

## Bipolar Radiofrequency to Ablate Atrial Fibrillation in Patients Undergoing Mitral Valve Surgery

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### ABSTRACT

**Background:** Atrial fibrillation (AF) affects 30% to 50% of patients undergoing mitral valve surgery. The optimum treatment of AF in these patients is unclear. The purpose of this study was to describe initial clinical experience using a bipolar radiofrequency clamp to facilitate AF ablation in patients undergoing mitral valve surgery.

**Methods:** From November 2001 through March 2003 a bipolar radiofrequency clamp was used to facilitate AF ablation in 108 patients undergoing mitral valve surgery. Preoperative AF was paroxysmal in 25%, persistent in 26%, and permanent in 49% of the patients. All patients underwent bilateral pulmonary vein isolation performed with the bipolar radiofrequency clamp and excision or exclusion of the left atrial appendage. Most patients had connecting lesions between the right and left pulmonary veins and between the left atrial appendage and the left pulmonary veins. Novel statistical methods were used to create a plot of the prevalence of AF versus time after surgery.

**Results:** Mean time required for AF ablation was  $17 \pm 4$  minutes (range, 9-28 minutes). All patients left the operating room with sinus rhythm or with atrial or atrioventricular pacing for an underlying nodal rhythm. Perioperative AF was common, affecting 64% of patients. At discharge, 33% of patients were in AF or atrial flutter. By 3 months postoperatively, the predicted prevalence of AF or atrial flutter was 15%. There were no device-related complications.

**Conclusions:** Bipolar radiofrequency facilitates rapid and safe AF ablation in patients with mitral valve disease. Perioperative AF is common and should be treated aggressively. By 3 months postoperatively, 85% of patients are free of AF or atrial flutter. Continued follow-up is necessary to document late results of this strategy.

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### INTRODUCTION

Atrial fibrillation (AF) affects 30% to 50% of patients undergoing mitral valve surgery [Handa 1999, Cox 2001, Bando 2002]. Optimum treatment of AF in these patients is unclear. Ideally, surgeons would both correct mitral valve dysfunction and ablate AF during the same operative procedure. Until recently, this strategy was uncommon, primarily because the only surgical option for AF ablation was the Cox maze III procedure. This operation is highly effective, eliminating AF in 75% to 95% of patients with coexisting AF and mitral valve disease [Handa 1999, Cox 2001, Bando 2002]. However, because of the relative complexity of the procedure and the additional 60 to 90 minutes of cardiac arrest that it requires, the operation has not been widely used by surgeons [Gillinov 2002a].

Recent advances in technology for surgical AF ablation and improved understanding of the pathogenesis of AF have resulted in a variety of new, simpler operations to ablate AF [Cox 2001, Gillinov 2002a, Kress 2002, Damiano 2003]. Ablation technologies used to create lines of conduction block and replace incisions of the Cox maze III procedure include radiofrequency, microwave, laser, ultrasound, and cryotherapy. Operations using these alternative energy sources usually concentrate on the left atrium and include pulmonary vein isolation, left atrial connecting lesions, and excision or exclusion of the left atrial appendage. Such procedures generally take 15 to 30 minutes. Although lesion sets and ablation technologies vary, these new operations ablate AF in 70% to 90% of patients [Cox 2000a, Sie 2001, Williams 2001, Gillinov 2003]. The speed and technical ease of these new procedures have rekindled interest in AF ablation in patients with coexisting mitral valve disease and AF.

Although similar results have been documented with different ablation modalities, each has distinguishing features. The largest reported clinical series involve the use of radiofrequency energy, which may be unipolar or bipolar, irrigated or dry [Sie 2001, Kottkamp 2002]. The ideal ablation technology should enable rapid creation of transmural atrial lesions without the risk of damage to adjacent structures [Gillinov 2001]. Kottkamp 2002]. Bipolar radiofrequency satisfies these criteria. The purpose of this study was to describe our initial experience with a bipolar radiofrequency clamp (AtriCure, West Chester, OH, USA) for ablation of AF in patients undergoing mitral valve surgery.

