Effectiveness of the Maze Procedure Using Cooled-Tip Radiofrequency Ablation in Patients With Permanent Atrial Fibrillation and Rheumatic Mitral Valve Disease

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**Background**—Although the Cox-Maze III procedure is effective for treating permanent atrial fibrillation (AF), its high complexity limits its use. The Saline-Irrigated Cooled-tip Radiofrequency Ablation (SICTRA) System is an alternative source of energy used to ablate AF. The aim of this study was to evaluate the effectiveness of the SICTRA for the treatment of permanent AF in patients with rheumatic mitral valve (MV) disease.

**Methods and Results**—Between February 2002 and April 2003, 70 patients with permanent AF and rheumatic MV disease were randomly assigned to undergo a modified Maze III procedure using SICTRA associated with MV surgery (group A) or MV surgery alone (group B). Groups A and B were similar in terms of baseline characteristics. The in-hospital mortality rate was 2.3% (1 death) in group A versus 0% (no deaths) in group B ($P=0.99$). The additional time required for the left-sided radiofrequency ablation in group A was 14.2±5.1 minutes and for right-sided ablation was 12.3±4.2 minutes. The mean postoperative follow-up periods were 13.8±3.4 and 11.5±7.3 months, respectively, in groups A and B. The overall mid-term survival rate was 95.1% in group A and 92.8% in group B ($P=0.99$). The cumulative rates of sinus rhythm were 79.4% in group A and 26.9% in group B ($P<0.001$). Doppler echocardiography documented biatrial transport function in 90.3% of group A patients in sinus rhythm.

**Conclusions**—The SICTRA is effective for treating permanent AF associated with rheumatic MV disease. (Circulation. 2005;112[suppl I]:I-20–I-25.)

**Key Words:** atrial fibrillation ▪ ablation ▪ mitral valve

Atrial fibrillation (AF) is a common arrhythmia, present in 0.4% of the general population and up to 60% of patients undergoing mitral valve (MV) operations.1 During the past decade, the Maze III procedure2 has evolved into the gold standard of treatment for medically refractory AF.

In patients with permanent AF associated with MV disease, the results of the Maze procedure in patients with rheumatic heart disease (RHD) were controversial.3,4 Even years after the acute phase of the RHD, persistent inflammatory activity in atrial myocardium5 may be an additional risk factor for the development of AF.

The Maze III is a complex procedure, a fact that precludes its widespread application. In an effort to reduce technical concerns with the operation, other sources of energy such as radiofrequency (RF) have been used to create transmural intra-atrial lesions, similar to those used in the original “cut and sew” technique.6 The aim of this study was to evaluate the safety, feasibility, and effectiveness of the Saline-Irrigated Cooled-tip Radiofrequency Ablation (SICTRA) System (Cardioblate, Medtronic Inc) for the surgical treatment of permanent AF in patients with rheumatic MV disease.

**Methods**

**Patient Population**

Between February of 2002 and April of 2003, 70 consecutive patients with permanent AF preexisting for more than 1 year and rheumatic MV disease were randomized to undergo a MV operation associated with a modified Maze III procedure using SICTRA (group A) or MV surgery alone (group B). Patients in groups A and B did not differ in terms of their baseline characteristics (Table 1). In group A, the primary indication for the MV operation was MV stenosis in 26 patients (61.9%) and MV regurgitation in 16 (38.1%). In group B, the primary indication for surgery was MV stenosis in 18 patients (64.2%) and MV regurgitation in 10 (35.8%).

The medical ethical committee of our institution approved the study, and informed consent was obtained from each patient. The same surgical team at the Heart Institute (InCor), University of São Paulo Medical School performed all of the operations.

**SICTRA Set-Up**

The SICTRA was used to create the intra-atrial transmural lesions. The SICTRA set-up consisted of a RF generator (CardioRhythm-ATAKR, Medtronic) and a unipolar catheter (Cardioblate; Medtronic). The catheter was irrigated with saline solution (0.9% NaCl) at a flow rate of 300 mL/h. The energy delivered by the SICTRA to create the lesions was 30 W. The temperature-guided...
energy applications were performed with a preselected catheter tip temperature of 60°C.

