 thermocouples. Early freezing interruption was performed when LET reached a prespecified cutoff temperature. A group of 32 patients who underwent CB2-PVI with observational LET measurement served as the control group. Postprocedural esophagoscopy was performed in all patients.

**RESULTS** Compared with observational LET measurement, a strategy of LET-guided CB-PVI significantly reduced the incidence of EL from 18.8% to 3.2% ($P = .008$). A progressive decline in the incidence of EL was observed with an increasing LET cutoff: 7.1% (2/28 patients, 12°C cutoff) and 1.5% (1/66 patients, 15°C cutoff, $P = .005$ vs control). Despite early freezing interruption at a single pulmonary vein in 27% (25/94) of patients, complete PVI was achieved in all patients using the 28 mm balloon. Repeat esophagoscopy confirmed healing of EL after 1 week. After a mean of 268 ± 119 days, 87% (76/87) of patients were free of recurrent atrial fibrillation or atrial tachycardia following a 90-days blanking period.

**CONCLUSION** LET-guided CB2-PVI significantly reduced the incidence of thermal EL. Interrupting cryoablation at 15°C LET was associated with the lowest incidence of esophageal injury.

**KEYWORDS** Ablation; Atrial fibrillation; Cryoballoon; Esophageal injury; Complication

**ABBREVIATIONS** **AEF** = atrioesophageal fistula; **AF** = atrial fibrillation; **AT** = atrial tachycardia; **CB** = cryoballoon; **CB1** = first-generation cryoballoon; **CB2** = second-generation cryoballoon; **CI** = confidence interval; **EFI** = early freezing interruption; **LET** = luminal esophageal temperature; **OR** = odds ratio; **PN** = phrenic nerve; **PV** = pulmonary vein; **PVI** = pulmonary vein isolation; **RIPV** = right inferior pulmonary vein

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## Introduction

Cryoballoon (CB) ablation is increasingly used to perform pulmonary vein isolation (PVI) as an alternative to point-by-point radiofrequency ablation.[1] Recently, the second-generation cryoballoon (CB2) has become available and improved procedural[2,3] as well as clinical[4–7] performance of the CB2 has been demonstrated compared with the first-generation cryoballoon (CB1). The CB2 differs from the CB1 by a widened zone of minimum temperature as well as a higher refrigerant flow rate in the larger 28 mm balloon. This possibly affects collateral structures such as the esophagus. Atrioesophageal fistula (AEF) formation has been reported after CB-PVI.[8–10] We previously demonstrated an association of low luminal esophageal temperature (LET) with esophageal thermal ulcerations.[11] A LET value of ≤12°C predicted lesions with the highest sensitivity and specificity (100% and 92%, respectively).[11] On the basis of these results, we hypothesized that LET-guided CB-PVI with interruption of cryoenergy deployment at ≥12°C LET

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reduces the incidence of esophageal lesions compared with observational LET measurement.

## Methods

### Patients

We conducted a prospective study in 94 consecutive patients with paroxysmal or persistent atrial fibrillation (AF). Exclusion criteria were as follows: a left atrial diameter of >55 mm, persistent AF for >6 months, intracardiac thrombi, and failure to consent to postprocedural gastroesophagoscopy. Patients underwent CB-PVI with interventional LET measurement, that is, early freezing interruption (EFI) at ≥12°C LET. Clinical baseline characteristics of the study patients are summarized in Table 1. The study protocol was approved by the local institutional review board. All patients provided written informed consent. A group of patients (n = 32) who underwent CB-PVI with observational LET measurement, that is, without a prespecified LET cutoff to guide freezing interruption, served as the control group. These results have been published previously.[11] The study cohort was treated consecutively to the control group.

