

Original
Article

Short and Intermediate Term Outcomes of the Convergent Procedure: Initial Experience in a Tertiary Referral Center

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Purpose: The Convergent procedure is a hybrid, multidisciplinary treatment for symptomatic atrial fibrillation (AF) consisting of minimally invasive surgical epicardial ablation and percutaneous/catheter endocardial ablation. We investigated outcomes following introduction of the Convergent procedure at our institution.

Methods: Retrospective study examining single-center outcomes. Demographic, procedural, and post-procedural variables were collected with follow-up data obtained at 3, 6, and 12 months.

Results: In all, 36 patients with paroxysmal (11%) or persistent/long-standing persistent (89%) AF underwent the Convergent procedure. 36% also underwent concomitant left atrial appendage (LAA) exclusion by thoracoscopic placement of an epicardial clip. Mean age 60.6 ± 8.0 years with mean arrhythmia burden of 3.9 ± 2.7 years. All patients had failed prior attempts at medical management, 81% had failed prior cardioversion, and 17% had failed prior catheter ablation. Convergent was performed successfully in all patients with no peri-procedural deaths or major complications. At 3 and 12 months, 77.8% and 77.3% of patients, respectively, were free from symptomatic arrhythmia. 65.8% were off anti-arrhythmic medication at 12 months.

Conclusions: The Convergent procedure is safe and has good short- and intermediate-term clinical success rates. This unique hybrid approach combines strengths of surgical and catheter ablation and should be part of any comprehensive AF treatment program.

Keywords: convergent procedure, atrial fibrillation, hybrid ablation, arrhythmia

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Introduction

Atrial fibrillation (AF) is a disease that affects more than an estimated 3.4–5.9 million people in the United States alone.^{1,2)} AF is associated with a negative impact on quality of life, is the leading cause of embolic stroke, and increases the risk of kidney disease, cardiac valvular disease, and heart failure as well as contributes to increased healthcare system costs.^{3–7)}

Medical management with an antiarrhythmic and anticoagulation regimen has traditionally been first-line therapy for patients with AF. This approach, however, can be limited by the inherent difficulties and toxicity associated with chronic use of these medications. Invasive

approaches to treat AF developed starting with the first “cut-and-sew” Cox-Maze operation. With advances in technology, surgical options developed to include numerous minimally invasive approaches for AF ablation. Simultaneously, the development of catheter-based endocardial ablation provided a percutaneous option for AF treatment. Pulmonary vein isolation (PVI) via radiofrequency ablation has been the cornerstone of treatment for patients with symptomatic, drug refractory AF. PVI is the preferred ablation technique for paroxysmal AF, with clinical trials demonstrating up to 70% effectiveness in these patients as compared to 7% success among those treated with anti-arrhythmic medical therapy alone.^{8,9)} However, the optimal treatment for persistent and long-standing persistent AF is less clear. Catheter ablation has had limited success in treating these subtypes of AF with the efficacy of a single catheter ablation procedure being reported as low as 20%–30% and with multiple procedures increasing the efficacy up to 50%–60%.⁹⁾ The reasons for such difficulty in treating persistent and long-standing persistent AF are unclear but have been postulated to include the presence of non-pulmonary vein foci of AF including the posterior wall and left atrial appendage (LAA), inherently varying electrophysiologic re-entrant circuits, and more advanced structural changes including intramyocardial fibrosis and anatomic remodeling.

Both catheter and surgical ablation approaches have intrinsic limitations. Endocardial catheter ablation, by design, is limited in the ability to create linear transmural lesions.^{10–12)} Moreover, some aspects of the left atrium, including the posterior wall, may be less amenable to transmural ablation by catheter approach due to concerns about esophageal injury. Surgical ablation techniques, on the other hand, lack the ability to define and map the electrical properties or the atrial substrate to customize the ablation procedure. The Convergent procedure was designed to combine the strengths of surgical and catheter ablation into a single procedure.^{13–16)} This procedure is performed in two stages: minimally invasive surgical epicardial ablation of the posterior left atrial wall (performed by a cardiac surgeon) followed by endocardial ablation (performed by an electrophysiologist) to isolate the pulmonary veins and address other portions of the left atrium such as the roof line. The hybrid technique overcomes the limitations of either the surgical or catheter approach alone and thereby is thought to improve the efficacy in the treatment of refractory or persistent and long-standing persistent AF.

We sought to review the outcomes of the first patients undergoing the Convergent procedure at our regional academic referral center.

Methods

This study is a retrospective analysis of patients that underwent the Convergent procedure between February 2016 and May 2017 at the University of Tennessee Medical Center in Knoxville, Tennessee. These were the first patients to undergo the procedure at this institution. The IRB of the University of Tennessee Medical Center and Graduate School of Medicine approved this study.

