Published in final edited form as:

Innovations (Phila). 2009 ; 4(2): 86–92. doi:10.1097/IMI.0b013e3181a348a2.

Epicardial Ablation on the Beating Heart: Limited Efficacy of a Novel, Cooled Radiofrequency Ablation Device

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Abstract

Objective—To perform a minimally invasive procedure for atrial fibrillation without cardiopulmonary bypass, it is necessary to create transmural lesions on the beating heart. Although bipolar radiofrequency clamps can isolate the pulmonary veins, they have difficulty in performing any other left atrial lesions, particularly those of the traditional Cox-Maze procedure. This study examined the performance of an internally cooled, bipolar radiofrequency device designed for such an application.

Methods—Eleven domestic pigs underwent median sternotomy. Five animals had eight atrial lesions created with the radiofrequency device at times of 20, 30, 40, and 50 seconds. In six other pigs, the device was compared with another technology that has been used clinically for epicardial, beating heart ablation, the Guidant Flex 4 microwave device. The tissue was stained with 2,3,5-triphenyl-tetrazolium chloride, and the lesions were sectioned at 5-mm intervals. Lesion width, depth, and transmurality were evaluated.

Results—The radiofrequency device had a linear dose-response relationship. Lesions were wider and deeper with increasing ablation times. A total of 40%, 45%, 60%, and 67% of lesions were transmural at times of 20, 30, 40, and 50 seconds, respectively. Ninety-one percent of lesions in tissue up to 4-mm thick were transmural after 50 seconds. However, performance in thicker tissue was poor. Lesions created by the device were deeper and more likely to be transmural than the Flex 4.

Conclusions—This internally cooled, bipolar radiofrequency device can reliably create transmural lesions on tissue up to 4-mm thick and performs better than a microwave device.

Keywords

epicardial ablation; atrial fibrillation; radiofrequency ablation; microwave ablation

Introduction

The Cox-Maze procedure has been the gold standard for the surgical treatment of atrial fibrillation since its introduction in 1987. This operation involved creating lines of conduction block by making incisions in both atria to interrupt the macro-reentrant circuits thought to be responsible for atrial fibrillation. In long-term follow-up, the Cox-Maze III has

achieved over 90% success in curing symptomatic atrial fibrillation.¹ Over the last 10 years, most groups have replaced the traditional cut-and-sew lesions of the Cox-Maze III with ablations using various energy sources in an effort to make the procedure technically simpler and faster to perform. These energy sources have included cryosurgery, microwave, laser, ultrasound, and unipolar and bipolar radiofrequency.^{2–11} Developing a minimally invasive surgical approach requires a technology capable of creating linear lesions off-pump, epicardially on the beating heart. This study describes a novel bipolar radiofrequency device with internally cooled electrodes designed for such an application.

Radiofrequency energy creates a lesion on atrial tissue through resistive and passive conductive heating that occurs as radiofrequency energy is emitted from a point source to a grounding pad in unipolar applications, or between two electrodes placed in contact with tissue for bipolar applications. Bipolar radiofrequency clamps have proven to be reliable and effective in creating transmural lesions.^{12, 13} However, these clamps have a few drawbacks. They are difficult to use in a minimally invasive, beating heart manner for creating lesions other than pulmonary vein isolation. For the other lesions of the Cox-Maze procedure, they require an incision and a pursestring suture in the atrium to ablate atrial tissue on the beating heart.¹⁴

Additionally, excess heating at the tissue-electrode interface can lead to char formation on the electrodes of radiofrequency devices. The resultant tissue char has high impedance, and limits the penetration of radiofrequency energy, thus reducing lesion depth in the target tissue. Incomplete ablations may be a reason for failure in the surgical treatment of atrial fibrillation.^{15, 16} Thus, devices that fail to achieve transmural ablation are unlikely to achieve long-term cure of atrial fibrillation.

