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Ten-year Experience With the Cox-Maze Procedure for Atrial Fibrillation: How Do We Define Success?

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Background. The Cox-maze procedure is the standard to which other surgical treatments of atrial fibrillation (AF) are compared. However, evaluation of new devices and lesion sets is difficult because of variable methods of reporting success in eliminating AF. We analyzed 10-year outcome with the “cut and sew” Cox-maze procedure and present rhythm at last follow-up, interval contact, and actuarial AF freedom.

Methods. Between March 1993 and December 2002, 335 patients (211 men) underwent the Cox-maze procedure (age, 22 to 83 years; median, 62 years). Atrial fibrillation was chronic (CAF) in 175 patients and paroxysmal (PAF) in 160.

Results. Concomitant mitral valve procedures were performed in 59%, coronary artery bypass grafting in 19%, and tricuspid valve repairs in 7%. Early mortality was 0.9%. During hospitalization, transient AF occurred in 29% of patients and 10% required implantation of a new permanent pacemaker (PPM). Dismissal electrocardiogram was normal sinus rhythm in 64%, junctional rhythm in 18%, AF in 11%, and PPM in 7%. At last follow-up (mean 42 ± 6 months), 88% of patients were free of AF. However, when analyzed by the Kaplan-Meier method, freedom from AF was lower for patients with preoperative lone PAF (5 years, 90%; 10 years, 64%), preoperative lone CAF (5 years, 80%; 10 years, 62%), and patients undergoing combined maze-mitral valve surgery (5 years, 68%; 10 years, 41%).

Conclusions. Ten-year results with the standard Cox-maze procedure confirm high effectiveness, but reporting methods should be standardized to account for patients who have transient atrial arrhythmias during long-term follow-up.

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The Cox-maze procedure has proved to be the most effective surgical procedure for treating atrial fibrillation (AF) and its adverse consequences of irregular rhythm, altered hemodynamics, and increased thromboembolic risk [1–5]. The indications for its application continue to evolve as new techniques and instruments have been developed. These modifications have simplified surgical ablation of AF and have expanded surgical ablation to additional subgroups of patients [6–9]. However, evaluation of outcome for patients who have undergone the maze procedure, as well as new devices and lesion sets, is difficult because of variable methods of reporting success in eliminating AF.

Outcomes of procedures for ablation of AF are influenced by thoroughness of follow-up as well as method of assessment of cardiac rhythm. The electrocardiogram is a “snap-shot” in time and has limited ability to detect those patients that may have transient atrial arrhythmias in the follow-up period. A better method is the Holter monitor, but widespread use for routine follow-up is not feasible. After clinical evaluation and follow-up of rhythm status are obtained, the second difficulty is in how the results of the analysis are reported. “Rhythm at last follow-up” may underestimate the recurrence rate of atrial arrhythmias in the follow-up period, and thus overestimate the success of the procedure. Conversely, actuarial methods used to delineate time-related events, “freedom from AF” define any recurrent arrhythmia as a failure of the procedure, and thus may underestimate the actual clinical success. Other factors that contribute to confusion in assessing results of surgical treatment of AF are viable terminology (intermittent versus paroxysmal, etc) and differing patient populations (lone paroxysmal AF, AF with mitral valve disease, etc). To examine the potential discrepancies in methods of reporting, we examined the early and late outcome of patients who underwent the biatrial “cut and sew” Cox-maze procedure, and compared different methods analysis.

Patients and Methods

From March 5, 1993 to January 1, 2003, a total of 443 operations were performed for ablation of atrial fibrillation; 335 patients underwent the standard “cut and sew” Cox-maze procedure and are the focus of this investigation. After Institutional Review Board approval, medical records were reviewed for patient demographics, past cardiac medical and surgical history, operative procedure, preoperative and postoperative cardiac rhythm, early and late morbidity, and survival. Protocols for the

This article has been selected for the open discussion forum on the CTSNet Web Site: http://www.ctsnet.org/sections/newsandviews/discussions/index.html

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postoperative management of patients who have undergone a Cox–maze operation vary, and are included in Table 1.

