CONTEMPORARY REVIEW

Cryoballoon Best Practices II: Practical guide to procedural monitoring and dosing during atrial fibrillation ablation from the perspective of experienced users

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Since the evaluation of the cryoballoon in the Sustained Treatment Of Paroxysmal Atrial Fibrillation trial, more than 350,000 patients with atrial fibrillation have been treated. Several studies have reported improved outcomes using the second-generation cryoballoon, and recent publications have evaluated modifications, refinements, and improvements in procedural techniques. Here, peer-reviewed articles published since the first cryoballoon best practices review were summarized against the technical practices of physicians with a high level of experience with the cryoballoon (average ≥6 years of experience in ≥900 cases). This summary includes a comprehensive literature review along with practical usage guidance from physicians using the cryoballoon to facilitate safe, efficient, and effective outcomes for patients with atrial fibrillation.

KEYWORDS Atrial fibrillation; Best practice; Catheter ablation; Cryoablation; Cryoballoon

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Introduction

The first-generation cryoballoon (Arctic Front, Medtronic Inc., Minneapolis, MN) was developed to isolate the pulmonary veins (PVs) via contiguous cryolesion for the treatment of patients with atrial fibrillation (AF).1 The second-generation cryoballoon (Arctic Front Advance, Medtronic Inc., Minneapolis, MN) achieved greater uniformity in cooling, which facilitated shorter time to PV isolation (PVI), higher rates of freedom from AF, and low rates of PV reconnection.2 A user’s consensus procedural guide for cryoablation has been published to facilitate consistent outcomes,3 but recent studies have enhanced our understanding of operator-controlled parameters for dosing, monitoring, and usage.

Important parameters of tissue injury by cryogenic application are rapid freezing, low nadir temperatures, long duration of freezing, long duration of tissue thawing, and repetition of freeze-thaw-refreeze cycles.4 While thermodynamic variables (refrigerant delivery volume/rate, refrigerant composition, and Joule-Thomson effects at the balloon surface4,5) are controlled by the CryoConsole (Medtronic Inc., Minneapolis, MN), there are 3 primary physician-operator–controlled parameters for cryoballoon dosing: tissue contact and location, ablation duration, and number of cryoapplications. Also, there are 3 procedural indicators that are assessed for circumferential/transmural lesions at the PV (Figure 1): assessment of cryoballoon contact before a freeze, assessment of PV potentials to determine time to isolation (TTI) observed by loss of PV potentials and conduction block, and a long thaw duration.1 While procedural complications are infrequent during ablations, the possibility of collateral tissue injury necessitates further evaluation of dosing.6–8 Here, we summarize important literature on the development of a dosing guide.
First-generation dosing
The Sustained Treatment Of Paroxysmal Atrial Fibrillation (STOP AF; ClinicalTrials.gov identifier NCT00523978) trial determined that cryoablation was a safe and effective alternative to antiarrhythmic therapy and resulted in FDA approval for cryoballoon PVI.8 First-generation cryoballoon dosing ranged from 120 to 300 seconds,3 but a 240-second cryoapplication became standard practice during the STOP AF trial.3,8 The mean cryoapplication time was 214.4 ± 1.5 seconds, and the mean total number of cryoapplications for all PVs was 12.5 ± 0.31 (mean of 3 cryoapplications per PV).8 The mean procedural time was 371 minutes, and the total cryoablation time was 66 minutes.8 However, observed collateral tissue injury during the STOP AF trial for cryoballoon-treated patients initiated increased monitoring of right-sided phrenic nerve function.

Technological changes in the second-generation cryoballoon included an increased number of injection ports and increased refrigerant flow.9 The homogeneous distribution of refrigerant improved the utility of cryoballoon.9 Improvements to the cryoballoon, modifications to dosing protocols, and operator experiences have resulted in improved efficiencies.10,11 The FIRE AND ICE trial reported short procedural time (124.4 ± 39 minutes) and left atrial (LA) dwell time (92.3 ± 31.4 minutes).10 However, reports of collateral tissue injury initiated research on second-generation balloon dosing.12–15 Recommendations included here are specific to the second-generation catheter.

