

Video-assisted bilateral pulmonary vein isolation and left atrial appendage exclusion for atrial fibrillation

Randall K. Wolf, MD,^a E. William Schneeberger, MD,^a Robert Osterday, PA,^a Doug Miller, MD,^a Walter Merrill, MD,^a John B. Flege, Jr, MD,^a and A. Marc Gillinov, MD^b



Schneeberger, Flege, Wolf, Merrill, Osterday, Miller (left to right)

Objective: Pulmonary vein isolation is curative in selected patients with atrial fibrillation. The objective of this study was to assess the feasibility and safety (midterm results) of video-assisted thoracoscopic epicardial pulmonary vein isolation.

Methods: Twenty-seven patients (22 male patients) with atrial fibrillation (18 paroxysmal, 4 persistent, and 5 permanent; average age, 57 years) underwent bilateral video-assisted thoracoscopic off-pump epicardial pulmonary vein isolation and exclusion of the left atrial appendage. All patients had had unsuccessful drug therapy or were intolerant to antiarrhythmic drug therapy or were intolerant to warfarin. The approach included two 10-mm ports and one 5-cm working port (non-rib spreading) bilaterally. Pulmonary vein isolation was achieved bilaterally by using a bipolar radiofrequency device. The left atrial appendage was excised with a surgical stapler.

Results: Bilateral pulmonary vein isolation and left atrial appendage excision was performed successfully in all patients. There were no conversions to sternotomy or thoracotomy. All patients were extubated in the operating room. Postoperative complications in 3 patients were minor and resolved within 48 hours. One morbidly obese patient had more serious complications related to comorbid conditions. Average postoperative follow-up is approximately 6 months (173.6 days). Twenty-three patients have been followed up for greater than 3 months, and 21 of these patients are free of atrial fibrillation (91.3%). The results of magnetic resonance angiography were normal (no pulmonary vein stenosis) in 12 of 12 patients evaluated 3 to 6 months postoperatively.

Conclusions: Bilateral video-assisted thoracoscopic pulmonary vein isolation with excision of the left atrial appendage is feasible and safe and offers a promising, new, minimally invasive, beating-heart approach for curative surgical treatment of atrial fibrillation.

Atrial fibrillation (AF) affects more than 2 million patients in the United States.¹ AF is associated with increased mortality, increased risk of stroke, and exacerbation of heart failure.²⁻⁴ Antiarrhythmic medications have limited efficacy in maintaining sinus rhythm and might have serious adverse effects.⁵⁻⁷ The Cox maze III open surgical ablation has a success rate of more than 95%,

From the Section of Cardiothoracic Surgery at The University of Cincinnati College of Medicine,^a Cincinnati, Ohio, and the Department of Thoracic and Cardiovascular Surgery at The Cleveland Clinic Foundation,^b Cleveland, Ohio.

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Address for reprints: Randall K. Wolf, MD, The University of Cincinnati College of Medicine, Medical Sciences Building, 231 Albert B. Sabin Way, PO Box 670558, Cincinnati, OH 45267 (E-mail: wolfr@ucmail.uc.edu).

