

Epicardial High-intensity Focused Ultrasound Cardiac Ablation for Surgical Treatment of Atrial Fibrillation

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Background: The available alternatives to an effective but technically complex Cox maze procedure for surgical treatment of atrial fibrillation include ablation using radiofrequency, microwave, laser, cryotherapy or ultrasound energy sources. The purpose of this study was to evaluate the safety and efficacy profile of high-intensity focused ultrasound cardiac ablation for the surgical treatment of atrial fibrillation.

Methods: 14 patients underwent epicardial high-intensity focused ultrasound treatment for atrial fibrillation using the Epicor cardiac ablation system between August 2006 and August 2007. The procedure was performed on the beating heart prior to the commencement of cardiopulmonary bypass for concomitant cardiac procedures. Physical examination, electrocardiography and 24-h Holter monitoring were used to determine the postoperative heart rhythm.

Results: There were no deaths directly related to the procedure. One patient with myelodysplastic syndrome died of septic complications. Three patients required cardioversion at 1 day, 3- and 4-month intervals postoperatively. The mean follow-up period was 9 months. Currently 10/13 (77%) patients are in sinus rhythm, one patient required insertion of a permanent pacemaker, one patient is in atrial fibrillation and another patient is in atrial flutter.

Conclusion: Epicardial high-intensity focused ultrasound ablation is a viable alternative to the Cox maze procedure for the surgical treatment of atrial fibrillation. It is a safe and efficient procedure that does not require cardiopulmonary bypass and may potentially be performed using less invasive surgical techniques.

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Introduction

The increased risk of complications and death associated with atrial fibrillation (AF) are well established. The incidence of AF is 1.7% at the age of 60–64 and 11.6% over the age of 75 [1]. It is a major contributor to later in life morbidity and mortality. AF is a leading cause of stroke in the elderly population [2]. Risk adjusted mortality associated with this arrhythmia is 1.5–2 times higher than in the general population [3].

The Cox maze III procedure is considered to be the benchmark procedure for the surgical treatment of AF. The effectiveness of this operation has been shown to be 80–95% at 6 months and maintained at a longer-term follow up [4,5]. However, it requires cardiopulmonary bypass, is technically complex and may lead to the

loss of atrial transport function and a requirement for permanent pacing. Because of these concerns, the Cox maze procedure is not widely used. Radiofrequency, cryotherapy, microwave and laser ablation of atrial tissue have been used to overcome problems with the Cox maze cut-and-sew technique. They have all shown varying degrees of safety and effectiveness.

A source of energy which can be applied epicardially on a beating heart and having advantages over other energy modalities is required. High-intensity focused ultrasound (HIFU) is an alternative method of surgical treatment of AF that incorporates these characteristics. The purpose of our study was to evaluate safety and effectiveness of HIFU as an energy source in the ablative therapy for AF.

Patients and Methods

At a single centre, 14 consecutive patients underwent epicardial ablation for AF with HIFU (Table 1). Operations were performed by four cardiothoracic surgeons between

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Table 1. Patient Characteristics (n = 14).

Variable	Mean	Range	n (%)
Age	70	50–84	14
Male:female			12:2
Duration of AF	44 months	3 months to 14 years	14
Permanent AF			10 (71%)
Paroxysmal AF			4 (29%)

August 2006 and August 2007. It was total unit's experience with this technology within that period of time. There were 12 male and 2 female patients in this group with a mean age of 70 years (range: 50–84 years). The mean duration of AF was 44 months (range: 3 months to 14 years). Ten patients (71%) had permanent and 4 (29%) had paroxysmal AF. All patients had concomitant cardiac procedures (Table 2). Seven had coronary artery bypass surgery, 3 had aortic valve replacement, 2 had mitral valve repair and 2 had combined valve (1 mitral and 1 aortic) and coronary artery bypass surgery. The proportion of coronary artery and aortic disease was higher in this cohort of patients than mitral pathology (21% of the entire group). However, it was a natural representation of patients with AF within that period of time rather than selection bias. All patients preoperatively underwent trans-thoracic echocardiography that showed various degrees of atrial enlargement.

