Evolving Technology

Efficacy and safety of right and left atrial ablations on the beating heart with irrigated bipolar radiofrequency energy: A long-term animal study

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Objective: The Cox maze procedure is the most effective surgical treatment for atrial fibrillation; however, its complexity has limited its clinical utility. The purpose of this study was to simplify the procedure by using an irrigated bipolar radiofrequency ablation device on the beating heart without cardiopulmonary bypass.

Methods: Six domestic pigs underwent median sternotomy. The pulmonary veins were circumferentially ablated. Electrical isolation was confirmed by pacing. Eight lesions were performed epicardially, and three lesions were performed through purse-string sutures with one of the jaws of the device introduced into the right atrium. After 30 days, magnetic resonance imaging was performed to assess atrial function, pulmonary vein anatomy, and coronary artery patency. Cholinergic stimulation and burst pacing were administered to induce atrial fibrillation. Histologic assessment of the heart was performed after the animal was killed.

Results: A modified Cox maze procedure was successfully performed with the irrigated bipolar radiofrequency device with no deaths. In every instance, the pulmonary veins were electrically isolated. Cholinergic stimulation with burst pacing failed to produce atrial fibrillation. Imaging studies revealed tricuspid regurgitation without evidence of pulmonary vein stenosis, coronary artery stenosis, or intra-atrial thrombus. Total atrial ejection fraction was 16.9% ± 7.5%, a significant reduction. Histologically, 99% of the lesions were transmural, and there was no evidence of coronary sinus injury.

Conclusion: Lesions on both the right and left atria can be created successfully on the beating heart with irrigated bipolar radiofrequency. The great majority of lesions with this device were transmural. This device should not be used on valvular tissue.

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Atrial fibrillation (AF) is the most common of all sustained arrhythmias, with incidences in the United States as great as 1% in the general population and 9% among people older than 80 years.[1] It is associated with significant morbidity as a result of compromised hemodynamics, tachycardia-induced cardiomyopathy, and increased vulnerability to thromboembolism. This gives patients with AF a 5-fold risk of stroke, especially as age increases.[2] Methods used in the treatment of AF include pharmacologic therapy, cardioversion, transvenous ablation, and surgery.

Abbreviations and Acronyms
AF = atrial fibrillation
CPB = cardiopulmonary bypass
IBRF = irrigated bipolar radiofrequency
IVC = inferior vena cava
PV = pulmonary vein
RF = radiofrequency

The Cox maze procedure is the most successful treatment for AF, with a long-term success rate of at least 90% and virtual elimination of late stroke.[3-5] The procedure consists of a series of mazelike incisions or ablations on both atria. These are designed to create conduction block and prevent the macroreentrant circuits throughout the atria considered to be responsible for AF.[5,6] After the first two iterations of the Cox maze procedure, the Cox maze III was first performed in 1988 and became the criterion standard for the surgical treatment of AF for more than a decade.[3,7]

Recently, modifications of the Cox maze procedure have been made that use various energy sources to create linear lines of ablation that replace the cut-and-sew lesions of the traditional procedure.[8-10] These new technologies hold the promise of a less technically difficult way to perform the atrial lesions. The long-term efficacy of the various modifications to the Cox maze procedure are as yet unproven; however, simplification of the Cox maze III procedure by allowing its completion on a beating heart without the use of cardiopulmonary bypass (CPB), while preserving its efficacy and safety, may lead to wider application of this operation.

In this study, a modification of the Cox maze lesion set was created on the beating heart with an irrigated bipolar radiofrequency (IBRF) device. IBRF has been shown to effectively produce transmural lesions ex vivo.[11] This device relies on saline solution as a conductor as alternating current is delivered between two approximated electrodes embedded into the jaws of a clamp. This allows focused delivery of energy that minimizes lesion width and reduces the risk of collateral damage to vital structures. An advantage of this technology is that by measuring real-time tissue impedance between the two electrodes it provides an indication of lesion transmurality. Dry bipolar radiofrequency (RF) energy has been shown in previous work to create discrete, transmural atrial lesions within 10 seconds.[12,13]

The purpose of this long-term animal study was to examine the feasibility and safety of using IBRF to perform left and right atrial ablations on the beating heart and to examine the effect of this energy on the atrial tissue, coronary arteries, and pulmonary veins (PVs) at 1 month.

Materials and Methods

Experimental Protocol

Six adult domestic pigs weighing 40 to 50 kg were used in this study. All animals received humane care in compliance with the "Guide for the Care and Use of Laboratory Animals" (http://www.nap.edu/catalog/5140.html).

Each animal underwent right and left atrial lesions on the beating heart. The animals were premedicated, intubated, and anesthetized with 2% to 4% isoflurane and monitored continuously during the procedure. The heart was exposed through a median sternotomy. The left and right PVs and the inferior vena cava (IVC) were isolated with umbilical tapes. The heart was paced from the right atrial appendage, the right atrial body, and the left and right PVs to establish pacing thresholds. The animals were given intravenous heparin (350 U/kg) to maintain an activated clotting time longer than 250 seconds. Intravenous bretylium tosylate (INN bretylium tosilate) was administered to prevent arrhythmias with manipulation of the heart.

An IBRF surgical ablation device, Cardioblate BP Surgical Ablation System (Medtronic Inc, Minneapolis, Minn) was used to create the lesion set. The device consists of a hand piece, embedded bipolar electrodes in a clamp, and RF generator. RF energy was delivered to the two electrodes located in the opposing jaws of the clamp, which were mounted on an articulating head. The head could be angulated through 90° and could also be rotated through 300° at its articulating surface. Additionally, the jaws of the clamp were malleable, providing another degree of flexibility to the device that allowed the device to be shaped to match the target tissue. During RF ablation the contact tissue surface was constantly irrigated with saline solution, which acted as a conductor for the delivered energy. The generator delivered RF energy while an online system in real time monitored tissue impedance, current, voltage delivered, and duration of ablation. The devices used in this study operated on the principle that tissue is fully ablated when impedance reaches a stable plateau. Initially, moderate power was applied to the tissue. Impedance was measured continuously, and the derivative of impedance was calculated every 200 ms. When impedance achieved a stable plateau, the algorithm logic determined that maximum ablation at this power level was complete. The power was then increased by a step function of 5 W. If the plateau in impedance was not sustained, then the algorithm determined that transmurality had not been achieved, and ablation continued until another plateau in impedance was detected. This process was repeated until an impedance plateau was sustained after an increase in power. At this point, the microprocessor determined that transmurality had been achieved, and the generator provided a signal to the user.

Surgical Procedure

The modified Cox maze procedure included nearly all the right and left atrial lesions of the traditional procedure (Figure 1). All lesions were performed with the IBRF device. In performing this procedure without CPB, it was necessary to make the following modifications of the classic Cox maze III procedure: (1) the right and left PVs were isolated separately, rather than as one large island; (2) a connecting lesion was performed between the right and left PVs; (3) the transseptal incision, which functions principally to aid