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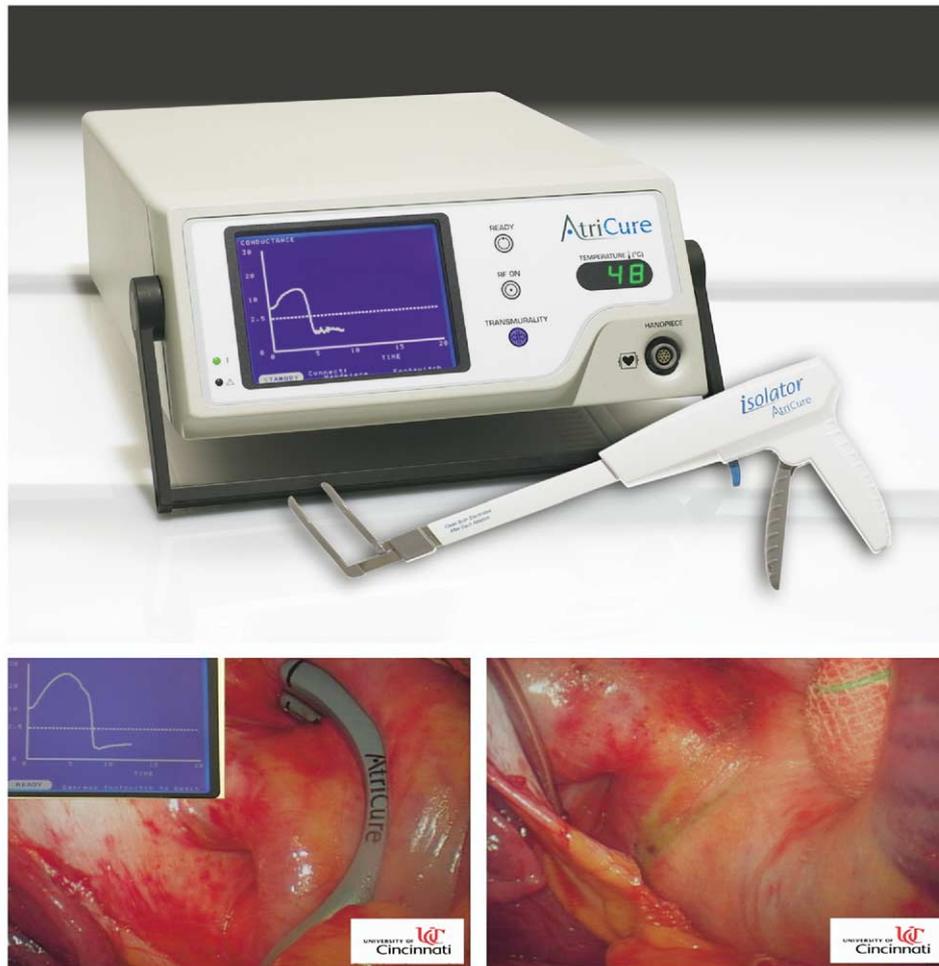


Figure 1. *Top*, Dry bipolar RF clamp and RF generator system (Atracure, Inc). *Bottom left*, Right thoracoscopic view of the dry bipolar clamp in place on the left atrial antrum, medial to the right pulmonary veins. *Inset*, Objective digital graph display of conductance of the tissue clamped between the devices. *Bottom right*, Visible ablation lines on the epicardial surface after 8-second applications.

although it has not been widely adopted because of the need to perform extensive incisions and suturing of the atria, resulting in lengthy procedure and crossclamp times.⁸ Alternative approaches with bipolar radiofrequency (RF) ablation to create transmural linear lesions have proved to be effective and substantially decrease procedure and cardiopulmonary bypass times.⁹ Catheter-based ablation, which attempts to eliminate or isolate pulmonary vein foci, has had limited success, has a high incidence of recurrence, and is associated with serious complications.¹⁰⁻¹⁵

A new, minimally invasive, video-assisted thoracoscopic surgical (VATS) technique enables surgical treatment of AF through an epicardial approach on a beating heart. The procedure uses a bipolar RF ablation device, which can reliably create bilateral, transmural, linear lesions around

the atrial cuff of the right and left pulmonary veins. This effectively achieves electrical isolation of the pulmonary veins without the need for cardiopulmonary bypass. Additionally, excision of the left atrial appendage (LAA), the major source of thromboemboli associated with AF, is incorporated into this minimally invasive procedure.¹⁶

Methods

Patient Selection

Patients with symptomatic AF between 18 and 80 years of age were selected on the basis of the following inclusion criteria: drug-refractory AF; inability to tolerate antiarrhythmic drugs or anticoagulation therapy; left ventricular ejection fraction of 30% or greater; able to provide written informed consent; life expectancy of at least 2 years; and able to attend scheduled follow-up visits. All patients consented



Figure 2. Lighted articulating dissector used to bluntly surround the pulmonary veins (Wolf dissector).

to minimally invasive or open surgical treatment of their AF. The study protocol was approved by the Institutional Review Board of the University of Cincinnati College of Medicine.

