CONTEMPORARY REVIEW

Best practice guide for cryoballoon ablation in atrial fibrillation: The compilation experience of more than 3000 procedures

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BACKGROUND Since the release of the second-generation cryoballoon (CB2; Arctic Front Advance™, Medtronic Inc) and its design modifications with improved cooling characteristics, the technique, dosing, and complication profile is significantly different from that of the first-generation cryoballoon. A comprehensive report of CB2 procedural recommendations has not been reported.

OBJECTIVE The purpose of this study was to review the current best practices from a group of experienced centers to create a user’s consensus guide for CB2 ablation.

METHODS/RESULTS High-volume operators with a combined experience of more than 3000 CB2 cases were interviewed, and consensus for technical and procedural best practice was established.

CONCLUSION Comprehensive review of the CB2 ablation best practice guide will provide a detailed technique for achieving safer and more effective outcomes for CB2 atrial fibrillation ablation.

KEYWORDS Cryoballoon; Atrial fibrillation; Cryoablation; Paroxysmal atrial fibrillation; Pulmonary vein isolation; Second-generation cryoballoon; Balloon; Phrenic nerve; Practice guidelines

ABBREVIATIONS AE = atrioesophageal; AF = atrial fibrillation; CB = cryoballoon; CB1 = first generation cryoballoon (Arctic Front); CB2 = second generation cryoballoon (Arctic Front Advance); CMAP = compound motor action potential; ICE = intracardiac echocardiography; LA = left atrium; PN = phrenic nerve; PNI = phrenic nerve injury; PV = pulmonary vein; PVI = pulmonary vein isolation; RF = radiofrequency; SVC = superior vena cava; TTI = time to isolation

Introduction

Catheter ablation is an established tool for the treatment of patients with atrial fibrillation (AF),¹ and pulmonary vein isolation (PVI) has been a cornerstone strategy for percutaneous management of paroxysmal AF.² Unfortunately, long-term success has been constrained by the time-consuming and unpredictable nature of point-by-point focal ablation and the technical limitations on the effectiveness of ablation lesions to create a durable PVI. These procedural complexities have been historically notable with nonirrigated radiofrequency (RF) catheters and are only marginally improved with external irrigation.

Although focal RF catheters have been the standard of care for AF ablation,³ balloon-based technologies were developed in an attempt to deliver ablative energy in a more continuous pattern without conduction gaps during cardiac tissue isolation.³,⁴ Since the release in 2010 of the first-generation cryoballoon (CB1; Arctic Front™, Medtronic Inc, Minneapolis, MN) in the United States, data from both single-center studies and multicenter registries have demonstrated acute PVI and freedom from AF at rates comparable to those of RF.¹,⁵,⁶

The cryoballoon ablates with minimal disruption of the endothelium, creates relatively discrete lesions, and preserves myocardial architecture, followed by replacement with fibrous tissue through the Joule–Thomson effect.⁷ The basic biophysical steps that result in cell death include the formation of intracellular and extracellular ice crystals, which causes withdrawal of intracellular water. Additional cell death results from the consequences of cell thawing, with
the return of fluid into the cell causing cell membrane rupture.

The second-generation cryoballoon (CB2; Arctic Front Advance™, Medtronic) was released in 2012. It was designed to achieve more uniform cooling across the entire distal hemisphere of the balloon using 8 injection tubes vs the original 4-port design of the CB1.8,9 Acutely, the time to achieve PVI has been shortened and acute PV reconnection is rare; chronically, freedom from AF seems to be higher in nonrandomized studies.10-18 Also, the rates of PV reconnection in patients with recurrent AF are remarkably low compared with historic controls.19

Although research has indicated consistent patient outcomes with CB2, a comprehensive report of CB2 procedural recommendations has not been published. In an effort to drive consistent outcomes and minimize complications, this report reviews the current best practices from a group of experienced centers to create a user’s consensus guide for cryoballoon ablation.

