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Predictors and Risk of Pacemaker Implantation After the Cox-Maze IV Procedure

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Abstract

Background—The incidence of and causes for permanent pacemaker implantation (PPM) after surgical arrhythmia procedures remain poorly understood because of the varied lesion patterns and energy sources reported in small series. This study characterized the incidence, indications, and risk factors for PPM after the Cox-maze IV (CMIV) procedure when performed as either a lone or a concomitant procedure.

Methods—A retrospective analysis of 340 patients undergoing a CMIV as either a lone ($n = 112$) or a concomitant ($n = 228$) procedure was conducted. The incidence, indication, and variables associated with PPM implantation within 1 year of the operation were assessed. Follow-up was conducted at 30 days and 1 year and was 90% complete.

Results—The incidence of PPM after a lone CMIV procedure was 5%. Patients with concomitant cardiac operations had a nonsignificant increase in PPM insertion at 30 days (11% vs 5%, $p = 0.14$) and 1 year (15% vs 6%, $p = 0.06$) when compared with lone CMIV patients. Of patients who required pacemakers, sinus node dysfunction was present in 79% (35/44) of patients in the entire series and in 88% (8/9) after lone CMIV. After PPM, 84% (37/44) of patients remained paced at last follow-up. Multivariate analysis identified age (odds ratio = 1.10 [1.06–1.14], $p < 0.001$) as the only variable associated with higher risk of a PPM after any CMIV procedure.

Conclusions—The risk of PPM implantation after a lone CMIV is 5% and increases with age. The need for a PPM after a CMIV is largely due to SA node dysfunction, which appears unlikely to recover. These data should help physicians counsel patients regarding the perioperative risks associated with the CMIV.

Worldwide, atrial fibrillation (AF) is the most common cardiac arrhythmia, affecting over 6.7 million people in the United States and the European Union alone [1]. Although there

remains ongoing debate about the efficacy of rate-control strategies, the restoration of sinus rhythm has particular benefits related to reducing the risk of thromboembolism and stroke, the most serious complications of AF [2–4]. Although most AF patients are initially treated with antiarrhythmic drugs, the limited efficacy and significant side effects of these medications have constrained their usage while simultaneously increasing the number of catheter-based and surgical-based procedures offered as a treatment for AF patients. The Cox-maze IV (CMIV) procedure is the latest iteration of the surgical Cox-maze procedures. It uses bipolar radiofrequency ablation and cryoablation to create a biatrial lesion pattern [5, 6] and, since its introduction in 2002, has increasingly been adopted by many groups as their AF corrective procedure of choice.

The need for early postoperative pacemaker (PPM) after biatrial surgical procedures has been reported as anywhere from 6% to 23% [6–10], depending on the lesion pattern chosen or energy source used. This study elucidates the requirement for both early and late PPM insertion after a single ablative procedure, the CMIV, when offered as either a lone or a concomitant procedure.

Patients and Methods

Patient Population and Data Collection

Between January 2002 and August 2011, 391 patients underwent a CMIV procedure for AF at our institution. Fifty-one patients with a preoperative pacemaker were excluded, leaving 340 patients who underwent either a lone ($n = 112$) or a concomitant ($n = 228$) procedure available for study. Patient demographics and peri-operative data were collected prospectively as part of the Society of Thoracic Surgeons database and the Washington University Cox-maze database per recent consensus guidelines [1]. Data regarding the indications for and timing of PPM implantation, specific underlying rhythm, pacing mode, and pacemaker use were collected retrospectively, and adjudications regarding the need for continued pacing at follow-up were made by a staff cardiologist specializing in electrophysiology (P.S.C.). Determination of SA and AV node dysfunction was performed by examining the percentage of time that the atria, the ventricles, or both were paced, and more than 20% pacing was considered pacemaker dependence. This study was approved by the Washington University in St. Louis Institutional Review Board.

