# Prospective Assessment of the CryoMaze Procedure With Continuous Outpatient Telemetry in 136 Patients

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*Background.* **Only 40% of patients with atrial fibrillation (AF) undergoing cardiac surgery are treated with surgical AF correction. We prospectively studied endocardial cryoablation of the Cox-maze III lesion set following prespecified rhythm assessment with outpatient telemetry.**

*Methods.* **Between 2007 and 2011, 136 patients underwent surgical AF correction using an argon-powered cryoablation device. Patients wore continuous electrocardiogram monitoring prior to and at 6, 12, and 24 months after surgery. The average length of monitoring was 6.5 ± 1 days prior to surgery and 11 ± 4 days at each time point after surgery. Patients were assessed for cardiac rhythm, interval cardioversion or ablation procedures, pacemaker placement, and the use of warfarin or antiarrhythmic medications. The primary endpoint of this study was freedom from AF at 1 year.**

*Results.* **Mean patient age was 66 ± 12 years, 50% (69 of 138) were male and 41% (55 of 134) had persistent AF. CryoMaze was done in conjunction with mitral valve operation in 95% (131 of 138) or other procedures in 41% (56 of 138). Follow-up was 96% complete at 1 year and 90% at 2 years. Freedom from AF was 76% at 1 year. Perioperative mortality and stroke rates were both 1.5% (2 of 138). Perioperative pacemaker implantation was required in 7% (9 of 136). In univariate analysis, younger age, female gender, decreased height and weight, smaller preoperative and postoperative left atrial diameter, intermittent AF, and freedom from AF at discharge were associated with freedom from AF at 1 year. Actuarial 2- and 4-year (Kaplan-Meier) survival were 93% and 80%, respectively.**

*Conclusions.* **The CryoMaze procedure is safe and is associated with 76% freedom from AF at 1 year.**

**(Ann Thorac Surg 2013;■:■–■)**


Approximately 12% of patients referred for cardiac surgery have atrial fibrillation (AF). Despite small randomized trials demonstrating higher rates of freedom from AF in treated patients and multiple observational series showing low risk of stroke, only 40% of patients with AF having cardiac surgery undergo AF correction operation [1, 2]. Addition of AF ablation to other cardiac operations does not increase the risk of stroke or death [1, 3–6]. Freedom from anticoagulation, antiarrhythmic medications, and reduced stroke risk have translated to improved quality of life and decreased mortality [7, 8].

Previous studies are limited by small patient numbers, mixed lesion sets, mixed energy sources, and reliance on static and inaccurate assessments of heart rhythm, such as electrocardiogram (ECG) or patient symptoms [9–12], accounting for heterogeneity of results with rates of freedom from AF being reported anywhere from 50% to 98%.

We have previously reported retrospective data demonstrating the safety and efficacy of the CryoMaze procedure [6]. In that experience, we performed a partial, epicardial right atrial ablation in 48% (57 of 119) of patients and did not perform an external direct coronary sinus ablation [6]. The present series represents our most contemporary experience and is characterized by its prospective nature, uniform rhythm follow-up using mobile continuous outpatient telemetry (MCOT), and uniform lesion set of right and left atrial endocardial lesions as defined in the original cut-sew Cox Maze III procedure [13, 14].

The aim of this study is to report prospective single center, long-term outcomes of the Cox III CryoMaze procedure using extended rhythm assessment methods.

## Patients and Methods

### *Sample Selection*

Between 2007 and 2011, 165 patients underwent the CryoMaze procedure at the University of Maryland Medical Center (Fig 1). Patients had a preexisting clinical diagnosis of AF and were classified according to 2012 American College of Cardiology Foundation/American Heart Association/

Accepted for publication Oct 11, 2013.

Presented at the Fifty-ninth Annual Meeting of the Southern Thoracic Surgical Association, Naples, FL, Nov 7–10, 2012.

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Dr Gammie discloses a financial relationship with CardioNet, Inc.



