Immediate balloon deflation for prevention of persistent phrenic nerve palsy during pulmonary vein isolation by balloon cryoablation

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BACKGROUND Persistent phrenic nerve palsy is the most frequent complication of cryoballoon ablation for atrial fibrillation and can be disabling.

OBJECTIVES To describe a technique—immediate balloon deflation (IBD)—for the prevention of persistent phrenic nerve palsy, provide data for its use, and describe in vitro simulations performed to investigate the effect of IBD on the atrium and pulmonary vein.

METHODS Cryoballoon procedures for atrial fibrillation were analyzed retrospectively (n = 130). IBD was performed in patients developing phrenic nerve dysfunction (n = 22). In vitro simulations were performed by using phantoms.

RESULTS No adverse events occurred, and all patients recovered normal phrenic nerve function before leaving the procedure room. No patient developed persistent phrenic nerve palsy. The mean cryoablation time to onset of phrenic nerve dysfunction was 144 ± 64 seconds. Transient phrenic nerve dysfunction was seen more frequently with the 23-mm balloon than with the 28-mm balloon (11 of 39 cases vs 11 of 81 cases; $P = .036$). Balloon rewarming was faster following IBD. The time to return to 0 and 20° C was shorter in the IBD group (6.7 vs 8.9 seconds; $P = .007$ and 16.7 vs 37.6 seconds; $P < .0001$). In vitro simulations confirmed that IBD caused more rapid tissue warming (time to 0°C, 14.0 ± 3.4 seconds vs 46.0 ± 8.1; $P = .0001$) and is unlikely to damage the atrium or pulmonary vein.

CONCLUSIONS IBD results in more rapid tissue rewarming, causes no adverse events, and appears to prevent persistent phrenic nerve palsy. Simulations suggest that IBD is unlikely to damage the atrium or pulmonary vein.

KEYWORDS Atrial fibrillation; Ablation; Cryoballoon; Phrenic nerve palsy

ABBREVIATIONS **PVI** = pulmonary vein isolation; **RF** = radiofrequency; **RSPV** = right superior pulmonary vein

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Introduction

Pulmonary vein isolation (PVI) is the cornerstone of atrial fibrillation ablation. Cryoablation is one technique that is commonly used and is an alternative to radiofrequency (RF) ablation. The most frequent adverse event associated with balloon cryoablation is persistent phrenic nerve palsy.[1–3] The right phrenic nerve can be damaged when attempting to isolate the right superior pulmonary vein (RSPV) or less commonly the right inferior pulmonary vein. This is due to the proximity of the right phrenic nerve to the right pulmonary veins. Techniques have been used to minimize this incidence of this complication,[4–7] but despite these methods, the incidence of persistent phrenic nerve palsy remains in the order of 5%.[8] Persistent phrenic nerve palsy is sometimes disabling, but fortunately the majority of these cases resolve within 1 year.

On the detection of phrenic nerve injury during cryoablation, the recommended practice is to immediately halt the flow of refrigerant to the balloon, which allows passive balloon rewarming. However, using this technique, balloon deflation and subsequent warming may not occur for several minutes. Training literature[9] describes an alternate procedure where the balloon is deflated without waiting for rewarming to occur. To our knowledge, this alternate procedure is rarely used and has not been described in the literature and no data exist regarding its efficacy. We hypothesized that immediate balloon deflation (IBD) at the first sign of phrenic nerve

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dysfunction would result in more rapid warming and prevent persistent phrenic nerve injury.

Methods

One hundred thirty consecutive cryo-PVI cases were analyzed retrospectively. Access to the clinical data was approved by the local ethics committee.

A standard approach to cryo-PVI was employed,[10] but in brief: A cardiac computed tomography scan was performed in the week prior to the procedure. Patients were placed under a general anesthetic. Muscle relaxant drugs were not used. A transesophageal echocardiogram was performed to exclude left atrial thrombus. Femoral venous access was gained from the right and left femoral veins. Transeptal access to the left atrium was gained with an SL0 guiding sheath (St Jude, St Paul, MN) and a Cook transeptal needle (Cook Medical, Bloomington, IN). This was changed "over the wire" for a 15-F steerable sheath (Flexcath, Medtronic, Minneapolis, MN). Pulmonary venograms were then acquired with fluoroscopy and contrast injection. Two balloon sizes are available 23 and 28 mm. The appropriate balloon size was selected by using venograms and computed tomography images. Pulmonary vein recordings were made with an Achieve (Medtronic) or Lasso (Biosense Webster, Diamond Bar, CA) recording catheter. A cryoablation balloon (Arctic Front, Medtronic) was then advanced to the pulmonary vein ostium and occlusion assessed by distal contrast injection. If vein occlusion was achieved, cryotherapy was applied for 4–5 minutes, with 2 applications per vein.