The AtriCure Coolrail (AtriCure Inc, West Chester, OH) device is an internally cooled, bipolar radiofrequency device designed for epicardial ablation. The device consists of 2 3 cm × 3 mm hollow electrodes that are cooled by internally circulated water. Radiofrequency energy is emitted between these two electrodes (Fig. 1). A motor circulates sterile water from a reservoir through the electrodes. This study was designed to establish a dose-response curve in a clinically relevant animal model as well as to compare the performance of this device with an older existing, FDA-approved surgical ablation device, the Guidant Flex 4 (Guidant Corporation, Indianapolis, IN) microwave device. Although no longer available, this latter device had been widely used clinically for epicardial beating heart ablation.^{17–20} Our laboratory previously has examined the efficacy of the Flex 4 in animal models.²¹

Methods

Eleven domestic pigs weighing between 75 and 100 kg were used in this study. All animals received humane care in compliance with the Guide for the Care and Use of Laboratory Animals, (National Academy Press, Washington, DC). Each animal was premedicated with Telazol and Ketamine, intubated, anesthetized with isoflurane, and monitored continuously throughout the procedure with electrocardiogram and invasive arterial pressure recordings. The study was divided into two parts, using five animals for an initial dosimetry phase, and six animals for a comparative study between the Coolrail and the Guidant Flex 4 microwave device.

In the dosimetry study, eight atrial lesions were created in each animal, with two lesions each at ablation times of 20, 30, 40, and 50 seconds. The locations of these ablations were randomized over the surface of both atria. In the second part of the study, a Coolrail lesion was created with an application for 30, 40, or 50 seconds adjacent to a Flex4 ablation for 60

or 90 seconds, as recommended by the manufacturers. A paired lesion was placed on the right atrial appendage, the right atrial free wall, and the left atrial appendage for a total of six ablations in each animal (Fig. 2). All animals received intravenous heparin prior to ablation, and the activated clotting time was maintained at greater than 350 seconds throughout the procedure.

Histologic Assessment

At the completion of the procedure, a concentrated potassium chloride solution was injected into the superior vena cava to arrest the heart and killed the animal. The aorta was cross-clamped, and 60 mL of 1% 2,3,5-triphenyltetrazolium chloride was perfused through the coronary circulation via infusion into the root of the aorta. The ablations were examined macroscopically for evidence of charring, clot formation, or tissue disruption. The hearts were then placed into a solution of 1% 2,3,5-triphenyltetrazolium chloride and allowed to incubate for 45 minutes at room temperature to stain viable myocardium. Each lesion was then sectioned at 5-mm intervals perpendicular to the long axis of the ablation. These cross sections were digitally photographed next to a caliper set to 1 cm for calibration. Lesion width, lesion depth, and tissue thickness were determined with commercial software (Adobe Photoshop, San Jose, CA). The accuracy of this technique is ± 0.03 mm.²¹ The lesion depth and width were measured from the unstained area to the pink halo region surrounding each lesion. A total of eight lesions from each animal in the dose-response phase of the study and six lesions from each animal in the comparative phase of the study were analyzed.

Statistical Analysis

Mean depth, width, and transmurality were compared with an analysis of variance with time as a repeated measure using Systat 12 (San Jose, CA). Post hoc multiple comparisons were made using the Fisher least significant difference test. Data were expressed as mean $\pm$ SD and comparisons were considered significant with $P < 0.05$.

Results

On gross inspection, all lesions created by the Coolrail were discernible and discrete. No tissue disruption was noted. There was some tissue charring on the epicardial surface, but no char extended across the entire width or length of any lesion. No clot formation was noted on the endocardial surface. Atrial lesion depth was compared with tissue thickness for each cross section and each sample was examined for transmurality. Mean atrial tissue thickness was 3.7 ± 1.9 mm for the dosimetry experiments. Mean atrial thickness was 2.9 ± 1.3 mm for the Coolrail lesions and 3.9 ± 2.3 mm for the Flex4 lesions in the comparative experiments; there was no statistical difference between these two groups ($P = 0.07$).

Dosimetry

The Coolrail device created transmural lesions in only 40% of cross sectional samples examined following a 20-second ablation. This increased to 45%, 60%, and 67% at 30, 40, and 50 seconds, respectively. There was no statistically significant difference in transmurality between 40 and 50 seconds ($P = 0.76$; Fig. 3). Width increased as dose went from 20 to 30 to 40 seconds; but there was no statistically significant increase in width between 40 and 50 seconds of ablation ($P = 0.13$). Depth did not increase from 20 to 30 seconds, but did increase at higher doses (Fig. 4).