0003-4975/$36.00
http://dx.doi.org/10.1016/j.athoracsur.2013.10.041

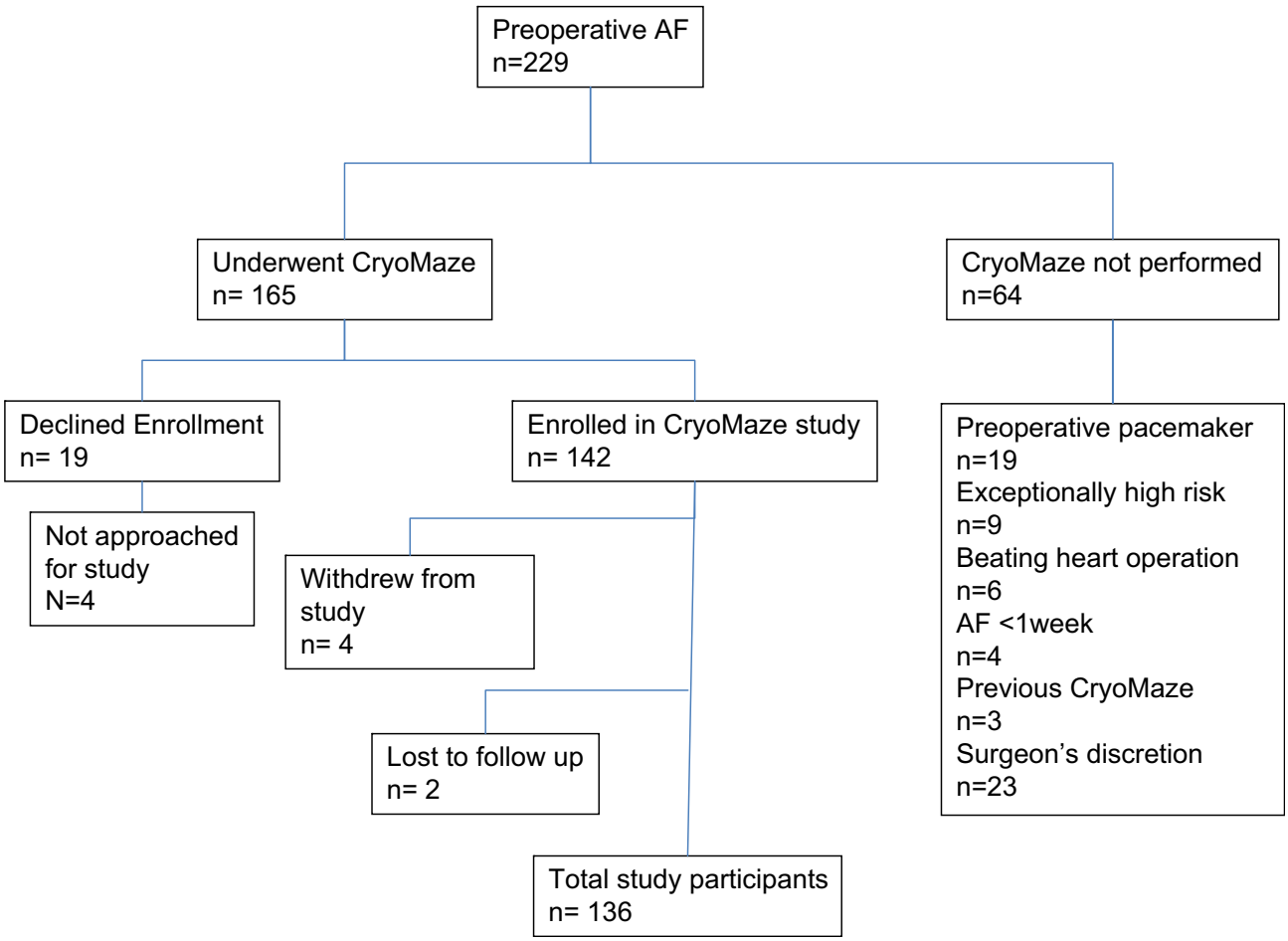


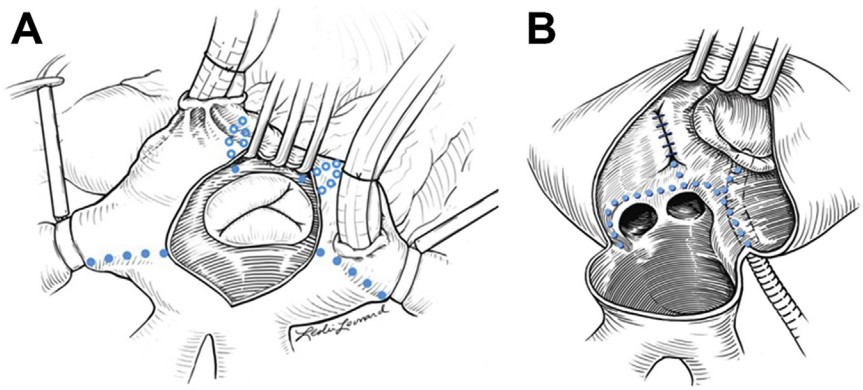

*Fig 1. CryoMaze patient population at The University of Maryland. (AF = atrial fibrillation.)*

Heart Rhythm Society (ACCF/AHA/HRS) Guidelines for the Management of Patients with Atrial Fibrillation [15]. This study was approved by the Institutional Review Board and consent was obtained prior to enrollment.