Surgical Approach

The CMIV was performed as previously described [5, 6]. All lesions were performed while the patients were under cardiopulmonary bypass, and left atrial lesions were performed during cardioplegic arrest. Briefly, a bipolar radiofrequency clamp was used to perform pulmonary vein isolation, posterior left atrial isolation, the lesion from the superior pulmonary vein to the left atrial appendage (LAA), and the lesions on the right atrial free wall, superior vena cava, and inferior vena cava. Cryoablation was used to complete lesions to the mitral and tricuspid valve annuli and for treatment of the coronary sinus. The superior pulmonary vein connecting lesion, the “roof line,” was introduced as standard in 2005 to isolate the entire posterior left atrium and create the “box lesion.” In cases where procedures were performed through a right minithoracotomy, cryoablation was used more extensively

to complete the posterior left atrial isolation, and the LAA was oversewn from the endocardial surface, whereas sternotomy patients underwent LAA excision. In a few cases, a unipolar radiofrequency ablation pen was used to complete the lesion set at the mitral annulus. The concomitant procedures in this series are listed (Table 1). All but 2 patients undergoing tricuspid valve repair did so in conjunction with mitral valve operations and were thus included in the mitral valve repair/replacement subgroup. Similarly, patients with coronary procedures performed in combination with valvular operations were grouped according to the valvular procedure performed, leaving the CABG subgroup to represent patients with a CMIV and only concomitant coronary bypass grafting.

Postoperative Care and Follow-Up

Follow-up after the CMIV procedure occurred at 1, 3, 6, and 12 months and annually thereafter. Since 2006, 24-hour Holter monitoring was routinely performed according to HRS guidelines at 3-, 6-, and 12-month intervals and annually thereafter. Class I or III antiarrhythmic medications and warfarin were started in all patients in the early postoperative period (unless contraindicated) and stopped at 2 months and 3 months, respectively, if patients were free of atrial tachyarrhythmias and had no evidence of atrial stasis or thrombus by echocardiography. Pacemaker follow-up visits were performed at 1 week and 3 months and every 3 months thereafter. Patient follow-up in this series was 90% at 1 year postoperatively.

Statistical Methods

Continuous and categorical variables are expressed as mean $\pm$ standard deviation and as number and percent, respectively, unless otherwise specified. Comparisons were performed with a two-tailed Student's *t* test for normally distributed continuous variables and a Fisher's exact test for categorical variables. Univariate logistic regression was performed on clinically relevant variables, and variables with a $p < 0.10$ were added to a multivariate logistic regression model to determine independent predictors of PPM requirement. Data analyses were performed with Sigma Plot 12.0 and Systat 13 (Systat Software, Inc, San Jose, CA) and GraphPad InStat 3 (GraphPad Software, La Jolla, CA). *P* values less than 0.05 were considered statistically significant.

Results

Baseline Characteristics

The baseline characteristics of the study group are described and stratified by need for postoperative PPM insertion (Table 2). The patients in the PPM group were significantly older (71 ± 9 years vs 61 ± 12 years, $p < 0.0001$), had a greater degree of peripheral vascular disease (20% vs 9%, $p = 0.03$), and had smaller left atrial diameters (5.0 ± 1.1 vs 5.3 ± 1.1 cm, $p = 0.05$). There were no differences with respect to AF type or duration or history of previous AF ablation between the two groups. When stratified by procedure (lone vs concomitant), patients undergoing lone CMIV procedures were younger (56 ± 11 vs 66 ± 11 years, $p < 0.001$), had AF of longer duration (88 ± 78 vs 60 ± 75 months, $p < 0.001$) and had smaller left atrial size (4.8 ± 1.1 vs 5.6 ± 3.4 cm, $p = 0.001$). Forty-seven percent of lone CMIV patients had a history of previous failed catheter ablation for atrial fibrillation.

Incidence of and Indications for Pacemaker Implantation

The incidences of postoperative PPM insertion at 30 days and 1 year varied with the presence and type of concomitant operations performed (Fig 1). The lowest incidence of postoperative PPM was seen in patients undergoing a lone CMIV procedure. Patients with concomitant cardiac operations had a nonsignificant increase in PPM insertion at both 30 days (11% vs 5%, $p < 0.14$) and 1 year (15% vs 6%, $p = 0.06$) in comparison with lone CMIV patients.

