Optimal contact forces to minimize cardiac perforations before, during, and/or after radiofrequency or cryothermal ablations

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BACKGROUND Catheter perforations remain a major clinical concern during ablation procedures for treatment of atrial arrhythmias and may lead to life-threatening cardiac tamponade. Radiofrequency (RF) ablation alters the biomechanical properties of cardiac tissue, ultimately allowing for perforation to occur more readily. Studies on the effects of cryoablation on perforation force as well as studies defining the perforation force of human tissue are limited.

OBJECTIVE The purpose of this study was to investigate the required force to elicit perforation of cardiac atrial tissue after or during ablation procedures.

METHODS Effects of RF or cryothermal ablations on catheter perforation forces for both swine (n = 83 animals, 530 treatments) and human (n = 8 specimens, 136 treatments) cardiac tissue were investigated.

RESULTS Overall average forces resulting in perforation of healthy unablated tissue were 406*g* ± 170*g* for swine and 591*g* ± 240*g* for humans. Post-RF ablation applications considerably reduced these forces to 246*g* ± 118*g* for swine and 362 ± 185*g* for humans ($P < .001$). Treatments with cryoablation did not significantly alter forces required to induce perforations. Decreasing catheter sizes resulted in a reduction in forces required to perforate the atrial wall ($P < .001$). Catheter perforations occurred over an array of contact forces with a minimum of 38*g* being observed.

CONCLUSION The swine model likely underestimates the required perforation forces relative to those of human tissues. We provide novel insights related to the comparative effects of RF and cryothermal ablations on the potential for inducing undesired punctures, with RF ablation reducing perforation force significantly. These data are insightful for physicians performing ablation procedures as well as for medical device designers.

KEYWORDS Catheter ablation; Cardiac tamponade; Arrhythmia; Cardiac perforation; Radiofrequency ablation; Cryoablation

ABBREVIATIONS AF = atrial fibrillation; **RF** = radiofrequency

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Introduction

Today, atrial fibrillation (AF) affects more than 5.1 million people in the United States, and, as the population continues to age, the incidence is expected to increase at least 2.5-fold by 2050.[1,2] Recently, a complication rate of 4% to 6% was reported for catheter ablation procedures performed for treatment of AF.[3,4] These complications can be prompted by a number of factors, ranging from induced septal defects after transseptal punctures to perforation of the atria. More specifically, cardiac tamponade has been reported to occur in 1.3% of ablation procedures.[3] It is considered that complications may arise throughout these procedures due to a number of factors, such as transseptal punctures, adverse catheter maneuvers, or excessive contact forces during energy applications.

Perforation of the atrial wall during ablation procedures, which may lead to pericardial effusions and/or life-threatening cardiac tamponade, has only recently gained attention. Cardiac perforation is most common during AF procedures and occurs less frequently during other cardiac procedures.[5] It is suggested that perforation may result from use of high power and/or high contact forces to ensure the creation of transmural lesions by radiofrequency (RF) energies. Unfortunately, no comprehensive studies investigating the causes of cardiac tamponade during ablation procedures have been reported in the literature. However, it is important to note that procedures such as transseptal puncture are associated with a complication rate as high as 0.79% and cardiac perforation with tamponade in 0.11% of cases.[6] It also is known that mechanical perforations with diagnostic catheters also are associated with cardiac tamponade. Interestingly, the presentation of pericardial effusion in RF and cryoablation procedures is not significantly different.[7] Furthermore, patients with AF have been reported to have thinner atrial walls; this likely elicits

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Table 1 Human heart demographics

Heart no,	Age (years)	Weight (kg)	Heart weight (g)	Gender	Cause of death	Cardiac history
1	45	96	537	M	Cerebral vascular accident	Hypertension, alcoholism
2	34	86	422	M	Cerebral vascular accident	None
3	62	73	456	F	Cerebral vascular accident	Hypothyroidism, hyperlipidemia
4	52	74	401	F	Cerebral vascular accident	None
5	81	75	504	F	N/A	Atrial fibrillation, mitral regurgitation
6	67	82	330	M	Bladder cancer	None
7	69	77	456	M	Chronic obstructive pulmonary disease	None
8	67	59	496	F	Chronic obstructive pulmonary disease	None

circumstances that allow for perforations to occur even more readily.[8] Other important factors to consider during these clinical procedures include movements of the heart throughout the cardiac cycle as well as those due to respiration, because these can alter the applications of desired contact forces and provide added challenges for clinicians.[9]