### *CryoMaze Procedure*

The CryoMaze procedure employed the classic Cox-maze III lesion set (13) (Fig 2). The only exception was the omission of the atrial septal lesion, which was secondary to surgeon preference. CryoMaze was always performed before valve operations. An argon-powered cryoprobe (SurgiFrost 10; ATS Inc, Minneapolis, MN) was used to ablate all atrial lesions which were performed on the arrested heart. Through an incision in the free wall of the right atrium (RA), endocardial cryolesions were created from the incision to the superior vena cava and the

*Fig 2. Atrial Cox III lesion set used in CryoMaze procedure. (A) = right atrium; (B) = left atrium.*



inferior vena cava taking care to avoid the phrenic nerve and sinoatrial node (Fig 2A). A lesion was performed from the superior aspect of the incision over the roof of the inferior RA and terminating at 1:00 o'clock on the tricuspid valve annulus. Another lesion originated from 11:00 o'clock on the tricuspid valve annulus extending up to the RA appendage.

Next, the left atrial (LA) and mitral valve were exposed through an interatrial incision. The LA appendage was oversewn. A circumferential lesion originating from both ends of the left atrial incision and encircling the pulmonary veins was performed. Additional lesions extending to the LA appendage and the mid portion of the posterior mitral valve annulus were created. The left atrial lesion set was completed with an exterior lesion from the inferior aspect of the left atrial incision externally through the oblique sinus extending to the coronary sinus in the P2 region (Fig 2B). The RA lesions were created with 1 to 1.5 minutes of cryoablation and left with 2 minutes, after which atria defrosted with warm saline.

Postoperative care included β-blockade, aspirin (325 mg), intermittent furosemide, and warfarin titrated to a goal international normalized ratio of 2.0 to 2.5. Postoperative AF was treated with intravenous then oral amiodarone. After surgical follow-up, management of anticoagulation and antiarrhythmic therapy was at the discretion of the primary cardiologist.

### *Data Collection*

Preoperative and perioperative data were prospectively collected using the Society of Thoracic Surgeons National Cardiac Database, as was course and complication data. Patients underwent preoperative MCOT using CardioNet monitors (Conshohocken, PA) for an intended 7 days. This 3-lead electrocardiogram (ECG) monitor acquires data continuously and transiting to a central location.

Postoperative follow up was done through cardiac surgery or cardiology clinic visits. Primary outcomes of interest included freedom from AF, need for catheter-based ablation or cardioversion procedures, warfarin and antiarrhythmic use, pacemaker placement, or incidence of stroke. Patients were asked to follow up and wear a MCOT for 14 days at 6, 12, and 24 months after surgery. All MCOT results were reviewed by a single, blinded electrophysiologist and rhythm was classified as AF if episodes of AF or atrial flutter lasted longer than 30 seconds. When MCOT was unavailable, ECG or pacemaker interrogation was used to assess cardiac rhythm. Freedom from AF was defined as normal sinus, sinus bradycardia, or junctional rhythms. Paced patients without device interrogation indicating AF were classified as free from AF. All patients with a history of preoperative pacemaker placement were excluded from freedom from AF analyses.

### *Statistical Analysis*

Data were analyzed using SAS 9.2 and JMP 8.0 software (SAS Inc, Cary, NC). Variables were examined overall and by freedom from AF or recurrence at 1 year using means and standard deviations for continuous variables and proportions for categoric variables. Categoric variables were compared with $\chi^2$ or Fisher exact tests, while 2-sample $t$ tests or Wilcoxon rank sum tests determined any significant differences in distribution of continuous variables. Kaplan-Meier estimates were done to assess actuarial survival and freedom from AF after CryoMaze. Analysis for effect modification due to patient sex included a Breslow-Day test comparing stratified and crude odds ratios. Logistic regression analysis of clinically relevant factors determined independent predictors of AF recurrence at 1 year. A $p$ value less than 0.05 was considered significant for all tests.

## Results

### *Baseline Demographics*

Between 2007 and 2011, 229 patients with AF had cardiac operations at our institution. Of those, 165 underwent CryoMaze and 142 were enrolled in the study (Fig 1). Of the 64 patients (28%) not offered CryoMaze, 19 had preoperative pacemakers, 4 had AF for less than 1 week, and 3 had had CryoMaze previously. Six patients underwent beating heart operations atrioventricular bypass, transplant, pericardial window) and were not candidates for endocardial ablation. Nine patients were deemed to be very high risk for cardiac surgery, suffering from multisystem organ failure, sepsis, or shock. The remaining 23 patients did not have CryoMaze at the single operating surgeon's discretion.

