Long-term outcomes of minimally invasive surgical ablation for atrial fibrillation: A single-center experience

Aditya Saini, MD,* Yuhning L. Hu, MD,* Vigneshwar Kasirajan, MD,†
Frederick T. Han, MD, FHRS,‡ Muhammad Z. Khan, MBBS,* Luke Wolfe, MS,†
Sampath Gunda, MD, MHA,* Jayanthi N. Koneru, MBBS,* Kenneth A. Ellenbogen, MD, FHRS*

*From the *Division of Cardiology, Pauley Heart Center, Virginia Commonwealth University, Richmond, Virginia, †Division of Cardiac Surgery, Pauley Heart Center, Virginia Commonwealth University, Richmond, Virginia, and ‡Division of Cardiology, University of Utah Health Sciences Center, Salt Lake City, Utah.*

BACKGROUND Minimally invasive surgical atrial fibrillation (AF) ablation (MISAA) delivers radiofrequency energy via a thoracoscopic approach to perform pulmonary vein isolation and left atrial ganglionic plexi ablation. Data on long-term outcomes of MISAA are lacking.

OBJECTIVE We report 5-year follow-up data from a prospective cohort of patients who underwent MISAA at a single center.

METHODS One hundred nine consecutive patients (60 paroxysmal, 49 persistent; mean age 62.7 ± 9.3 years) underwent MISAA with left atrial appendage exclusion by a single surgeon between 2006 and 2012. Patients were followed with transtelephonic monitoring at 1, 6, and 12 months and annually thereafter for up to 5 years. Recurrence was defined as any atrial tachyarrhythmia lasting ≥30 seconds from 90 days after surgery onward.

RESULTS Mean follow-up duration was 1738.5 ± 661.5 days. Single-procedure success rate was 38% (37 of 98 patients). Atrial arrhythmias occurred in 22%, 42%, 55%, 59%, and 62% of patients by 1, 2, 3, 4, and 5 years. Seventy-eight (79.6%) patients remained AF free with or without additional interventions including catheter ablation, antiarrhythmic drugs, or cardioversion. There was no significant difference in AF-free survival between paroxysmal and persistent AF groups ($P = .725$). Multivariate analyses showed hypertension to be a significant predictor of AF recurrence (odds ratio 6.6, confidence interval 1.41–30.80; $P = .016$). Five (5.1%) patients had a stroke or transient ischemic attack during follow-up.

CONCLUSION AF-free survival was 38% at 5 years after MISAA. A total of 79.6% of patients remained AF free with or without additional intervention. Patients may have an ongoing risk of stroke even in the absence of AF recurrences.

KEYWORDS Atrial fibrillation; Surgical ablation; Mini maze; Catheter ablation; Cardiac monitoring

(Heart Rhythm 2017;14:1281–1288)

Introduction

Atrial fibrillation (AF) is the most common arrhythmia encountered in clinical practice and remains one of the major causes of stroke, heart failure, and cardiovascular morbidity and mortality worldwide. The first surgical procedure to treat AF was introduced by Cox in 1987 as a biatrial "cut-and-sew" technique in an attempt to block reentrant circuits in the atria while preserving sinus impulse conduction to both atria and the atrioventricular node. Since then, multiple modifications to the Cox maze procedure have occurred in order to reduce complexity, risk of complications, and procedure times. Although the Cox maze III procedure emerged as the gold standard for surgical treatment of AF,[1] it failed to achieve widespread adoption as a stand-alone surgical treatment because of its complexity and need for cardiopulmonary bypass (CPB). With introduction of the Cox maze IV procedure, the cut-and-sew lesion set can be replicated by use of ablation technology with comparable results but shorter clamp times.[2] Minimally invasive surgical ablation for AF (MISAA) has been shown to be safe and provide effective short-term freedom from AF. However, long-term data on safety and efficacy of this technique remain limited.[3–5]

Haissaguerre and colleagues[6] demonstrated that pulmonary veins are an important trigger of AF, and pulmonary vein isolation (PVI) has become a cornerstone for successful catheter-based and surgical AF ablation.[7,8] Although epicardial ganglionic plexi (GP) and the ligament of Marshall (LOM) have been shown to trigger pulmonary vein (PV) ectopy initiating AF,[9–11] long-term follow-up data regarding the contribution of GP and LOM ablation to success of AF ablation are limited. We report long-term follow-up from a prospective cohort of patients who

Conflicts of interest: Dr Kasirajan received honoraria and research support from Atricure Inc. Dr Ellenbogen received honoraria and research support from Atricure Inc, Ablation Frontiers, Biosense Webster, Medtronic, Boston Scientific, and St. Jude Medical. **Address reprint requests and correspondence:** Dr Aditya Saini, Virginia Commonwealth University Medical Center, Richmond, VA 23298. E-mail address: draditysaini@gmail.com.

underwent MISAA with PVI, GP, and LOM ablation at our institution.