Demographic and other patient-related data were obtained from Mayo Clinic medical records. Follow-up information included clinical status, rhythm status, medication profile, and any complications the patient suffered during that time interval. This was obtained from subsequent clinic visits, written correspondence from local physicians, and mailed questionnaires to patients or families. Continuous data were expressed as median and range, as well as mean ± standard deviation. Outcome was calculated in three different ways. First, rhythm was noted at each patient’s most recent follow-up and this was defined as “rhythm at last follow-up.” Second, a Kaplan-Meier curve was employed to delineate time-related recurrence of AF. Third, rhythm of all patients who were available for follow-up at regular intervals was noted, and this was defined as “rhythm at interval contact.” Univariate and multivariable analyses were utilized to identify characteristics that were predictive of recurrence of AF. Statistical significance was considered at \( p \) less than 0.05. Operative mortality was defined as death occurring within 30 days of operation or at any time during the index hospitalization. The Mayo Foundation Institutional Review Board approved this study, and all patients or their families gave written informed consent.

Two hundred and eleven patients (63%) were men, and median age at operation was 62 years (range, 22 to 83 years). The duration of preoperative AF ranged from 3 months to 19 years (median, 2.9 years). The arrhythmia was chronic (present continuously ≥3 months) in 175 (52%) and paroxysmal in 160 (48%). The arrhythmia was lone paroxysmal in 51 patients (32%), and lone chronic in 29 (17%). The most common antiarrhythmic medications taken preoperatively were digoxin in 188 patients (56%), beta-blocker (26%), calcium-channel blocker (26%), and amiodarone (10%). Fifty-seven percent of patients were taking warfarin preoperatively. The most common preoperative clinical features present were mitral regurgitation in 191 patients (57%), coronary artery disease in 80 (24%), hypertension in 74 (22%), prior cerebrovascular accident or transient ischemic attack in 34 (10%), atrial septal defect in 30 (9%), diabetes in 10 (3%), previous permanent pacemaker (PPM) in 7 (2%), hypertrophic obstructive cardiomyopathy in 7 (2%).

Results

A standard biatrial “cut and sew” Cox-maze procedure was performed in all patients, as described by Cox and colleagues [10], utilizing cardiopulmonary bypass at normothermia or moderate hypothermia (28 to 32°C). The right atrial incisions were performed prior to aortic cross-clamping, and the left atrial incisions were performed after cardiac arrest with cold blood cardioplegia.

We have utilized two minor modifications to the original Cox-maze procedure. On the medial aspect of the right atrium, we avoid incision and apply a linear cryolesion from the cut edge of the appendage to the tricuspid valve. This avoids division of the frequently seen branch of the right coronary artery, which supplies the sinoatrial node and may decrease the risk of postoperative sinus node dysfunction. In the left atrium, we prefer to extend the incision, which encircles the pulmonary veins to the orifice of the amputated left atrial appendage, and then close the orifice transversely as part of the encircling incision. Alternatively, cryolesions can be utilized as part of the lesion encircling the pulmonary veins in order to avoid the conjunction of the encircling suture line and left atrial appendage suture line.

Cardiac rhythm was monitored continuously after operation, and temporary epicardial wires were used for atrial and (or) ventricular pacing as needed. All patients were dismissed with warfarin and advised to continue for a minimum of three months.

Concomitant procedures performed at the time of the maze procedure are listed in Table 2, and most commonly included mitral valve surgery in 198 patients (59%), coronary artery bypass grafting in 64 (19%), and atrial septal defect closure in 34 (10%). For the 158 patients undergoing combined mitral valve surgery, 171 had mitral valve repair and 27 had mitral valve replacement. For all patients, mean cross-clamp time was 58 ± 7