**Best practices: The cryoballoon ablation procedure**

**Femoral and left atrial access**

The current FlexCath™ (Medtronic) sheath for delivery of CB2 has an outer size of 15Fr; therefore, we recommend initial femoral vein access with a shallow angle of entry and then predilation with a 14Fr short dilator. The FlexCath can be exchanged over a long stiff guidewire using a corkscrew motion or rotation for initial engagement. Full anticoagulation with IV heparin bolus should be given before initial transseptal access, because unacceptable incidences of thrombus formation have been observed via intracardiac echocardiography (ICE) shortly after any sheath placement in the left atrium (LA) even if heparin was given immediately after transseptal access. A target activated clotting time between 350 and 400 seconds is recommended. Patients who already are taking warfarin typically continue on a therapeutic international normalized ratio level. However, the management of patients taking novel oral anticoagulants varies, and most agree that until reversal agents are available, the management of patients taking novel oral anticoagulants should not be different than prior AF ablation practices.

Initial LA access is best achieved using a standard transseptal sheath (both Mullins and SL-1 curve have been used) that is then exchanged for a FlexCath steerable sheath over a long stiff wire. We recommend a low anterior transseptal puncture that is near or on the limbus of the septum to allow more space for the balloon to be rotated posteriorly to the right inferior PV as well as mechanical advantages while accessing the other PVs (Figure 1). Without sufficient distance between the puncture site and the right inferior PV, optimal balloon positioning and occlusion may be difficult. Also, a low puncture location improves balloon contact with the inferior aspects of the PVs. We highly recommend using ICE to improve the safety of transseptal catheterization. ICE will also provide early detection of complications (eg, catheter-related thrombus and pericardial) in ablation cases. The location of the transseptal access is best at the lower third of the septum and anterior reach at the plane of ICE where the mitral valve is in view (Figure 2). Bending of the distal 15-cm portion of the typical transseptal needle can improve transseptal needle engagement with the anterior portion of the septum.20

While monitoring with ICE and maintaining a steady manual pressure, a simple “clockwise” and “counterclockwise” movement of the handle can ease the sheath across the septum. Slowly remove the dilator and exchange it for a guidewire. Occasional difficulties may be encountered pushing the FlexCath sheath across the septum, especially at the transition of the dilator to the sheath. Some have found that placing the stiff exchange guidewire in the left superior PV or maneuvering the guidewire to the right superior PV will allow an easier push from the inferior vena cava directly across the septum and up toward the right superior PV in a straighter manner, thereby overcoming the tougher septal transition. Next, aspirate (by syringe) approximately 15–20 mL to remove any possible air in the sheath while tapping the handle to release trapped air. Flush and connect the sheath to a low-flow drip saline bag (1–3 mL/min).

After preparing the balloon and balloon sleeve in heparinized saline, insert the cryoballoon into the sheath using the protective sleeve. Slowly advance the cryoballoon catheter over the entire length of the sheath. Advance the Achieve™ (Medtronic) mapping catheter using the cryoballoon shaft markers to confirm appropriate positioning. The mapping catheter should always lead the cryoballoon catheter to prevent trauma from the stiffer cryoballoon catheter tip. Fluoroscopy can be minimized by using markers on the cryoballoon body. When the first white band is at the valve of the sheath, the balloon is at the distal tip of the sheath. The second white band indicates the cryoballoon is out of the sheath and is ready for full inflation.
Positioning and occluding the vein

We describe 6 simple but critical maneuvers that can be used to improve outcomes, reduce complications, ensure circumferential lesion creation, and create substantial antral LA substrate modification. An antral level of isolation contributes to the success of cryoballoon PVI, and it may reduce complications by maximizing the distance between the balloon and collateral structures beyond the LA chamber. The 6 critical maneuvers are given in chronological order, as follows.

1. When maneuvering the sheath to the desired PV, always lead the balloon with the soft-tipped mapping catheter to avoid sheath trauma in the LA or PV. Contrary to the focal RF catheter technique in which the majority of catheter maneuvering occurs at the ablation handle, the majority of cryoballoon positioning is dependent on the sheath and maintenance of forward pressure on the balloon shaft. Because the cryoballoon sheath is stiff, there is a predictable 1:1 transference of movement force. Thus, the cryoballoon tool sets are easier to master and require shorter “learning” periods.