Procedural monitoring
Before ablation: PV contact/occlusion
Preprocedural imaging is not required for the assessment of PV anatomies. It is our experience that techniques described below are sufficient for cryoablation. Balloon to PV occlusion is fundamental to successful usage of the cryoballoon. The balloon inner lumen facilitates delivery of devices (eg, Achieve mapping catheter (Medtronic Inc., Minneapolis, MN) and guidewires) and liquid reagents (eg, contrast media and saline). Retention of contrast delivered through the balloon’s tip (observed under fluoroscopy) confirms PV occlusion.17 Leak(s) of contrast into the LA indicates incomplete occlusion. A qualitative 4-point occlusion score determined via contrast retention has been identified through multivariate analysis as an independent predictor of AF recurrence (P = .021).16

While contrast retention is the traditional method, nonionizing radiation approaches (echocardiography and pressure monitoring) to verify occlusion exist.17 During early experiences, we found that pressure monitoring and transesophageal echocardiography (TEE) were effective methods for confirming occlusion. Pressure waveforms measured at the distal balloon lumen will change from a pressure waveform consistent with the LA into a venous-only waveform when occluded. Usage of pressure monitoring is not feasible when the PV cannot be occluded on the basis of PV size/shape and cannot identify a deep-seated balloon. TEE in the Doppler mode can confirm that there are no leaks and has been further developed to use 3-dimensional (3D) TEE to guide occlusion.18 Using 3D TEE, a leak was detected in 13% of occlusion attempts; however, 100% acute PVI was eventually obtained.18 Patients in this evaluation demonstrated 82% freedom from arrhythmia recurrence at a mean follow-up of 278 days.18

Recently, 3D electroanatomic mapping (3D EAM) systems have been used to evaluate occlusion. The authors agree that 3D EAM is a useful adjunctive tool during cryoablation, and it may be used to reduce fluoroscopy. In this method,
pre- and post-3D EAM measurements are used to record the distention of a PV when successful occlusion has occurred. This method further evaluates balloon occlusion at the inferior borders of the PV, and specifically, the inferior border of the right inferior PV, which is a common site of reconnection.

Cryoballoon contact with cardiac tissue is an important criterion for lesion formation and PVI. The cryoballoon is noncompliant; thus, operators may encounter difficulty occluding variable PV anatomies. Consequently, when antral occlusion is not possible, a segmental ablation approach is recommended to avoid deep seating of the cryoballoon. The authors routinely use this approach with 120-second applications and have not excluded cryoballoon as an effective tool for large PVs or common ostia. Stöcker et al reported success in isolating 139 left common PVs (LCPVs) using the cryoballoon and demonstrated no difference in outcomes when compared to patients without LCPVs. To achieve a wide-area circumferential lesion in a noncircular/large PV antrum, the authors recommend multiple ablations of the antrum. In an ovoid-shaped antrum, the largest diameter runs superiorly-inferiorly; therefore, the first ablation should maximize superior anchoring to engage the superior portion of the antrum to create the first segment (Figure 2A). This is accomplished with the sheath minimally flexed (or even deflected upward) to support the cryoballoon for maximum superior engagement. Subsequently, the sheath should be maneuvered at a sharper bend to engage the inferior portion of the antrum with the balloon (Figures 2C and 2D). It is acceptable/expected to have a leak in the contralateral side (Figure 2C). The cryoballoon can create a lesion where it is in contact with the PV antrum, as evidenced by corresponding voltage-map recordings (Figures 2B and 2D). Similarly, Miyazaki et al demonstrated the utility of a wider ablation set using a segmental approach specifically at the left superior PV. The authors recommend the 28-mm balloon in most LA/PV anatomies. We sometimes use the 23-mm balloon when all PVs are small (longitudinal PV diameters ≤15 mm).

