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## **Review Article**

### **Cryoballoon Ablation for Atrial Fibrillation**

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#### Abstract

Focal point-by-point radiofrequency catheter ablation has shown considerable success in the treatment of paroxysmal atrial fibrillation. However, it is not without limitations. Recent clinical and preclinical studies have demonstrated that cryothermal ablation using a balloon catheter (Artic Front©, Medtronic CryoCath LP) provides an effective alternative strategy to treating atrial fibrillation. The objective of this article is to review efficacy and safety data surrounding cryoballoon ablation for paroxysmal and persistent atrial fibrillation. In addition, a practical step-by-step approach to cryoballoon ablation is presented, while highlighting relevant literature regarding: 1) the rationale for adjunctive imaging, 2) selection of an appropriate cryoballoon size, 3) predictors of efficacy, 4) advanced trouble-shooting techniques, and 5) strategies to reduce procedural complications, such as phrenic nerve palsy.

Keywords: Cryoballoon Ablation; Atrial Fibrillation

#### Introduction

Atrial fibrillation (AF) is the most common sustained cardiac arrhythmia. It accounts for the majority of arrhythmia-related emergency room visits and hospital admissions,[1-3] and is associated with reductions in quality of life, functional status, cardiac performance, and overall survival.[1] Catheter ablation, which is centered on electrical isolation of triggering foci within the pulmonary veins (PV) through circumferential lesions around PV ostia, has been shown to result in sustained improvements in quality of life, decreased hospitalizations and, potentially, improved survival.[4-6]

Radiofrequency (RF) catheter ablation has shown considerable success in treating symptomatic AF, particularly in comparison to anti-arrhythmic drugs [7,8]. Unfortunately, major complications including thromboembolism, cardiac perforation, and injury to adjacent structures are not infrequently observed [2,3,7,9,10]. Further, the procedure is complex, time-

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consuming and highly dependent on operator competency given the inherent difficulties associated with creating contiguous curvilinear lesions with a technique originally developed for focal ablation. As such, considerable effort has been directed towards developing technologies specifically for PV isolation (PVI) as a means to achieve safer and more effective PVI that is less reliant on operator dexterity. Recently clinical and preclinical studies have demonstrated that cryothermal ablation using a balloon catheter (Artic Front©, Medtronic CryoCath LP, Kirkland, Canada) is an effective alternative treatment for AF.

#### Efficacy of Cryoballoon Ablation

To date over 20,000 cryoballoon-based PV ablation procedures have been performed worldwide. In a recent systematic review and meta-analysis, we reported the cumulative early experience with cryoballoon-based ablation (CBA).[11] CBA resulted in a high procedural success rate (>98% of patients achieving complete PVI) and 1-year freedom from recurrent AF (single cryoballoon procedure off anti-arrhythmic drugs 1-year success of 60%; 73% if a 3-month blacking period was included) [11,12]. In comparison, the longer-term freedom from recurrent AF after RF catheter ablation has been reported to be 50% to 64% after a mean follow-up of 14 months in the meta-analysis by Calkins et al. and 39.8±5.1% at 1 year in the prospective long-term cohort study by Weerasooriya et al.[7,13] Thus, the early experience suggests that cryoballoon ablation is efficacious for the maintenance of sinus rhythm at 1 year in patients with paroxysmal AF.

When compared to other rhythm control strategies, CBA has performed favourably. (See **Table 1**) The first randomized trial comparing AAD therapy and cryoballoon ablation, the Sustained Treatment of Paroxysmal Atrial Fibrillation (STOP-AF) trial, enrolled 245 patients with paroxysmal AF and randomized them (2:1) to cryoballoon-based PV isolation (n=163) or to AAD therapy (n=82).[14] The mean age of participants was 57 years, and those enrolled had already failed an average of 1.2 AADs. Balloon-only PVI was realised in 90.8% of participants, with an overall procedural success ( $\geq$ 3 PVs isolated) of 98.2% when focal cryoablation was added. Nineteen percent of patients required a repeat procedure within the 3-month blanking period. At 12 months of follow-up, 69.9% of the cryoballoon group (114/163) vs. 7.3% of the AAD group (6/82) were free of recurrent AF (p<0.001). Moreover, there was a statistically significant improvement in symptoms and quality of life in the cryoballoon group. For all quality-of-life metrics, the improvement was greater in the cryoballoon group when compared to the AAD group.

Likewise, in comparison to other contemporary AF ablation technologies, CBA has performed favourably. In general, CBA is associated with procedure and fluoroscopy times that are somewhat longer than duty-cycled multi-electrode RF ablation but shorter than conventional RF ablation.[15-19] Despite these procedural differences, efficacy outcomes at all of time points sampled did not differ between CBA and conventional, magnetic guided, and duty-cycled multi-electrode RF ablation. [15-19,20]

#### Safety of Cryoballoon Ablation

Major complications have been reported in approximately 5-6% of patients undergoing RF ablation for AF [7,9,10]. The rate of acute procedural complications reported with cryoballoon-based ablation (CBA) is relatively low (<3-5%) and compares favourably with irrigated RF and duty-cycled multi-electrode RF ablation [7,9,10,21]. With CBA, the reported rate of peri-procedural stroke or transient ischemic attack (TIA) is 0.3%, cardiac tamponade 0.6%, and groin complications 1.8%. In comparison, corresponding reported complication rates with RF ablation are 0.3-0.9% for stroke or TIA, 0.8-1.3% for cardiac tamponade, and 1-1.5% for groin complications.[11] Longer-term complications such as symptomatic PV stenosis and esophageal injury occurred infrequently with CBA (0.17% for symptomatic PV

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