2. Distal positioning of the Achieve (in the PV) will facilitate advancement of the balloon to the respective PV. We recommend using the lower PV branch for isolation of inferior veins to provide the best angle for balloon engagement of the lower portion of the PV ostium, which frequently is the worst area of balloon-to-PV contact. Navigation of the Achieve into each of the PVs is best facilitated with the use of ICE, which can reduce the need for fluoroscopy. The PVs, FlexCath, and Achieve are easily visualized with ICE.

3. Advance the balloon outside the sheath toward the PV ostium while taking precautions not to deep-seat the balloon. The sheath should be aligned with the angle of the targeted PV. Because balloon inflation occurs using low pressure, it is unlikely to cause mechanical trauma to the PV; however, inadvertent inflation inside the PV should still be avoided.

4. The Achieve can provide additional support for the cryoballoon, but the majority of the control of balloon–PV engagement is via the deflectable FlexCath sheath, which should be used to provide the primary support during PV occlusion. The sheath can be advanced against the proximal hemisphere of the balloon during cryoablation for both support and catheter advancement for better occlusion. Achieve positioning relative to the balloon is not critically important as long as balloon-to-PV antrum is maximized.

5. PVI is best achieved by application of forward pressure to ensure the optimal balloon-to-PV ostium contact, which will result in successful isolation of the respective vein. With full occlusion of the PV, a 1- to 2-mL initial injection of radiopaque contrast will provide venographic evidence of balloon occlusion or leak detection.

A. If the venogram does not reveal a leak at the ostium, do not immediately ablate. If no leak is visible on venogram, withdraw the cryoballoon slightly and allow a leak around the PV–balloon interface to better define the PV ostium and ensure a proximal ablation. In some cases, this technique will reveal that the balloon was inside the PV and not at the PV ostium. Reapply only the minimal amount of pressure needed to regain occlusion before ablation. This technique is often denoted as the “proximal-seal” technique. Ablation can also be initiated before advancing the balloon to increase the balloon pressure and assist in keeping the balloon more proximal antrum, thereby achieving a lesion set with closer resemblance to the typical wide area circumferential ablation. This technique also lessens the risk for phrenic nerve injury (PNI) at the right superior PV (Figure 3).
B. If the venogram detects a leak, small adjustments with additional pressure toward the side of the leak will often secure occlusion at an optimal location. If complete occlusion cannot be made, then the PV antrum cross-section is likely more ovoid. In this case, separate application of ablation from a different angle should be performed, keeping in mind the area of best contact and that the summation of the contact should surround the PV antrum. Color flow Doppler imaging to search for leak and poor contact may be used in place of contrast injection with a sweep of the array across the balloon. Using ICE in Doppler mode imaging is particularly important in patients with renal insufficiency or a history of contrast agent intolerance/allergic reaction(s).

6. With the best-fit occlusion, the Achieve mapping catheter should be used to obtain PV potential recordings for real-time monitoring before initiation of the ablation. Torque can be applied to the Achieve mapping catheter to prolapse the circular mapping poles toward the antrum to be able to record approximately more than 90% of all PV potentials to assess the time to isolation (TTI). Optimal Achieve position is demonstrated in Figures 1 and 3. One of the most critical indicators and predictors of permanent PVI is the TTI (best if <90 seconds). Reduction of the ablation time is also considered when a short TTI is seen (<30 seconds) by reducing the total ablation time to 150 seconds. If desired, exit block from the PV can also be established during the ablation by pacing from the Achieve. Rarely is the Achieve required to provide distal cryoballoon anchoring for optimal positioning as a tradeoff for the inability to record the proximal PV electrogram. Most of the support for the balloon should be provided by the FlexCath sheath. In this setting, PV recording on the Achieve can be re-established after initiation of a freezing cycle within approximately 10 seconds, with a pullback on the Achieve until the PV electrogram can be seen. After approximately 15 seconds into the freezing cycle, the central lumen is frozen, and the wire cannot be moved.

Figure 3  Proximal seal technique. Instead of initiating ablation after initial venogram, CB is first gently pulled back to reveal the real pulmonary vein (PV) ostium by noting contrast leak. The true antrum is much further back than initially realized. CB at left superior PV (A) and venogram (B) showing CB pulled back to reveal the real PV ostium (see Online Supplementary video).