Mean age of patients was 66 ± 12 years, 50% were male, and 82% white (Table 1). Mean duration of AF was 3.8 ± 5 years and mean $CHADS_2$ [congestive heart failure, hypertension, age > 75, diabetes mellitus, and prior stroke or transient ischemic attack] score was 1.8 ± 1. Forty-one percent had persistent or long-standing persistent AF. Forty-five percent of patients wore MCOT prior to surgery for an average of 4 days. Five percent of the sample had an implanted permanent pacemaker before operation and 30% took antiarrhythmic medication. No standalone CryoMaze procedures were done. Concomitant procedures are shown in Table 2.

### *Morbidity and Mortality*

Perioperative mortality, defined by in-hospital or death within 30 days of surgery, was 1.4%. One patient died of stroke, sepsis, and multisystem organ failure, while another died secondary to pneumonia and gastrointestinal bleeding. There were 5 in-hospital reoperations, 3 for bleeding, 1 for valve dysfunction, and 1 for acute right heart failure. Perioperative strokes causing permanent disability occurred in 3 patients (2.2%). Renal failure occurred in 5 patients (3.6%), 1 requiring dialysis. In-hospital (n = 9) pacemaker placement was required for heart block in 7% of patients. The median length of stay was 8 days. There were 5 readmissions within 30 days of surgery; 2 for pneumonia, 1 pericardial effusion, and 2 deep sternal wound infections.

### *Follow-Up*

At 6 months, 97% of those eligible for follow-up returned to clinic and 95% participated in rhythm assessment. At

*Table 1. Demographics of the CryoMaze Patient Population*

| Characteristics | Total (n = 138) | Freedom from AF at 1 Year[a] 76% (90/118) | AF Recurrence at 1 Year 24% (28/118) | *p* Value |
|---|---|---|---|---|
| Age (years) | 66 ± 12 | 65 ± 11 | 70 ± 12 | 0.05 |
| Height (cm) | 171 ± 11 | 169 ± 11 | 175 ± 10 | 0.01 |
| Weight (kg) | 82 ± 21 | 79 ± 19 | 91 ± 25 | 0.02 |
| Sex | | | | |
| Male | 50% (69/138) | 40% (36/90) | 75% (21/28) | 0.001 |
| Race | | | | |
| White | 82% (113/138) | 83% (75/90) | 89% (25/28) | 0.44 |
| Non-white | 18% (25/138) | 17% (15/90) | 11% (3/28) | |
| Duration AF (years) | 3.86 ± 5 | 3.39 ± 5 | 4.75 ± 5 | 0.19 |
| Type of AF | | | | |
| Paroxysmal | 59% (79/134) | 67% (59/88) | 37% (10/27) | 0.005 |
| Persistent[b] | 41% (55/134) | 33% (29/88) | 63% (17/27) | |
| $CHADS_2$ score | 1.8 ± 1 | 1.75 ± 1 | 2.04 ± 1 | 0.075 |
| History of TIA/CVA | 12% (17/138) | 13% (12/90) | 11% (3/27) | 0.76 |
| Anti-coagulation | 71% (98/138) | 69% (62/90) | 68% (19/28) | 0.91 |
| Warfarin | 60% (83/138) | 59% (53/90) | 61% (17/28) | 0.86 |
| LA diameter (mm) | 49 ± 9 | 48 ± 9 | 52 ± 8 | 0.05 |
| Ejection fraction | 0.52 ± 0.13 | 0.53 ± 0.12 | 0.52 ± 0.10 | 0.31 |

[a] Analysis excludes those with preoperative permanent pacemakers. [b] Includes long-standing persistent. Continuous variables are expressed as a mean ± standard deviation.

AF = atrial fibrillation; $CHADS_2$ = Congestive heart failure, Hypertension, Age >75, Diabetes mellitus, and prior Stroke or transient ischemic attack; LA = left atrium; TIA/CVA = transient ischemic attack/cerebrovascular accident.

12 months, 96% returned for clinical follow-up, and 95% participated in rhythm assessment. At 24 months, 90% returned for clinical follow-up and 89% participated in rhythm assessment. The percentage of MCOT use in follow-up decreased with time as seen in Table 3.

### *Primary Outcomes*

Six-month mortality was 2.9%. There were 2 out-patient deaths within 6 months, 1 of which was due to stroke. One year mortality was 5.9%. Overall 4-year actuarial survival was 80%. Four-year survival in those free from AF at 1 year was 86% and 75% in those with AF recurrence ($p = 0.77$). Table 4 demonstrates 3% of patients suffered a stroke within the first 6 months after CryoMaze. Additionally, 9% required pacemaker placement within 6 months (9 in-hospital, 3 after discharge).

