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

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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.[1,2] 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,[1] 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

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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.

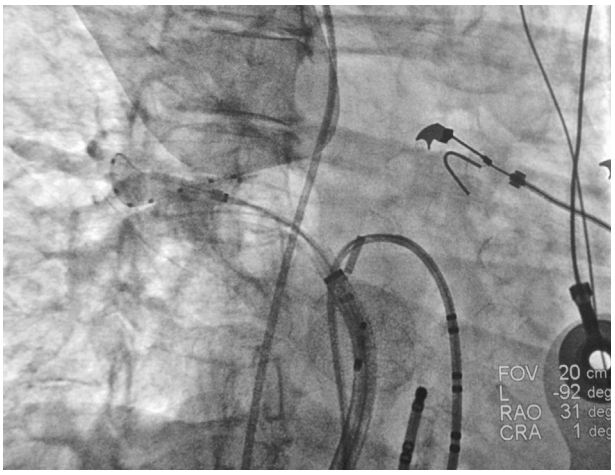

Figure 1 Right anterior oblique (RAO) view of right inferior pulmonary vein cryoballoon engagement angle when transseptal site is lower and more anterior. Example of patient with atrial septal occlusion device at the secundum defect location better demonstrates the transseptal location.

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, 12 to 24 hours of freedom from novel oral anticoagulants should be obtained. In general, anticoagulation management 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 recommended 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.