During ablation: TTI

Acute PVI is a physiological predictor of durable isolation and can be monitored in real time using the Achieve mapping catheter. Recent cryoballoon dosing protocols incorporated assessment of real-time acute PVI. TTI, or time to effect, denotes the elapsed time from the start of...
cryoablation until acute PVI. Isolation is confirmed by loss of PV potentials while pacing with the Achieve mapping catheter during a cryoapplication. Studies that evaluated the association of TTI with AF recurrence identified a trend that longer-duration TTI predicts a higher risk of AF recurrence. To visualize TTI, there are 3 critical variables: the muscular sleeves becomes thinner in more distal segments of the vein; the Achieve mapping catheter should be positioned as proximally as possible without sacrificing stability; and the tip of the balloon may preclude visualization of TTI. As PV musculature undergoes cryoablation, a conduction delay is observed at temperatures that are below ~−20°C. For permanent PVI, we recommend that operators continue cryoablation time beyond TTI.

Three studies used a TTI cutoff of 60 seconds, in which cryoablations with a longer duration of TTI were deemed unsuccessful in achieving durable PVI (Table 1). Upon examining PVI durability, it was found that 41 of 212 patients who were ablated with cryoballoon had AF recurrence and 29 patients underwent reablation (115 PVs). In 29 patients who underwent reablation, 1.25 PVs per patient were reconnected and a TTI of 60 seconds was an independent predictor of AF recurrence. Multivariate analysis revealed that a longer duration of TTI was an independent predictor of PV reconnection (P = .01). In another study, 143 consecutive patients were examined, and at a mean follow-up of 12.1 months, 80.4% of patients were free of recurrence. Multivariate analysis revealed that TTI was a predictor of arrhythmia recurrence (P = .02) and a TTI of ≤40 seconds trended toward no recurrence (90% sensitivity; 81% specificity). Moreover, every additional 10 seconds required for PVI increased the risk of recurrence by 1.3 times.

The Individualized Cryoballoon Energy- Trial (ICE-T) trial evaluated whether a TTI dosing strategy could titrate ablation energy and reduce cryoapplications. In the ICE-T trial, 50 subjects were treated with a standard freeze-thaw-refreeze protocol of 240 seconds and a bonus freeze of 240 seconds. This was compared to 50 subjects who were treated using a TTI dosing strategy. When TTI was ≤75 seconds, a bonus freeze (ablation beyond established block) was not administered. A single-freeze protocol was used for 88% of PVs, and TTI was observed in 79% of PVs regardless of cohort designation. The mean number of cryoablations in the control cohort was 8 ± 1 cryoapplications per subject, while the TTI cohort had 5 ± 1 cryoapplications per subject (P < .001). There was no statistical difference in recurrence at 12 months between the groups (82% vs 88% freedom from arrhythmia for control and TTI cohorts, respectively; P = .804) nor in total complications between the groups (P = .06). Multivariate statistical analysis determined that TTI was the only predictor of recurrence (P = .011). Recently, Aryana et al demonstrated that the short-tip cryoballoon led to improved visualization of TTI (89.2% vs 60.2%; P < .001), fewer cryoapplications (1.6 ± 0.8 vs 1.7 ± 0.8; P = .023), shorter LA dwell time (43 ± 5 minutes vs 53 ± 16 minutes; P < .001), and shorter procedural time (71 ± 11 minutes vs 89 ± 25 minutes; P < .001) with similar freedom from recurrence (81.8% vs 79.9%; P = .658).

TTI and dosing are important considerations for both efficacy and efficiency of cryoablation. Long-term PVI was demonstrated when TTI was achieved in ≤60 seconds. However, a bonus freeze may be appropriate when TTI is not visualized or when TTI is ≥60 seconds. Indeed, a TTI of >60 seconds indicates poor balloon-to-PV circumferential contact. In this instance, we recommend continuing the initial ablation for 2 minutes to ensure a transmural lesion (without risk of a reversible injury). A second segmental ablation procedure will ensure a true wide-area mural lesion. Prolonged temperatures should be avoided. Brief, the authors caution against prolonged temperatures below −55°C and nadir temperatures below −60°C should be avoided.