Surgical Procedure

The heart was exposed through a standard median sternotomy. Cardiopulmonary bypass was instituted with the use of ascending aortic and bicaval cannulations during moderate hypothermia (32°C). The MV was either repaired or replaced in both groups of patients. An additional modified Maze III procedure using SICTRA was performed in group A, based on the Maze III procedure described by Cox et al. All atrial incisions currently used in the Cox-Maze III procedure were replaced by ablation lines, as illustrated in Figure 1 through Figure 3, except for the incisions to enter the right and left atrial cavity. According to the original Maze III procedure, both atrial appendages were excised as well.

Right-Sided SICTRA Procedure

The right-sided SICTRA procedure was performed on the beating heart before aortic cross-clamping. Ablation lines were created between the superior and inferior caval cannulation sites. Additional lines were drawn from the medial aspect of the base of the excised right atrial appendage into the annulus of the tricuspid valve, and from the caudal end of the surgical incision at the atrioventricular groove to the posterior part of the annulus of the tricuspid valve. The septal part of the procedure was performed in a later stage of the operation, just before closing the left atrium, to prevent tearing of the septum. The ablation line was drawn on the right-sided aspect of the interatrial septum starting from the middle of the posterior or longitudinal right atriotomy across the interatrial septum up to the caudal aspect of the coronary sinus. It is recommended that surgeons terminate it at the bottom of the thin portion of the fossa ovalis. The ablation line was extended to the inferior vena cava cannulation site and the inferior border of the annulus of the tricuspid valve. Figure 4 illustrates the intraoperative aspect of the right-sided SICTRA procedure.

Left-Sided SICTRA Procedure

The aorta was cross-clamped and the heart was arrested with cold cardioplegic solution. Access to the inside of the left atrium was gained via a standard atriotomy in the interatrial groove. The MV procedure was performed; after excision of the left atrial appendage, the left-sided Maze procedure was performed using linear ablation lines. In addition to the incision in the interatrial groove, isolation of the right pulmonary veins was completed by a unilateral ablation line. The left pulmonary veins were encircled, and a transversal connecting line was drawn between both islands of pulmonary veins. In cases of enlarged left atria (diameter >65 mm), an additional longitudinal line was performed between both pulmonary vein

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Table 1. Baseline Characteristics

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Group A (n=42)</th>
<th>Group B (n=28)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y</td>
<td>55.4±12.8</td>
<td>50.7±9.7</td>
<td>0.103</td>
</tr>
<tr>
<td>Sex, % female</td>
<td>66.6</td>
<td>57.1</td>
<td>0.419</td>
</tr>
<tr>
<td>Duration of PAF, mo</td>
<td>66.1±57.4</td>
<td>43.8±28.8</td>
<td>0.061</td>
</tr>
<tr>
<td>LAD, mm</td>
<td>61.1±11.2</td>
<td>58.8±4.7</td>
<td>0.309</td>
</tr>
<tr>
<td>CHF: NYHA functional class</td>
<td></td>
<td></td>
<td>0.749</td>
</tr>
<tr>
<td>III, %</td>
<td>71.4</td>
<td>67.8</td>
<td></td>
</tr>
<tr>
<td>IV, %</td>
<td>28.6</td>
<td>32.2</td>
<td></td>
</tr>
<tr>
<td>LVEF, %</td>
<td>62.8±9.2</td>
<td>66.1±10.5</td>
<td>0.169</td>
</tr>
<tr>
<td>MV reoperation, %</td>
<td>16.6</td>
<td>35.7</td>
<td>0.069</td>
</tr>
</tbody>
</table>

Values are presented as mean±SD unless otherwise indicated. PAF indicates permanent atrial fibrillation; LAD, left atrial diameter; CHF, congestive heart failure; NYHA, New York Heart Association; and LVEF, left ventricular ejection fraction.

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Figure 1. Right-sided SICTRA procedure. A and B, Dotted lines indicate radiofrequency ablation lines in the right atrium between the superior and inferior caval cannulation sites. C, Left atrial incision in the interatrial groove. RAA indicates right atrial appendage excised; B, vertical incision toward the inferior vena cava in the right atrium; A, second posterior-longitudinal incision in the right atrium; SVC, superior vena cava; and IVC, inferior vena cava.

Figure 2. Right-sided SICTRA procedure. Ablation lines performed in the right atrium. Dotted lines (c, d, and e) show radiofrequency ablation lines in the right atrium. RAA indicates right atrial appendage excised; TV, tricuspid valve; CS, coronary sinus; FO, fossa ovalis; SVC, superior vena cava; and IVC, inferior vena cava.