<table>
<thead>
<tr>
<th>Procedure</th>
<th>No. Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mitral valve repair</td>
<td>171</td>
</tr>
<tr>
<td>Coronary bypass grafting</td>
<td>64</td>
</tr>
<tr>
<td>Atrial septal defect repair</td>
<td>34</td>
</tr>
<tr>
<td>Mitral valve replacement</td>
<td>27</td>
</tr>
<tr>
<td>Tricuspid valve repair</td>
<td>23</td>
</tr>
<tr>
<td>Aortic valve replacement</td>
<td>10</td>
</tr>
<tr>
<td>Septal myectomy</td>
<td>7</td>
</tr>
<tr>
<td>Aortic valve repair</td>
<td>3</td>
</tr>
</tbody>
</table>
minutes, and mean cardiopulmonary bypass time was 117 ± 7 minutes. For patients having isolated maze procedure, mean cross-clamp time was 49 ± 5 minutes, and mean total cardiopulmonary bypass time was 102 ± 8 minutes.

There were three early deaths (0.9%). One patient expired intraoperatively due to massive hemoptysis caused by lung injury during placement of a Swan-Ganz catheter. A second death occurred due to pneumonia in a patient who had an otherwise uncomplicated operation. The third patient died from persistent ventricular arrhythmias despite aggressive medical interventions. One perioperative death occurred in a patient undergoing the maze for lone AF, and the other two deaths were in patients having concomitant mitral valve surgery and coronary artery bypass grafting.

Early nonfatal morbidity in the 332 early survivors included postoperative AF in 96 patients (29%), junctional rhythm in 53 (16%), new PPM in 33 (10%), mediastinal bleeding requiring reexploration in 17 (5%), and stroke in 3 (1%). The most common dismissal medications included digoxin in 86 (26%), beta-blockers in 46 (14%), amiodarone in 43 (13%), and calcium-channel blockers in 17 (5%). Two hundred and seventy-nine patients (84%) were dismissed on warfarin anticoagulation. Cardiac rhythm of the 332 early survivors at the time of hospital dismissal included sinus rhythm in 212 patients (64%), junctional rhythm in 60 (18%), atrial fibrillation (or flutter) in 37 (11%), and paced rhythm in 23 (7%). In those patients who required new PPM, rhythm at dismissal included paced rhythm in 13 patients (40%), sinus rhythm in 11 (33%), AF in 6 (18%), and junctional rhythm in 3 (9%).

Of the 332 early survivors, 23 (7%) were lost to follow-up beyond initial hospitalization; many were from foreign countries. Late follow-up in 309 patients extended up to 10.5 years (median, 3 years). There were 9 late deaths, 5 due to cardiac causes and 4 due to noncardiac causes. Late nonfatal morbidity included nondisabling stroke or transient ischemic attack in 34 patients (11%), pneumonia in 25 (8%), deep venous thrombosis in 12 (4%), and myocardial infarction in 6 (2%). Overall, 226 patients (73%) were free from warfarin anticoagulation. For patients undergoing isolated maze for lone AF, risk of nondisabling stroke or transient ischemic attack was 1.3% (1 of 68) and freedom from warfarin anticoagulation was 88% (60 of 68).

At last contact, excluding those who had no late follow-up, 272 patients (88%) were free from AF, and 235 (76%) were in sinus rhythm; thirty-one patients (10%) were in a paced rhythm, and 6 (2%) remained in a junctional rhythm. When analyzed in a product limit estimate (Kaplan-Meier), freedom from AF was 76% at 5 years and 51% at 10 years (Fig 1). Utilizing rhythm at interval contact as a third method of assessing outcome (Fig 2), overall freedom from AF was 80% at 3 years, 78% at 6 years, and 76% at 9 years.

We analyzed the influence of preoperative clinical characteristics on late outcome and cure of AF (Fig 3). At last follow-up (median 41 months), 93% of patients with preoperative lone paroxysmal AF were free from their arrhythmia, with an actuarial free from AF of 90% at 5 years and 64% at 10 years. Patients with preoperative lone chronic AF had 83% freedom from AF at last follow-up (median, 28 months) with an actuarial freedom from AF of 80% at 5 years and 62% at 10 years. The Cox-maze operation appears less durable for patients undergoing combined Cox-maze and mitral valve surgery with 70% of patients free from AF at last follow-up (median, 33 months) and an actuarial freedom from AF of 68% at 5 years and 41% at 10 years.

