Original Article

Increased Incidence of Esophageal Thermal Lesions Using the Second-Generation 28-mm Cryoballoon

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Background—Pulmonary vein isolation is an established treatment option for atrial fibrillation. To date, the incidence and quality of ablation-induced esophageal thermal lesions (ETLs) using the recently introduced second-generation cryoballoon (CB, ArcticFront Advance, Medtronic) is unknown.

Methods and Results—In patients with drug-refractory paroxysmal atrial fibrillation or short-standing persistent atrial fibrillation, pulmonary vein (PV) isolation was performed using the second-generation CB. The endoluminal esophageal temperature was monitored via a temperature probe. After PV isolation, esophagogastroduodenoscopy (EGD) was performed to assess the incidence of ETLs. In 50 patients (18 women; age, 61±11 years; left atrial diameter, 43±5 mm), successful CB-based PV isolation was performed. Lowest median balloon temperature and esophageal temperature for the right superior PV were −51°C and 35.8°C, −47°C and 35°C for the right inferior PV, −51°C and 34.4°C for the left superior PV, −48°C and 34.6°C for the left inferior PV, and −54°C and 34.5°C for the left common PV, respectively. EGD performed 2±1 days post ablation demonstrated superficial thermal lesions and thermal ulcerations in 1 of 50 (2%) and 5 of 50 (10%) patients, respectively. In patients with ETLs, during ≥1 freeze cycle the endoluminal esophageal temperature measured <3.0°C. All thermal lesions were in the healing process on repeat EGD 4±2 days after initial endoscopy.

Conclusions—Using the second-generation 28-mm CB, ETLs were detected in 6 of 50 (12%) patients. All ETLs were in the healing process on repeat EGD. An esophageal temperature safety cutoff may prove valuable in the prevention of ETLs and requires further evaluation. (***Circ Arrhythm Electrophysiol***. 2013;6:769-775.)

Key Words: ablation ◼ atrial fibrillation ◼ complications

Pulmonary vein isolation (PVI) using the cryoballoon (CB, ArcticFront, Medtronic Inc) is an established ablation technology commonly used in patients experiencing drug-refractory paroxysmal atrial fibrillation (AF). Although CB PVI is considered safe and effective, procedure-related complications have been reported.[1–3] The incidence of esophageal thermal lesions (ETLs) using the first-generation CB ranges between 0% and 18% depending on the balloon size used.[4,5] Recently, the first published case of an atrioesophageal fistula after use of the first-generation CB was reported.[6]

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The second-generation CB (Arctic Front Advance, Medtronic Inc) was introduced in 2012. Rather than cooling of only the distal equatorial ring sparing the CB tip, the second-generation CB incorporates a revised refrigerant injection system that allows for more homogeneous cooling of the total distal balloon hemisphere. Although these modifications are expected to increase efficacy, enhanced cooling may result in

a higher rate of collateral damage to noncardiac tissue. In this context, the current study set out to investigate the incidence of ETLs using the second-generation 28-mm CB.

Methods

Inclusion and Exclusion Criteria

Consecutive patients experiencing symptomatic, drug-refractory paroxysmal AF or short-standing persistent AF (persistent AF with a duration of ≤3 months) were admitted and eligible for CB-based PVI. Exclusion criteria were prior left atrial (LA) ablation, LA diameter >55 mm, severe valvular heart disease, and contraindications to postinterventional oral anticoagulation. Transesophageal echocardiography was performed before PVI to assess LA diameter and to rule out intracardiac thrombi. No additional preinterventional imaging was performed. Each patient gave written informed consent.

Intraprocedural Management

The procedure was performed under deep sedation using boluses of midazolam, fentanyl, and a continuous infusion of propofol (1%, 10–30 mL/h). Vital parameters (pulse, blood pressure, oxygen saturation, and body temperature) were continuously monitored. Before

transseptal puncture (TP), 2 diagnostic catheters introduced via a right femoral vein access were placed within in the coronary sinus (7F, Webster, Biosense Webster, Inc, Diamond Bar, CA) and along the His-bundle region (6F, Webster, Biosense Webster, Inc), respectively. Subclavian vein access was attempted only if the coronary sinus catheter could not be positioned from the femoral vein. Double TP was performed under fluoroscopic guidance using a modified Brockenbrough technique and 2 8.5F transseptal sheaths (TS; SL1, St. Jude Medical, Inc, St. Paul, MN). One TS was exchanged over-the-wire for a 12F steerable TS (Flexcath, Medtronic, Inc, Minneapolis, MN).