Procedural Technique

A unique VATS procedure was developed to electrically isolate the pulmonary veins bilaterally. A bipolar RF clamp and RF generator system (Isolator, Atricure Inc) is used to achieve linear, transmural ablation lesions (Figure 1, A). RF energy is delivered between 2 gold-plated electrodes (1 mm wide \times 5 cm long) embedded in the jaws of the clamp. The temperature of the tissue 1.5 mm from the electrode (within the clamped section) is displayed on the generator. A digital graph, located on the front panel of the generator, displays the conductance of the tissue clamped between the device jaws (Figure 1, B). When the conductance of the tissue decreases to less than 0.0025 siemens, typically after 8 seconds, an audible signal is automatically generated to indicate that the lesion is transmural. Ablation lines are visible on the epicardial surface (Figure 1, C).

The procedure is conducted after achievement of general anesthesia administered with a double-lumen endotracheal tube. Transesophageal echocardiography is performed in the operating room to verify the absence of a left atrial thrombus before the start of the procedure and adequacy of LAA excision at the end of the procedure.

The right pulmonary veins are accessed first. The patient is positioned with the left side down and the right arm abducted above the head. The right lung is deflated, and a 10-mm trocar is introduced in the sixth intercostal space in the anterior axillary line. A 10-mm 30° thoracoscope is introduced through this port. Insufflation is delivered at approximately 8 mm Hg to assist in resorptive atelectasis. A 6-cm access port in the third intercostal space just anterior to the anterior axillary line provides direct visualization. The pleural space is entered, and a soft tissue retractor (CardioVations, Ethicon, Inc, Somerville, NJ) is placed without spreading the ribs.

Blunt dissection of the right pulmonary veins is accomplished under thoracoscopic guidance through the access port and lower port site. First, the pericardium is incised from the superior vena

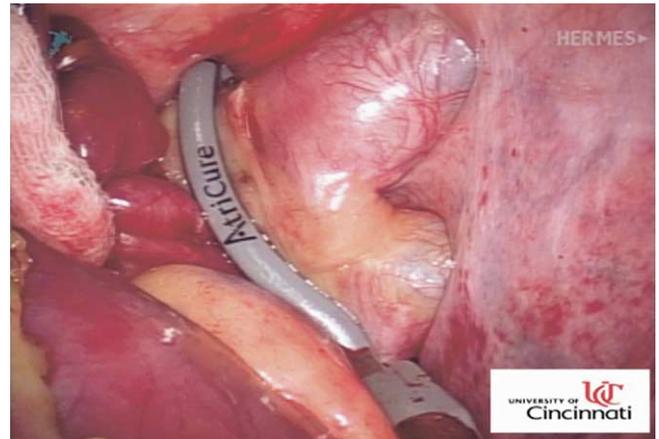


Figure 3. Left thoracoscopic view of the dry bipolar clamp in place on the left atrial antrum, medial to the left pulmonary veins.

cava to the inferior vena cava 3 cm anterior and parallel to the phrenic nerve. Stay sutures in the posterior pericardial edge are brought through the skin and anchored. Blunt dissection is used to enter the oblique sinus behind the heart. An articulated lighted dissector (AtriCure, Inc, Cincinnati, Ohio; Figure 2) is then introduced into the chest through a port and passed into the oblique sinus beneath the right inferior pulmonary veins. While the superior vena cava is distracted medially, dissection around the pulmonary veins is completed with the lighted dissector.

The dissector is exchanged for an 18F red rubber catheter to secure the path beneath the right pulmonary veins. The bipolar clamp, with its lower jaw placed in the end of the red rubber catheter, is introduced through the port incision. The red rubber catheter is then used to guide the lower jaw of the clamp behind the left atrial cuff adjacent to the right pulmonary veins as the upper jaw passes in front of the veins. The red rubber catheter is then removed. Correct positioning of the clamp on the atrium and not on the pulmonary vein is verified by means of direct inspection of the device after closing the jaws of the clamp (Figure 1, B). Once the position of the jaws has been confirmed, bipolar RF energy is applied to electrically isolate the pulmonary veins; 2 or more overlapping lesions are created to ensure isolation. A 20F chest tube or Blake silicone drain (Ethicon) is placed, the right lung is reinflated, and the port sites are closed.