Thirteen percent of patients were in AF at the time of dismissal (Table 4). Freedom from AF was 74% at 6 months, 76% at 12 months and 79% at 24 months after CryoMaze. Freedom from AF in patients not taking antiarrhythmic medications at 1 year was 77%. Actuarial freedom from AF is shown in Figure 3. The freedom from AF at 1 and 2 years was 86% and 90% in patients with paroxysmal AF and 63%, and 64% in those with persistent AF. With patients in AF during follow-up, the majority were in paroxysmal rather than persistent AF at 77%, 78%, and 81% at 6, 12, and 24 months, respectively.

*Table 2. Procedures Performed With CryoMaze*

| Concomitant Procedures | Total n = 138 (%) |
|---|---|
| Isolated mitral: | 59 (82/138) |
| Mitral: | |
| + Tricuspid | 19 (26/138) |
| + CABG | 9 (12/138) |
| + Tricuspid + CABG | 3 (4/138) |
| + AVR | 2 (3/138) |
| + Tricuspid + AVR | 2 (2/138) |
| + AVR + CABG | 2 (2/138) |
| Isolated CABG: | 3 (4/138) |
| Isolated tricuspid: | 2 (2/138) |
| + AVR | 1 (1/138) |

AVR = aortic valve replacement; CABG = coronary artery bypass grafting.

*Table 3. Follow-Up Among CryoMaze Patients*

| Variable | 6 Months (%) | 12 Months (%) | 24 Months (%) |
|---|---|---|---|
| Rhythm assessment | 95 (125/132) | 95 (122/128) | 89 (77/87) |
| MCOT | 75 (95/125) | 66 (80/122) | 56 (43/77) |
| EKG | 21 (26/125) | 32 (39/122) | 39 (30/77) |
| PM interrogation | 3 (4/125) | 3 (3/122) | 5 (4/77) |
| Clinical follow-up | 99 (131/132) | 96 (123/128) | 90 (78/87) |

EKG = electrocardiogram; MCOT = mobile cardiac outpatient telemetry; PM = pacemaker.

*Table 4. Primary Outcomes Among CryoMaze Patients Eligible for Follow-Up*

| Variable | At Discharge (%) | 6 Months (%) | 12 Months (%) | 24 Months (%) |
|---|---|---|---|---|
| Freedom from AF[a] | 87 (112/129) | 74 (90/122) | 76 (90/118) | 79 (59/75) |
| AF | 13 (17/136) | 28 (35/125) | 23 (28/122) | 21 (16/77) |
| NSR | 77 (105/136) | 62 (77/125) | 62 (75/122) | 65 (50/77) |
| JR | 0 | 1 (1/125) | 3 (4/122) | 1 (1/77) |
| Paced | 10 (14/136) | 10 (12/125) | 12 (15/122) | 13 (10/77) |
| Ablation | 0 | 2 (3/130) | 3 (4/123) | 4 (3/78) |
| Cardioversion | 0 | 6 (8/131) | 4 (5/123) | 1 (1/78) |
| Coumadin use | 90 (123/136) | 85 (111/130) | 62 (76/123) | 46 (36/78) |
| Antiarrhythmic use | 23 (31/136) | 20 (26/130) | 12 (15/123) | 19 (15/78) |
| Pacemaker placement[b] | 7 (9/136) | 9 (12/131) | 4 (5/123) | 3 (2/78) |
| Stroke[b] | 2.2 (3/137) | 0.8 (1/131) | 0 | 1 (1/79) |

[a] Patients with preoperative permanent pacemaker are excluded for freedom from AF analysis. [b] Indicated new pacemaker placement or stroke within stated time period.

AF = atrial fibrillation; JR = junctional rhythm; NSR = normal sinus rhythm.

Warfarin and antiarrhythmic use significantly decreased over the follow-up period (Table 4). Although management was left at the cardiologists' discretion, anticoagulation and antiarrhythmics were generally discontinued in those free from AF at any time point.

Catheter-based ablations and cardioversions for recurrent AF are shown in Table 4. Of patients with rhythm assessment available after catheter ablation, 75% (6 of 8) were successful in establishing normal sinus rhythm. Forty percent (4 of 10) of patients with rhythm assessment available after cardioversion maintained normal sinus rhythm.

### *Univariate Analysis*

Age, height, weight, sex, type of AF, LA, and LV diameter, and freedom from AF at discharge and 6 months were associated with freedom from AF at 1 year (Tables 1, 5). Freedom from AF at 1 year was more common with decreased age, height, weight, LA diameter, female sex, and paroxysmal AF. Patients with paroxysmal AF rather than persistent AF were more likely to be free of AF at 1 year with an odds ratio of 0.29. Those with AF recurrence at discharge or 6 months had over 5 times odds of AF recurrence at 1 year. Similarly to preoperative LA diameter, 1 year LA and left ventricle size was predictive of freedom from AF, demonstrating smaller cardiac dimensions protected against AF.