Lesion depth is plotted against tissue thickness in Figure 5 for the Coolrail device. As ablation time was increased, more lesions reached full thickness. As demonstrated on the plot, ablation is less likely to be transmural in thicker tissue. After 50 seconds of ablation,

91% of all lesions in tissue less than 4-mm thick were transmural whereas only 48% of lesions in tissue thicker than 4 mm achieved transmural.

Comparative Performance

The Coolrail was compared with an existing technology that has been widely used in the clinical treatment of atrial fibrillation. The Guidant Flex4 microwave device failed to reliably create transmural lesions a majority of time, even at the manufacturer's recommended ablation time of 90 seconds (Fig. 6). Only 38% of lesions were transmural. Fifty-eight percent of lesions in tissue less than 4-mm thick were transmural for the microwave device and none of the lesions in tissue thicker than 4-mm were transmural.

Comparing the lesions at the maximum time tested for each device in a side by side manner, the Coolrail performed more reliably than the Flex4 in creating transmural lesions (Fig. 7). Similarly, the Coolrail created deeper lesions than the Flex 4, averaging 2.8 ± 1.1 mm in depth versus 2.0 ± 1.1 mm for the Flex 4 device ($P = 0.005$).

Discussion

The traditional incisions of the Cox-Maze III have been replaced in clinical practice by linear lines of ablation using various energy sources. Many of these devices were used clinically before dose-response data were published.^{17, 22} Subsequent studies have shown that some did not consistently create transmural lesions.^{21, 23–27} As the demand for minimally invasive techniques has led to the development of new technologies, establishing dose-response before widespread use is paramount. Knowledge of device performance characteristics is vital to effectively treat patients with atrial fibrillation.

This study demonstrated that the Coolrail device was capable of creating transmural lesions 91% of the time in atrial tissue up to 4-mm thick; however, it did not perform well in thicker atrial tissue. Above 4 mm, only 21% and 48% of lesions were transmural at 40 and 50 seconds, respectively. At shorter ablation times, even thin tissue sections presented a challenge for the Coolrail. Twenty percent of lesions between 2.0 and 2.5 mm were not transmural at ablation times of 20 and 30 seconds.

This laboratory has previously published our animal work with microwave devices, including the one tested in this study.²¹ The results of the this study were similar. The microwave device had a difficult time creating a transmural lesion in the beating heart with less than 40% of lesions transmural at any time tested. A follow-up study in this laboratory demonstrated the dependence of lesion thickness on intracavitary blood flow and cardiac output, which may serve as a heat sink in the beating heart, and thus shielding the endocardium from thermal damage and preventing transmural ablation.²⁸

This study demonstrated that the internally cooled, bipolar radiofrequency-based Coolrail can overcome some of the limitations of earlier generation devices like the Flex 4, penetrating deeper into beating atrial tissue and achieving more consistent transmural, especially in thin atrial tissue. Forty-two percent of all lesions less than 4-mm thick were not transmural with the microwave device as compared with only 9% for the Coolrail device at the maximum time tested.

With the introduction of technology capable of creating transmural lesions epicardially on the beating heart, the goal of achieving a minimally invasive procedure for all patients with atrial fibrillation becomes more achievable. To date, most published reports on minimally invasive atrial fibrillation surgery have limited their procedures to pulmonary vein isolation with or without ablation of the ganglionated plexuses.^{29–33} Although early results have

been encouraging in patients with paroxysmal atrial fibrillation, success rates have been poor for patients with long-standing or persistent atrial fibrillation. In these subsets, the most effective option remains a full Cox-Maze lesion set.^{1, 34}

This study demonstrated that the Coolrail can create linear, transmural lesions on the beating heart, up to 4 mm. However, in thicker tissue, it did not have sufficient efficacy. Because it is usually not practical to determine tissue thickness at every proposed ablation site intraoperatively, this is a significant shortcoming of this technology. Pathologic atria can achieve thicknesses greater than 4 mm,³⁵ and even normal atria get very thick in areas such as the crista terminalis and Bachman's bundle.^{36, 37} This would suggest that it will be necessary to test lesion integrity in the operating room at the time of surgical ablation when this device is used.