Methods

Patient selection

One hundred nine consecutive AF patients (60 paroxysmal, 49 persistent) who underwent MISAA between May 2006 and June 2012 at a single center were prospectively followed with a mean follow-up duration of 1738.5 ± 661.5 days (4.7 ± 1.8 years). Consecutive patients with medically refractory symptomatic AF who had failed 1 or more antiarrhythmic drugs (AAD), had failed catheter ablation, or were not candidates for catheter ablation were enrolled. Some patients were preferentially referred for MISAA, including patients with morbid obesity and with anatomic issues limiting catheter placement from the femoral vein (interrupted inferior vena cava, or history of trauma resulting in inferior vena cava occlusion). Definitions of type of AF, procedural success, adverse events, and follow-up monitoring were based on the Heart Rhythm Society consensus statement for the catheter and surgical ablation of AF.[12] The study was approved by the institutional review board and all patients gave informed consent for inclusion in this prospective registry. The study was registered at ClinicalTrials.gov (NCT00747838).

Surgical procedure

Details of this procedure have been previously described by our group[13] (a video of the procedure can be viewed at https://www.youtube.com/watch?v=BavbXkhll2w&authuser=0). Briefly, the surgical procedure was performed under general anesthesia and from 2006 to 2009 a mini-thoracotomy was performed while sparing the ribs. From 2010 onward, we switched to a fully thoracoscopic approach with the addition of roof and floor lines to create posterior left atrial (LA) box lesions whenever feasible. The pericardium was opened anterior to the phrenic nerve on the right and usually posterior to the phrenic nerve on the left. The rhythm was determined by placing a bipolar pen probe (Atricure Inc, Cincinnati, OH) on the left atrium, and recordings were made with a physiological recorder. Autonomic ganglia were identified by high-frequency stimulation to detect a vagal response at 20 predetermined epicardial sites. GP mapping was performed by placing the bipolar pen at each site and stimulating with an 18-mV, 1.5-ms pulse width impulse at 1000 pulses per minute from a temporary external pacemaker. A positive response to GP stimulation was defined as prolongation of the sinus cycle or mean AF cycle length by 50%. A lighted dissector was used to encircle the pulmonary venous antrum after fat was removed from the PV trunk. Ablation of the antral area was performed using a bipolar radiofrequency (RF) clamp (Atricure Inc). Entrance block was defined as failure to capture the pulmonary veins during pacing from the left atrium at 7.5 V and 1.5-ms pulse width. Exit block was defined by failure to capture the left atrium when pacing from the pulmonary veins distal to the RF lesions at 7.5 V and 1.5-ms pulse width. Demonstration of complete and bidirectional block was the endpoint. Once impedance changes demonstrated transmural injury, the algorithm terminated RF energy (maximum, 28 W). Clamp applications were repeated a minimum of 2–3 times after bidirectional block was achieved. GPs were mapped again at end of ablation and bipolar RF energy at 15 W was delivered through the bipolar pen at sites demonstrating a vagal response until no further response to vagal stimulation was elicited. We surgically divided the LOM using thermal energy in all patients, then ablated this area with bipolar RF energy. The left atrial appendage (LAA) was stapled and excised after absence of flow was confirmed by intraoperative transesophageal echocardiography. The transition to the AtriClip (AtriCure, Inc, Blue Ash, OH) from stapling for LAA exclusion was made in November 2010 after the first 92 patients.

Certain procedural modifications occurred during the course of the study and were fueled by technological advances. Patients underwent PVI + GP + LOM ablation from May 2006 to January 2009 (Isolator clamp; Atricure, Inc, with 1 pair of electrodes and energy applied between jaws). From February 2009 onward, a PVI + GP + LOM ablation was further supplemented by a posterior LA ablation to create a "box" lesion set (Coolrail RF Pen; AtriCure, Inc, 2 electrodes side-by-side and internally cooled). Concomitantly, more extensive fat dissection prior to ablation was performed starting in 2009. The bipolar RF clamp used after July 2009 had 2 pairs of electrodes (Isolator Synergy; Atricure Inc) to perform a wider and deeper ablation.