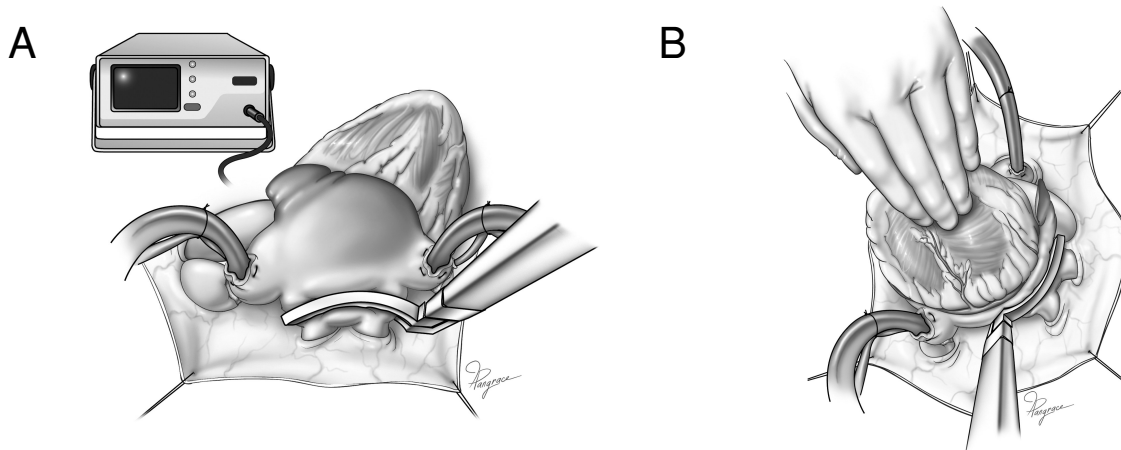


Figure 1. A, AtriCure clamp placed on left atrium adjacent to right pulmonary veins. B, AtriCure clamp applied to left atrium adjacent to left pulmonary veins.

## MATERIALS AND METHODS

### Patients

From November 2001 through March 2003, bipolar radiofrequency was used to facilitate AF ablation in 108 patients with preexisting AF who presented for surgical treatment of mitral valve disease. Mean patient age was  $67 \pm 11$  years (range, 32-86 years); 49% of the patients were male. Fourteen percent of the patients were in New York Heart Association functional class I, 71% in class II, 14% in class III, and 1% in class IV. Mean left ventricular ejection fraction was  $52\% \pm 14\%$  (range, 20%-70%), and mean left atrial diameter was  $5.4 \pm 1$  cm (range, 3.2-8 cm). Twelve (11%) of the patients had a history of previous cardiac surgery.

AF was paroxysmal in 25%, persistent in 26%, and permanent in 49% of the patients. Sixty-five percent of the patients had preoperative AF for more than 6 months. Preoperative treatment of AF included antiarrhythmic medications (90% of the patients), warfarin sodium (Coumadin) (81%), and electrical cardioversion (32%). Six (6%) of the patients had a history of systemic embolism, and 8 (7%) of the patients had preoperative permanent pacemakers.

### Surgical Procedures

This study represented our initial experience with bipolar radiofrequency, and lesion sets and techniques of application varied. The choice of lesion set was at the surgeon's discretion. However, management of the pulmonary veins and left atrial appendage was consistent. In all patients, the pulmonary veins were isolated by application of the bipolar radiofrequency clamp to the left atrial cuff adjacent to each set of pulmonary veins (Figure 1). After dissection, each set of pulmonary veins was isolated with 2 overlapping applications of the bipolar radiofrequency clamp [Gillinov 2002b]. The clamp was first introduced from below, the jaws initially engaging the left atrial cuff adjacent to the inferior pulmonary veins. Then an overlapping radiofrequency lesion was created by rotating the clamp  $180^\circ$  and introducing the clamp from above. This strategy was used to ensure that the entire circumference of the left atrium adjacent to each set of pulmonary veins was treated. Care was taken to ensure that the clamp was applied to left atrial tissue rather than to the pulmonary veins themselves.

