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Incremental Risk of the Cox-Maze IV Procedure for Patients with Atrial Fibrillation Undergoing Mitral Valve Surgery

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Abstract

Objective—Over 50% of atrial fibrillation surgery occurs in the setting of mitral valve surgery. Despite this, no risk models have been validated for concomitant arrhythmia surgery. The purpose of this study was to quantify the additional risk of performing the Cox-Maze IV procedure for patients undergoing mitral valve surgery.

Methods—Between January 2002 and June 2011, 213 patients with mitral valve disease and preoperative atrial fibrillation underwent mitral valve surgery only (n=109) or in conjunction with a Cox-Maze IV procedure (n=104). Operative mortality for the mitral valve procedure alone was predicted for each group using the Society of Thoracic Surgeons perioperative risk calculator. The risk attributed to the added Cox-Maze IV procedure was calculated by comparing the predicted mortality rate of an isolated mitral valve procedure and the actual mortality rate of mitral valve surgery with a concomitant Cox-Maze IV procedure.

Results—For patients not undergoing a Cox-Maze IV, the predicted and actual postoperative mortality was 5.5% and 4.6% (5/109), respectively. For patients receiving mitral valve surgery and a concomitant Cox-Maze IV, the predicted and actual postoperative mortality of the mitral valve procedure was 2.5% and 2.9% (3/104), respectively, and not significantly different. Patients not offered a Cox-Maze IV had significantly more serious comorbidites.

Conclusions—For patients with atrial fibrillation and mitral valve disease undergoing mitral valve surgery, the decision to offer a concomitant Cox-Maze IV procedure is influenced by underlying comorbid conditions. Nonetheless, in selected lower-risk patients, the addition of a Cox-Maze IV procedure did not significantly affect the procedural mortality.

Keywords

arrhythmia therapy; MAZE; atrial fibrillation; mitral valve operative risk

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INTRODUCTION

The Cox-Maze procedure was originally designed as a concomitant procedure by Dr. James Cox for the treatment of atrial fibrillation (AF) in patients undergoing mitral valve (MV) surgery. However, both the complexity of the operation and the time required to complete the procedure limited its clinical application to patients with lone AF for many years. After several iterations, the Cox-Maze IV (CMIV) procedure was introduced in 2002. The CMIV simplified the procedure by replacing most of the atrial incisions of the Cox-Maze lesion set with linear lines of ablation, making the operation technically easier and faster to perform (1). With the introduction of ablation devices, the number of surgeries performed in the United States for the correction of atrial fibrillation (AF) has more than doubled (2). Currently, over 80% of these procedures are completed with the assistance of ablation technology, and over 95% are performed as concomitant operations to other cardiac surgical procedures (2).

For patients undergoing cardiac surgery, the prevalence of AF is highest among patients with MV disease. Concordantly, over half of all AF correction surgeries performed each year occur in patients undergoing MV operations (2). Despite the proven efficacy of AF correction surgery in patients with AF undergoing MV surgery, there is a subgroup of patients with AF and concomitant MV disease that is less likely to be offered surgical AF correction (3–5). There are many possible reasons for this omission, but one possibility is that the operating surgeon feels that an additional operative risk is conferred by the AF correction procedure itself. Currently, there are no risk models available for concomitant arrhythmia surgery; as such, the extent of the additional associated risk is poorly defined.

Given these data, the importance of characterizing the additional risk of concomitant AF surgery in this group of patients is critical. The purpose of this study was to quantify the additional risk of performing the CMIV procedure in selected patients undergoing MV surgery.

METHODS

Participants and Procedure

The CMIV procedure has been previously described and was similar for all patients during the study period, with the exception of a “superior connecting lesion” that was added in 2005 (6). This additional lesion connected the right and left superior pulmonary veins, isolating the entire posterior left atrium as part of the “box-lesion set” (6). Of the patients that underwent MV surgery with a concomitant CMIV, 89% (n=92) had a “box lesion set.” Pulmonary vein isolation was confirmed when possible in all patients undergoing a CMIV procedure via demonstration of exit block from each of the pulmonary veins. Confirmation of exit block from the pulmonary veins was not performed in those patients with left atrial appendage thrombus precluding cardioversion, or in patients that were unable to be successfully cardioverted at the time of surgery.