Antiarrhythmics were avoided whenever possible postoperatively. Unless patients had a $CHADS_2$ score of 2 or higher, warfarin was discontinued after freedom from AF was confirmed at the 6-month monitor. If patients had a $CHADS_2$ score of 2 or higher, warfarin was continued indefinitely in the absence of contraindications. All procedures were performed by a single surgeon (V.K.) and followed by electrophysiologists (K.E. and J.K.). Symptomatic atrial tachyarrhythmias unresponsive to beta blockers in the postoperative period were preferentially treated with amiodarone for 4–8 weeks. All antiarrhythmic drugs were discontinued by 8 weeks.

Follow-up

All patients except those who had a pacemaker were followed with 30-day ambulatory monitoring at 6 and 12 months and every 12 months thereafter. Any patient not in sinus rhythm before the 3-month follow-up visit was cardioverted. Recurrent symptomatic palpitations occurring >3 months postoperatively were further evaluated with a transtelephonic event monitor (TTM). Monitoring was performed with an external loop recorder (Cardiolabs, Franklin, TN or Cardionet, Conshohocken, PA) with an automatically triggered algorithm to detect AF. Single-procedure success was defined as no episode of AF, atrial flutter (AFL), or any atrial tachycardia (AT) lasting longer than 30 seconds while off AAD from 90 days after surgery through the duration of follow-up.

Additionally, success with intervention was defined in patients with initial recurrence of atrial arrhythmia out of the blanking period with successful maintenance of sinus rhythm after a second intervention like AAD, direct current cardioversion (DCCV), or catheter ablation (CA) through the end of follow-up. AT was defined as any atrial rhythm other than sinus with a rate greater than 100 beats per minute. Nineteen patients had pacemakers, which were used to monitor for AF recurrence.

Statistical analysis

Data were prospectively entered into a database and separate tables were created for demographic information, baseline characteristics, surgical and in-hospital postoperative data, outpatient follow-up, and home monitoring data. Patients were grouped by preoperative classification of AF and by the success or failure of the procedure. Recurrence was defined as any episode of AF, AFL, or atrial tachyarrhythmia lasting greater than 30 seconds detected after the 90-day post-surgical blanking period by follow-up electrocardiography, pacemaker interrogation, or continuous event monitor performed at 6 and 12 months, and yearly thereafter. Numerical data were compared using *t* tests or Wilcoxon rank tests, depending on the normality of the data distribution. Categorical data were compared using the Fisher exact test. Postoperative AF-free survival curves were calculated using the Kaplan-Meier method. Logistic regression was used to identify preoperative risk factors that were independent predictors of failure. Probability (*P*) values less than .05 were considered statistically significant. All statistical analyses were 2-tailed tests and were performed using SPSS (Version 23.0; IBM Corp, Armonk, NY).

Results

Baseline demographics

One hundred nine consecutive patients (60 paroxysmal, 49 persistent AF) underwent MISAA between May 25, 2006 and June 8, 2012. Mean follow-up duration was 1738.5 ± 661.5 days (4.7 ± 1.8 years). Mean age was 62.7 ± 9.3 years. Mean left ventricular ejection fraction was 53.8% ± 8.9%. Other baseline patient characteristics are shown in Table 1. Twenty-four patients (22%) had history of prior RF catheter ablation of AF. Information on presence of reconnections was available for 18 of 24 patients; 16 out of 18 had reconnection of at least 1 PV (mean: 2.3 veins, range: 1–4 veins). The mean duration of AF prior to MISAA was 3.6 ± 4.0 years (paroxysmal AF 3.6 ± 4.2 years, persistent AF 3.6 ± 3.8 years). The mean $CHAD_2S_2VASc$ score in our patients was 2.0 ± 1.3.

Table 1 Baseline demographics (n = 109)

Variables	Value
Gender	
Male	60 (55%)
Female	49 (45%)
Age, y	62.7 ± 9.3
Body mass index	32.9 ± 8.2
LVEF, %	53.8 ± 8.9
Mitral regurgitation	
No/trivial	91 (83.5%)
Mild	7 (6.5%)
Moderate	9 (8.2%)
Severe	2 (1.8%)
LA diameter, cm*	2.7–6.1 (4.4 ± 0.7)
CHA_2DS_2VASc	2.0 ± 1.3
CAD	14 (12.8%)
HTN	65 (59.6%)
DM	13 (11.9%)
Prior stroke	6 (5.5%)
Prior TIA	3 (2.7%)
Prior catheter ablation	24 (22%)
Preoperative anticoagulation	80 (73.3%)
Preoperative antiarrythmics	33 (30.2%)
OSA on treatment	18 (16.5%)
AF duration prior to MISAA, y	3.6 ± 4.0
Paroxysmal AF	3.6 ± 4.2
Persistent AF	3.6 ± 3.8

Values are presented as mean ± SD or as n (%).