Electrophysiologic testing of ablations represents a difficult challenge. Initial success with late recurrences has been observed consistently in follow up after ablation procedures. Electrophysiologic study at the time of ablation procedure consistently documents isolation of the pulmonary veins in catheter-based treatments, but repeat studies of these patients after treatment failure demonstrate recovery from isolation.^{38–40} A reliable, expedient method for documenting permanent conduction block remains to be elucidated, although several groups are working on this challenge.^{41–43} A number of centers are exploring a hybrid approach in which surgeons and electrophysiologists collaborate closely in the performance and testing of surgical ablation procedures. Until reliable methods for documenting conduction block are available, application of any energy source, including the Coolrail, on the epicardial surface of the beating heart must be done with caution.

Limitations

The main limitation of this study is that ablations were examined in the acute setting. Chronic results with the Coolrail may be different.²⁶ However, TTC staining has been shown to reliably delineate the extent of necrosis, and experience in our laboratory has demonstrated similar results in the acute and chronic setting using the techniques of sampling and analysis used in this study.^{13, 44, 45}

A second limitation of the study is that the healthy, normal porcine atria do not completely mimic the clinical situation. Average tissue thickness was less than 4 mm whereas pathologic atria can be greater than 10-mm thick in humans and may contain significant tissue fibrosis, both of which can limit the extent of lesion formation. In addition, epicardial fat has been shown to limit the penetration of radiofrequency energy.⁴⁶ The placement of lesions in this study specifically avoided the epicardial fat pads present in normal porcine anatomy. Furthermore, these lesions were planned so that the maximum number of lesions could be created in any one animal to reduce the number of animals needed to acquire sufficient dosimetry data and not to simulate clinical lesion sets designed to treat atrial fibrillation. For example, no lesions were made to encircle the pulmonary veins in this study as the anatomy of the pig made this area difficult to ablate. This lesion has been critical in both the surgical and catheter-based treatment of atrial fibrillation. This has electrophysiologic implications, but no attempt was made to document the electrophysiological consequences of the lesions in this study. Finally, as lesions were sectioned every 5 mm, the contiguity of the lesions were not measured along the entire length of the ablation.

Acknowledgments

The authors acknowledge the technical assistance of Diane Toeniskoetter and Naomi Still.

Disclosures: The research was supported in part by National Institutes of Health grants 5R01HL32257, R01 HL085113, T32HL07776, and a grant to Dr. Damiano from AtriCure, Inc. (West Chester, Ohio). Richard B. Schuessler, PhD, has received honorarium.

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Figure 1.
The AtriCure Coolrail device.

Figure 2.

Diagram depicting the locations for the ablations for the dosimetry and comparative parts of the study on the left and right, respectively.

Figure 3. Percent of tissue cross sections that were transmural in the dosimetry phase of the study using the Coolrail device. The number of cross sections that were transmural and the total number of cross sections examined for each dose are shown.

Figure 4. Coolrail lesion depth and width are plotted against time for the dosimetry phase of the study. * $P = 0.13$ compared with width at 40 seconds. ** $P = 0.94$ compared with depth at 20 seconds. $P < 0.001$ for all other comparisons of width. $P < 0.05$ for all other comparisons of depth.

Coolrail Lesion Depth vs. Tissue Thickness

Figure 5.

Lesion depth is plotted against tissue thickness for each cross section examined in the dosimetry study for the Coolrail device. If a lesion is transmural, its point will fall on the line of identity.

Flex 4 Lesion Depth vs. Tissue Thickness

Figure 6.
Lesion depth is plotted against tissue thickness for the Flex 4 device.

Lesion Depth vs. Tissue Thickness Device Comparison

Figure 7.

Lesion depth is plotted against tissue thickness for both devices at the maximum dose examined in this study.