After successful TP, a heparin bolus was administered targeting an activated clotting time of >300 seconds. Selective PV angiography aided in identifying the individual PV ostia. A spiral mapping catheter (Lasso, Biosense Webster, Inc) was positioned at the PV ostium and baseline PV potentials were recorded.

During freeze application at the septal PVs, continuous phrenic nerve (PN) pacing was performed (12 mA, 2.9 ms) via a diagnostic catheter placed in the superior vena cava. Cryoablation was immediately terminated in the event of loss of PN capture.

Cryoballoon-Based PVI

In brief, the second-generation CB (Arctic Front Advance, Medtronic, Inc) is available as a noncompliant balloon with diameters of 23 or 28 mm. Compared with the first-generation CB, it incorporates a modified refrigerant injection system (8 instead of 4 injection jets; injection jets in a more distal position) providing more homogeneous cooling of the distal hemisphere of the balloon surface. The deflated CB is advanced into the LA via a 12F steerable TS using an over-the-wire technique and a stiff wire or a spiral mapping catheter (15 or 20 mm diameter; Achieve, Medtronic, Inc, Minneapolis, MN). The stiff wire or spiral mapping catheter is advanced into the target PV and the CB inflated within the LA before proper positioning at the antral aspect of the target PV. Contrast medium is injected through the central lumen of the CB to verify complete sealing of the balloon-to-PV/LA interface. A freezing cycle of 240 seconds is applied, while the balloon temperature is automatically stored. In case of successful PVI verified by spiral mapping catheter recordings, an additional freeze cycle of 240 seconds is applied.

In the current study, only the 28-mm second-generation CB was used irrespective of the PV diameter. The end point of cryoablation was achieved once all PVs demonstrated persistent isolation verified by spiral mapping catheter recordings after a 30-minute waiting period after the last freeze application.

Temperature Monitoring

An esophageal temperature probe equipped with 3 thermistors (SensiTherm, St. Jude Medical, Inc) was inserted transorally for continuous observation of esophageal temperature changes during the freeze cycle. The temperature probe was positioned at the level of and the closest distance to the CB during ablation and readjusted as needed using the respective fluoroscopic projection. Only the lowest endoluminal esophageal temperature was recorded for each PV because the unit does not allow storage of temperature-over-time curves. There was no predefined temperature cutoff.

Postprocedural Care

All patients underwent transthoracic echocardiography and thoracic fluoroscopy the day after ablation to rule out pericardial effusion and pneumothorax, respectively. After ablation all patients were treated with pantoprazol 40 mg twice daily for 6 weeks. Low molecular-weight heparin was administered in patients on warfarin and an International Normalized Ratio <2.0 until a therapeutic International Normalized Ratio of 2 to 3 was achieved or until the initiation of a new oral anticoagulant. Anticoagulation was continued for 3 months post ablation and then based on the individual CHA$_2$DS$_2$-VASC score. Previously ineffective antiarrhythmic drug therapy was continued for 3 months.

Esophagogastroduodenoscopy

Two days after ablation, esophagogastroduodenoscopy (EGD) was performed in all patients to assess for the presence and quality of ETLs. EGD was repeated after 5 days in case of detected ETLs. EGD findings were classified as no lesion, superficial thermal lesion (erythema with intact mucosa), or esophageal ulceration.[7]

Follow-Up

A blanking period of 3 months post PVI was defined. Outpatient clinic visits at 3, 6, and 12 months, including 24-hour Holter-ECGs, were performed. In addition, outpatient clinic visits, ECG, and Holter ECG were immediately initiated in case of symptoms suggestive for a recurred arrhythmia.