AF = atrial fibrillation; CAD = coronary artery disease; DM = diabetes mellitus; HTN = hypertension; LA = left atrial; LVEF = left ventricular ejection fraction; MISAA = minimally invasive surgical atrial fibrillation ablation; OSA = obstructive sleep apnea; TIA = transient ischemic attack.
*LA diameter measured in parasternal long axis.

Perioperative data

The median length of the surgical procedure was 4.2 hours (range: 3–6.5 hours), which includes the time from initial skin incision to final skin closure. Mean length of hospital stay was 6.1 ± 2.7 days (range: 3–18 days). Mean intensive care unit (ICU) stay for postoperative recovery was 1.9 ± 1.7 days (range: 1–10 days). Bidirectional block was achieved in all patients. After GP ablation, no site produced a vagal response. No blood transfusions were required. There were no deaths. Extubation was performed either in the operating room or within 6 hours in the ICU in all but 5 patients, who were extubated after 16 hours in the ICU.

Follow-up

There was 100% compliance with the continuous 30-day monitor at 6 months; and 100% compliance with TTM at 12 months, 98% at 24 months, 96% at 36 months and 48 months, and 91% at 60 months. Eleven patients were lost to follow-up during the study. At 5-year follow-up, 37 out of 98 (37.8%) patients remained AF free with no additional interventions or medication (Figure 1). Atrial arrhythmias occurred in 22%, 42%, 55%, 59%, and 62% of patients by 1, 2, 3, 4, and 5 years, respectively. An additional 41 (41.8%) patients had AF recurrences post MISAA but maintained sinus rhythm after subsequent CA, AAD, and/or DCCV. These were classified as success with intervention (Figure 1). Hence, 78 (79.6%) patients remained AF free with or without additional intervention. Overall, 45 patients required AAD therapy. Thirty of these remained AF free for subsequent duration of follow-up. Twenty-eight (25.6%) patients, 11 with paroxysmal AF and 17 with persistent AF, had an attempt at catheter ablation after MISAA

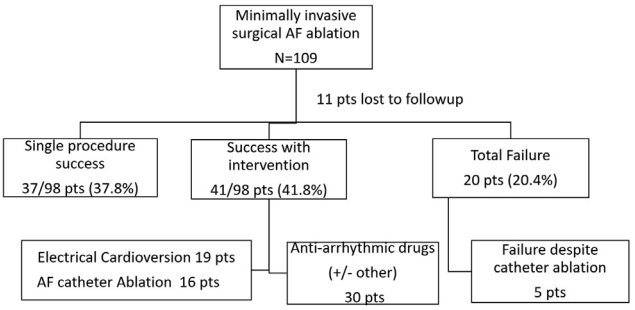


Figure 1 Outcomes after minimally invasive surgical atrial fibrillation (AF) ablation in our prospective cohort of patients.

(21 for recurrent AF, 5 for AT, 1 for AFL, 1 for atrioventricular nodal reentrant tachycardia). PV reconnections were noted in 13 of 21 patients (range: 1–3 PV), while 8 had no identifiable reconnections. Non-PV triggers were investigated and targeted in these patients. Five patients failed to maintain sinus rhythm despite AF catheter ablation. The mean time to first catheter ablation after MISAA was 810.6 ± 560.9 days (range: 187–1989 days; 667.0 ± 520.3 in paroxysmal AF and 903.6 ± 581.7 days in persistent AF). Figure 2 shows Kaplan-Meier curves for AF-free survival for the total group as well as by type of AF. There was no significant difference in long-term AF-free survival between paroxysmal and persistent AF groups ($P = .725$). There was no statistically significant difference in AF-free survival curves based on whether PVI + GP ablation or complete LA box isolation was performed (Figure 3), even when further subcategorized by type of AF (Figure 4).

