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Epicardially Based Pulmonary Vein Isolation for the Treatment of Atrial Fibrillation Utilizing Laser Energy in the Pig Model

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Abstract

Purpose - Atrial fibrillation is a common disease that increases the incidence of cerebrovascular embolic events and cardiac dysfunction. Foci for atrial fibrillation have been mapped and found to be for the most part located within the ostia of the pulmonary veins. Since 2002 microwave and radiofrequency energy sources have been used to create pulmonary vein isolation lesions. This abstract summarizes the safety and efficacy of performing vein isolation lesions with laser as the energy source.
Description - The large pig model was utilized for creation of isolation lesions around the pulmonary veins. The Optimaze E360 Surgical Ablation Handpiece from Edwards Lifesciences was utilized, it contains a 4 centimeter diffusing diode laser (980nm). All six of the pig models tolerated the procedure with a 40-day normal post procedure growth pattern.
Evaluation - Upon reoperation one pig developed ventricular fibrillation with resection of adhesions. All five remaining pigs were fully tested and demonstrated complete electrical isolation. Gross pathology revealed intact well defined ablation lesions with an otherwise completely normal cardiac structure. All lesions were fully transmural at each histological sectioned point.
Conclusions - Laser technology in the form of the Optimaze E360 Surgical Ablation Handpiece from Edwards Lifesciences, is able to reliably and consistently produce well defined electrical isolation scars around the pulmonary veins. This device is also amenable to performing the isolation procedure using a minimally invasive approach.

Key Words: atrial fibrillation, pulmonary vein, laser

Introduction

Atrial fibrillation is a disease that affects over 5 million people worldwide. [1] People with atrial fibrillation have greatly higher risks of cerebrovascular embolic events and long-term cardiacdysfunction. [2] Methods to treat atrial fibrillation have been attempted since 1989, but because of the invasiveness of the various procedures the availability to patients have been small in numbers. [3] The significant focus for atrial fibrillation has been mapped out since 1994, and been found to be centered within the ostia of the pulmonary veins.[4] Therefore attention has been focused more recently on performing simplified isolation patterns around the pulmonary vein ostia. [5]

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Since 2002, epicardial attempts to create a pulmonary vein isolation lesions have utilized both microwave and radiofrequency energy sources. [6,7] The success rates of these therapies have been fairly good, but some variances among the different groups have lead to continued research into energy sources with greater predictability of penetration and therefore greater safety and hopefully less variability on long-term success rates. Laser therapy has been identified as a potentially more incisive penetrating energy source relatively unaffected by intervening fat and fluid interfaces.

This abstract summarizes a safety and efficacy study looking at performing epicardially based lesions to completely electrically isolate the pulmonary veins from the rest of the heart using laser energy. Laser energy seems to be potentially the ideal energy source to lead into a minimally invasive surgical method for pulmonary vein isolation, which would then make this procedure available for the vast majority of patients afflicted by atrial fibrillation worldwide.

Materials and Methods

The large pig model was utilized for creation of these isolating lesions of the pulmonary veins. Midline sternotomies were performed in 6 large pigs (94 kg – 105 kg). Pericardium was carefully incised and careful dissection was performed to dissect free the superior vena cava inferiorly from the right superior pulmonary vein. Careful dissection was also made to free the inferior vena cava from the pericardial surface and superiorly from the right inferior pulmonary vein. Careful dissection of the hemiazygos vein was performed on all six pigs with actual transection of the hemiazygos vein in the first pig and then later dissection of the hemiazygos from the left atrial surface in the latter five pigs.