When ablating near the right pulmonary veins, the diaphragm was paced by using a quadripolar catheter placed in the right innominate vein. The operator placed a hand on the abdomen of the patient and assessed the strength of contraction and periodically observed the diaphragmatic contraction using fluoroscopy. If during cryoablation there was any diminution of strength of contraction, cryoablation was halted immediately and the balloon deflated actively. Following isolation of all pulmonary veins, each of the veins was checked for entry and exit block by using standard methods.[11,12] Additional ablation for persistent atrial fibrillation was not performed at the initial procedure.

If transient phrenic nerve dysfunction occurred, the operator either chose to repeat the freeze at a more proximal location or elected not to perform a second freeze for that vein if isolation had been achieved. If PVI was not achieved for a particular vein, either further cryoablation was performed or RF ablation undertaken, depending on the initial contrast-guided occlusion and minimum temperature achieved. For analysis, patients who developed transient phrenic nerve dysfunction and underwent IBD were compared with patients who did not have transient phrenic nerve dysfunction and did not undergo IBD ("controls").

Transient phrenic nerve dysfunction was defined as loss of right diaphragmatic movement during stimulation of the phrenic nerve with the current of twice capture threshold, where normal function recovered prior to the end of the procedure. Persistent phrenic nerve palsy was defined as phrenic nerve dysfunction that persisted beyond the end of the procedure.

Immediate balloon deflation

We used the immediate deflation technique if decreased diaphragmatic contraction was observed during cryoablation of the right pulmonary veins. The stop button on the console was pressed, which halted the refrigerant flow, and 2 seconds later the button was pressed a second time, which caused the pump to apply a vacuum to the balloon, causing immediate deflation. The 2-second delay is required for the console to accept successive stop signals.

The time for the balloon temperature to rise from the final temperature to 0 and 20° C was compared for the IBD group and the normal balloon deflation group (RSPVs).

Simulations of IBD to investigate mechanical effects on the endocardium

In order to investigate the interactions between the balloon and the endocardium during IBD, a number of in vitro simulations were performed. In brief, a warmed saline bath (maintained at 37°C) was used to simulate the atrial blood pool. Vein phantoms were constructed by using a 25-mm-diameter plastic tube, with different covering materials to simulate the endocardium. Initially, a surgical cotton gauze was used to allow identification of surface fiber displacement. The 28-mm cryoballoon was pressed against the vein phantom, and following immersion in the warmed saline, cryoablation started. After periods of 90–240 seconds, the balloon/vein phantom was removed from the saline and the balloon deflated rapidly (Video 1).

Simulations were repeated by using a plastic tube fixed to a ring of chicken pectoral muscle to provide a vein model with intracellular and extracellular water. Occlusion and flow from the vein ostium were qualitatively assessed by

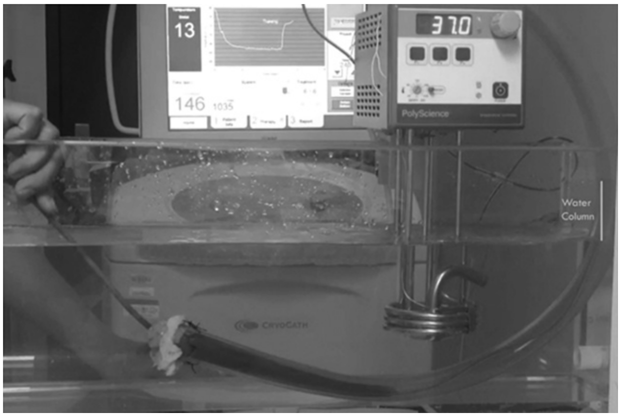

Figure 1 Apparatus for assessing cryoadherence and the effect on pulmonary vein. The saline tank has active flow and is maintained at 37°C. The cryoballoon temperature displays 13°C, 24 seconds after the end of ablation, but it is still predominantly adhered to the vein. At this point in time, a small leak has occurred inferiorly and a small amount of dye flow can be seen although "pulmonary vein" pressure remains elevated (note standing column). See also Video 2 and supplementary notes.