**Table 1** Summary of studies examining acute PVI by using a landmark TTI of <60 s

<table>
<thead>
<tr>
<th>Study</th>
<th>No. of patients with repeat ablation</th>
<th>TTI in reconnected PVs (s)</th>
<th>TTI in durable PVI (s)</th>
<th>P</th>
<th>TTI &lt;60 s predicts durable PVI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ciconte et al</td>
<td>29</td>
<td>71.4 ± 18.8</td>
<td>42.3 ± 27.2</td>
<td>&lt;.001</td>
<td>86.7</td>
</tr>
<tr>
<td>Aryana et al</td>
<td>71</td>
<td>67.6 ± 19.7</td>
<td>39.1 ± 11.7</td>
<td>&lt;.001</td>
<td>83.3</td>
</tr>
<tr>
<td>Ciconte et al</td>
<td>26</td>
<td>71.1 ± 20.2</td>
<td>50.2 ± 32.9</td>
<td>.030</td>
<td>Not reported</td>
</tr>
</tbody>
</table>

*PV = pulmonary vein; PVI = pulmonary vein isolation; TTI = time to isolation.*

**After ablation: Thaw time**

We recommend monitoring thaw times to predict durable PVI. This variable may be a by-product of an effective cryoablation (ie, robust occlusion with a low nadir

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temperature), and/or prolonged thaws may create thermodynamic advantages that enhance efficacy (eg, elongated ice formation and resultant membrane disruptions). Slow thaw was first described in the study by Ghosh et al, in which 51 of 196 patients had symptomatic recurrence. Multivariate analysis identified that balloon thaw time (from −30°C to 15°C) was the strongest predictor of AF recurrence (P < .0001) and thawing for ≤25 seconds predicted PV reconnection (70% sensitivity; 69% specificity). Durable PVI was achieved in every case in which thaw time was ≥67 seconds. Aryana et al examined various thaw time intervals (from the termination of cryoablation through specific predefined temperatures). The most robust thawing period (predicting PV reconnection) was the time from freeze termination until 0°C (interval thaw time to 0°C, or iTT0). Here, 111 of 435 PVs were reconnected during follow-up of 71 of 112 consecutive patients. iTT0 was longer in PVs that remained isolated (14.8 ± 10.9 seconds vs 7.1 ± 2.0 seconds; P < .001). By multivariate analysis, a TTI of ≤60 seconds and an iTT0 of ≥10 seconds were sole predictors of durable PVI. If both criteria were met, there was a <0.9% risk of long-term PV reconnection. Subsequently, Aryana et al reported that not only did iTT0 emerge as the strongest marker of PVI but it was the most powerful predictor of TTI. An iTT0 of ≥10 seconds represented the most powerful predictor of an optimal TTI of <60 seconds (91% sensitivity; 84% specificity). The authors concluded that when TTI cannot be visualized, an iTT0 of ≥10 seconds can provide a dosing guide.

Thaw time of ≥25 seconds between −30°C and +15°C predicted durable PVI; however, an iTT0 of ≥10 seconds may offer greater sensitivity and specificity. iTT0 has enhanced linearity, but thaw time from the termination temperature to 0°C is also influenced by the nadir temperature. Specifically, a lower nadir temperature profile is an independent parameter for effective cryoaclation. Inherently, our experience supports the premise that lower temperatures will take additional thaw time to reach 0°C.

### Dosing evidence and strategy

#### Reducing freeze duration and applications

The STOP AF trial routinely used 240- to 300-second ablations with a bonus freeze. Since the introduction of the second-generation balloon, operators have explored dose reduction protocols to potentially reduce cold transfer to collateral tissues. Initial studies challenged the usage of bonus freezing during 240-second dosing. While examining 45 patients, investigators used a 28-mm cryoballoon and applied lesions in 240-second intervals without a bonus freeze. The acute PVI rate was 99% (176 of 177 PVs), and the mean number of cryoablation applications per PV ranged from 1.1 to 1.7. A high percentage of acute PVI was observed during the first cryoapplication attempt (67% in the left superior PV, 89% in the left inferior PV, 67% in the LCPV, 76% in the right superior PV, and 58% in the right inferior PV). During 12 months of clinical follow-up, the study demonstrated an 82% (36 of 44) freedom from AF, atrial tachycardia, and atrial flutter recurrence. In this study, 5 patients required reablation, in which 45% of PVs were reconnected at repeat ablation (which were initially treated with a single cryoapplication). By comparison, no PVs treated with a bonus freeze were reconnected at reablation. A second study compared a group of 53 patients who were ablated with no bonus freeze (single-freeze cohort) with a group of 139 patients who were ablated with a bonus freeze. Each group was treated with the 28-mm cryoballoon, and all freezes were of 240 seconds. The single-freeze cohort used adenosine testing in 188 PVs, and dormant conduction was unmasked in 2% of the PVs (4 of 188) and 8% of patients (4 of 53). There was a significant difference in freeze duration between the single-freeze and bonus-freeze cohorts (1059 ± 174 seconds vs 1725 ± 334 seconds, respectively; P < .001), but there were no other differences in procedural time, fluoroscopy time, or complications. At a mean follow-up of 458 ± 107 days, 81% of patients (43 of 53) in the single-freeze cohort and 79% of patients (110 of 139) in the bonus-freeze cohort were free of arrhythmia recurrence with no statistical difference between the groups.