The Optimaze E360 Surgical Ablation Handpiece from Edwards Lifesciences was utilized, which is a 4 centimeter diffusing diode laser (980 nm). The diffusing tip of the laser contains scattering particles in a silicone matrix that directs the energy radially and perpendicular to the fiber direction. The 4-centimeter laser is contained within a 25-centimeter sheath, which can be placed in one dissection around the pulmonary veins and then allows for mere advancement of the laser within the sheath itself. The laser generates 12 watts of power output per centimeter with the E360 Hand piece. Laser energy heats the water molecules to 50 degrees Celsius causing permanent cell death in these areas and fibrotic scarring, thereby causing an electrically impenetrable lesion. Ninety second energy bursts were performed at each 4-centimeter interval as the laser tip was advanced within the Optimaze sheath after the sheath had been placed Circumferentially around the pulmonary veins along the base of the left atrium. Careful inspection of the laser sheath was made to ensure placement superior to the coronary sinus, lateral to the left atrial appendage, and under the hemiazygos vein.

Upon completion of a circumferential isolating lesion around the pulmonary veins, confirmation of immediate electrical isolation of the pulmonary veins was performed with pacing being attempted from the right and left superior pulmonary veins. Hemostasis was affirmed and sternotomy closure was performed with stainless steel wires, 2-0 Vicryl, and 3-0 Vicryl sutures. A 24 french silicone chest tube was inserted laterally into each pericardial space. Average surgical time was 1.7 hours.

All 6 pigs were explored via bilateral thoracotomies at 40 days post ablation. Gross examination of the heart and left atrial contractility was performed and then sensing/recording electrodes were placed at the right atrial appendage, left ventricular anterior surface, and left atrial appendage. Pacing electrodes were placed on the surfaces of the right and left superior pulmonary veins. Pacing electrodes were then placed on the left atrialappendage to investigate the electrical competence of the left atrium. All pigs were then sacrificed with removal of the hearts and preservation in Prefer fixative. Pathologic gross examinations were performed of the hearts in general, and also specific histological examination of the ablation lesions in 6 different areas as well as examination for any potential abnormalities was performed.

Results

All six animals tolerated the ablation surgery well with appropriate weight gain post procedure over the ensuing 40 days in normal growth patterns. Careful gross examination was performed and there were no intra-operative complications noted during the ablation surgery such as coronary ar-

Table 1 Pathological Findings

CS = Across or overlying the coronary sinus (posterior and inferior to the left pulmonary veins)

L = Lateral to the left pulmonary veins

P = Posterior left atrium (approx. midway between the left and right pulm. veins)

A = Anterior/superior left atrium (approx. midway between the left and right pulm. veins).

The specific findings for each of the pig hearts are presented below. Data include location and number of sections or slides examined, and the maximum dimensions of lesions identified in any (but not necessarily all) of the sections examined for that location. Lesions were measured along the endocardial surface, maximal width within the atrial myocardial wall, and thickness of transmural lesion extending from endocardium to epicardial connective tissue.

PIG # 391

Site	# of sections	endocardial	myocardial	thickness
CS:	2	14 mm	16 mm	5 mm
L:	3	6 mm	9 mm	5 mm
P:	1	10 mm	13 mm	6 mm
A:	1	2 mm	8 mm	5 mm

NOTES: There was a 3-4 mm slightly dark spot on a mitral valve leaflet. Sections showed a few superficial telangiectatic vessels and a nearby small lymphoid aggregate, but no evidence of fibrosisor necrosis.

PIG # 404

Site	# of sections	endocardial	myocardial	thickness
CS:	4	6 mm	>16 mm	5 mm
L:	2	2 mm	>8 mm	5 mm
P:	4	4 mm	7 mm	6 mm
A:	2	7 mm	7 mm	3 mm

NOTES: There was a 5 mm dark thrombus identified within a vessel, close to but distinct from the coronary sinus. Sections show a vessel in the epicardial region with very recent clot (intact RBC membranes and no organization) within the lumen and some surrounding Masson's lesion (papillary angioendotheliomatosis / organizing clot) in the surrounding connective tissue. Coronay sinus showed no thrombosis.