PV antrum ablation

Once the balloon is in the correct position at the PV antrum, the ablation process is initiated at the CryoConsole (Medtronic) interface. Although a single operator technique is possible, a dual-operator method is more common whereby the second operator is typically a nursing staff member who will assist in operations more distal to the cryoballoon catheter, including CryoConsole operation. The following 5 steps highlight the procedural period that is encompassed during the cryoballoon ablation.

1. Before ablation, prepare a small 1-mL injection of contrast to ensure continued occlusion after freeze initiation. In some cases, the onset of freezing and balloon compliance change can dislodge the balloon and create a leak. We recommend a 180-second initial ablation with CB2, at a minimal temperature no colder than –55°C.

2. Avoid maneuvering the cryoballoon after initiation of ablation. A “post-cryo initiation” maneuver may increase the risk of mechanical trauma and provide a false sense of durable ablation. Within the first 15 seconds of ablation, a layer of ice can be observed on the surface of the balloon, which will act as a thermobarrier and decrease energy transfer to the tissue. The acute block that may be observed before initiating a pulldown technique is transient. If a lower-positioned seal is challenging, it is better to improve the ablation by ablating the upper portion of the PV ostium and then the lower portion of the PV ostium in 2 full separate applications. This situation occurs frequently because the majority of PV antrum cross-sections are ovoid.

3. After freeze application, allow the balloon and tissue interface to thaw. The postablation thawing process can be slow. Do not move the balloon catheter until the catheter temperature reading reaches 35°C (even though the balloon automatically deflates at 20°C). The balloon may remain attached to tissue after balloon deflation in a phenomenon known as “late adhesion,” and mechanical manipulation might result in tissue damage or even perforation.
4. Before the second freeze, initiate the freeze and allow the balloon to enlarge and stiffen, then engage the PV ostium. The ostium should be fully engaged on the second ablation. This maneuver can help expand the antral location of the intended lesion and can be confirmed on ICE with the equator of the balloon outside of the vein yielding the “golf ball on tee” appearance (Figure 4).

5. To enhance the timesaving advantage of cryoballoon ablation, parallel processing and planning can be performed during the freeze cycle. Review the venogram of the current ablation to assess contact and determine if another ablation at a different angle is needed. The operator can also review the PV venogram and plan the next ablation site, balloon angle, or target branches for placement of the Achieve catheter. Also, while ablating the left-sided PV, the operator can identify an optimal pacing location for the right phrenic nerve (PN). This will save procedure time when transitioning from left- to right-sided PV.

**Cryoballoon dosing and temperature**

Various dosing regimens exist with recommendations from 2 to 5 minutes per freeze. Historically, 4 minutes was the standard for CB1 based on procedures in the STOP AF clinical trial protocol. Since the release of CB2, shorter application times have been explored as a strategy to avoid collateral tissue injury without compromising efficacy. For example, a recent investigation by Ciccone et al demonstrated an 80% freedom from AF in 143 consecutively enrolled subjects treated with a single 3 minute freeze using CB2.

The operator must understand the physiology of cryoenergy transfer in order to understand dosing. In brief, cryoballoon energy transfer is dependent on the source of cryoenergy, balloon–tissue contact area, collateral warming, and time. The 2 most important operator-controlled factors are time and balloon–tissue contact. These 2 factors (along with nadir temperature) have a direct impact on lesion depth in an exponentially decrementing manner. Simply, longer ablation time will correlate to a deeper lesion; however, the final ablation time is shortened when considering the balance of safety and collateral tissue freezing. Lastly, this longer ablation time to deeper lesion correlation is not completely linear. There is a penultimate depth of lesion penetration (regardless of time) that is established by the limitation of heat dissipation over space.