### *Multivariate Analysis*

With logistic regression modeling for freedom from AF at 1 year, only sex, LA diameter, and freedom from AF at discharge significantly predicted outcome while controlling for other factors (Table 6).

## Comment

Key findings of this study include a low perioperative morbidity and mortality associated with the CryoMaze procedure performed concomitantly with other cardiac operations and a 2-year freedom from AF of 79%. Confirming the safety of the procedure, the results of this study highlight important considerations regarding CryoMaze. The success rate of the procedure is favorable and supports the addition of the CryoMaze as a useful adjunct to patients with AF undergoing cardiac operations [3, 5, 16].

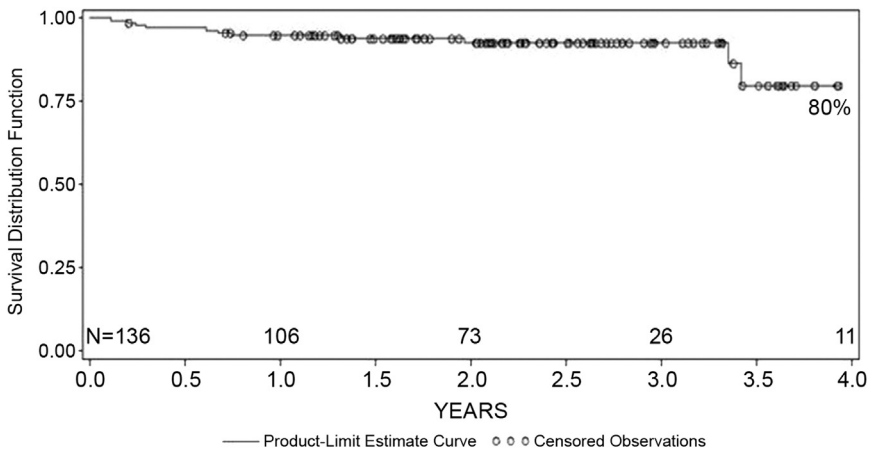



*Fig 3. Kaplan-Meier survival after CryoMaze procedure.*

*Table 5. Predictors of Freedom From AF at 1 Year Among CryoMaze Patients*

| Predictors | Total n = 138 | Freedom From AF 76% (90/118) | AF Recurrence 24% (28/118) | *p* Value[a] |
|---|---|---|---|---|
| Procedure type | | | | |
| Mitral | 95 (131/138) | 94 (85/90) | 93 (2/28) | 0.66 |
| Tricuspid | 25 (35/138) | 21(19/90) | 32 (9/28) | 0.23 |
| CABG | 16 (22/138) | 17 (15/90) | 14 (4/28) | 1.0 |
| AVR | 6 (8/138) | 7 (6/90) | 4 (1/28) | 1.0 |
| Left atrial appendage oversewn | 96 (133/138) | 97 (87/90) | 93 (26/28) | 0.59 |
| Length of stay (days) | 9.9 ± 10 | 8.7 ± 5 | 8.3 ± 3 | 0.71 |
| Freedom from AF at discharge | 87 (112/129) | 93 (84/90) | 71 (20/28) | 0.002 |
| Freedom from AF at 6 months | 74 (90/122) | 82 (71/87) | 44 (12/27) | 0.001 |
| Ablation at 6 months | 2 (3/130) | 2 (2/89) | 0 | 0.62 |
| Cardioversion at 6 months | 6 (8/131) | 22 (2/90) | 7 (2/90) | 0.39 |
| Antiarrhythmics at 6 months | 20 (26/130) | 21 (19/90) | 7 (2/28) | 0.09 |
| Ejection fraction at 1 year | 0.56 ± 0.09 | 0.56 ± 0.09 | 0.55 ± 0.10 | 0.81 |
| LV end diastolic dimension at 1 year (mm) | 48 ± 6 | 47 ± 6 | 51 ± 7 | 0.02 |
| LA diameter at 1 year (mm) | 46 ± 9 | 45 ± 7 | 51 ± 12 | 0.004 |
| Mitral insufficiency at 1 year[a] | 18 (20/112) | 15 (12/78) | 22 (6/27) | 0.55 |

[a] Includes mild, moderate, and severe.

AF = atrial fibrillation; AVR = aortic valve replacement; LA = left atrium; LV = left ventricle.

An additional benefit of the CryoMaze is avoidance of long-term oral anticoagulant use.