PIG # 405

Site	# of sections	endocardial	myocardial	thickness
CS:	3	7 mm	15 mm	5 mm
L:	2	3 mm	5 mm	4 mm
P:	1	4 mm	5 mm	6 mm
A:	2	3 mm	7 mm	3 mm

PIG # 406

Site	# of sections	endocardial	myocardial	thickness
CS:	2	8 mm	9 mm	5 mm
L:	2	>2 mm	5 mm	3 mm
P:	7	5 mm	6 mm	4 mm
A:	2	>3 mm	>4 mm	5 mm

PIG # 407

Site	# of sections	endocardial	myocardial	thickness
CS:	2	5 mm	6 mm	4 mm
L:	1	5 mm	5 mm	4 mm
P:	3	3 mm	5 mm	5 mm
A:	2	4 mm	6 mm	4 mm

PIG # 409				
Site	# of sections	endocardial	myocardial	thickness
CS:	2	8 mm	>12 mm	7 mm
L:	1	7 mm	7 mm	>6 mm
P:	4	3 mm	5 mm	4 mm
A:	3	3 mm	7 mm	3 mm

tery injury, pulmonary vein injury, coronary sinus injury, or left atrial perforation. Pulmonary vein isolation was confirmed in all six pigs utilizing the aforementioned methods of pacing from the right and left superior pulmonary veins and sensing from the skin place EKG electrodes.

Upon performing the redo surgery, one pig developed ventricular fibrillation with the resection of adhesions and could not be recovered. This expiration was directly related to the redo dissection and had no relationship to the ablation surgery itself. However, this pig could not then be tested for continued electrical isolation but did have the additional pathological examinations. All five remaining pigs were fully tested and demonstrated complete electrical isolation. Competent left atrial electrical conduction was demonstrated in all five pigs and good left atrial function was grossly identified in all six pigs. No gross evidence of cardiac injury was noted upon this exploration in all six pigs.

Gross pathology revealed all six heart specimens to be completely intact with no evidence of thrombus in any of the heart cavities, coronary sinus, coronary arteries, or pulmonary veins. The immediate gross examination revealed intact well defined ablation lesions with an otherwise completely normal cardiac structure. All chronic lesions had undergone a fibrotic change with occasional inflammatory residual changes at the borders of the fibrotic field. All lesions were fully transmural at each histologic sectioned point. Average depth of lesion for transmurality was 4 mm (range 3 mm – 7 mm) and average width of lesion was 7 mm (range 4 mm – 16 mm) (See table 1). The lesions were all well defined between scar zone and normal myocardial tissue. There was neither evidence of necrosis of endocardial tissue nor any evidence of thrombus material associated with any of the scar lesions. All lesions were close in proximity to the coronary sinus but the coronary sinus structure was noted to be patent without thrombus in all specimens. One pigs' mitral valve had a pigmented spot on the posterior leaflet which was separately sectioned and inspected to assure that this was just a pigmented spot and not an inadvertent injury to the valvular structure; all other valves were completely normal in the other 5 pigs.

Comment

Laser technology in the form of the E360 hand piece is able to reliably and consistently produce a well-defined electrical isolation scar around the pulmonary veins with minimal dissection with complete isolation block and complete safety. This technology should be able to successfully and safely treat all atrial fibrillation patients whose primary focus originates in the pulmonary veins. The most exciting aspect of this epicardial therapy with the E360 hand piece is its' amenability to minimally invasive approaches to place the probe and there by perform the ablation surgery in solitary atrial fibrillation patients without an actual sternotomy.

Disclosure and Freedom of Investigation

The above protocol complied with the 1996 "Guide for the Care and Use of Laboratory Animals and was performed at the Edwards Lifesciences Biological Resource Center. One Edwards Way, M/S#PRT44 Irvine, CA 92614. For additional information contact: Jane M. Olin, DVM, Diplomat ACLAM 949-250- 3508. All funding and testing equipment was provided by Edwards Lifesciences at no cost to the authors. All authors had full control of the design of the study, methods used, outcome parameters, analysis of data and production of the written report.

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