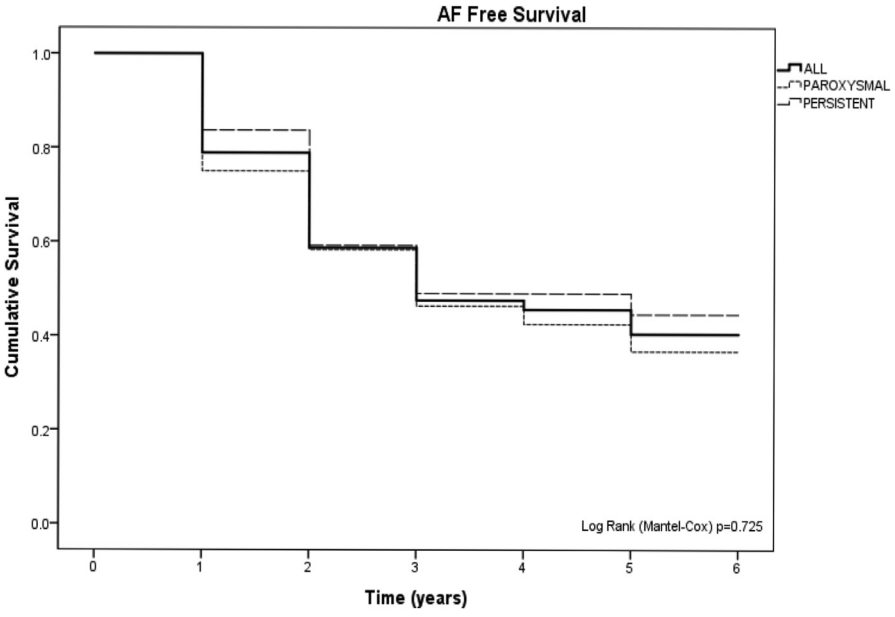
The number of hospitalizations occurring after the 90-day blanking period related to clinical symptoms of AF requiring AAD and/or DCCV are depicted in Figure 5. Twenty-nine patients had recurrent hospitalizations.

A univariate and multivariate analysis was performed to predict recurrent AF. Variables that were analyzed were gender, diabetes, hypertension, ejection fraction, age, coronary artery disease, prior stroke, left atrium size, preoperative AF classification, use of AAD at discharge, body mass index, obstructive sleep apnea, presence of more than mild mitral regurgitation, and history of prior CA. In multivariate logistic regression, hypertension was the only significant predictor of recurrent AF (odds ratio: 6.6, confidence interval: 1.414–30.803, $P = .016$).

Complications

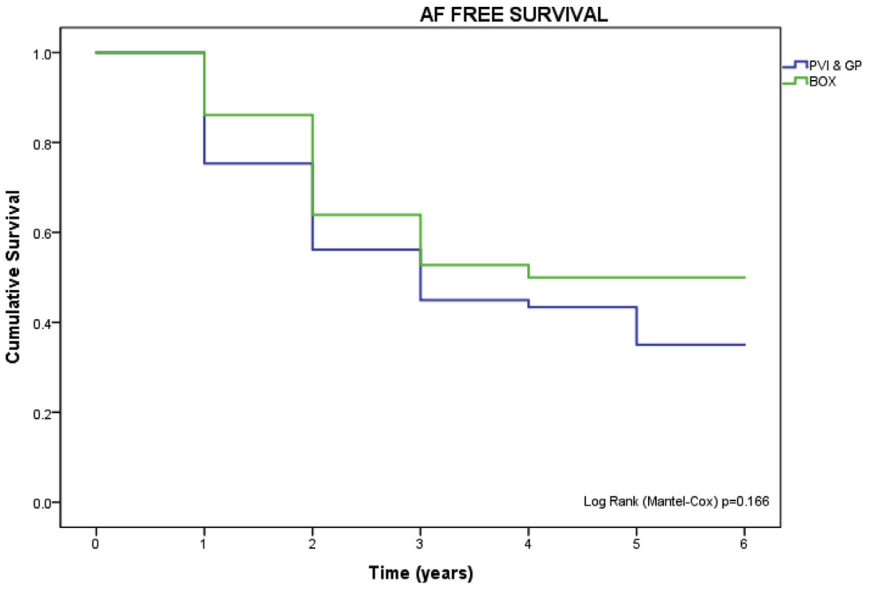
There were no deaths. The overall surgical complication rate was 6.4% (7 events). One patient developed bilateral pneumothoraces requiring chest tubes and mechanical ventilation >24 hours, and a second patient required mechanical ventilation >24 hours for obesity hypoventilation syndrome. One patient had permanent right phrenic nerve paralysis. Two patients had pleural effusions; 1 had a pleural effusion with 300 cc of fluid requiring drainage before discharge and the other had a pleural effusion drained 1 month after surgery. One patient required repair of the left ventricle on CPB after injury from a trocar. One patient underwent CPB for intraoperative LA tear requiring urgent repair.