Statistical Analysis

Continuous data are shown as mean and SD in case of normally distributed data and as median, interquartiles, minimum, and maximum otherwise. Differences in esophageal and balloon temperatures between patients with and without ETLs were tested with the Wilcoxon–Mann Whitney test. The Kolmogorov–Smirnov and Shapiro–Wilk tests on normal distribution were used. In addition, Q-Q plots of the data were applied.

For associations between continuous variables, the nonparametric correlation coefficient of Spearman was calculated. Receiver operating characteristic curves, which represent false and right positive rates for all cut point values of a continuous variable, were used to achieve ideal cut point values for esophageal and balloon temperatures to predict the presence or absence of lesions. The cut point values were optimized for specificity. The rate of right positives and right negatives for these values is mentioned in the text.

All *P* values are 2-sided and a *P*<0.05 was considered significant. All calculations were performed with the statistical analysis software SAS (SAS Institute, Inc, version 9.2, Cary, NC). All authors have read and agreed to the article as written.

Results

Patient Characteristics

Fifty patients (18 women, mean age, 61±11 years; mean LA diameter, 43±5 mm) with a history of paroxysmal AF (36/50 patients [72%]) or short-standing persistent AF (14/50 patients [28%]) underwent CB-based PVI using exclusively the 28-mm second-generation CB. Thirty-seven of 50 (74%) patients, 6 of 50 (12%) patients, and 8 of 50 (16%) patients had a known history of arterial hypertension, stable coronary artery disease, and diabetes mellitus, respectively. None of the patients had a previous LA ablation attempt. The mean creatinine level measured in the patient cohort was 0.9±0.2 mg/dL (range, 0.7–1.4 mg/dL).

Ablation Results

In 50 patients, a total of 192 PVs was identified. A total of 191 of 192 (99%) PVs were isolated successfully using only the second-generation CB. One of 50 (2%) right inferior PVs (RIPVs) was not targeted because of loss of PN capture during CB ablation of the ipsilateral right superior PV (RSPV). Electric PVI during the first cryo-application was achieved in 46 of 50 (92%) RSPVs, 41 of 50 (82%) RIPVs, 37 of 42 (88%) left superior PVs (LSPVs), 42 of 42 (100%) left inferior PVs (LIPVs), and in 4 of 8 (50%) left common PVs (LCPVs). The mean number of cryo-applications resulting in PVI was 1.1±0.5, 1.3±0.6, 1.1±0.3, 1.0±0, and 1.5±0.5 for the RSPV, RIPV, LSPV, LIPV, and LCPV, respectively. In all PVs, one safety cryo-application was applied after successful PVI. Mean

Table 1. Ablation Results

	RSPV	RIPV	LSPV	LIPV	LCPV
No. of PVs (n)	50	50	42	42	8
Isolated PVs, n (%)	50/50 (100)	49/50 (98)	42/42 (100)	42/42 (100)	8/8 (100)
Isolation with first cryo-application, n (%)	46/50 (92)	41/50 (82)	37/42 (88)	42/42 (100)	4/8 (50)
No. of cryo-application until PVI, mean±SD	1.1±0.5	1.3±0.6	1.1±0.3	1.0±0	1.5±0.5
Minimal balloon temperature, median (q1–q3), °C	−51 (−54 to −45)	−47 (−52.3 to −43)	−51 (−55 to −45)	−48 (−52 to −44)	−54 (−57 to −47.5)

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

total number of CB applications, including the safety freeze cycle, was 2.2±0.5, 2.2±0.7, 2.1±0.3, 2.0±0, and 2.5±0.5 for the RSPV, RIPV, LSPV, LIPV and LCPV, respectively.

Median minimal balloon temperature was RSPV −51°C (−54°C to −45°C; q1–q3), RIPV −47°C (−52.3°C to −43°C), LSPV −51°C (−55°C to −45°C), LIPV −48°C (−52°C to −44°C), and LCPV −54°C (−57°C to −47.5°C; Table 1).

Median procedure and fluoroscopy times were 135 (125–154; q1–q3) minutes and 25 (21–29) minutes, respectively. The median fluoroscopy dose-area product was 5077 (3001–8048) cGy×cm². The mean amount of contrast used per patient was 174±55 mL.