Figure 3. Left-sided SICTRA procedure. Ablation lines in the left atrium. Dotted lines (f, g, h, i, j, and k) show radiofrequency ablation lines in the left atrium. LAA indicates left atrial appendage excised; MV, mitral valve; LPVs, left pulmonary veins; RSPV, right superior pulmonary vein; and RIPV, right inferior pulmonary vein.
Postoperative Care

Early postoperative care was similar to that for routine open-heart surgery. The cardiac rhythm was continuously monitored after surgery until a stable rhythm returned. The basic rhythm was classified as sinus rhythm, AF, atrial flutter, atrial tachycardia, or atrioventricular junctional rhythm disturbances. Antiarrhythmic prophylactic treatment was administered on a routine basis; amiodarone was the first choice antiarrhythmic drug given intravenously, starting at a dose between 900 mg to 1200 mg/d after weaning from cardiopulmonary bypass. After the patients were discharged, and temporary ventricular or atrioventricular epicardial wires were attached to the right ventricle, as well the right atrium.

As early postoperative arrhythmias may be caused by mechanisms other than chronic AF, patients were given amiodarone on a routine basis for a period of 3 to 6 months. Antiarrhythmic therapy was tapered gradually after cardiac rhythm was considered stable and was subsequently discontinued only if the patient remained in sinus rhythm, documented with a 24-hour ECG analysis performed during this period of postoperative follow-up. If atrial arrhythmias ensued, external electric cardioversion with direct transsthoracic current was performed. After these procedures, if sinus rhythm was not restored, a drug to control the ventricular response rate was introduced (ie, digitalis, β-blocker).

The anticoagulation management protocol was the same as that applied for routine open heart surgery. Heparin continuous drip was administered after resolution of postoperative bleeding. After removal of chest tubes, oral anticoagulant therapy with warfarin sodium was started to prevent thromboembolism secondary to recurrent AF. All patients were maintained on anticoagulant therapy during the first 3 to 6 months of follow-up. In the treated group, this therapy was subsequently discontinued if the patients remained in sinus rhythm, documented with a 24-hour ECG analysis. If AF or other atrial rhythm disturbance ensued, warfarin therapy was maintained.

Follow-Up

All data were obtained for each patient during the postoperative period, before hospital discharge, and after the third, sixth, and twelfth postoperative month. The clinical examination and a 12-lead ECG were obtained at each visit, and a 24-hour ECG analysis was performed after 3, 6, and 12 months. To evaluate left and right atrial transport function, transthoracic echocardiography, including transmitral and tricuspid Doppler examination, was obtained after 3, 6, and 12 months. Direct evaluation of the right and left atrial transport function was determined by the presence of atrial systole, documented by the presence of A wave on Doppler echocardiography of the tricuspid and the mitral valves. The A wave velocities (cm/s) were measured.

Statistical Analysis

Continuous variables were expressed as the mean±standard deviation (median). Student’s unpaired t test (2-tailed) was used for comparisons between the 2 groups. Categorical variables were expressed in relative frequencies, and the χ² test was used for comparison between the 2 groups. Differences were considered significant at a probability value less than 0.05. The survival rate and sinus rhythm (SR) maintenance rate were calculated according to the Kaplan-Meyer method, and groups were compared using the Log-rank test (significant difference postulated at P<0.05).

Results

MV replacement was performed in 29 patients (69.1%) in group A and in 27 patients (96.5%) in group B. Table 2 shows the operative data. In group A, the additional cardiopulmonary bypass time required to perform the right-sided maze procedure was 12.3±4.2 minutes, and the additional ischemic time needed to perform the left-sided procedure was 14.2±5.1 minutes.

The in-hospital mortality rate was zero in group B and 2.3% in group A (P>0.99). One 67-year-old woman in group

<table>
<thead>
<tr>
<th>TABLE 2. Operative Data</th>
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<tr>
<td>Characteristics</td>
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<tr>
<td>-------------------------</td>
</tr>
<tr>
<td>CPB time, min</td>
</tr>
<tr>
<td>ACC time, min</td>
</tr>
<tr>
<td>MV replacement, n (%)</td>
</tr>
<tr>
<td>Mechanical valve, n (%)</td>
</tr>
<tr>
<td>Biological valve n (%)</td>
</tr>
<tr>
<td>MV repair, n (%)</td>
</tr>
<tr>
<td>TV repair, n (%)</td>
</tr>
</tbody>
</table>

CPB indicates cardiopulmonary bypass; ACC, aortic cross clamp; TV, tricuspid valve.
A died of septic shock after pneumonia on the 17th postoperative day. Table 3 summarizes the in-hospital morbidity. One patient (2.3%) in group A and 1 patient (3.5%) in group B received a permanent pacemaker because of symptomatic bradyarrhythmia (the group A patient had junctional rhythm, the group B patient had AF with slow ventricular response).