No heparin is used during the procedure because the clamp is only in place for a maximum of 20 seconds. In addition, in multiple laboratory studies in animals, no char or thrombus has been observed on the endocardial surface of the ablation line.

The patient is repositioned with the right side down and the left arm above the head. The technique is repeated on the left side with the addition of division of the ligament of Marshall. As on the right side, a red rubber catheter is placed beneath the left pulmonary veins and is used to guide the bipolar clamp into place to ablate the left atrial cuff adjacent to the left pulmonary veins (Figure 3).

The LAA is then excised by stapling it with an EZ 45 stapler (Ethicon Endosurgery), which is introduced through one of the inferior port sites. The LAA exclusion is verified on transesopha-

TABLE 1. Patient characteristics

Characteristic	Results
Age (y)	57.2 ± 14.9 (range, 23-79)
Sex	81.5% male (22/27)
Prior cardiac surgery	3.7% (1/27)
CAD	3.7% (1/27)
Mitral valve disease	3.7% (1/27)
Congestive heart failure	14.8% (4/27)
Cardiomyopathy	7.4% (2/27)
Prior stroke-TIA	14.8% (4/27)
Previous MI	3.7% (1/27)
Prior catheter ablations	7.4% (2/27)
Preoperative pacemaker	7.4% (2/27)
Preoperative cardioversion	55.6% (15/27)
Preoperative AADs	
None	22.2% (6/27)
1	74.1% (20/27)
2	3.7% (1/27)

CAD, Coronary artery disease; TIA, transient ischemic attack; MI, myocardial infarction; AADs, antiarrhythmic drugs.

geal echocardiography. The pericardium is closed on the left side. If the patients are not in sinus rhythm by the end of the procedure, they are positioned supine and given a synchronized direct-current shock to establish sinus rhythm. Extubation is routinely performed in the operating room.

Data Analysis

Data were tabulated with an electronic database system (Kika, Inc, Boston, Mass), and standard descriptive statistics were applied.

Results

From August 19, 2003, to August 13, 2004, the VATS procedure described above has been performed in 29 patients with primary AF. Data on 27 of 29 patients treated are presented in this report. One patient could not be reached for enrollment, and the other patient was not entered because of an ongoing drug addiction. Complete follow-up (100%) was obtained on the remaining 27 patients from office visits, medical records, telephone calls to the patients, and records from cardiology visits.

Patient age ranged from 23 to 79 years (mean, 57.2 years), and the mean follow-up time for the 27-patient cohort presented herein is currently (as of October 20, 2004) 173.6 ± 88.2 days (range, 67-421 days). Patient characteristics and underlying diseases are detailed in Table 1. Atrial size was not specifically documented but was less than 6 cm in all but 1 patient (who weighed 410 pounds). Preoperatively, 18 patients had paroxysmal AF, 4 patients had persistent AF, and 5 patients had permanent AF. The duration of preoperative AF ranged from 1 to 34 years (average, 7.5 years). Twenty-five patients were unresponsive to or did not tolerate antiarrhythmic drugs (AADs). The remaining 2

TABLE 2. Patient outcomes

Outcome	Results
Perioperative mortality	0%
Procedure time (min)*	178.4 ± 55.9 (range, 93-299)
Hospital stay (d)	3.3 ± 1.0 (range, 2-5)
Late mortality	0%
Reintervention	0%
Free of AF at 3 mo	91.3% (21/23)
Off AADs at 3 mo	65.2.9% (15/23)

AF, Atrial fibrillation; AADs, antiarrhythmic drugs. *Data recorded on 13 patients.

patients qualified for the study because they had complications (bleeding) associated with warfarin therapy.