Additional lesions were created in most patients. Figure 2 illustrates the most common lesion sets used; these sets were

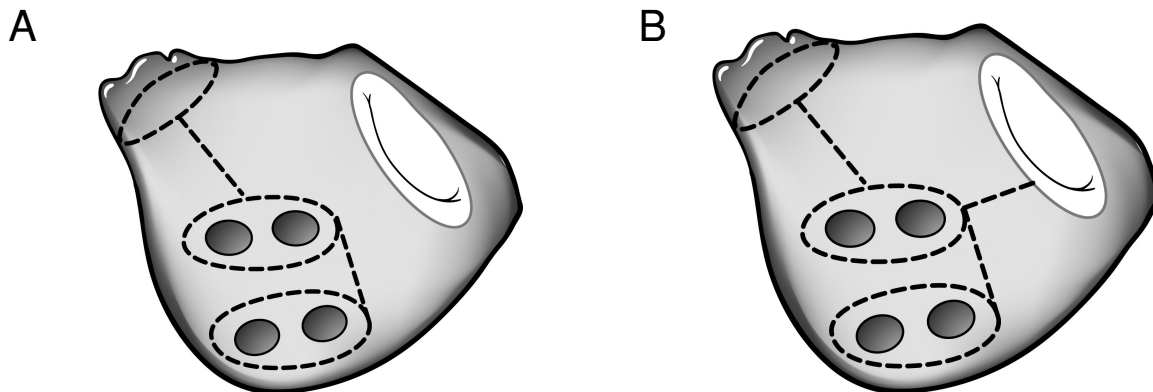


Figure 2. Left atrial lesion sets. A, Each set of pulmonary veins is isolated with the bipolar radiofrequency clamp. Through a left atriotomy, a connecting lesion is created from the right inferior pulmonary vein to the left inferior pulmonary vein. A connecting lesion is created from the stump of the left atrial appendage to the left pulmonary veins. B, In addition to the lesions in Figure 2A, a cryoablation lesion is created from the left pulmonary veins to the mitral annulus.

used in 71% of the patients. In Figure 2A, all lesions are created with the bipolar clamp. The connecting lesion between the inferior pulmonary veins is fashioned by opening the left atrium and placing one jaw of the clamp on the endocardium and one on the epicardium. In Figure 2B, a lesion from the left pulmonary veins to the mitral annulus is added. This lesion is created with 2-minute application of a linear cryoprobe at a temperature of  $-60^{\circ}\text{C}$  (Cooper Surgical, Shelton, CT, USA). Patients receiving the lesion set illustrated in Figure 2B also received a cryolesion on the right atrial isthmus.

Other lesion sets included simple bilateral pulmonary vein isolation in 6% of the patients and a lesion set designed to simulate the Cox maze III procedure in 23%. The latter lesion set, developed by Dr. Ralph Damiano, includes use of bipolar radiofrequency to isolate both sets of pulmonary veins, create a connecting lesion between the pulmonary veins and a lesion from the left atrial appendage to the left pulmonary veins, and create the right atrial lesion set of the Cox maze III procedure. In addition, an incision is carried to the mitral annulus, and cryolesions are created at the annulus and at the coronary sinus.

The left atrial appendage was excluded or excised in all patients. Techniques for treating the left atrial appendage included stapled excision (68% of patients), excision with scissors followed by suture closure (19%), and oversewing of the orifice from inside the left atrium (13%).

In 15 patients, conduction block was assessed after pulmonary vein ablation was performed on a beating, decompressed heart during cardiopulmonary bypass. In each of these cases, a bipolar pacing catheter was positioned on each set of pulmonary veins distal to the ablation line. Inability to pace the heart from this site using a stimulus strength up to 10 mA confirmed the presence of conduction block.

Additional cardiac surgical procedures included mitral valve repair (71% of patients), mitral valve replacement (29%), coronary artery bypass grafting (30%), tricuspid valve repair (30%), and aortic valve replacement (18%). Mean cardiopulmonary bypass and aortic cross-clamp times were  $115 \pm 36$  and  $90 \pm 30$  minutes, respectively.