In order to determine the additional risk conferred by the CMIV procedure for patients undergoing MV surgery, operative mortality for the MV procedure alone was predicted for each group using the Society of Thoracic Surgeons (STS) perioperative risk calculator. The risk attributed to the added CMIV procedure was calculated by comparing the predicted mortality rate of an isolated MV procedure and the actual mortality rate of MV surgery with a concomitant CMIV procedure. Late death was defined as all-cause mortality occurring at a median follow-up of 2.3 and 3.3 years (IQR 1.2–5.2 and 1.8–6.2 years) for the patients

undergoing isolated MV surgery and MV surgery with a concomitant CMIV, respectively, as determined by individual patient follow-up via the Social Security Death Index.

This study was approved by the Washington University School of Medicine institutional review board. Informed consent and permission for release of information were obtained from each participant.

Statistical Analysis

Continuous variables are expressed as mean ± standard deviation or as median with intra-quartile range (IQR: 25%–75%) where data is not normally distributed. Categorical variables are expressed as frequencies and percentages. Categorical outcomes are compared by using either the X^2 or Fisher exact test. Continuous outcomes are compared by using the *t* test for means of normally distributed continuous variables and Wilcoxon rank-sum nonparametric test for skewed distributions.

Significant covariates identified by univariate analysis ($p \leq 0.10$) or covariates deemed clinically relevant were entered into a multivariate binary logistic regression analysis. Twelve preoperative and perioperative variables were evaluated by multivariate analysis to identify predictors of 30-day mortality and late death; these included age, preoperative renal failure, diabetes mellitus, COPD, previous MI, hypertension, hyperlipidemia, CVD, previous CVA, prior CABG, prior valve surgery, and concomitant CMIV procedure. All data analyses were done using SPSS (SPSS 20.0 for Windows; SPSS Inc, Chicago, Ill).

RESULTS

From January 2002 through June 2011, 213 patients with preoperative AF and concomitant MV disease underwent MV surgery only (n=109), or in conjunction with a CMIV procedure (n=104).

Although patients in the two groups were similar with regard to age, gender, NYHA classification and preoperative ejection fraction, the groups differed with respect to several comorbidities (Table 1). Patients in whom a concomitant CMIV was not performed were more likely to have renal failure ($p<0.01$), diabetes mellitus ($p=0.02$), COPD ($p<0.01$), hyperlipidemia ($p=0.01$), previous MI ($p<0.01$), previous CVA ($p<0.01$), and previous CABG or valve surgery ($p<0.01$). The increased comorbidities in this group were reflected in a predicted STS 30-day mortality score of 5.5%, which was significantly higher than the predicted mortality score of 2.5% for the patients that underwent MV surgery and a concomitant CMIV ($p<0.01$).

The types of MV pathology also differed significantly between the two groups (Table 2). The distribution of the etiology of MV disease was skewed for patients undergoing MV surgery with concomitant CMIV, favoring etiologies such as rheumatic heart disease, mitral stenosis, annular dilatation, and degenerative disease. Conversely, the distribution of the etiology of MV disease for patients in the isolated MV surgery group was skewed to reflect a history of endocarditis and ischemic disease ($p<0.01$). Despite the difference in etiology of MV disease, the two groups were similar with regard to the coexistence of pulmonary hypertension with their MV dysfunction (69% vs 63%, $p=0.39$).

Of patients that underwent MV surgery with a concomitant CMIV, 41% had paroxysmal AF, 16% had persistent AF, and 43% had long-standing persistent AF. Eleven percent of patients in this group had a previous failed catheter ablation. The mean duration of AF in this group was 60.2 ± 89.4 months. Unfortunately, the AF history of patients not offered a CMIV was not well characterized with respect to AF type and duration.

The MV procedures performed were similar between groups (p=0.17), as was the use of bioprosthetic valves in the case of MV replacement surgery (p=0.55, Table 3). The aortic cross clamp and cardiopulmonary bypass times were significantly longer in patients undergoing MV surgery with a concomitant CMIV procedure (93 ± 23 and 187 ± 40 minutes) than in patients that underwent isolated MV surgery (80 ± 35 and 126 ± 60 minutes, respectively, p<0.01). Importantly, the amount of additional cross clamp time required to perform the CMIV was minimal, averaging only 13 minutes between the two groups. Isolated MV patients were more likely to require an intraoperative or postoperative balloon pump (p=0.02), while other perioperative features, such as surgical status, and the presence of thrombus in the left atrial appendage were no different between groups.