Established risk factors for recurrent AF after CryoMaze, including age, male sex, LA size, and persistent AF [17], were confirmed in this experience. While duration of AF is seen as a risk factor in other studies [18, 19] , we did not find this to be statistically significant. Height and weight were significant factors, with larger patients carrying an increased risk of AF recurrence. While this trend has been observed previously [20], the underlying mechanism is unclear as the effects of height were not significantly modified by sex. Additionally, the effects of LA size were not modified by height and weight in a stratified analysis.

Additional factors for long-term freedom from AF established include freedom from AF at discharge and 6 months, demonstrating success of the CryoMaze procedure is related to establishment of sinus rhythm in the early postoperative course. While the 2012 HRS guidelines [15] identify the 6 to 12 month time period as the most vulnerable for AF recurrence and catheter-based AF ablation series show progressive recurrence of AF over time, we have demonstrated consistent rates of freedom from AF over time.

Success rates for AF ablation procedures are influenced by the sensitivity of methods used to determine heart rhythm. Original studies based on reported symptoms of AF reported 98% AF cure [11, 21] while more recent studies using ECG or 24-hour monitoring report success rates between 80% and 95% [3, 17]. We performed postoperative heart rhythm assessment using MCOT for an average of 11 days and believe this provides the greatest sensitivity for detecting episodes of AF. Stroke risk is not related to AF burden, therefore avoidance of sampling errors using ECG and 24-hour Holter monitoring is important to correctly diagnose post-CryoMaze AF.

Ad and colleagues [22] reported the sensitivity of different rhythm assessment methods and found ECG overestimated the success rate of CryoMaze by 12% as compared with longer term monitoring. The MCOT used in this study offers a longer, more accurate examination of rhythm compared with a snapshot ECG or 24-hour Holter assessment. A limitation of MCOT methods is patient compliance as seen in the decrease in average use and an increase ECG assessment with time. Despite the establishment of the improved accuracy of MCOT in diagnosis of AF, when ECG assessments were removed from our analysis, the rate of freedom from AF was not significantly different among those participating in MCOT.

Interestingly, among the 46% of the patients who underwent preoperative MCOT, significant discrepancies existed between clinically reported type and AF burden. Five percent of patients with reported persistent AF had extended periods of normal sinus rhythm on MCOT, while 25% with reported paroxysmal AF had no documented AF in 7 days of MCOT. This finding raises the possibility that clinical and ECG methods of determining the type of AF are over-reporting AF burden. We believe 2-week ECG monitoring represents the "gold standard" for rhythm assessment after surgical AF ablation.

*Table 6. Multivariate Analysis of Freedom of AF at 1 Year*

| Variable | Odds Ratio | 95% CI | *p* Value |
|---|---|---|---|
| Sex (female vs male) | 4.87 | 1.69–16.66 | 0.002 |
| LA Diameter at 1 year | 1.09 | 1.02–1.17 | 0.003 |
| Freedom from AF at discharge | 5.20 | 1.16–26.31 | 0.031 |

AF = atrial fibrillation; CI = confidence interval; LA = left atrium.

In addition to a substantial decrease in AF rates after the CryoMaze procedure we have observed among patients remaining in AF after operation, the rates of persistent AF were lower at all time points (23%, 21%, 19%) compared with the overall rate of persistent AF before operation (41%). This demonstrates that CryoMaze was more effective in those with paroxysmal AF and paroxysmal AF was more common in AF recurrence after CryoMaze. While this could be biased by the greater percentage of preoperative paroxysmal AF patients, the increase from 59% to 78% paroxysmal AF at 1 year illustrates a possibility that the procedure serves to convert cases of persistent to paroxysmal AF.

A strength of this study is the high follow-up rate. Over 89% at all time points surpasses previously reported rates (60% to 80%) in other CryoMaze studies. Additionally, we found significantly higher rates of freedom from AF compared with our previous study. Since reporting freedom from AF of 60%, we have modified our technique to include both endocardial right atrial lesions and an epicardial cryoablation of the coronary sinus. Overall freedom from AF rates increased to 79% in the present study. While evolution of our technique modeling the Cox maze III procedure has improved freedom from AF, these technique changes may have also contributed to a higher incidence of pacemaker implantation (7% vs 3%). In-hospital pacemaker placements were secondary to atrioventricular block (n = 4), symptomatic bradycardia (n = 3), and bradycardia-tachycardia syndrome (n = 2), indicating both sinoatrial and atrioventricular node dysfunction as possible complications of the CryoMaze procedure. However, the exact indication for pacemaker implantation in outpatients was not consistently available in surgical follow-up.

In conclusion, this experience supports the safety of CryoMaze when performed as a concomitant procedure, with a high percentage of patients having stable freedom from AF at 2 years after operation. Compared with our earlier experience, modification of the CryoMaze procedure to include the precise Cox-maze III lesion set in addition to an exterior coronary sinus cryoablation has resulted in substantially higher success rates. Wider application of the CryoMaze procedure to patients with AF presenting for cardiac operations will extend the benefits of this procedure to a wider population.