Previous heart surgery, endocarditis, severe heart failure (NYHA class IV), emergency surgery were the exclusion criteria as well as patients unwilling to participate in trial of a new technology. All other consequently operated patients with pre-existing AF within the mentioned period of time were included.

High-intensity focused ultrasound was delivered by the Epicor Cardiac Ablation System (St Jude Medical, St. Paul, MN, USA). The system consists of four main components: (1) the Ablation Control System (ACS) which provides fully automated ultrasound energy to the transducers and continuously monitors frequency, temperature and energy levels, (2) the Positioning and Sizing System (PAS) which is placed around the pulmonary veins and measures the appropriate size for the UltraCinch band, (3) the UltraCinch ablation device which creates a continuous transmural lesion around the orifices of pulmonary veins, and (4) the UltraWand which provides additional linear ablation lesions.

HIFU is an acoustic energy which causes oscillation of cells in the atrial wall with generation of frictional heat of up to 60 °C. This temperature produces denaturation of proteins thus creating an ablative lesion. HIFU energy travels up to a distance of 10 mm through the all layers of the left atrial wall. It is delivered in three sequential

Table 2. Concomitant Cardiac Procedure (Total n = 14).

Procedure	n	%
Coronary artery surgery	7	50
Aortic valve replacement	3	21
Mitral valve repair	2	14
Mitral valve repair + coronary artery surgery	1	7
Aortic valve replacement + coronary artery surgery	1	7

phases from epicardium to endocardium. During the first phase the energy provides ablation of the subendocardial tissue. The second phase ablates myocardial tissue, and epicardium is ablated during the final phase. This process of pulmonary vein isolation is usually completed within 10 min using the UltraCinch device. An additional "mitral line" lesion between left inferior pulmonary vein and the mitral valve annulus is created by the UltraWand within 1 min. All phases of the ablation procedure were performed on the beating heart without the use of cardiopulmonary bypass.

Median sternotomy access was utilised for all patients in our study. However, minimally invasive surgical access in a form of lower mini-sternotomy or right antero-lateral thoracotomy may be used. The surgical procedure involved four steps. Initially, the pericardial reflection was dissected between the superior vena cava and right superior pulmonary vein providing an access to the transverse sinus. Then pericardium was then dissected around inferior vena cava providing access to the oblique sinus. An introducer-sizer was passed behind the superior vena cava into the transverse and subsequently into the oblique sinus. The introducer was brought behind the inferior vena cava to completely encircle the pulmonary veins. The circumference around the ostia of the pulmonary veins was measured and an appropriately sized UltraCinch band was selected. After priming with Normal saline, the UltraCinch band replaced the sizer and pulmonary vein isolation commenced. During the ablation process the surgeon continues preparation for cannulation for cardiopulmonary bypass used for the concomitant cardiac surgical procedure. Finally, an additional "mitral line" lesion was produced using UltraWand handheld ablation device.

Postoperatively, the patients' cardiac rhythm was assessed by clinical examination and with serial 12-lead electrocardiography. After discharge patients were reviewed in the outpatient clinic or private rooms. The assessment was completed with 24-h Holter monitoring.

All patients received Amiodarone therapy for 3 months as per protocol adopted by the unit. After this period of time, Amiodarone was stopped in those patients in sinus rhythm. Anticoagulation therapy with Warfarin was also discontinued in patients with sinus rhythm at that time.

Results

There were no deaths or complications attributable to the HIFU ablation observed in our study. One patient with neutropaenia and thrombocytopenia due to myelodysplastic syndrome died of sepsis of unknown origin on the sixth postoperative day. For the rest of the patients the mean hospital stay was 8 days (range: 5–14 days). Of the 13 patients, 8 patients (62%) were in sinus rhythm at the time of discharge from hospital. One patient developed AF with signs of haemodynamic instability and required cardioversion during his stay in Intensive Care Unit. Later this patient developed periods of sinus bradyarrhythmia alternating with paroxysms of rapid AF and required insertion of a permanent pacemaker.

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