Postoperatively, the MV surgery and concomitant CMIV group required fewer blood products (p<0.01). However, there were no differences in postoperative outcomes with regard to rates of stroke, reoperation for bleeding, postoperative renal failure, and length of stay in the ICU (Table 4). The patients that underwent MV surgery with a concomitant CMIV procedure experienced more early atrial tachyarrhythmias (p<0.01) than did patients who underwent isolated MV surgery.

The observed 30-day mortality in patients not offered a CMIV procedure at the time of their MV surgery was 4.6% (expected 5.5%), yielding an observed/expected 30-day mortality ratio of 0.84 (95% CI 0.13–1.54) in this group. The observed 30-day mortality in patients undergoing MV surgery with a concomitant CMIV was 2.9%. The STS predicted score for isolated MV surgery in this group was 2.5%. The resultant observed/expected 30-day mortality ratio was 1.16 (95% CI 0.13–2.44), and not statistically significant.

By multivariate analysis, the only significant predictor of 30-day mortality for either group was age. However, at a median follow-up of 2.3 and 3.3 years (IQR 1.2–5.2 and 1.8–6.2 years for patients undergoing isolated MV surgery and MV surgery with a concomitant CMIV, respectively), age, COPD, CVD, previous MI, and renal failure were found to be significant predictors of late death. Interestingly, the addition of a concomitant CMIV procedure was identified as protective from late death, and this trend nearly reached statistical significance (p=0.06).

In patients with AF that received a concomitant CMIV procedure at the time of MV surgery, freedom from AF and atrial tachyarrhythmias was 85%, 91%, and 84% at 3, 6, and 12 months, respectively. Freedom from AF and atrial tachyarrhythmias off of anti-arrhythmic medications in this population was 54%, 77%, and 77% at 3, 6, and 12 months, respectively.

COMMENTS

There has been a substantial increase in arrhythmia surgery in recent years due to both the increase in AF frequency in our aging population, and the introduction of ablative technologies that make AF correction procedures easier to perform. Since AF correction procedures are most commonly performed as concomitant operations to other cardiac surgery, the ability to determine the incremental risk incurred by a concomitant AF correction surgery is an important component of surgical decision-making, and counseling of the surgical patient.

In our series, patients who were not offered a concomitant CMIV at the time of their MV surgery were generally sicker, having more comorbidities than those in whom a CMIV was performed. There was a paucity of data characterizing the type of AF that these patients experienced preoperatively, and this is a recognized weakness of this study. Not surprisingly, both the observed and expected risks of 30-day mortality were higher for these

higher-risk patients than the observed and expected mortality rates in those lower-risk patients that received a concomitant CMIV procedure.

The STS perioperative risk calculator, the use of which is becoming more commonplace in clinical trials and other arenas, was accurate in predicting risk for this population of patients (7). This risk calculator has previously been validated in patients undergoing isolated mitral valve procedures, as well as in patients undergoing other cardiac surgical procedures, most notably aortic valve surgery (8, 9). Despite the multiple comorbidities present in these patients, the only predictor in the higher-risk isolated MV surgery group for 30-day mortality on multivariate analysis was age, which is consistent with reported series of MV procedures (10).

The principle finding of this investigation is that, for properly selected patients at an experienced center, the addition of a CMIV procedure to MV surgery did not add any incremental risk to the patients. In this study, the observed 30-day mortality for patients undergoing a concomitant CMIV procedure was not different than that predicted for isolated MV surgery in these patients. While the CMIV procedure did require an increase in CPB time and a small increase in ischemic time, no additional quantifiable risk with respect to death, stroke, or major postoperative morbidity could be identified. The only increased postoperative morbidity associated with this group was the presence of early atrial tachyarrhythmias, which is common in patients undergoing a CMIV procedure, and has been shown to have no demonstrable effect on the late recurrence of AF (11).