The technique was successfully completed in all patients, with no conversions to sternotomy or thoracotomy. No patients received blood products intraoperatively or during the hospitalization, and all patients were extubated in the operating room. The average procedure time was recorded for 13 patients and ranged from 93 to 299 minutes. The majority of patients were discharged within 3 days. Patient outcomes are summarized in Table 2.

There has been no mortality in this population. No patients required pacemaker insertion. Four patients had complications; 3 were minor and quickly resolved. These included a right pneumothorax (which resolved without treatment), a right forearm phlebitis, and one case of suspected pericarditis that resolved after oral steroid administration.

More significant postoperative complications occurred in a morbidly obese patient (410 lbs) with a 2-year history of persistent AF, hypertension, and angina. The patient's body habitus made the procedure more difficult (approximately doubling the procedure time), but there were no perioperative complications. The patient was readmitted 3 weeks after surgical intervention because of dyspnea and possible AF. He was treated with antiarrhythmic medication and electrical cardioversion. The patient was anemic, with an increased international normalized ratio requiring transfusions with packed red blood cells and fresh frozen plasma. He was discharged home after 9 days in stable condition, although he was readmitted 3.5 months postoperatively with exacerbation of congestive heart failure and atrial flutter. He responded to medical management, including the initiation of amiodarone. He has since undergone an electrophysiologic study with right flutter line and is now in normal sinus rhythm.

Twenty-three of the 27 patients have more than 3 months of postoperative data. Twenty-one (91.3%) of these 23 patients are free of AF, as confirmed on 12-lead electrocardiography (10 patients) or outpatient telemetry monitor (11

patients; CardioNet),* and all are asymptomatic. Two patients had episodes of AF on outpatient telemetry monitoring (5 and 6 months postoperatively). Preoperatively, one of these patients had paroxysmal AF, and the other had permanent AF. The protocol included the use of AADs postoperatively for approximately 3 months. Patients were then to be weaned off AADs as tolerated. Fifteen of the 23 patients evaluated beyond 3 months have been successfully weaned from AADs, and 6 were being weaned off AADs as of their 3-month visit. The remaining 2 patients are continuing on AADs (1 receiving amiodarone and 1 receiving sotalol). The results of magnetic resonance angiography were normal (no pulmonary vein stenosis) in 12 patients evaluated to date at greater than 3 months postoperatively.

Discussion

Optimal therapy for AF has been a challenge. Achieving and maintaining sinus rhythm could result in fewer symptoms, lower stroke risk, eventual discontinuation of anticoagulation (with its attendant bleeding risk), better exercise tolerance, improved quality of life, and lower mortality.¹⁷ An extremely effective and nonpharmacologic approach has been well established: surgical treatment of AF with the maze procedure. Dr James Cox has reported success rates of more than 95% in patients undergoing the Cox maze III procedure.⁸ The complexity and morbidity associated with the relatively prolonged cut-and-sew maze procedure have limited its acceptance in the surgical community. These open-chest techniques requiring cardiopulmonary bypass are considered by many to be too invasive to be used for the majority of patients with lone AF. Efforts to simplify this procedure have used a variety of energy sources to create lesions, including unipolar RF and microwave energy.^{18,19} The endocardial application of these unipolar energy sources (as opposed to bipolar) does not easily enable confirmation of transmural lesions, possibly producing an incomplete and ineffective lesion.²⁰ A lesion that is not confined to the target tissue might result in injury to collateral structures, particularly to the esophagus and pulmonary veins.²¹⁻²³ Gaynor and colleagues⁹ recently reported the use of a bipolar RF ablation system (AtriCure Inc) to create linear transmural lesions during cardiac surgery. The non-irrigated bipolar clamp delivers energy between 2 electrodes embedded in the jaws of the device, essentially eliminating the risk of collateral damage. This technique has a success rate of 91% at 6 months' follow-up.