Although the operator does not directly control nadir temperature, it is important for operators to understand and monitor temperature during the procedure. Importantly, the operator does determine when to terminate a freeze. The temperature displayed on the CryoConsole is not tissue temperature; instead it is a return gas temperature measurement. The balloon–tissue interphase temperature is typically –70 to –80ºC, but the temperature on the CryoConsole is the return gas temperature, and it often ranges between –40 to –50ºC for optimal lesions. Therefore, the only conclusion that can be made from the return gas temperature is that if the temperature is cold (eg, below –40ºC), it likely reflects good tissue ablation. A steep and rapid descent in temperature (colder than –40ºC at 30 seconds) and nadir temperatures of –55 to –60ºC are potential indicators of a distal cryoballoon location (rather than an antral position). We recommend that the ablation be terminated in either scenario and cryoballoon positioning confirmed.

The most important physiologic end-point to predict successful PVI is TTI as identified by the Achieve catheter, as this is the only true tissue physiology that can be monitored. PV potentials should be closely monitored at the initiation of the freezing cycle, during the freeze, and after the ablation is complete. Although data are needed to clearly correlate long-term outcomes with abbreviated freeze protocols, our experience supports a more conservative dosing time of 150 seconds if TTI is achieved at 30 seconds or less. If the PV is not isolated within 180 seconds, we recommend against increasing time or advancing the cryoballoon deeper into the PV. Rather, the operator should modify the cryoballoon–tissue contact.

To allow deep tissue warming, maximize cryoablation efficiency, and reduce the risk of collateral damage, we recommend against an immediate follow-up application if the cryoballoon nadir ablation temperature reaches below –55ºC. This tissue rewarming time may potentially reduce the risk of PNI or esophageal injury. If desired, ablation can be performed at another target PV while allowing warming.

With regard to dosing, esophageal temperature monitoring (discussed later) also may be helpful. For example, application of a 180-second first lesion is rarely associated with an esophageal temperature below 25ºC. Reducing application duration during a repeat freeze to 150 seconds or less may be warranted because of the faster temperature decline on the repeat freeze thus avoiding deeper tissue injury. Repeated ablations for more than 2 times at a similar location should be avoided to prevent collateral injury.
Safety considerations

As demonstrated in recently published studies, the improved cooling characteristics of CB2 translate into improved acute and long-term efficacy. However, enhanced cooling characteristics may also result in a greater potential for collateral damage to noncardiac structures such as the PN and the esophagus. We recommend closely monitoring temperature, application duration, contact force, anesthesia, TTI, type of esophageal tissue, and distances between the catheter and collateral structures (PN, lungs, esophagus). Following we discuss techniques to avoid PNI and esophageal damage.

Prevention of PNI

Right PN palsy is the most common complication associated with cryoballoon ablation; persistent PNI lasting after the procedure has been reported as high as 8.3%. Our experience suggests that the risk for persistent PNI can be minimized by ensuring the cryoballoon position is as antral as possible as described in the ablation section. Most important are active monitoring of the PN during ablation and terminating ablation immediately at the first sign of hypothermic effect. To pace and monitor PNI, paralytics should not be administered during cryoablation. If paralytics were administered during the induction of general anesthesia, sufficient time should be allowed for the paralytic effect to reverse before ablation, or neostigmine may be used as a reversal agent.

To monitor PN function, the nerve should be paced at twice the capture threshold using a deflectable catheter. We recommend placing the pacing catheter in the superior vena cava (SVC) and above the level of the ablation. A consistent site for PN capture is near the junction of the SVC and the right subclavian vein or the anterolateral portion of the SVC, near the atrial–SVC junction.

Palpation of the strength of diaphragmatic excursion during PN pacing, below the costal margin, is the most common method of monitoring PN function. In addition to palpation, monitoring of the diaphragmatic compound motor action potential (CMAP) can increase the sensitivity of PNI early detection (Figure 5). Several other methods proposed for monitoring PN in conjunction with CMAP and palpation are ICE, fetal heart monitoring, and external thoracic pressure monitoring (Table 1). A detailed review of all the methods for monitoring of PN were reported by Kowalski et al. The ICE catheter can also provide confirmation of correct positioning of the balloon by visualizing the main portion of the balloon outside of the vein, thus reducing the risk of freezing deeply in the vein and the risk of PNI (Figure 4).