The findings of this investigation are consistent with other published reports regarding the additional risk of concomitant arrhythmia surgery performed at the time of MV surgery (2, 3, 12). However, unlike previous reports, this study was the first to examine the impact of a single arrhythmia procedure, the CMIV procedure, on perioperative morbidity and mortality when performed at the time of MV surgery. Other reports have been hampered by the fact that “arrhythmia surgery” is often an amalgamation of a wide variety of procedures ranging from pulmonary vein isolation to a traditional cut and sew Cox-Maze III, each with a very distinct risk and benefit profile. Additionally, this series is unique in that the cohorts were homogeneous with respect to valvular heart disease, and described only patients undergoing isolated mitral valve surgery. The only surgical variable in this study was the presence or absence of a concomitant CMIV procedure.

A recognized weakness of this study was that the group of patients with AF that received a concomitant CMIV was a selected lower-risk population. The lesser extent to which the these patients suffered from preoperative comorbid conditions is reflected in the treatment assignment bias evident in this study, whereby the operating surgeon made a decision that these patients should be able to tolerate the additional surgical time and manipulation incurred by a concomitant CMIV procedure. The judgment and skill of an experienced mitral valve and arrhythmia surgeon cannot be underestimated, and is perhaps most responsible for the low morbidity and mortality demonstrated in this series.

It is likely that the incorporation of ablation technology is also largely responsible for the lack of increased risk demonstrated in this series of concomitant CMIV patients. Ablation technology simplifies the technical aspects of performing the Cox-Maze lesion set and reduces procedural cross clamp and cardiopulmonary bypass times when compared to the traditional Cox-Maze III procedure (13). Fewer incisions are required, minimizing bleeding complications, and newer technologies allow for minimal collateral tissue damage, if correctly applied (14–17). Lastly, MV surgery is particularly well-suited for the addition of a CMIV procedure, as compared to coronary artery bypass grafting or aortic valve procedures. Performing a concomitant CMIV procedure at the time of MV surgery is relatively

straightforward and does not require changes in surgical strategy, as the atrial incisions and cannulation sites for cardiopulmonary bypass are not necessarily different from those required for an isolated MV procedure.

The number of patients with AF and concomitant MV disease continues to increase as the population ages, and represents a group of patients that may derive substantial benefit from surgical AF correction. The benefits of AF correction surgery include fewer bleeding complications from chronic anticoagulation, and a decreased risk of thromboembolism and subsequent stroke(18). Moreover, it has been shown in several studies that patients with AF and concomitant MV disease are unlikely to experience a return to normal sinus rhythm after MV surgery alone (3, 5). In contrast, the efficacy of the CMIV procedure in these patients is excellent, with freedom from AF and atrial tachyarrhythmias of 85%, 91%, and 84% at 3, 6, and 12 months in this series, respectively. Freedom from AF and atrial tachyarrhythmias off of anti-arrhythmic medications in this population was 54%, 77%, and 77% at 3, 6, and 12 months, respectively.

Although not demonstrated in this series, the CMIV procedure does have its own attendant risks; namely, the higher rate of permanent pacemaker implantation in patients receiving a concomitant CMIV at the time of MV surgery (2). However, the benefits of restoration of sinus rhythm, and the consequential diminutive risk of chronic anticoagulation or stroke likely outweigh these risks (12, 18–20). Additionally, although it did not reach significance in this study, the addition of a CMIV procedure to MV surgery in select patients was associated with being protective against late death.

In conclusion, for select low-risk patients, the addition of a concomitant CMIV procedure does not appear to increase operative risk above that expected for MV surgery alone, and produces a high degree of freedom from AF and antiarrhythmic medications in these patients. While the decision to offer a concomitant CMIV procedure at the time of MV surgery appears to be primarily influenced by underlying comorbid conditions, the remaining question is whether a concomitant CMIV procedure should be offered to a wider population of higher-risk patients with AF and MV disease. In this series, the only predictor of 30-day mortality in the isolated MV group was age, which may represent the highest-risk group. These data suggest that there might be an advantage to the addition of a concomitant CMIV procedure in younger patients, despite other comorbidities.

There are several recognized limitations of this study. As mentioned previously, the type and duration of AF in patients that were not offered a concomitant CMIV procedure at the time of their MV surgery were not well characterized; thus, it is unknown whether the preoperative AF burden was comparable between groups. Additionally, this was a single-center retrospective review incorporating cases performed by 2 principle surgeons, both with substantial experience in mitral valve and arrhythmia surgery. Furthermore, the focus of this investigation was 30-day morbidity and mortality. Longer followup on a broader group of patients with AF and MV disease is needed in order to fully characterize the additional risk and benefit of performing the CMIV procedure in this group of patients at the time of MV surgery.