### Follow-up

All patients (107 of 108) surviving to hospital discharge were contacted for assessment of morbid events and for determination of medication histories. In addition, copies of all electrocardiograms (ECGs) performed both in the hospital and in follow-up were obtained. Mean follow-up for clinical events was  $5.4 \pm 4$  months (range, 1 week–15 months). Seven hundred fourteen ECGs were available for analysis. Mean interval between operation and last available ECG was 3.1 months; 20 (19%) of the patients underwent ECGs more than 6 months after surgery.

### Analysis and Depiction of Data

Data are expressed as mean  $\pm$  SD. Heart rhythm was presented in 2 complementary ways. With a traditional method, the rhythm at last follow-up evaluation was reported; however, this method does not allow presentation of heart rhythm in a time-related fashion. Therefore novel statistical

techniques were developed to enable depiction of the prevalence of AF versus time.

The approach to analysis was an attempt to simultaneously solve multiple challenges—repeated ECG recordings for each patient (repeated measures), variable times of recording, censoring by death, and a nonlinear temporal pattern of prevalence of various postoperative rhythms that likely represented the effects of different modulating factors across time. The approach taken was temporal decomposition with several simple additive components (early hazard, constant hazard, and late hazard) into which separate streams of modulating variables were incorporated for simultaneous analysis. The mathematical models used were derived from those previously used for decomposition of time-to-event data [Blackstone 1986]. A nonlinear mixed model (Proc NL Mixed; SAS, Cary, NC, USA) statistical package was used to simultaneously obtain optimum parameter estimates and to model the error term.

Because ECG follow-up extending beyond 6 months was limited, we did not perform multivariable analyses to attempt to identify factors associated with late AF or surgical failure.

## RESULTS

### Hospital Results

Mean time required to create the 2 most common lesion sets (Figure 2) and to excise or exclude the left atrial appendage was  $17 \pm 4$  minutes (range, 9–28 minutes). Among the 15 patients undergoing testing for conduction block at the pulmonary veins, 14 had conduction block after 2 applications of the bipolar clamp to the left atrial cuff adjacent to each set of veins. In 1 patient, a third application to 1 set of pulmonary veins was necessary to achieve conduction block.

There was 1 hospital death, which was caused by sepsis. Morbidity included stroke in 5 patients and transient ischemic attack in 2 patients. In each case, the neurologic event was judged to be related to the underlying disease (atherosclerosis or calcified valvular heart disease requiring extensive debridement).

### Heart Rhythm

All patients left the operating room in sinus rhythm or junctional rhythm with atrial or atrioventricular pacing. Perioperative AF was common, occurring in 69 (64%) of the patients. When it occurred, perioperative AF was treated aggressively with antiarrhythmic drugs and, if necessary, electrical cardioversion. Forty-one (38%) of the patients had electrical cardioversion in the hospital. All patients experiencing perioperative AF were discharged with an antiarrhythmic medication and warfarin sodium (Coumadin). The planned duration of this therapy was 6 months. New permanent pacemakers were required in 10 (9%) of the patients. Indications for pacemaker insertion included sinus node dysfunction in 8 patients and complete heart block in 2 patients.

At hospital discharge, 32 (30%) of the patients had AF and 3% had atrial flutter. At last ECG follow-up evaluation these values were 19% and 6%, respectively (Table 1). The predicted prevalence of AF or atrial flutter 3 months postoperatively was 15% (Figure 3). At last follow-up evaluation, 61%

Table 1. Heart Rhythms at Discharge and at Last Follow-Up Electrocardiogram

	Discharge, %	Follow-up, %
Sinus rhythm	57	68
Paced (atrial or atrioventricular)	6	6
Atrial fibrillation	30	19
Atrial flutter	3	6
Nodal rhythm	4	2

of the patients were taking antiarrhythmic medications, and 48% were taking warfarin sodium. Fifteen patients had electrical cardioversion after hospital discharge, and 1 had a new permanent pacemaker implanted for sinus node dysfunction. During the follow-up period, there were 4 additional deaths. The causes of death were renal failure in 1 patient and unknown in the other 3.