On univariate analysis, the following characteristics were predictors of recurrent AF in the follow-up period: advanced New York Heart Association (NYHA) class (95% confidence interval [CI]: 1.048 to 1.692), preoperative mitral valve regurgitation (95% CI: 1.334 to 3.534), left atrial enlargement (95% CI: 1.014 to 1.068), concomitant aortic valve surgery (1.157 to 6.155), concomitant mitral
valve surgery (95% CI: 1.307 to 3.507), and AF at hospital dismissal (95% CI: 1.527 to 4.753). When compared with patients with lone paroxysmal AF, patients who underwent combined Cox-maze and mitral valve surgery have a significantly increased risk of developing recurrent AF in the follow-up period ($p < 0.0027; 95\% \text{ CI}: 1.370$ to $4.495$).

In a multivariable model, only left atrial enlargement (atrial dimension) remained as a significant predictor of recurrent AF in the follow-up period ($p = 0.0026, \text{ hazard ratio (HR) } 1.041, 95\% \text{ CI}: 1.014$ to $1.068$). Left atrial size was significantly ($p = 0.006$) smaller in patients who did not have recurrent arrhythmias (mean $= 51$ mm, median $= 49$ mm) compared with patients who did have recurrent AF (mean $= 56$ mm, median $= 55$ mm). Left atrial size of $50$ mm was identified as a cutoff above which patients were almost twice as likely to experience recurrent AF (HR $= 1.89$).

**Comment**

Success with the standard Cox-maze procedure has varied from 79% to 99% in published reports (Table 3). In general, approximately 90% of patients who undergo the Cox-maze operation are free from AF at last follow-up. However, as illustrated in this report, outcomes (success) of the procedure depend on method of analysis. For example, in our patients overall freedom from AF is $88\%$ when we used rhythm at last follow-up as the endpoint. When outcome is analyzed in a product limit estimate (Kaplan-Meier), freedom from AF was $76\%$ at five years and $51\%$ at 10 years (Fig 1). Utilizing a third method of reporting success, freedom from AF at interval contact was $80\%$ at three years, $78\%$ at six years, and $76\%$ at nine years (Fig 2). In addition, different subgroups of patients may experience different durability from the Cox-maze procedure, and this represents another variable that affects the reporting of outcomes (Fig 3). At last follow-up (median, 41 months), $93\%$ of patients with preoperative lone paroxysmal AF were free from their arrhythmia with an actuarial freedom from AF of $90\%$ at five years and $64\%$ at ten years. Patients with preoperative lone chronic AF had $83\%$ freedom from AF at a last follow-up (median, 28 months) with an actuarial freedom from AF of $80\%$ at five years and $62\%$ at ten years. The Cox-maze operation is less durable for patients undergoing combined Cox-maze and mitral valve surgery with $70\%$ of patients free from AF at last follow-up (median, 33 months) and an actuarial freedom from AF of $68\%$ at five years and $41\%$ at ten years.

These results highlight some of the difficulties in assessing and reporting patient outcome after the Cox-maze procedure, or any treatment for AF. In most of the large series published for patients undergoing the Cox-maze procedure, the most commonly employed method of reporting success is “rhythm at last follow-up” (Table 3). This is the first study to report outcome utilizing three different methods, and by doing so, discrepancies in success were observed. We demonstrate these differences for the same procedure performed for the same patients with only the method of reporting being different. In order to accurately compare efficacy of the existing Cox-maze procedure, as well as newer methods and technologies, it is important that results are reported and analyzed in a similar manner.