The indications for PPM implantation are described in Table 3. The majority of PPMs were inserted for SA node dysfunction, and less commonly for isolated AV node dysfunction (20%); 11% of patients demonstrated both SA and AV node dysfunction. In lone CMIV patients, all but one PPM was inserted for SA node dysfunction. Although AV node dysfunction was more commonly identified among patients with concomitant operations, no association between PPM indication and particular type of surgical procedures could be identified. The most common indication for PPM insertion remained SA node dysfunction across all concomitant operation subgroups. Ten patients (23%) were in AF at the time of PPM insertion. The indication for PPM insertion in these patients was significant intermittent bradyarrhythmia precluding the ability to treat the AF. All patients requiring a PPM received a dual chamber device, with the expectation for a return of an atrially paceable rhythm and restoration of AV synchrony.

Fifty-five percent (24/44) of postoperative PPMs were inserted within 2 weeks postoperatively, and 91% (29/32) of patients who received a PPM within 30 days had it implanted before discharge. For these patients, the average interval between operation and insertion of PPM was 15 days for patients undergoing a lone CMIV and 10 days for patients undergoing CMIV and concomitant procedures. Late PPMs, defined as those inserted between 31 days and 1 year postoperatively, accounted for 27% (12/44) of the study population and were inserted at a mean 115 days postoperatively. At last follow-up (mean 30 ± 29 months), 84% of patients who had a PPM inserted continued to require pacing support (Table 3). Only 7% of patients (3/40) no longer required pacing. PPM follow-up was unavailable for 4 patients.

Risk Factors Associated With Pacemaker Implantation

At 30 days, age was the only univariate variable to significantly predict PPM implantation and the only variable to remain in the model after multivariate analysis (odds ratio 1.08 [1.04–1.12], $p < 0.001$). At 1 year, age and peripheral arterial disease were significant predictors of pacemaker implantation by univariate analysis, and cardiac operations and diabetes were identified as trending toward significance (Table 4); however, age was, again, the only significant predictor of pacemaker implantation by multivariate analysis (odds ratio = 1.10 [1.06–1.14], $p < 0.001$). A logistic regression curve showing the probability of PPM insertion with increasing age is shown in Figure 2.

Comment

The CMIV procedure is based on the same lesion set as proposed in the classic “cut and sew” Cox-maze III, but it incorporates ablative technology to replace the majority of the

atrial incisions. This has simplified the procedure, making it faster, safer, and easier for surgeons to perform without diminishing procedural efficacy with respect to freedom from both AF and stroke [4, 6, 11]. These technical improvements, coupled with the increasing numbers of AF patients undergoing cardiac operations, have resulted in more patients being offered surgical ablation either as a lone procedure or concomitantly with other open heart procedures [9]. Despite these trends, however, over 40% of patients are not offered surgical correction of AF because of potential increases in perioperative risk, including the need for PPM after a Cox-maze procedure.

A principal finding of this study is that the need for a PPM after a lone CMIV procedure is 5%. The relatively low incidence for early PPM implantation in this series is in contrast to the higher reported rates of PPM insertion after a Cox-maze III procedure, wherein perioperative pacemakers were required in 8% to 23% of patients after lone and concomitant procedures, respectively [12–14]. The reduced rates of PPM insertion after a CMIV may reflect the intrinsic advantages of ablative instrumentation, which in the case of bipolar radiofrequency energy has the ability to produce discrete lesions with minimal thermal spread [15]. These advantages are particularly realized in the creation of lesions on the superior vena cava that intrinsically carry the greatest potential risk for injury to the SA node. The discrete lesion afforded by the bipolar clamps should minimize collateral tissue injury and facilitate creating a lesion in as lateral a location as possible to avoid the SA node complex. Animal studies from our laboratory further support this hypothesis, inasmuch as bipolar RF clamps have the ability to maintain tissue microcirculation and do not appear to create coronary injury, thus minimizing the risk of nodal devascularization [16, 17]. The lower rates of PPM insertion in this series are consistent with reports from other centers where ablation technology has similarly been used to perform complex biatrial procedures [8, 12, 18].