Esophageal Temperatures
The median minimal esophageal temperature during cryo-application was RSPV 35.8°C (34.8°C–36.3°C; q1–q3), RIPV 35°C (31.5°C–36°C), LSPV 34.4°C (32.6°C–35.8°C), LIPV 34.6°C (25.8°C–35.3°C), and LCPV 34.5°C (30.2°C–35.1°C). During 6 freeze cycles in 5 patients endoluminal esophageal temperature was measured <0°C (range, −1.5°C to −14.0°C); in these patients below zero temperatures were recorded during cryoablation of the LIPV (Table 2). The absolute minimal esophageal temperature assessed in any patient according to treated PV was RSPV, 23.3°C; RIPV, 2.9°C; LSPV, 5.9°C; LIPV, −14.0°C; and LCPV, 7.2°C.

Endoscopic Findings
EGD was performed in all patients 2±1 days post ablation. Superficial thermal lesions and thermal ulcerations were found in 1 of 50 (2%) and 5 of 50 (10%) patients, respectively (Figure 1). In 2 of 50 (4%) patients, signs of gastric hypomotility were detected, including 1 patient with a thermal ulceration. All patients with ETLs were asymptomatic. In patients with superficial thermal lesions or ulcerations, repeat EGD performed 4±2 days after the initial pathological endoscopy demonstrated healing lesions.

Median minimal balloon temperature in patients with and without ETLs was −57°C (−54.8°C to −50.8°C; q1–q3) and −50°C (−53°C to −43°C; P=0.43); −46°C (−51°C to −40.5°C)

and −48°C (−52.8°C to −57°C; P=0.74); −56°C (−58°C to −54°C) and −49°C (−54°C to −43°C; P=0.013); and −51.5°C (−56°C to −47.5°C) and −48°C (−52°C to −43°C; P=0.066) for the RSPV, RIPV, LSPV, and LIPV, respectively (Figure 2). Median minimal balloon temperature for the LCPV was −54°C (−57°C to −47.5°C). None of the patients with an LCPV developed ETLs.

Median minimal endoluminal esophageal temperature in patients with and without ETLs was 35.9°C (34.8°C–36.4°C) and 35.7°C (34.8°C–36.3°C; P=0.74); 36.0°C (35.6°C–36.3°C) and 34.6°C (31.0°C–34.5°C; P=0.37); 33.2°C (28.6°C–34.5°C) and 34.8°C (33.0°C–35.8°C; P=0.045); and −0.45°C (−5.8°C to 13.0°C) and 34.6°C (29.8°C–35.3°C; P=0.019), respectively (Figure 3). Median minimal endoluminal esophageal temperature for the LCPV was 34.5°C (31.0°C–35.0°C). All patients with detected ETLs had a minimal endoluminal esophageal temperature of ≤2.9°C during ≥1 freeze cycle (range, −2.9°C to −14°C). This occurred in 5 of 6 (83%) patients along the LIPV and 1 of 6 (17%) along the RIPV (Table 3). All ETLs were located at the opposite side of the posterior LA. No ETL was detected if the minimal endoluminal esophageal temperature was ≥3.0°C.

Complications
Despite continuous stimulation of the PN throughout the freeze cycle targeting the right-sided PVs, PN palsy occurred in 1 of 50 (2%) patients. Loss of PN capture was noted during the second freeze cycle targeting the RSPV. Although cryoenergy application was immediately stopped, PN palsy persisted throughout the procedure. No thromboembolic events, no pericardial effusion or pericardial tamponade, or severe groin complications occurred in the study population.

Follow-Up
Forty-four of 50 (88%) patients had completed the blanking period. One of 44 (2%) patients outside the blanking period was lost to follow-up (FU). During a median FU of 147 (132–169; q1–q3) days, 35 of 43 (81%) patients remained free of any

Table 2. Endoluminal Esophageal Temperatures

	RSPV	RIPV	LSPV	LIPV	LCPV
Minimal esophageal temperature, median (q1–q3), °C	35.8 (34.8–36.3)	35.0 (31.5–36.0)	34.4 (32.6–35.8)	34.6 (25.8–35.3)	34.5 (30.2–35.1)
Lowest esophageal temperature, °C	23.3	2.9	5.9	−14.0	7.2
No. of applications with esophageal temperature <0°C	0	0	0	6	0

LCPV indicates left common pulmonary vein; LIPV, left inferior pulmonary vein; LSPV, left superior pulmonary vein; RIPV, right inferior pulmonary vein; and RSPV, right superior pulmonary vein.