Efforts to develop a less invasive approach to AF ablation were spurred by the identification of the importance of the pulmonary veins in the pathogenesis of AF.¹⁰ To date,

catheter-based ablation has met with limited and variable success, frequent failures, and occasional serious complications. As with endocardial surgical ablation, catheter-based unipolar RF ablation is associated with potentially fatal formation of fistulas between the left atrium and esophagus.⁴ The use of saline-irrigated or cooled RF catheters, in an effort to achieve deep transmural lesions, has a greater risk of tissue eruption and cardiac perforation.²⁴ Endoscopically assisted techniques with unipolar and microwave ablation devices are also under development.

The minimally invasive VATS approach to ablation of AF we describe is safe and effective at intermediate follow-up. This novel approach uses a bipolar nonirrigated RF clamp to achieve pulmonary vein isolation. When the conductance falls below a threshold value, a transmural lesion is achieved.²⁵ An additional benefit of bipolar ablation is that current density is tightly confined to the tissue region between the electrodes. This limits lateral thermal spread of the lesion, decreasing the possibility of collateral injury that has been reported with unipolar surgical and catheter-based RF ablations.

The minimally invasive surgical approach overcomes the concerns related to the perceived invasive nature of the Cox maze procedure. Our approach avoids the need for a sternotomy or rib-spreading thoracotomy. The epicardial approach enables this procedure to be performed on a beating heart, avoiding the need for cardiopulmonary bypass. This less invasive alternative might be viewed as a viable option for younger patients with paroxysmal AF rather than a procedure of last resort. The age of patients reported in this series reflects this viewpoint.

Many of the limitations present with catheter ablation of AF are addressed by using this approach. This technique reliably and rapidly achieves continuous transmural lesions encircling the pulmonary veins. Along with the previously described technologic advantages of bipolar RF in creating transmural lesions, direct visualization of the pulmonary veins enhances the safety of this procedure. With this controlled application of bipolar RF energy on the atrial cuff, no patients had pulmonary vein stenosis. Catheter ablation has a risk of stroke associated with thrombus that forms when the tissue impedance increases, heating the blood pool. The bipolar nonirrigated device is not associated with this risk because the ablation line is confined within the jaws of the device. This protects both surrounding structures, as well as the blood pool.²⁶ Finally, the ability to exclude the LAA, which is not possible with catheter-based ablation, further decreases the risk of thromboembolic complications in this patient population.

There is concern that pulmonary vein isolation without connecting lesions can lead to decreased efficacy¹¹ and can potentially lead to postablation atrial flutter. Concerns have also been raised regarding the efficacy of pulmonary vein

*The CardioNet system is an ambulatory electrocardiographic monitor that analyzes, stores, and transmits electrocardiographic data. The device is cleared by the US Food and Drug Administration for use in patients with non-life-threatening arrhythmias, such as AF (K012241).

isolation procedures in patients with permanent and persistent AF.²⁷ Our approach results in wide isolation of the pulmonary veins and antrum, resulting in isolation of a large left atrial volume. Although the extent of left atrial ablation required to achieve success in a given patient is uncertain and the overall volume that should be isolated is debated, there is evidence that more extensive ablation of the atrium increases success of the procedure.^{28,29} Atrial tachyarrhythmias (including atrial flutter) after ablation procedures are most commonly caused by incomplete and nontransmural ablation lines.^{30,31} Bipolar ablation reduces these risks by ensuring lesion transmural. Only one patient in this study had atrial flutter. Nine of the 27 patients treated had either persistent or permanent AF, and success was achieved in all these patients. Further follow-up is necessary to determine the long-term cure rate and to elucidate the effect of AF type on success.

This minimally invasive technique is safe, effective, and appears to be an attractive alternative to antiarrhythmic medical therapy, long-term anticoagulation, or catheter-based ablation. We are now performing this procedure on patients with prior cardiac surgery and previous catheter ablations. We have also added intraoperative pacing and sensing to confirm bidirectional block of the ablation lines. In addition, we attempt to identify and map the ganglionic plexi, which are then ablated to decrease autonomic innervation of the heart, which we believe might enhance results. Continuing study evaluating the long-term safety and efficacy of this approach is indicated.

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