Five (5.1%) patients (mean $CHAD_2S_2VASc$ score: 2.8, range: 1–4) had a stroke or transient ischemic attack (TIA)



No. at risk						
All	109	88	67	54	50	45
Paroxysmal AF	60	45	34	24	22	19
Persistent AF	49	41	29	24	22	20

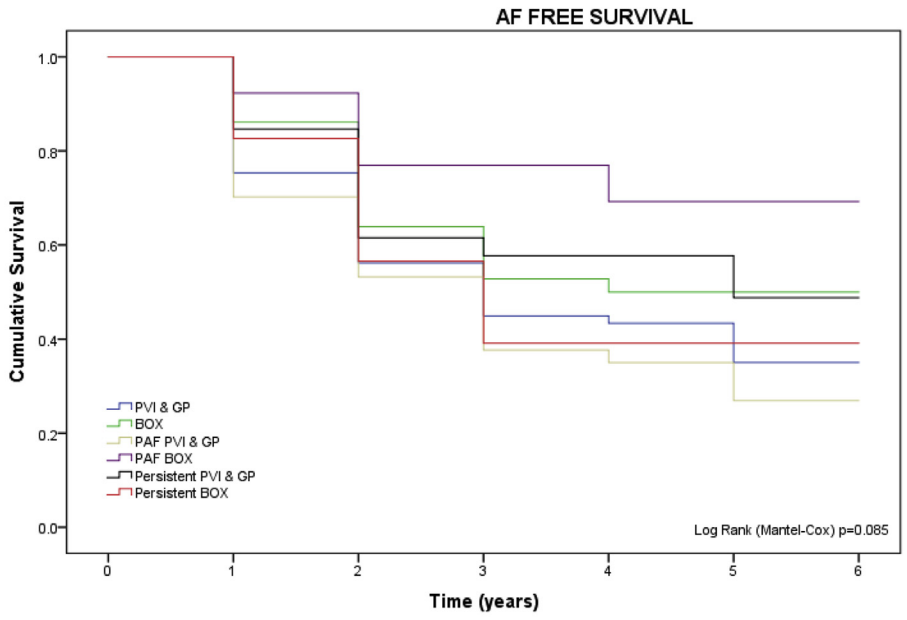
Figure 2 Kaplan-Meier atrial fibrillation (AF)-free survival curves by AF type.



No. at risk						
All	109	88	67	54	50	45
PVI & GPI	73	55	40	29	26	21
BOX	36	31	23	19	18	18

Figure 3 Kaplan-Meier atrial fibrillation (AF)-free survival curves for patients with pulmonary vein isolation (PVI) + ganglionic plexi (GP) vs left atrial box ablation.

during follow-up (Table 2). One patient did not have the LAA exclusion performed and had a stroke in the postoperative period while in AF and off anticoagulation. The other 4 patients (80%) were in normal sinus rhythm (NSR) at the time of the event. One patient never had any documented AF prior to or following the stroke but had recurrent TIAs



No. at risk						
PVI&GP	79	55	40	29	26	21
BOX	36	31	24	20	19	19
PAF PVI&GP	47	33	24	14	13	10
PAF BOX	13	12	10	10	9	9
Persistent PVI&GP	26	22	16	15	13	11
Persistent BOX	23	19	14	10	10	10

Figure 4 Kaplan-Meier atrial fibrillation (AF)-free survival curves for patients with pulmonary vein isolation (PVI) + ganglionic plexi (GP) lesions vs left atrial box set lesions, and by type of AF (persistent or paroxysmal AF [PAF]).

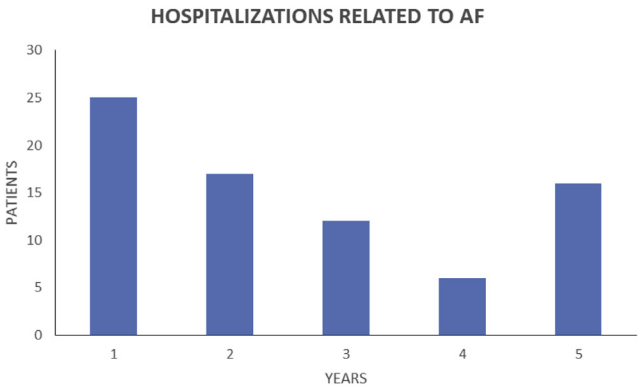


Figure 5 Number of hospitalizations (occurring after the 90-day blanking period) related to atrial fibrillation (AF) for clinical symptoms requiring antiarrhythmic drugs and/or direct current cardioversion. Totals for years 1–5 were 25, 17 (7 previous hospitalizations [PH]), 12 (7 PH), 6 (4 PH), and 16 (11 PH), respectively.