The 12-month follow-up was completed in all surviving patients of both groups. The mean postoperative follow-up duration was 13.8 ± 3.4 months in group A and 11.5 ± 7.3 months in group B (P = 0.080). Survival after 12 months in group A and group B was 95.1% (39 of 41 patients) and 92.8% (26 of 28 patients), respectively (P = 0.99; Figure 6). Except for a group B patient who died because of a complication of anticoagulant therapy (cerebral hemorrhage), the other late deaths (n = 3) were not related to the surgical procedure. No systemic thromboembolic complications occurred in any patient during the follow-up.

Cardiac Rhythm
After 3, 6, and 12 months, the respective cumulative frequencies of SR for the group A and B patients were 0.625, 0.75, and 0.794 for group A and 0.25, 0.269, and 0.269 for group B patients (P = 0.001; Figure 7). The most frequent atrial arrhythmias observed in the postoperative period are described in Table 4 and Table 5 and shown in Figure 8A and 8B. In both groups, the cases of atrial flutter were atypical; they were the right-sided type and persistent flutter that were not reverted by external cardioversion with direct current.

Echocardiographic Results
The preoperative echocardiographic parameters observed in group A patients were mean left ventricular ejection fraction of 64.2 ± 8.8% and an average left atrial diameter of 61.1 ± 7.9 mm. At 12 months postoperatively, the mean left ventricular ejection fraction was 57.1 ± 11.1% (P = 0.07), and the mean left atrial diameter was 57.9 ± 9.3 mm (P = 0.27).

In the control group, the mean left ventricular ejection fraction was 66.6 ± 10.5% and the mean left atrial diameter was 58.8 ± 4.7 mm in the preoperative period. At 12 months postoperatively, the mean left ventricular ejection fraction was 68.6 ± 10.8% (P = 0.18), and the mean left atrial diameter was 52.8 ± 4.1 mm (P = 0.22).

Atrial Transport Function
Left atrial contractile function (transmitral A wave) was observed in 28 of 31 group A patients (90.3%) after the 12th month of follow-up. For the group B patients in SR, this corresponding figure was 7 of 7 patients (100%). Right atrial transport function (transtricuspid A wave) was detected in all patients in SR. At 12 months postoperatively, in group A patients, the mean transmitral A wave velocity was 58.4 ± 29.5 cm/s and the mean transtricuspid A wave velocity was 39.5 ± 16.3 cm/s.

Discussion
The structural changes in the atrial myocardium observed in MV disease might generate ectopic atrial beats and unidirectional conduction blocks, as well as macroreentrant circuits,

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### Table 3. In-Hospital Morbidity

<table>
<thead>
<tr>
<th></th>
<th>Group A (n=42)</th>
<th>Group B (n=28)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pericardial effusion, n (%)</td>
<td>1 (2.3)</td>
<td>3 (10.7)</td>
</tr>
<tr>
<td>Permanent pacemaker, n (%)</td>
<td>1 (2.3)</td>
<td>1 (3.5)</td>
</tr>
<tr>
<td>Sternal wound infection, n (%)</td>
<td>4 (9.5)</td>
<td>...</td>
</tr>
<tr>
<td>Endocarditis, n (%)</td>
<td>...</td>
<td>1 (3.5)</td>
</tr>
<tr>
<td>Pneumonia, n (%)</td>
<td>3 (7.1)</td>
<td>1 (3.5)</td>
</tr>
<tr>
<td>Pneumothorax, n (%)</td>
<td>1 (2.3)</td>
<td>...</td>
</tr>
<tr>
<td>Mediastinitis, n (%)</td>
<td>1 (2.3)</td>
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</tr>
</tbody>
</table>

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### Table 4. Postoperative Atrial Arrhythmias Observed in Group A and Antiarrhythmic Therapy Used