### CB ablation

We previously described the technique of CB2-PVI and LET measurement.[2,11] Briefly, vitamin K antagonists were continued, aiming for an international normalized ratio of 2–2.5 at the day of the procedure, and direct oral anticoagulants were discontinued 2 days before the procedure. Transesophageal echocardiography to rule out left atrial thrombi was performed immediately before the procedure. All procedures were performed under sedoanalgesia using boluses of midazolam and fentanyl and a continuous infusion of propofol. After single transseptal puncture, the CB2 (Arctic Front Advance, 28 mm, Medtronic, Inc, Minneapolis, MN) was introduced into the left atrium via a 12-F steerable sheath (FlexCath, Medtronic). Mapping of the pulmonary veins (PVs) was performed before, during, and after freezing with an endoluminal spiral mapping catheter (Achieve, Medtronic). To assess the exact position of the inflated balloon in relation to the PV ostium, contrast medium was injected from the distal lumen of the CB. Target application time was 240 seconds. After successful PVI, 1 "bonus" application was performed per PV unless low LET or right phrenic nerve (PN) dysfunction mandated freezing interruption. The ablation protocol consisted of CB-PVI only without additional ablation using a focal catheter. If necessary, sinus rhythm was restored by cardioversion during the procedure. A temperature probe with 3 thermocouples (SensiTherm, St Jude Medical, Inc, St Paul, MN) was inserted into the esophagus transorally under fluoroscopic guidance. The position of the temperature probe was adjusted to the position of the balloon before each cryothermal application. Minimum LET was defined as the temperature nadir occurring during or shortly after cryothermal energy deployment in any of the thermocouples. The right PN was paced from the superior caval vein during freezing at the septal PVs. In the case of cessation or weakening of right hemidiaphragm contractions, freezing was immediately stopped. The procedural end point was the absence or dissociation of all PV potentials as confirmed by the endoluminal spiral mapping catheter after a waiting period of 30 minutes.

**Table 1** Baseline characteristics of patients

| | |
|---|---|
| Sex: male | 68 |
| Age (y) | 64 ± 10 |
| AF history (y) | 3 ± 3 |
| Persistent AF | 10 |
| LA size (mm) | 40 ± 5 |
| LVEF (%) | 62 ± 11 |
| Hypertension | 69 |
| Diabetes | 7 |
| Stroke/TIA | 4 |
| CAD | 17 |

Values are presented as mean ± SD and as percentages.AF = atrial fibrillation; CAD = coronary artery disease; LA = left atrial; LVEF = left ventricular ejection fraction; TIA = transient ischemic attack.

### Analysis of LET and balloon temperature

In a subset of patients (n = 17), continuous videoscopic recordings of esophageal and CB temperature readouts were performed during the procedure. From these recordings, during each cryothermal application, LET and balloon temperature curves were constructed with a 5-second sampling interval. The distance between the temperature probe and the CB was measured fluoroscopically in right anterior oblique 30° and left anterior oblique 40° projections (Figure 1). If both structures overlapped, the distance was set to zero. The larger distance of the 2 fluoroscopic projections was used for the analysis.

### Postprocedural care and esophagoscopy

Details of the postprocedural protocol and esophagoscopy have been described previously.[11] In short, low-molecular-weight heparin was administered starting 6 hours after ablation in patients with previous direct oral anticoagulant treatment or in patients receiving vitamin K antagonists if the international normalized ratio was <2. Gastroesophagoscopy was performed within 3 days of the procedure. The endoscope was introduced under continuous videoscopic surveillance. The gastroenterologist performing esophageal endoscopy was blinded to procedural parameters including LET measurement. Thereafter, oral anticoagulation was restarted according to the previous regimen and prescribed for at least 2 months. A proton pump inhibitor was administered for 2 weeks starting on the day of ablation. Patients were scheduled for outpatient clinic visits at 3, 6, 9, and 12 months at which time 72-hour Holter electrocardiogram recording was performed. In the case of symptoms suggestive of atrial tachyarrhythmia recurrence, additional visits were scheduled. Atrial tachyarrhythmia recurrence was defined as AF or atrial tachycardia (AT) lasting >30 seconds