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Table 1

Demographics

	Lone MV	MV + CMIV	*p*-value
	N=109	N=104	
Age (years)	65.6 ± 13.2	63.5 ± 11.8	0.21
Gender (female)	53 (49%)	57 (55%)	0.41
NYHA Class III or IV	84 (77.1%)	74 (71%)	0.35
Ejection Fraction (%)	50 ± 14	51 ± 11	0.17
Renal failure	12 (11%)	1 (1%)	<0.01
Diabetes	29 (27%)	14 (14%)	0.02
COPD	41 (38%)	20 (19%)	<0.01
Hyperlipidemia	63 (58%)	42 (40%)	0.01
Previous MI	30 (28%)	4 (4%)	<0.01
Previous CVA	20 (18%)	5 (5%)	<0.01
Previous CABG	22 (20%)	3 (3%)	<0.01
Previous valve operation	44 (40%)	12 (12%)	<0.01
Predicted STS Operative Mortality (%)	5.5 ± 5.2	2.5 ± 1.9	<0.01

Abbreviations: CMIV, Cox-Maze IV; COPD, chronic obstructive pulmonary disease; CABG, coronary artery bypass graft; CVA, cerebral vascular accident; MI, myocardial infarction; MV, mitral valve; NYHA, New York Heart Association; STS, Society of Thoracic Surgeons.

Table 2

Valve Pathology

	Lone MV	**MV + CMIV**	***p*-value**
	N=109	**N=104**	
Mitral Valve Disease Etiology			<0.01
Calcific	2 (2%)	5 (5%)	
Endocarditis	15 (14%)	1 (1%)	
Myxomatous	32 (30%)	42 (41%)	
Rheumatic	20 (18%)	34 (33%)	
Prosthetic valve failure	18 (17%)	5 (5%)	
Annular Dilatation	7 (6%)	17 (16%)	
Ischemic	15 (14%)	0	
Mitral Stenosis	24 (22%)	37 (36%)	0.03
Pulmonary hypertension	75 (69%)	65 (63%)	0.39

Abbreviations: CMIV, Cox-Maze IV; MV, mitral valve.

Table 3

Perioperative details

	Lone MV	MV + CMIV	*p*-value
	N=109	**N=104**	
Urgent/emergent procedure	3 (3%)	1 (1%)	0.62
Required IABP intra/post op	15 (14%)	4 (4%)	0.02
MV Replacement	60 (55%)	47 (45%)	0.17
Bioprosthetic replacement valve	40 (67%)	28 (60%)	0.55
Aortic cross clamp time (min)	80 ± 35	93 ± 23	<0.01
CPB time (min)	126 ± 60	187 ± 40	<0.01
LAA thrombus	0/109 (0%)	4/104 (4%)	0.06
Lesion set			
Box	N/A	82/104 (89%)	
Non-box		12/104 (12%)	

Abbreviations: CBP, cardiopulmonary bypass; CMIV, Cox-Maze IV; IABP, intraoperative aortic balloon pump; LAA, left atrial appendage; MV, mitral valve.

Table 4

Postoperative morbidity

	Lone MV	MV + CMIV	*p*-value
	N=109	N=104	
Operative Mortality	5 (5%)	3 (3%)	0.72
Stroke	2 (2%)	1 (1%)	0.99
Pneumonia	19 (17%)	10 (10%)	0.11
Ventilation time (hours)	20 (IQR: 11–49)	17 (IQR: 6–42)	0.09
Required reintubation	9 (8%)	6 (6%)	0.60
Reoperation for bleeding	9 (8%)	4 (4%)	0.25
Postoperative blood products	85 (78%)	58 (56%)	<0.01
Deep sternal wound infection	1 (1%)	0	0.99
Renal failure	8 (7%)	8 (8%)	0.99
Heart block	2 (2%)	6 (6%)	0.16
Early atrial tachyarrhythmias	10 (9%)	62 (60%)	<0.01
Postoperative pacemaker placement	5/80 (6%)	11/96 (11%)	0.30
Length of stay in ICU (hours)	79 (IQR: 45–143)	73 (IQR: 44–129)	0.40

Abbreviations: CMIV, Cox-Maze IV; ICU, intensive care unit; MV, mitral valve.