Once PNI occurs, the operator should immediately stop ablation by “double stop” technique or immediate balloon deflation. Ghosh et al. concluded that rapid balloon deflation results in more rapid tissue rewarming, leading to prevention of persistent PNI with no adverse events. Continued pacing of the PN could assist in evaluating the time for recovery of function. If the duration of recovery is

Figure 5  Recordings of the diaphragmatic compound motor action potential (CMAP) during pacing from the coronary sinus (CS) catheter at 60 bpm located in the superior vena cava and during application of cryoenergy to the right superior pulmonary vein. CMAP amplitude (asterisk) significantly decreased at 180 seconds of cryoballoon application. Note that the pulmonary vein is isolated. At the time of phrenic nerve palsy, CMAP amplitude is a fraction of baseline CMAP amplitude. CMAP amplitude increased after cryoenergy was discontinued but did not return to its original value. A decrease in CMAP amplitude by 35% from baseline predicted and prevented phrenic nerve injury. (Reproduced from Lakhani M, Saiful F, Parikh V, Goyal N, Bekheit S, Kowalski M. Recordings of diaphragmatic electromyograms during cryoballoon ablation for atrial fibrillation accurately predict phrenic nerve injury. Heart Rhythm 2014;11:369–374.)
short, another ablation can be attempted after wiring a different PV branch and with a more antral position of the balloon. If palsy persists after the procedure, an inhalation–exhalation chest X-ray film is recommended to establish a baseline for PNI for comparison to recovery assessment at a later time. Intravenous steroids may be administered to decrease inflammation.

**Prevention of esophageal injury**

Esophageal injury is a complication observed in both RF and cryoballoon procedures. It is a direct result of the proximity of the esophagus and the posterior wall of the LA. The severity of the injury can vary, manifesting as esophageal erythema, esophageal ulcer/lesion, or atrioesophageal (AE) fistula. Recent research has demonstrated CB2 esophageal lesion rates of 3.2% to 19% as observed through postprocedural endoscopies, with the lowest rates (3.2%) reported when a luminal esophageal temperature (LET) cutoff of 12°C–15°C is used.\(^2^7–^3^1\) When LET and other measures are used, damage can be limited to esophageal lesions, which frequently heal in a few weeks. If unmonitored, esophageal damage may result in rare and generally fatal AE fistula. The reported rate of AE fistula with CB1 and CB2 is approximately 1 in 10,000, whereas the incidence of AE fistula with RF varies between 0.1% (1:1000) and 0.25% (1:400).\(^1^,^3^2\) Even though the root cause has not been determined, caution should be used when treatment time exceeds 4 minutes, more than 2 freezes are applied to a PV, and balloon nadir temperatures exceed –60°C.

The impact of CB2 ablation on esophageal thermal injury was recently investigated by 2 different groups.\(^2^8,^2^9\) Freeze cycles of 240 seconds were followed by a safety freeze cycle of another 240 seconds. Whereas Metzner et al\(^2^5\) did not have a predefined temperature cutoff, Fürnkranz et al\(^2^9\) stopped the freeze cycles at an esophageal endoluminal temperature of <5°C. The lowest temperature in the esophagus and the lowest temperature in the CB were noted. Postablation, all patients were treated with pantoprazole 40 mg daily for 6 weeks, and an endoscopy was performed at 2 days postablation. Metzner et al\(^2^8\) demonstrated a 12% incidence (6/50 patients) of esophageal thermal injury, whereas Fürnkranz et al\(^2^9\) reported an incidence of 19% (6/32 patients). Compared to esophageal thermal lesions after RF-based ablation, lesions after CB ablation tended to be more superficial; most patients were completely asymptomatic and all lesions were resolved during repeat endoscopies. Importantly, none of the patients developed an atrial-to-esophageal fistula.

Based on their statistical analysis of correlating the lowest esophageal temperature and the endoscopic findings, Metzner et al\(^2^8\) recommend an esophageal temperature cutoff of 10°C (sensitivity 100%, specificity 93%), whereas Fürnkranz et al\(^2^9\) suggest a cutoff of 12°C (sensitivity 100%, specificity 92%) for causing esophageal fistula injury.