These results highlight some of the difficulties in assessing follow-up in patients who have undergone the Cox-maze procedure. The first lies in the method of evaluation. The electrocardiogram is a “snap-shot” in time and has limited ability to detect those patients that

Table 3. Large Reported Series of Patients Undergoing the Cox-Maze Procedure

<table>
<thead>
<tr>
<th>Author</th>
<th>Year</th>
<th># pts</th>
<th>Last FU</th>
<th>% AF free</th>
<th>Actuarial</th>
<th>Interval Contact</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>5 yr</td>
<td>10 yr</td>
<td>3 yr</td>
<td>6 yr</td>
</tr>
<tr>
<td>McCarthy [18]</td>
<td>2000</td>
<td>100</td>
<td>90</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Izumoto [19]</td>
<td>2000</td>
<td>104</td>
<td>78</td>
<td>88</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Cox [4]</td>
<td>2000</td>
<td>346</td>
<td>99</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Schaff [20]</td>
<td>2000</td>
<td>221</td>
<td>85-90%</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Bando [21]</td>
<td>2002</td>
<td>258</td>
<td>82</td>
<td>79</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Prasad [22]</td>
<td>2003</td>
<td>198</td>
<td>97</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Current study</td>
<td>2006</td>
<td>335</td>
<td>88</td>
<td>76</td>
<td>51</td>
<td>80</td>
</tr>
</tbody>
</table>

AF = atrial fibrillation; FU = follow-up; N/A = not available; yr = years.
may have transient atrial arrhythmias in the follow-up period. The ideal method for assessment of recurrent arrhythmias is the Holter monitor; however, widespread use for routine follow-up is not feasible. After clinical evaluation and follow-up are obtained, the second difficulty is in how the results of the procedure are reported. “Rhythm at last follow-up” may underestimate the recurrence atrial arrhythmias in the follow-up period, and thus overestimate the success of the procedure. Conversely, actuarial methods used to delineate time-related events, “freedom from AF” define any recurrent arrhythmia as a failure of the procedure, and thus may underestimate the true success. As new instruments and lesion sets are being utilized and scrutinized, outcomes should be reported in a standardized fashion. Other factors that contribute to confusion in assessing results of surgical methods for treating AF include viable terminology (intermittent versus paroxysmal, etc) and differing patient populations. In addition, the measure of outcome is variable, including terms such as “freedom from AF” (as in this study) and “AF burden” (although difficult to assess because continuous rhythm monitoring technology is not currently available).

In addition to the specific method of assessment that is employed, several patient-related variables appear to be associated with return of atrial fibrillation after maze operations. Gillinov and colleagues [11] found that older patient age, longer duration of arrhythmia preoperatively, and increased left atrial size were predictors of late recurrence of AF after the Cox-maze procedure. Gaynor and colleagues [12] found that duration of preoperative arrhythmia and type of operation (Cox-maze II vs Cox-maze III) were predictors of recurrent AF. In our study, only left atrial size was a predictor of recurrent AF in patients after the Cox-maze operation. Indeed, patients with left atrial dimension 50 mm or greater were almost twice as likely to experience late recurrence of AF (HR: 1.9).

Outcome is influenced by preoperative and intraoperative decision making, subsequently, there are many unanswered questions regarding clinical application of the maze operation in conjunction with other cardiac procedures. Is pulmonary vein isolation equally effective as a full Cox-maze procedure for patients with paroxysmal AF and mitral valve disease? Gillinov and colleagues [13] reported that the choice of ablation procedure (full Cox-maze versus pulmonary vein isolation) did not affect the late recurrence of AF or the rate of ablation failure. Perhaps the pathogenesis of AF in patients with mitral valve disease and paroxysmal arrhythmia is different from that of patients with chronic AF in the setting of mitral valve disease and a dilated left atrium [14]. Another unresolved issue is whether concomitant left reduction atrioplasty should be performed at the time of valve repair and maze procedure for patients with AF and a dilated left atria from mitral valve disease. Romano and colleagues [15] have reported an 89% rate of return of sinus rhythm in patients who underwent left atrial reduction combined with a Cox-maze operation. Finally, should a “prophylactic” maze procedure be performed in a patient with preoperative sinus rhythm and a dilated left atrium undergoing surgery for mitral valve disease? The altered atrial tissue in these patients represents an arrhythmogenic substrate, which renders them at high risk (approximately 40%) for the development of postsurgical AF even after the mitral valve disease is repaired [16, 17]. Clearly, the risks and benefits should be weighed before an additional procedure is performed, which carries with it the added risk of PPM implantation, with new permanent pacemakers required in 10% to 15% of patients [2, 5].