Additionally, it is regarded that the biomechanical properties are altered during the heating and cooling of tissues. For example, loss of pulmonary vein compliance and denaturation of collagen occurs at temperatures of 60–65°C, yet elastin remains unchanged until temperatures of 80°C are reached.[10] During cryoablation, structural proteins remain intact, although realignments occur as a result of ice crystal formations.[11] Therefore, better understanding of the contact forces required for proper lesion formation, while minimizing ruptures, may lead to reduced occurrences of cardiac tamponade. This study provides novel insights into the biomechanical effects of RF and cryoablations relative to the potential to induce punctures of cardiac atrial tissues. The study could be considered translational because we compared results for both isolated viable swine and human atrial samples.

Methods

Sample preparation

Human heart specimens (n = 8) were obtained from nonviable organ transplant donors through our local organ procurement organization LifeSource (St. Paul, MN; Table 1). These tissues were considered viable because they typically were acquired and tested within 6 to 12 hours after explantation. All non-AF hearts had a nondilated atrial pathology. Healthy 7- to 9-month-old Yorkshire Cross swine cardiac specimens (n = 83, animal weight 75–110 kg, heart weight 400–650 g) were acquired from the University of Minnesota Meat Sciences Laboratory and the Visible Heart Lab (waste tissue from unrelated experiments) and stored in saline before testing. Fresh atrial samples from the free wall (atrial appendage and atrial roof) were carefully dissected out.

Atrial samples (n = 666) were randomized to the following study groups: (1) no treatment; (2) RF ablation with a nonirrigated RF Marinr catheter (Medtronic, Minneapolis, MN) for 1 minute at 30 W with a temperature limit of 65°C; (3) RF ablation using the same parameters as (2), with induced perforation during the last 5 seconds of applied ablation; or (4) focal cryoablation with a Freezer MAX catheter (Medtronic) for 2 minutes (Figure 1). Cryoablated samples were permitted a sufficient amount of time for ice to thaw before the induced perforations. All samples were carefully anchored and submerged in saline before each ablative modality was applied. Each catheter was subsequently advanced at a rate of 500 mm/min with a mechanical force tester (Chatillon, Largo, FL) until perforation occurred. An array of catheter sizes (5, 7, and 8Fr) was also investigated in these experiments.

Statistical analysis

The maximum force readings corresponding to the perforation forces were analyzed with Minitab (State College, PA). All

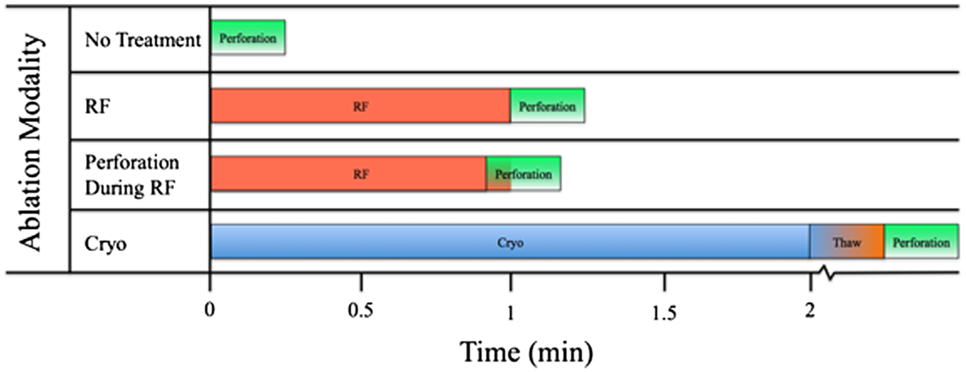

Figure 1 Graphic depiction of the treatment groups in relation to the application of ablation and the induction of catheter perforation. Cryo = cryoablation treatment; RF = radiofrequency treatment.