<table>
<thead>
<tr>
<th></th>
<th>Hospital Discharge</th>
<th>3 Months</th>
<th>6 Months</th>
<th>12 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atrial fibrillation, n (%)</td>
<td>7 (17.1)</td>
<td>10 (25)</td>
<td>6 (15)</td>
<td>5 (12.8)</td>
</tr>
<tr>
<td>Atrial tachycardia, n (%)</td>
<td>3 (7.3)</td>
<td>2 (5)</td>
<td>1 (2.5)</td>
<td>1 (2.6)</td>
</tr>
<tr>
<td>Atrial flutter, n (%)</td>
<td>...</td>
<td>2 (5)</td>
<td>2 (5)</td>
<td>1 (2.6)</td>
</tr>
<tr>
<td>Junctional rhythm, n (%)</td>
<td>...</td>
<td>1 (2.5)*</td>
<td>1 (2.5)*</td>
<td>1 (2.6)*</td>
</tr>
<tr>
<td>Antiarrhythmic therapy (amiodarone)</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>...</td>
</tr>
<tr>
<td>Drug to control ventricular response rate</td>
<td>...</td>
<td>...</td>
<td>...</td>
<td>+</td>
</tr>
</tbody>
</table>

* indicates positive.

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*Patient presented junctional rhythm with symptomatic bradycardia and had a permanent pacemaker implanted. He did not receive antiarrhythmic therapy or drugs to control the ventricular response rate.
all of which are involved in the maintenance of AF. Allessie described electrical atrial remodeling as an associated mechanism for maintaining AF.

Electrical remodeling might or might not be associated with anatomic remodeling (ie, enlargement or stretching of the atria). In patients with RHD, a state of chronic inflammation in the atrial endocardium and myocardium leads to fibrosis of the atrial muscle and contributes to atrial anatomic remodeling. In the present study, the histological analyses of the excised atrial appendages demonstrated enhanced atrial fibrosis and inflammation. In rheumatic patients, the effectiveness of the Maze procedure is questionable. Depending on the report, this procedure appears to have similar or diminished efficacy in rheumatic versus nonrheumatic patients.

Regarding the use of RF ablation to manage AF, few reports in the literature have analyzed the results in patients with associated rheumatic MV disease. For most patients in permanent AF at the time of MV surgery, arrhythmia will remain after surgical correction of the underlying cardiac disease. Cox’s Maze procedure cures AF in nearly 100% of patients; unfortunately, it is so complex that its adoptability is quite limited, and less complex operations, like SICTRA procedure, are currently being used to ablate AF.

Early and late atrial arrhythmias may occur after operations to cure AF. Some studies have shown that an increased inflammatory response correlates with the postoperative recurrence of AF. Inflammation in the atrial myocardium caused by the extensive atrial incisions and suture lines or ablation lesions may be associated with postoperative atrial arrhythmias. This is even more significant in rheumatic patients, who already have atrial inflammation.

The current study is the first controlled randomized trial involving patients with RHD who underwent MV surgery associated with the SICTRA procedure. Not only did we find that addition of the SICTRA procedure was more likely to restore SR (79.4% in group A versus 26.9% in group B), but also that this population experienced a comparable rate of sinus conversion to other reports in the literature. Thus, we conclude that SICTRA is effective independent of the etiology of the MV disease.

Restoration of atrial transport function is another important goal of the Maze procedure. Poor left atrial contractility can cause a decrease in cardiac output of as much as 30%. Sinus rhythm conversion, however, does not necessarily imply effective atrial transport function postoperatively. Atrial transport function can be restored in 70% to 100% of patients after the Maze procedure. Similar results were described with the use of SICTRA. In the present study, we have demonstrated similar success (90.3%) in restoring atrial contractile function in rheumatic patients.

The underlying mechanisms of less vigorous results of atrial transport function restoration when compared with the patients who did not have the Maze procedure observed in our study as in others reports remain unclear. Feinberg et al have suggested that surgical trauma to the left atrial wall might be involved.

In summary, our results demonstrate that SICTRA treatment of AF in patients with rheumatic MV disease is a safe, feasible, and effective means of restoring SR and bialtrial contractile function.

Limitations
A limitation of this study is that the transmurality of the ablation lines were confirmed visually. We intend to associate
the electrophysiological mapping to confirm the electrical isolation created by the ablation lines.

References
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