While the above-mentioned studies challenged the routine use of a bonus freeze, other studies examined the utility of the 180-second vs 240-second freeze as a method to reduce dosing. Straube et al examined a 180-second dosing group of 57 patients against a 240-second dosing group of 57 patients, with a bonus freeze of 180 and 240 seconds, respectively. The mean number of cryoapplications per patient was not statistically different between the 180- and 240-second cohorts (12.2 ± 2.7 vs 11.7 ± 2.5, respectively; P = .344), and 100% acute PVI was achieved in both. At 12-month follow-up, there was no statistical difference between the 180- and 240-second cohorts with regard to freedom from arrhythmia recurrence (83.6% vs 76.8%, respectively; P = .272). A second comparison study evaluated a 180-second cryoapplication (with no bonus freeze) against a 240-second cryoapplication (with a bonus freeze).
of 240 seconds). This study evaluated 80 patients in each group and reported 100% acute PVI. Of the 640 PVs in the study, 91% (583) were isolated during the first cryoapplication (90.6% in the 180-second cohort vs 91.6% in the 240-second cohort; \( P = .78 \)). As a result of the bonus freeze in the 240-second cohort, the 180-second cohort had fewer cryoapplications in each PV (1.3 ± 0.4 vs 2.0 ± 0.5; \( P < .001 \)). The mean follow-up was 24.7 ± 6.5 months for the 180-second group and 26.3 ± 8.4 months for the 240-second group (\( P = .18 \)). Freedom from arrhythmia recurrence was not different (180-second group: 77.5%; 240-second group: 78.8%; \( P = .82 \)).

Two additional studies evaluated a 180-second single-freeze dosing protocol in a single-arm design. In the first study of 143 consecutive patients, a 28-mm cryoballoon was used with a 180-second cryoapplication and no bonus freeze. Complete PVI was achieved with a mean of 1.1 ± 0.4 cryoapplications, and 94% of the PVs were isolated during the first cryoapplication. During a mean follow-up of 12.1 ± 4.4 months, 80% of patients were free of arrhythmia recurrence. Miyazaki et al. investigated a 180-second single cryoapplication protocol in 54 patients and assessed 217 PVs. In this study, all PVs were isolated with a mean number of cryoapplications not exceeding 1.3 freezes, with the exception of the LCPV (which used a segmental approach; LCPV, 3.0 ± 1.4). During a mean follow-up of 7.7 ± 1.6 months, the study determined that 82% of patients were free of recurrence.

Aryana et al. tested a dosing protocol guided exclusively by TTI in 355 patients compared with 400 control patients who underwent cryoablation using a conventional approach (Figure 3). The authors found that the dosing protocol was associated with shorter (149 ± 34 seconds vs 226 ± 46 seconds; \( P < .001 \)) and fewer (1.7 ± 0.8 vs 2.9 ± 0.8; \( P < .001 \)) cryoapplications as well as shorter total ablation time (16 ± 5 minutes vs 40 ± 14 minutes; \( P < .001 \)), LA dwell time (51 ± 14 minutes vs 118 ± 25 minutes; \( P < .001 \)), and total procedural time (84 ± 23 minutes vs 145 ± 49 minutes; \( P < .001 \)), but with similar nadir balloon temperature (−47°C ± 8°C vs −48°C ± 6°C; \( P = .41 \)) and thaw time (43 ± 27 seconds vs 45 ± 19 seconds; \( P = .09 \)) in comparison to the conventional approach. While the rates of overall adverse events (2.0% vs 2.7%; \( P = .48 \)) including persistent phrenic nerve injury (0.6% vs 1.2%; \( P = .33 \)) and 12-month freedom from all atrial arrhythmia recurrence (82.5% vs 78.3%; \( P = .14 \)) were similar, the dosing arm reported fewer atypical atrial flutters/tachycardias during long-term follow-up (8.5% vs 13.5%; \( P = .02 \)) and fewer PV reconnections at reablation (5.0% vs 18.5%; \( P < .001 \)).