Figure 1. Esophageal ulceration in patient no. 10, 2 days post pulmonary vein isolation using the second-generation 28-mm cryoballoon. Lowest endoluminal esophageal temperature was –2.8°C during cryo-application along the left inferior pulmonary vein.

symptomatic and documented AF episode after a single CB procedure and including a 3-month blanking period. A symptomatic and documented AF episode was observed in 7 of 43 (16%) patients. In 1 of 43 (2%) patients, both AF and right isthmus-dependent atrial flutter was documented. Nine of 35 (26%) patients without recurrent AF were still using antiarrhythmic drug therapy.

Discussion

The current study reports on the results of acute PVI using the second-generation 28-mm CB. The study found that (1) the incidence of CB-induced ETLs is 12%; (2) there is a statistically significant correlation between endoluminal esophageal temperature and the incidence of ETLs; and (3) a suggested esophageal temperature cutoff of +10°C may prevent the occurrence of ETLs, demonstrating a sensitivity of 100% and a specificity of 93%.

The first-generation CB was initially developed as a single-shot device, which should overcome limitations of conventional radio frequency current (RFC) on the basis of PVI. It is easy to handle, effective, and safe. The over-the-wire system permits safe access to the respective PV. Acute and long-term results are comparable with RFC-based procedures.[8–12] The incidence of procedure-related complications, such as ETLs, is favorable for the 28-mm CB when compared with the 23-mm device.[4,5] The zone of optimal cooling in the first-generation CB is a ring around the equator of the balloon providing less effective cooling along the distal pole. However, depending on the individual PV anatomy and PV size this cooling characteristic eventually demanded different ablation techniques, such as the cross-talk for successful PVI or even radio frequency touch-up had to be performed.[8,12] The second-generation CB was modified to overcome these limitations by incorporating an improved refrigerant injection system. It uses 8 injection jets at a more distal position of the balloon shaft and thus provides homogeneous cooling of the complete distal balloon hemisphere. This improved cooling results in an impressive ice cap formation of the distal CB pole (Figure 4). A recently published case report even described a remaining ice cap after deflation of the CB at the end of the freeze cycle.[13] The massive and homogeneous ice formation allows for an effective cooling of variable PV diameters. Even smaller PVs in which isolation could be challenging when using the first-generation CB can be effectively treated with the modified device. The previously described cross-talk phenomenon which was occurring in a high percentage of procedures when treating the left-sided PVs because of ineffective freezing of the inferior portion of the LSPV is rare when using the second-generation CB because even a noncoaxial position of the balloon will result in homogeneous cooling of the complete PV circumference. Consequently, in the current study, 170 of 192 (89%; Table 1) PVs were successfully isolated with the first CB freeze. No radio frequency touch-up was necessary in any PV. This improved device efficacy in combination with a shorter freezing duration of 240 seconds per application further reduces procedure times.

However, increased efficacy may result in greater collateral damage to noncardiac structures. The incidence of ablation-related ETLs has been previously investigated and published for different ablation systems and different energy sources: ≤18% for RFC-based PVI,[14,15] 18% for endoscopic PVI using laser energy,[16] and between 0% and 18% for cryothermal energy
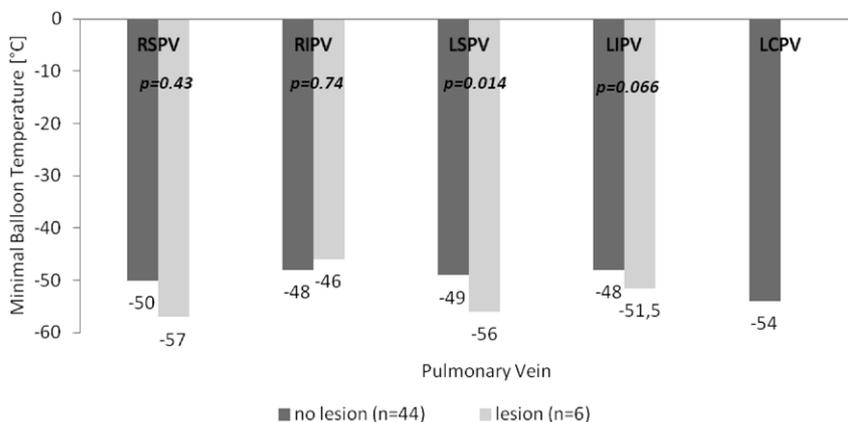