By multivariate analysis, only age was demonstrated to predict the need for a postoperative PPM at both 30 days and 1 year. In several series from both medical and surgical literature, age has similarly been identified as an independent predictor for PPM insertion, and although the mechanism for this finding remains unclear, it is likely related to underlying atrial substrate and pathophysiology that deteriorates with aging [19, 20]. Specific to surgical series of open valve replacement and more recently from findings within the transcatheter valve literature, the need for a postoperative PPM appears dependent on host factors such as baseline conduction system abnormalities and preoperative myocardial infarction, all of which are more commonly found within the elderly population [21, 22].

Although concomitant cardiac operation appeared to increase the risk of PPM both at 30 days and over the ensuing year, this failed to reach statistical significance. Although this is consistent with earlier reports from our group in patients undergoing mitral valve procedures [23], the data set in this series is not particularly robust in clarifying the PPM risk afforded by concomitant cardiac operations. The rates of PPM placement in this investigation were driven by age alone; however, the patients undergoing concomitant cardiac procedures were on average a decade older than the lone CMIV patients. In this series, only 1% of lone CMIV patients were older than 75 years. Although it is possible that concomitant operation does not increase the risk with regard to postoperative PPM, a larger population or at least a

larger group of older patients undergoing lone CMIV procedures would be required to clarify the difference between age and concomitant surgical procedure as independent risk factors for PPM.

The predominant indication for PPM placement in this study was SA node dysfunction, regardless of whether the patient had a lone or a concomitant operation or whether PPM insertion occurred early (< 30 days) or late (between 31 days and 1 year). This study further highlights a particular late hazard for AF patients with structural heart disease. Whether the ongoing hazard of PPM insertion in concomitant patients is a reflection of their sinus node dysfunction, advanced age, or concomitant cardiac disease is unclear, but concomitant patients demonstrate an ongoing risk for later PPM insertion both in this series and in others [14, 18]. Most importantly, it should be emphasized that sinus node function fails to recover in most patients who receive a PPM at any time after a CMIV. Although we remain increasingly cautious regarding the use of antiarrhythmics and nodal agents in the first few weeks after a CMIV, and we use a conservative strategy of waiting a minimum of 7 to 10 days before considering PPM insertion (in most cases), the likelihood is that patients without evidence of adequate conduction within the first 2 weeks are unlikely to recover without a PPM.

Limitations

The major limitations of this study are those inherent to retrospective analyses, and some findings may be limited by sample size and number of patients who received a PPM. Additionally, the definition of pacemaker dependence is not well defined in either the surgical or the electrophysiologic literature and may be affected by the programmed pacing rate, but we consider a pacing requirement of more than 20% to be a relatively conservative criterion. Nevertheless, this study draws from the largest reported CMIV clinical experience available and benefits from our close follow-up of these patients. Although speculation exists regarding the role of the right atrial lesion set in leading to postoperative PPM requirement, we cannot address these concerns because we do not regularly perform limited lesion sets. The relationship between preoperative sick sinus syndrome and postoperative PPM requirement, which was suggested in our Cox-maze III series, could also not be assessed in this analysis. Most importantly, as with any single-institution experience, caution should be used in extrapolating the results to different clinical practices.

Conclusions

The incidence of postoperative pacemaker requirement is 5% after a lone CMIV procedure but increases with age. Most patients requiring a pacemaker postoperatively continue to be paced, regardless of the indication for PPM insertion. These data may have implications for aiding surgeons with regard to the appropriate timing of postoperative pacemaker placement after a Cox-maze IV and may be used as a reference against which complications for new ablation procedures and lesion sets may be compared. When we counsel patients, the risk of PPM implantation should be weighed against the proven benefits of the Cox-maze IV procedure, which include reductions in stroke risk, freedom from AF, and the potential to discontinue oral anticoagulant therapy.

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Fig 1.

Timing and incidence of permanent pacemaker (PPM) insertion by procedure performed. (AVR = aortic valve replacement; CABG = coronary artery bypass grafting; CMIV = Cox-maze IV; MVR = mitral valve repair/replacement.)