Although this research brings us closer to better understanding techniques to prevent esophageal injury, it is important to understand that no direct correlation has been made between esophageal fistula formation and temperature. Other predisposing factors may be more important than temperature alone. The suggested endoluminal esophageal temperature cutoff values need to be evaluated prospectively in future studies; however, consideration of the currently recommended minimal esophageal temperatures may contribute to safer use of CB2.

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**Table 1** Comparison of different strategies for monitoring phrenic nerve palsy during cryoballoon ablation: Pros and cons of various PN monitoring strategies

<table>
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<tr>
<th>Method</th>
<th>Description</th>
<th>Advantages</th>
<th>Disadvantages</th>
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<tbody>
<tr>
<td>Fluoroscopy</td>
<td>Direct visualization of diaphragmatic motion</td>
<td>Sensitive method for monitoring diaphragmatic motion</td>
<td>Additional radiation exposure to patient and operator</td>
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<tr>
<td>Palpation</td>
<td>Palpation of diaphragmatic excursion</td>
<td>Reliable and practical method for monitoring diaphragmatic motion</td>
<td>Does not predict PN injury</td>
</tr>
<tr>
<td>Electromyography</td>
<td>Recording of diaphragmatic CMAP by 2 standard surface electrodes positioned across the diaphragm or by advancing a quadripolar catheter in the right hepatic vein during PN pacing</td>
<td>Earliest detection of PN injury Simple, reliable, and easily applicable Only technique that predicts PN injury</td>
<td>CMAP signals might be susceptible to respiratory variations Baseline amplitude must be adequate</td>
</tr>
<tr>
<td>Auditory cardiography</td>
<td>Decrescendo pitch on fetal heart monitor (placed across patient's chest; can detect diaphragmatic contractions)</td>
<td>Auditory cue to the operator May portend PN injury before palsy</td>
<td>Affected by paralytic agents Difficult to record in obese patients</td>
</tr>
<tr>
<td>Intracardiac echocardiography</td>
<td>Direct visualization of diaphragmatic excursion</td>
<td>Minimal radiation exposure to patient and operator</td>
<td>Requires additional venous access and intracardiac ultrasound</td>
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CMAP = compound motor action potential; PN = phrenic nerve.

In the interim, as outlined in the 2012 HRS/EHRA/ECAS expert consensus statement, the authors reinforce luminal esophageal temperature monitoring, a barium swallow to outline the esophagus, duration of energy application, prescription of proton pump inhibitors, and reduced contact force as options to minimize esophageal injury.  

Postablation care

Immediate postablation testing should be similar to that for other AF ablation methods; however, our experience to date indicates that adenosine for assessment of PV connection recovery has been of limited use and rarely positive. Postprocedural groin management also is not different than that for traditional RF ablation. An increased rate of groin access complication due to larger sheath size has not been reported. Postablation anticoagulation duration, given the lesser endocardium injury with cryoablation, is considered to be adequate at 1 month’s time; this duration correlates with the complete tissue healing time observed in animal and in vivo experiences.

Outcomes

Cryoablation is a safe and effective tool for the treatment of paroxysmal AF with a high rate of durable procedural PVI and long-term freedom from AF. Eight single-center studies on CB2 have demonstrated a single procedure, off-antiarrhythmic drug, freedom from AF ≥80%. In contrast, freedom from paroxysmal AF in recent, large RF multicenter studies and surveys (since 2010), including clinical study results from recent RF technology advancements, has been reported to be 61%–74%. In addition, RF catheter studies evaluating PVI durability at remapping procedures have reported between 23% and 35% of patients who had complete PVI at 3 months and only 8% of patients at 12 months. The safety profile for the 2 therapies is similar. In a large multicenter registry (German Ablation Registry), the overall rate of major complications were similar for cryoablation (CB1) and RF (4.6% for both groups), with PN palsy constituting nearly half of cryocomplications (2.1%).

Conclusion

Cryoablation of AF is a useful tool for PVI and antral modification. The specific technical recommendations discussed here in detail will make the cryoballoon procedure a safer and more effective tool for treatment of AF.

Appendix

Supplementary data

Supplementary material cited in this article is available online at http://dx.doi.org/10.1016/j.hrthm.2015.03.021.

References