while in NSR and on warfarin. Four out of 5 patients had imaging of the LAA; 3 patients had no residual LAA flow by imaging with transesophageal echocardiography or cardiac magnetic resonance imaging and 1 had small residual LAA with no leak.

Discussion

We present our single-center experience with MISAA. This is the first report documenting a single-procedure success rate for MISAA and additional interventions in those patients with recurrence, with a systematic 5-year follow-up in a prospective cohort using an aggressive monitoring protocol.

Our single-procedure success rate of 38% after 5 years of follow-up is based on electrocardiography and home TTM data rather than symptom monitoring alone. In the absence of an aggressive monitoring strategy like the one we used, asymptomatic or minimally symptomatic recurrences of AF could have potentially been missed.

Data from catheter ablation studies have shown that the presence of early recurrences is an independent predictor of long-term single-procedure failure and could possibly be used to identify those patients requiring a repeat ablation.[14] Whether or not early recurrences in a minimally invasive surgical cohort correlate with long-term recurrences of AF remains to be determined. Additionally, we cannot compare our results to those of patients undergoing CA, as many patients had failed multiple prior CA procedures, many had persistent AF, and some were poor candidates for CA. However, our study suggests that MISAA remains a viable option in patients who have failed CA or in whom CA may not be possible or feasible. This, however, has to be viewed in light of cost-effectiveness, operator experience, and institutional capabilities.

Despite the acute procedural success of entrance and exit block after epicardial PVI, 28 patients required further catheter ablation for recurrent AF. Because not all patients with recurrent AF underwent electrophysiologic study, the contribution of PV reconnection to recurrent AF cannot be assessed in this study. Whether or not a hybrid approach of minimally invasive and endocardial ablation or epicardial/endocardial catheter ablation would serve to increase single-procedure efficacy remains to be determined.

Previous studies have found a significant difference between the efficacy of catheter-based and surgical ablation for paroxysmal compared with persistent AF.[15–19] However, our study did not find any statistically significant difference. This could be related to inadequate sample size to detect a difference or related to advancements in technique and extent of ablation during these procedures over time. The 5-year AF-free rate improved in 2009–2012 compared to 2006–2008, although without statistical significance (Figure 6, $P = .094$). Factors that may have changed by 2009 included operator learning curve, technique, and technological advances (PVI + GP vs PVI + GP + posterior LA ablation, clamp type, greater dissection of epicardial fat). For the last 63 patients enrolled from 2008 to 2012, 13 of 33 (39.3%) persistent AF patients remained AF free with a single MISAA procedure. We did not find a significant difference in AF-free survival during follow-up when comparing patients who had extensive LAA ablation with box strategy to patients with PVI and GP ablation alone.

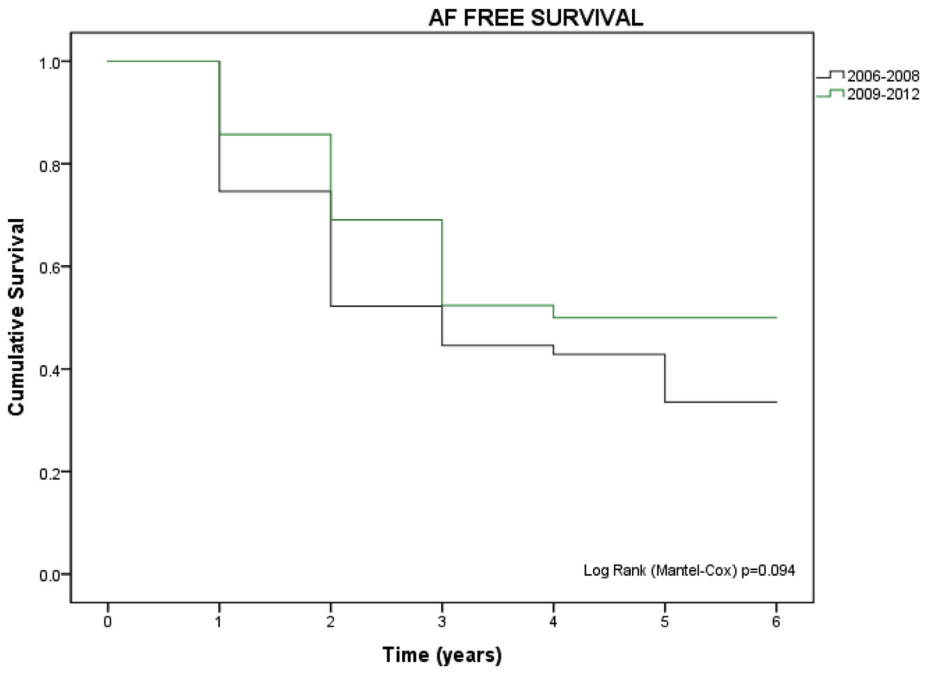
Table 2 Characteristics of patients who had a stroke or transient ischemic attack after procedure