Figure 2. Correlation between incidence of esophageal thermal lesions and minimal cryoballoon temperature. LCPV indicates left common pulmonary vein; LIPV, left inferior pulmonary vein; LSPV, left superior pulmonary vein; RIPV, right inferior pulmonary vein; and RSPV, right superior pulmonary vein.
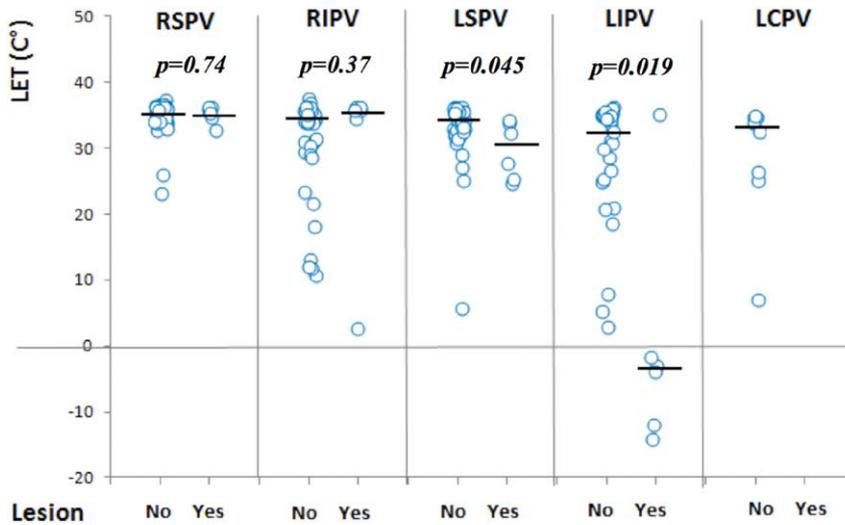
Figure 3. Correlation between incidence of esophageal thermal lesions and lowest esophageal temperature. LCPV indicates left common pulmonary vein; LET, lowest esophageal temperature; LIPV, left inferior pulmonary vein; LSPV, left superior pulmonary vein; RIPV, right inferior pulmonary vein; and RSPV, right superior pulmonary vein.

using the first-generation CB, depending on balloon size used.[4,5] For the first-generation CB an atrioesophageal fistula was recently reported.[6] However, the incidence of ablation-related ETLs using the second-generation CB was unknown. As discussed in one of our previous studies, we could not detect any ETLs when using the first-generation 28-mm CB.[4] In the current study, an identical ablation approach and endoscopic follow-up were performed. However, using the second-generation CB the cryo-freeze duration was reduced from 300 seconds to 240 seconds. But despite that the incidence of ETLs significantly increased to 12%. All patients were completely asymptomatic and all lesions resolved on repeat endoscopy under treatment with pantoprazol twice daily. The critical absolute esophageal temperature predictive for occurrence of ETLs in our patient cohort was ≤2.9°C. In all patients with

ETLs, minimal esophageal temperatures of ≤2.9°C were measured during ≥1 cryo-application either along the LIPV or along the RIPV. None of the patients with a minimal endoluminal esophageal temperature in any PV of ≥3.0°C developed ETLs. An endoluminal esophageal temperature of 3°C as a cutoff value predictive for occurrence of ETLs has a sensitivity of 100% and a specificity of 100%. However, on the basis of our experience, esophageal temperatures may further drop for ≤4°C after cessation of cryo-application. To have a safety margin, we, therefore, recommend an esophageal temperature cutoff of 10°C (sensitivity 100%, specificity 93%). The total number of cryoenergy applications one could have abandoned early adhering to the defined temperature cutoff of 10°C is 0 for RSPVs, 1 for RIPVs, 1 for LSPVs, 12 for LIPVs (8 patients), and 2 for LCPVs (1 patient). However, the cutoff temperature