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## DISCUSSION

**DR JENNIFER SUE LAWTON** (St. Louis, MO): I have no disclosures. Claire, that was a fabulous presentation, great job. You and Dr Gammie should be congratulated for your 2-year follow-up and also for the low morbidity and mortality of your patients, as it wasn't quite clear in your presentation but it was in your manuscript that all of these patients had additional surgery, either mitral valve, aortic valve, or CABG.

I was also pleased that in your manuscript you mentioned the EKG, perhaps as an overestimation of success, as the only rhythm monitoring method used, and over the course of your study, the percentage of patients with only EKG for rhythm monitoring went up to 39%. So based on that, do you now advocate patients get a more permanent monitoring device? That is my first question.

**DR WATKINS:** Yes. I think both in our study and others, it is clear that a snapshot ECG or even a Holter monitor is really too quick an assessment to quantify paroxysmal or persistent atrial fibrillation. You are correct that our use of continuous telemetry declined as the duration from operation increased, and that could very well have resulted in some degree of overestimation of the freedom from atrial fibrillation.

**DR LAWTON:** And did you find that patients just didn't want to wear your monitoring device? Is that the problem?

**DR WATKINS:** Yes, The average number of days wearing the monitor at all time points was 11 to 12 days, which aided in diagnosing paroxysmal AF. We also found that the compliance rate of wearing the monitor declined over time; patients simply refused to do it.

**DR LAWTON:** And my second question is you mentioned in your manuscript that for different areas, and whether it was during beating heart for the right sided lesions, you used different times for the linear cryoprobe freezing and then in your picture you showed using two at once. Could you explain a little bit about how you choose different times and to use two probes?

**DR WATKINS:** I apologize if that was unclear or has changed in the manuscript, but all of our right atrial lesions were one and a half minutes and the left atrial lesions were two minutes. In our previous study, there was some variability in the duration of freezing, but in this study it was more consistent, at one and a half and two minutes.

**DR LAWTON:** And in which lesions did you use two probes?

**DR WATKINS:** We used two probes simultaneously throughout the CryoMaze procedure; using two probes allows us to create the superior and inferior venal caval lesions, the two tricuspid lesions, and two left atrial lesions simultaneously, cutting operative time in half.

**DR LAWTON:** Do you think you get a wider transmural lesion with two?

**DR WATKINS:** No, we just cut down on operative time.

**DR LAWTON:** Thank you.

**DR WATKINS:** Thanks.

**DR VINAY BADHWAR** (Pittsburgh, PA): Congratulations on a fine presentation. The fact that you are following updated guidelines and reporting the longitudinal method of study I think is laudable, and the work that your group has been doing on the CryoMaze is exemplary. I have a few questions. First pertains to the study group. Have you done a subset analysis of looking at outcomes just in the patients that had isolated mitral surgery?

**DR WATKINS:** I did a univariate analysis looking at patients who had mitral procedures, aortic procedures, or coronary revascularization and procedure type did not significantly predict freedom from A fib at one year. However, the vast majority of our patients had multiple procedures done, and 95% included a mitral procedure. So while mitral disease was a major factor in our population, the high degree of concomitant procedures prevents a clear analysis of procedure type as a predictor of A-fib recurrence.

**DR BADHWAR:** Second, in the blanking period between the zero and six month mark, did all patients get amiodarone medical prophylaxis? What is your policy?

**DR WATKINS:** Twenty-three percent of our patients were discharged on amiodarone. Additionally, 87% of patients were in sinus rhythm at discharge. We do not routinely start amiodarone after CryoMaze operation but rather reserve it for patients with recurrent AF. We saw patients a month after operation and then again at six months. At these and all time points, the medical decisions regarding antiarrhythmics and anticoagulation were generally made by the patient's cardiologist. We did recommend to referring cardiologists that both Coumadin and amiodarone be discontinued in patients free from AF.

**DR BADHWAR:** Do you have a time point where you normally stop your antiarrhythmic prophylaxis? Is it up to the cardiologist?

**DR WATKINS:** If patients remained in sinus rhythm after surgery, they were not started on amiodarone as prophylaxis. After hospital discharge, that decision was at their cardiologist's discretion. We encouraged discontinuation of warfarin at 3 months.

**DR BADHWAR:** Finally, just a general question. Have you embarked on a minimally invasive thoracotomy approach to the CryoMaze, since I know this approach is popular for mitral surgery at your institution?

**DR WATKINS:** About twenty percent of our small-incision mitral valve repair experience includes a CryoMaze procedure.

**DR BADHWAR:** Thank you.