**DISCUSSION**

We document our initial experience and early results with application of bipolar radiofrequency to facilitate AF ablation in patients undergoing mitral valve surgery. The principle findings of this study were as follows: (1) bipolar radiofrequency ablation was rapid and safe; (2) perioperative AF was common; and (3) 3 months after surgery, 85% of the patients were free of AF. These results supported continued application of bipolar radiofrequency ablation in patients with coexisting mitral valve disease and AF.

AF is the most common sustained arrhythmia, affecting approximately 2.2 million Americans [Sra 2000]. AF is particularly prevalent in the elderly and in those with cardiovascular disease [Sra 2000]. In cardiac surgical practice, AF is most frequently encountered in patients with mitral valve disease. Thirty percent to 50% of patients presenting for mitral valve surgery have preexisting AF [Handa 1999, Cox 2001, Bando 2002]. The rationale for restoring sinus rhythm in these patients includes (1) reducing the risks of stroke and other systemic forms of embolism, (2) eliminating the need for warfarin sodium, (3) reducing symptoms associated with tachycardia, and (4) improving cardiac output [Cox 2000b]. In addition, preoperative AF is a risk factor for mortality in patients undergoing mitral valve surgery, although the effect of restoration of sinus rhythm on survival is not clear.

Until recently the Cox maze III procedure was the only surgical option for patients with AF and mitral valve disease. The Cox maze III procedure restores sinus rhythm or atrioventricular paced rhythm in 75% to 95% of patients [Cox 2000b, McCarthy 2000, Schaff 2000]. Although highly effective, the Cox maze III procedure has not been widely applied by surgeons. The reasons for surgeons' reluctance to perform the operation relate to its complexity and the additional 60 to 90 minutes of cardiac arrest required to complete the procedure. Elderly patients and those who need complex operations are particularly poor candidates for a full Cox maze III procedure.

Recently there has been a resurgence of interest in the surgical treatment of AF. This phenomenon is attributable to increased understanding of the pathogenesis of AF and the development of new ablation technologies. In most patients, the triggers and substrates for AF are anatomically situated in the left atrium and pulmonary veins [Haissaguerre 1998]. Therefore ablation is now focused on these areas, reducing the number of incisions or lesions necessary to treat AF. Alternative energy sources enable rapid creation of lines of conduction block without the laborious cutting and sewing of the Cox maze III procedure. In addition, the risk of bleeding is greatly reduced with these techniques.

The optimum left atrial lesion set and energy source for AF ablation have not yet been defined. In the current series, most patients received one of the lesion sets depicted in Figure 2. Similar results have been achieved with a variety of approaches [Cox 2000a, Sie 2001, Williams 2001]. It is likely that the best approach in a given patient depends on anatomic and electrophysiologic characteristics specific to that patient; however, such factors have not yet been identified. The surgical treatment of AF is in a phase of rapid evolution. As the number of treated patients increases and long-term results become available, creation of more clearly defined treatment guidelines will be possible.

On the basis of currently available information, we have devised the following strategy for the surgical treatment of AF in patients with mitral valve disease (Table 2). Patients with paroxysmal AF are treated by pulmonary vein isolation with the bipolar radiofrequency clamp. This strategy is based on the observations that (1) paroxysmal AF arises from foci in the pulmonary veins in approximately 90% of patients [Haissaguerre 1998] and (2) pulmonary vein ablation in patients with paroxysmal AF cures AF in 60% to 90% of patients [Chen 1999, Lickfett 2002]. Treatment of persistent and permanent AF is more complicated. It is generally accepted that patients with persistent and permanent AF should receive left atrial connecting lesions in addition to bilateral pulmonary vein isolation. In a young, healthy patient who needs a simple mitral valve procedure, we favor a classic Cox maze III procedure. In contrast, if the patient is elderly or high risk, or if the cardiac surgery is complex and lengthy, we perform a procedure such as that depicted in Figure 2, including excision or exclusion of the left atrial appendage. The early results

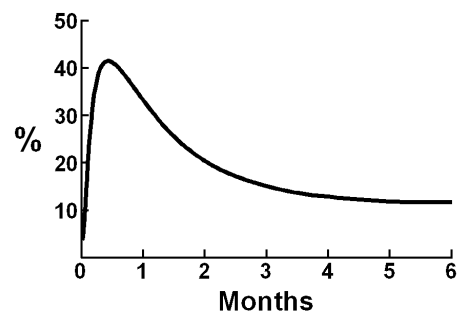


Figure 3. Prevalence of atrial fibrillation versus time after ablation with bipolar radiofrequency in patients undergoing mitral valve surgery.