Table 3.   Procedural Characteristics of Patients With Ablation-Related Esophageal Thermal Injury

	Patient No. 10	Patient No. 14	Patient No. 21	Patient No. 23	Patient No. 36	Patient No. 42
Quality of Lesion	Ulceration	Ulceration	Superficial Thermal Lesion	Ulceration	Ulceration	Ulceration
RSPV						
No. of application	2	2	2	2	2	2
Minimal balloon temperature, °C	−57	−65	−54	−52	−47	−53
Minimal esophageal temperature, °C	34.8	36.5	35.9	36.3	32.9	35.6
RIPV						
No. of application, mean±SD	2	4	4	2	2	2
Minimal balloon temperature, °C	−52	−64	−40	−53	−47	−48
Minimal esophageal temperature, °C	34.6	36.3	35.9	36.3	2.9	35.9
LSPV						
No. of application, mean±SD	2	2	2	2	2	2
Minimal balloon temperature, °C	−50	−56	−59	−63	−57	−57
Minimal esophageal temperature, °C	24.9	25.5	34	32.4	34.4	27.8
LIPV						
No. of application, mean±SD	2	2	2	2	2	2
Minimal balloon temperature, °C	−61	−51	−54	−52	−59	−46
Minimal esophageal temperature, °C	−2.8	−14	−1.5	−11.7	35.3	−3.8

LIPV indicates left inferior pulmonary vein; LSPV, left superior pulmonary vein; RIPV, right inferior pulmonary vein; and RSPV, right superior pulmonary vein.
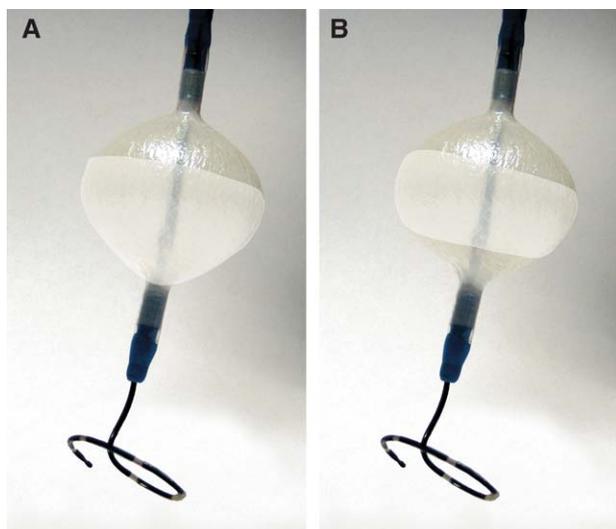
Figure 4. The second-generation cryoballoon provides homogeneous cooling of the complete northern balloon hemisphere (**A**), whereas the first-generation cryoballoon is characterized by an annular equatorial cooling zone (**B**).

of 10°C may only be reached at the end of the respective freezing cycle, resulting in a significant number of already successfully isolated PVs without the need for additional cryoenergy application. In case of nonisolation, a different balloon position should be attempted. Alternatively, a second freezing cycle could be applied adhering to the defined cutoff temperature. In summary, additional studies are needed to evaluate the impact of a predefined esophageal temperature cutoff.

Mechanical damage to the esophagus caused by manipulation of the temperature probe cannot be ruled out with certainty. However, all esophageal lesions were detected in patients with low esophageal temperatures and not in patients without a significant endoluminal drop in esophageal temperature. Furthermore, all esophageal lesions abutted the posterior LA wall, implying thermal rather than mechanical injury.