Altogether, these studies successfully reduced the freezing interval to 180 seconds and/or eliminated the bonus freeze without reductions in long-term efficacy. The most recent studies examined 180-second single-freeze dosing protocols and found long-term efficacy to be aligned with 240-second dosing.

### Safety during dose reduction

Dosing may have implications for collateral tissues. Best practices for monitoring the phrenic nerve and esophagus...
have been previously published. However, the authors would like to reiterate that cryoballoon positioning, anatomy, temperature, dosing, and distance to collateral structures are important factors and recommend usage of adjunctive methods. While the authors do not suggest that esophageal monitoring is required, the risk/benefit should always be considered. Here, we share data from investigations of esophageal temperature monitoring to mitigate the risk of atrioesophageal (AE) fistula (or at least esophageal injury).

AE fistula is a rare but known complication of ablation. The mechanism(s) of AE fistula formation are still debated; however, injury to the esophagus by collateral energy transfer during AF ablation is likely a contributing factor. By monitoring esophageal temperatures, investigators have attempted to define temperature guidelines that may avoid esophageal erosion (and potentially AE fistula). Initial studies by Fürnkranz et al and Metzner et al (discussed in detail in Supplement 2) as well as recent follow-up studies recommend a luminal esophageal temperature (LET) cutoff range >10°C–15°C to minimize injury (Table 3). While the 2 aforementioned studies used a multisensor esophageal temperature probe, the authors do not have a recommendation on which esophageal probe to use (as long as the specifications allow accurate readings to 0°C). The presented data support a target LET no lower than 15°C, but it is critical to understand that the absence of low LET does not necessarily indicate an absent injury. Here, the authors discourage immediate consecutive ablations of the targeted vein to allow rewarming of collateral tissue. Furthermore, the authors propose that routine post-cryoablation adenosine testing is not required (detailed discussion is given in Supplement 3).

**Dosing conclusion**

We highlighted important operator-controlled dosing considerations to reduce complications and maximize effectiveness, including using the lowest number of cryoapplications, ensuring proper cryoballoon occlusion/positioning without deep seating, and performing segmental ablation when necessary. We recommend that ablations should not be performed for >180 seconds and immediate consecutive ablations should be avoided. We propose that cryoballoon ablations should be terminated at temperatures <−55°C. A TTI of <30 seconds can predict a durable lesion, and a TTI of >60 seconds can indicate poorer contact. We deduce that ablations with greater TTI should be continued for an additional 2 minutes beyond TTI. In our experience, a second segmental ablation should be performed in PVs with longer TTI to ensure a wide-area circumferential lesion. Lastly, careful monitoring of collateral tissue injury should be used consistently.

**Study limitations**

This report includes both prospective and retrospective study evaluations; however, the authors were deliberate in their selection and inclusion of quality publications that used the second-generation cryoballoon. While the learning curve for cryoballoon ablation is relatively short, variability in user experience may result in different outcomes. A further limitation of the review was the variability in operator technique, patient selection criteria, and study design/data reporting. Finally, the introduction of new technologies (eg, short-tip cryoballoon) necessitates continued evaluation of current practices, and periodic reevaluation will be necessary in any current “best” practice.

**Appendix**

**Supplementary data**

Supplementary data associated with this article can be found in the online version at https://doi.org/10.1016/j.hrthm.2018.04.021.

**References**


37. Su et al Cryoballoon Best Practices II