Table 2. Ablation of Atrial Fibrillation (AF) in Patients with Mitral Valve Disease\*

	Paroxysmal AF	Persistent or Permanent AF
Low risk, simple cardiac procedure	PVI	PVI/connecting lesions or maze
High risk or complex cardiac procedure	PVI	PVI/connecting lesions

\*PVI indicates pulmonary vein isolation.

reported here and by others support this strategy [Williams 2001]. It must be stressed, however, that late results of these new operations are not yet available, and there is much that we do not know about AF.

We have demonstrated that bipolar radiofrequency is safe and rapid. Bipolar radiofrequency entails precisely controlled and focused delivery of energy, preventing collateral damage to adjacent structures, such as the esophagus [Prasad 2002]. In addition, a built-in algorithm provides real-time assurance of lesion transmuralty. When using bipolar radiofrequency, surgeons must avoid certain pitfalls. The electrodes of the clamp must be wiped clean between applications; failure to do so can result in incomplete ablation. As the clamp is closed, the surgeon must ensure that atrial tissue does not extrude beyond the tip of the clamp or become bunched within the jaws. Finally, when 2 lesions are created on a set of pulmonary veins, the lesions must overlap to ensure a continuous line of conduction block. With reference to the latter point, recent experience has demonstrated that a single application is sufficient to create conduction block at the pulmonary veins.

Perioperative AF is common, affecting 64% of patients. Some surgeons have observed a similarly high incidence of early postoperative AF, most patients returning to sinus rhythm in 3 to 6 months after surgery [Pasic 2001, Williams 2001]. The reason for this high incidence is unclear. With the classic Cox maze III procedure, perioperative AF occurs in only 30% to 40% of patients [Cox 2000b]. When perioperative AF occurs, we use standard antiarrhythmic medications and electrical cardioversion as necessary. In spite of these measures, 33% of patients leave the hospital in AF or atrial flutter. In an assessment of the utility of routine prophylactic antiarrhythmic therapy, a group of 60 patients receiving bipolar radiofrequency ablation received intraoperative and perioperative amiodarone. This treatment had no effect on the incidence of perioperative AF. One reason for this lack of effect may be that amiodarone was frequently discontinued because of bradyarrhythmias; many of these patients subsequently developed AF. It is possible that different strategies for prophylactic antiarrhythmic therapy will be more effective.

All patients are discharged on warfarin sodium. When patients leave the hospital in AF, they are discharged with antiarrhythmic medication, and a plan is made to perform electrical cardioversion in 4 to 6 weeks. Patients who develop AF after hospital discharge receive similar therapy. The need for warfarin sodium is debatable, because the left atrial

appendage has been excised or excluded in all patients. By 3 months, rhythm stabilizes in most patients, and only 15% have AF or atrial flutter. We recommend discontinuing warfarin sodium and antiarrhythmic therapy 3 to 6 months after surgery. The outcome of this strategy will require careful analysis as late results become available.

Success or failure of surgical AF ablation is determined 6 months after surgery [Gillinov 2002b]. Therefore these early results do not allow detailed assessment of the success rate of the use of bipolar radiofrequency to create left atrial lesion sets for AF ablation. Nor can we determine risk factors for failure at this time. Determination of the importance of patient characteristics (eg, duration of AF and left atrial size) and surgical procedure (eg, lesion set and energy source) require further study. Nevertheless, available data suggest that bipolar radiofrequency holds great promise for rapid, safe, and effective ablation of AF in patients undergoing mitral valve surgery.

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