Because of the close proximity of the right-sided PN and the right-sided PVs, PN palsy is a characteristic complication of CB-based PVI. Using the first-generation 23-mm CB, an incidence of PN palsy of 12.4% was described, as compared with 3.5% using the 28-mm CB.[17] In the current study, no 3-dimensional reconstruction of the LA and the pulmonary veins with pace-identification of the course of the PN was performed. However, to stay as antral as possible and as far away from the PN as possible during cryoablation of the septal PVs, we only use the 28-mm CB. In addition, the PN is continuously stimulated during ablation of the septal PVs. In case of loss of PN capture the energy application is immediately stopped. However, PN palsy occurred in 1 of 50 (2%) patients during ablation of a RIPV and was persistent during the procedure. On 2-month follow-up, the patient symptoms had improved, whereas repeat fluoroscopic evaluation is currently pending. In another 1 of 50 (2%) patients, hypomobility of the diaphragm occurred during procedure, although permanent pacing and capture of the right-sided PN was obtained. We cannot explain the mechanism. However, the hypomobility of the diaphragm was still present 2 days post ablation. No

pericardial effusion or tamponade and no severe groin complications occurred in our study population.

In the current study, double TP was performed in case we had to switch from the endoluminal spiral catheter to a stiff wire because of insufficient mechanical support. In this case, the second TP was used for a standard spiral catheter to check for PVI after cryo-application. However, in our experience, the endoluminal spiral catheter provides sufficient mechanical support for most PVs and we currently perform CB-based procedures with a single TS.

The improved efficacy of the second-generation CB may justify further reduction in the freeze cycle duration or abandonment of an additional safety freeze cycle after successful PVI. Shortening the cryoenergy application time will result in shorter procedure times and may further contribute to reduce complications. This hypothesis needs to be evaluated in future studies.

Limitations

The current study focused on acute success rates and peri- and postprocedural complications when using the second-generation 28-mm CB. No comparison group using the first-generation CB or another energy source is included. However, the incidence and quality of esophageal thermal injury for the first-generation CB as well as for other ablation systems and energy sources has been investigated and described in detail in previous publications from our laboratory.[4–7,14–16,18] Our temperature unit measuring the endoluminal esophageal temperature does not store temperature-over-time curves. Consequently, only the minimal esophageal temperature is provided. Although extreme caution was undertaken to position the temperature probe at the level of and in closest proximity to the CB during ablation, failure to measure the true lowest esophageal temperature cannot be excluded.

The procedures were performed in an electrophysiology laboratory equipped only with a monoplane fluoroscopy system. During ablation of the septal PVs only the right anterior oblique 30°-projection and during ablation of the lateral PVs only the left anterior oblique 40°-projection were used. Consequently, the exact anatomic relationship between the esophagus and the target PV was not assessed.

Conclusions

As compared with the first-generation CB the incidence of ETLs increased to 12% when using the second-generation 28-mm CB. ETLs only occurred if the intraluminal esophageal temperature was ≤2.9°C. All ETLs resolved completely on repeat EGD.

Disclosures

Dr Kuck received a research grant and speaker's honoraria from Medtronic. Drs Metzner and Wissner received speaker's honoraria from Medtronic. The other authors report no conflict.

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CLINICAL PERSPECTIVE

Recently, the second-generation cryoballoon (CB, Arctic Front Advance, Medtronic Inc) was introduced. Improvements include a revised refrigerant injection system allowing more uniform cooling of the distal balloon hemisphere, including its distal pole. Although these modifications may increase ablation efficacy, a higher rate of collateral damage to noncardiac tissue may ensue. In this context, the current study set out to investigate the incidence of esophageal thermal lesion using the second-generation 28-mm CB. In 50 patients (18 women; age, 61±11 years; left atrial diameter, 43±5 mm) with paroxysmal or short-standing persistent atrial fibrillation, successful CB-based pulmonary vein isolation was performed. The endoluminal esophageal temperature was measured during cryoenergy application. Endoscopy performed 2±1 days after ablation demonstrated superficial thermal lesions and thermal ulcerations in 1 of 50 (2%) and 5 of 50 (10%) patients, respectively. All thermal lesions were in the healing process on repeat esophagogastroduodenoscopy 4±2 days after initial endoscopy. In these patients, ≥1 freeze cycle demonstrated an endoluminal esophageal temperature of <3.0°C. In some patients a drop in esophageal temperature of ≤4°C occurred even after cessation of cryoenergy application. On the basis of these observations, we propose an esophageal temperature safety cutoff of +10°C (sensitivity 100%, specificity 93%).

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Increased Incidence of Esophageal Thermal Lesions Using the Second-Generation 28-mm Cryoballoon

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