Fig 2.

Logistic regression curve showing the relationship between patient age and probability of postoperative permanent pacemaker (PPM) placement (Pr[PPM]) with 95% confidence intervals.

Table 1

Procedures Performed

Procedure	% (n)
Lone CMIV	33 (112/340)
Concomitant MVR	43 (146/340)
Concomitant CABG	10 (35/340)
Concomitant AVR	10 (33/340)
Concomitant Other	4 (14/340)

AVR = aortic valve replacement; CABG = coronary artery bypass grafting; CMIV = Cox-maze IV; MVR = mitral valve repair/replacement.

Table 2

Baseline Characteristics of Patients Undergoing the Cox-Maze IV Operation

Variable	No PPM % (n) ^a	PPM % (n) ^a	<i>p</i> Value
Age (years)	61 ± 12 (296)	71 ± 9 (44)	<0.0001
BMI	30 ± 7 (296)	28 ± 7 (44)	0.18
Female	35 (104/296)	47 (21/44)	0.13
Duration of AF (months)	70 ± 76 (288)	66 ± 80 (44)	0.74
Paroxysmal AF	39 (114/295)	30 (13/44)	0.32
Persistent AF	61 (181/295)	70 (31/44)	0.32
Preoperative EF (%)	51 ± 13 (296)	54 ± 9 (44)	0.21
Preoperative LA size (cm ± SD)	5.3 ± 1.2 (293)	5.0 ± 1.1 (42)	0.051
Previous failed ablation	24 (61/259)	14 (5/36)	0.28
Diabetes	16 (46/296)	27 (12/44)	0.08
NYHA Class III or IV	48 (143/296)	45 (20/44)	0.75
Hyperlipidemia	55 (162/296)	54 (24/44)	0.99
Hypertension	63 (184/292)	71 (31/44)	0.40
Prior MI	11 (32/296)	9 (4/44)	0.99
Prior stroke	11 (32/296)	11 (5/44)	0.99
Chronic lung disease	19 (56/296)	18 (8/44)	0.99
Renal failure	3 (8/296)	7 (3/44)	0.16
Peripheral vascular disease	9 (26/296)	20 (9/44)	0.03
Smoker	44 (131/296)	48 (21/44)	0.75

^aUnless otherwise stated.

AF = atrial fibrillation; BMI = body mass index; EF = ejection fraction; LA = left atrial; MI = myocardial infarction; NYHA = New York Heart Association; PPM = permanent pacemaker; SD = standard deviation.

Table 3

Indications for PPM Insertion

Indication	% (n)
<u>Initial indication for placement</u>	
SA node dysfunction	68 (30/44)
AV node dysfunction	20 (9/44)
Combined SA + AV node dysfunction	11 (5/44)
<u>Pacing support 20% at last follow-up</u>	
Continued requirement	84 (37/44)
Pacer no longer needed	7 (3/44)
Unknown	9 (4/44) ^a

^aDeceased (2), lost to follow-up (2).

AV = atrioventricular; PPM = permanent pacemaker; SA = sinoatrial.

Table 4

Univariate Analyses with 1 Year PPM Endpoint

Variable	Odds Ratio	95% CI	p Value
Age	1.10	1.06–1.14	<0.001
Peripheral vascular disease	2.67	1.16–6.16	0.02
Concomitant cardiac surgical procedure	2.08	0.96–4.49	0.06
DM	2.04	0.98–4.25	0.06
Gender	1.69	0.89–3.19	0.11
Persistent AF	1.50	0.75–2.99	0.25
EF	1.02	0.99–1.05	0.21
Duration of AF	0.99	0.99–1.00	0.74
NYHA Class III/IV	0.89	0.47–1.68	0.72
Prior MI	0.83	0.28–2.46	0.73
LA size	0.80	0.59–1.05	0.11

AF = atrial fibrillation, CI = confidence interval; DM = diabetes mellitus, EF = ejection fraction, LA = left atrium; MI = myocardial infarction, NYHA = New York Heart Association; PPM = permanent pacemaker.