Our experience is similar to others in that operative risk is low, 0.9% overall, which includes patients having concomitant intracardiac repair. A new transvenous PPM was required in 10% of our patients, and the indication in almost all was bradycardia due to sinus node dysfunction. This incidence of pacing postoperatively is lower than expected, based on initial reports. In the earlier experience, clinicians were hesitant to allow patients to remain in junctional rhythm early postoperatively, but in many such patients, a stable sinus mechanism will return. Thus, some patients may have had pacemakers implanted prematurely. Additionally, technical modifications to the original Cox-maze operation may reduce injury to the sinoatrial node.

Preoperatively, patients are counseled that this operation reliably eliminates AF in most individuals, but does not necessarily restore sinus rhythm. In older patients especially, there is an underlying incidence of sick sinus syndrome, and when AF is eliminated, a new PPM may be necessary to manage sinus node dysfunction. Important also is the fact that conduction disturbances may also develop in those patients who require concomitant intracardiac procedures at the time of surgery for AF. Eighty percent of patients undergoing the standard biatrial maze procedure at Mayo Clinic have combined procedures. In our experience, 89% of patients are free from AF upon dismissal from the hospital. This includes patients with sinus rhythm, paced rhythm, or junctional rhythm with an adequate rate. It is important to recognize that the Cox-maze procedure, like other cardiac operations, predisposes patients to transient AF in the early postoperative period.

We did not assess atrial contractility in this study, and thus, did not include this as a measure of outcome. Some argue that atrial contractility is a major endpoint and has to be taken into account when anticoagulant therapy is to be discontinued. We recommend systemic anticoagulation with Coumadin (Bristol-Myers Squibb, New York, NY) for three months postoperatively, but there is no consensus on the need for anticoagulation beyond this interval. Some clinicians prefer to continue Coumadin believing that risk of thromboembolism is not reduced sufficiently to avoid systemic anticoagulation. Others argue that if AF is eliminated and ventricular function is normal, the risk of an intracardiac source of thromboemboli from a postoperative patient without a left atrial appendage is very low [23, 24]. Thus, the additional risk and inconvenience of using Coumadin is not justified.
The limitations of this study lie mostly in its retrospective nature, and all the bias that this introduces. Our method of assessment was the electrocardiogram, which, as mentioned above, is a “snapshot” in time and is not the ideal method for assessing rhythm during the follow-up period. However, it is a more objective manner than survey letters and phone conversation follow-up. The median length of follow-up in this study is relatively short, reflecting the increase in volume of maze procedures performed in our institution in the more recent years of the study.

This study examines the challenges that surgeons must face with the Cox-maze operation including proper patient selection, appropriate procedure, postoperative management, and assessment of outcome. The indications for operation continue to evolve as do instruments and operative techniques. Standardization for the assessment of outcome is necessary and will facilitate the evaluation of efficacy of future tools, approaches, and lesion sets as these procedures are applied to a more expansive population of patients.

We would like to thank Francie Cordts for her assistance in data collection, and Donna Stucky for her assistance in the editorial review.

References

INVITED COMMENTARY

I would like to congratulate Stulak and associates [1] on their article that is of importance to those of us involved in the treatment of atrial fibrillation (AF).

The surgical treatment of AF was initiated more than two decades ago with atrioventricular node ablation and evolved in the 1980s to the left atrial isolation procedure and the corridor operation.

These operations had in common that they were merely designed to achieve a nonphysiological regular rhythm, irrespective of functionality of both atria.

It was not until 1987, when the maze procedure was introduced by Dr Cox. This operation was designed to restore sinus rhythm as well as atrial contractility. Because of the excellent reported results, even now, 20 years later, we still consider the Cox maze procedure the gold standard in the surgical treatment of AF.
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