Outcome	Age(y)	AF type at baseline	CHA_2DS_2-VASc	LAA exclusion	LAA residual/leak	Anticoagulation status	Rhythm at diagnosis	AF recurrences
TIA, 9 months	77	Paroxysmal	3	Y, staple	N	N (patient refusal)	NSR	Y,* 36 seconds of AF on monitor
TIA, 22 months	72	Persistent	4	Y, staple	N	Y, warfarin	NSR	N
TIA, 32 months	52	Paroxysmal	2	Y, staple	Small residual without leak	N	NSR	Y, pacemaker interrogation
Stroke, perioperative	45	Persistent	4	NE†	NE	N (dabigatran held perioperatively)	AF	Y
Stroke, 60 months	58	Paroxysmal	1	Y, staple	N	N	NSR	Y, but detected 3 years after stroke

AF = atrial fibrillation; LAA = left atrial appendage; N = no; NSR = normal sinus rhythm; TIA = transient ischemic attack; Y = yes.

*Patient lost to follow-up at 1 year.

†Not excised; broad base and small, and felt to be high risk for hemorrhage.



No. at risk						
All	109	88	67	54	50	45
2006-2008	66	50	34	26	23	18
2009-2012	43	36	29	22	21	21

Figure 6 Comparison of atrial fibrillation (AF)-free survival for procedures performed between 2006 and 2008 and between 2009 and 2012.

Previous studies have shown that extensive LAA ablation by box strategy is feasible[20,21] and may result in better clinical outcome when compared to a PVI-alone strategy.[22] Even in our study, 18 of 36 (50%) patients who underwent the box lesions in the LA remained AF free. Further studies with higher sample size designed specifically to compare extent of ablation during minimally invasive procedures are needed before any conclusions can be made.

Another important finding with long-term follow-up pertains to strokes and TIA. The incidence of stroke and TIA after MISAA with LAA exclusion was 5.1% at 5 years. Events occurred despite absence of residual LAA and while in NSR at time of event. Patients may thus have an ongoing risk of stroke even in the absence of AF recurrences. It may therefore be important to continue risk factor modification for concurrently existing cardioembolic and atherothrombotic risk factors after the procedure.[23]

Study limitations

We did not conduct a formal assessment of changes in the quality of life in our study. Our study demonstrates a significant reduction in AF burden with MISAA with an aggressive follow-up protocol involving use of remote monitoring rather than symptom monitoring alone. Additionally, our study had a high proportion of patients with prior failed catheter PVI as well as many patients who were preferentially referred for MISAA owing to high risk for catheter PVI. For the above reasons, we cannot make direct comparisons between the 2 techniques from this study. However, continued application of the Heart Rhythm Society consensus criteria for defining procedural success should improve the accuracy of future studies designed to compare different ablation techniques. This is a single-center study with limited numbers of patients, which prevents any definitive conclusions from being drawn with univariate and multivariate regression analyses. In addition, our study may be subject to referral bias. Patients with obesity and patients who had anatomy making catheter ablation difficult may have been preferentially referred for surgery. Owing to the small sample size and limited absolute number of patients with strokes and TIA, further analysis of predictors of these events is not possible.

Conclusion

A minimally invasive surgical approach employing PVI combined with the mapping and ablation of autonomic GP and LOM for medically refractory AF has a single procedural success rate of 37.8% with a 5-year follow-up. Recurrences are responsive to CA, AAD, and/or DCCV with 79.5% AF-free survival at 5 years. In our cohort, LAA removal did not negate the risk of stroke and there is ongoing risk even in absence of AF recurrences.

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