Surgical ablation

The surgical portion of the procedure was performed by a single surgeon (LSL). The catheter ablation portion of the procedure was performed by three different electrophysiologists. For the surgical portion, access to the intrapericardial space was achieved via laparoscopic transabdominal transdiaphragmatic approach 11 patients, and subxiphoid approach in 25 patients. The specific details of the surgical technique, including delineation of the location and extent of epicardial ablation lesions, have been previously described.¹⁶⁾ Briefly, general anesthesia is induced via single lumen endotracheal tube (double lumen or bronchial blocker is utilized for patients who will undergo concomitant left thoracoscopy as described below). Once access into the pericardial space is obtained, the pericardioscopy SUBTLE cannula (AtriCure, Inc., Mason, Ohio, USA) and a 5 mm camera scope are inserted. In all patients, sequential epicardial superior and inferior ablation lines were performed across the posterior left atrium extending from pulmonary vein to pulmonary vein using the monopolar Episense device (AtriCure, Inc., Mason, Ohio, USA). Additional ablation lines were also placed on the anterior portion of the left inferior pulmonary vein and connected to the posterior wall. The esophageal temperature was continuously monitored and did not increase by more than 1°C from baseline throughout the surgical portion. In a subset of patients, following completion of the epicardial ablation, LAA occlusion was performed by placement of an epicardial AtriClip device (AtriCure, Inc., Mason, Ohio, USA) via left video-assisted thoracoscopic (VATS) approach with real-time transesophageal echocardiography (TEE) guidance.¹⁶⁾

Endocardial ablation

After the surgical portion of the procedure, the patient underwent endocardial ablation. The first four patients

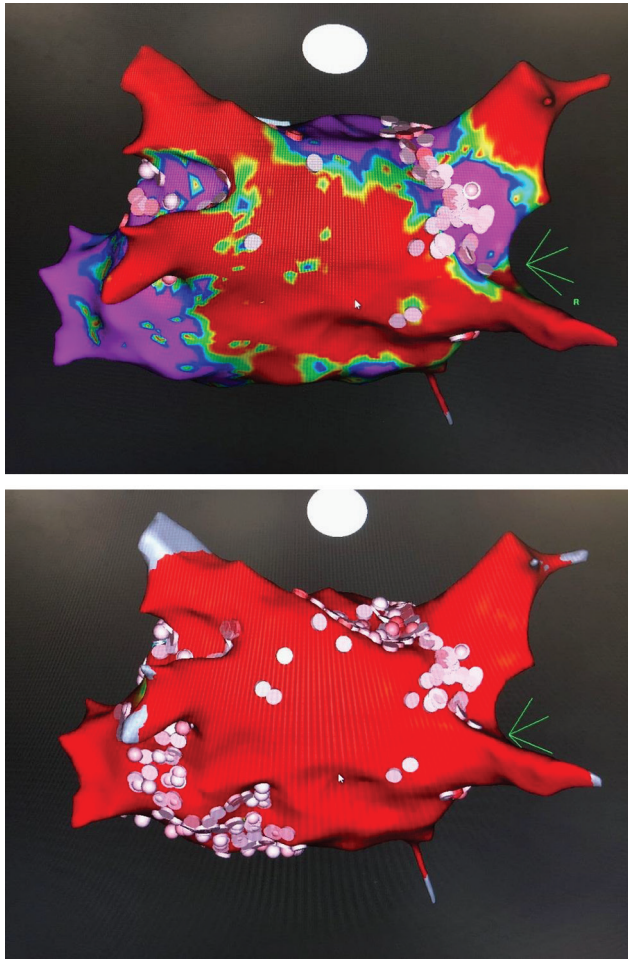


Fig. 1 Representative left atrial voltage map of a patient after the epicardial (top) and endocardial (bottom) portions of the Convergent procedure. This view is a posterior–anterior perspective, with the left and right pulmonary veins being on the left and right of the image, respectively. Purple indicates viable electrical signals (and thus sites of AF triggers and substrate) and red indicates the absence of electrical signals; the goal of ablation is to attain near complete electrical silence (red) of the pulmonary veins and left atrium such that AF triggers cannot propagate. The top image shows electrical silence of the posterior wall after the epicardial ablation portion of the procedure. This epicardial ablation is performed from pulmonary vein to pulmonary vein, with the superior extent of ablation determined by the location of the pericardial reflection which can vary from patient to patient. After completion of the endocardial ablation portion of the procedure (bottom image), there is complete pulmonary vein isolation and electrical silence of the left atrium. AF: atrial fibrillation

had the endocardial portion performed the day after the surgical portion, and the remainder of patients had both portions completed the same day. This required transportation of the intubated patient from the operating room to

the electrophysiology suite. The endocardial catheter ablation procedure was a single transeptal technique, and CARTO 3D with Pentaray catheter or Lasso catheter was used to obtain the atrial and pulmonary vein voltage maps (**Fig. 1**). PVI was accomplished with radiofrequency ablation, and any gaps along the posterior wall were completed. A roof line and isthmus line were also performed. Atrial flutter ablation was performed in some patients at the operating physician's discretion. At the end of the procedure, pacing maneuvers were used to confirm isolation of all four pulmonary veins as well as successful creation of the roof and flutter lines. Direct current cardioversion was performed in patients who were not in sinus rhythm at the end of the procedure.

Postoperative care

Postoperatively, all patients received a regimen consisting of steroids, colchicine, and non-steroidal anti-inflammatory medications to combat the expected pericarditis. The pericardial and/or pleural drains were removed when the output fell below 75 mL for a 24-hour period. All preoperative antiarrhythmic medications and anticoagulants were resumed prior to discharge.¹⁶⁾

Follow-up

All patients received follow-up at our institution. Symptom recurrence was obtained by patient reporting. AF recurrence was determined by electronic medical record review for documentation of AF on electrocardiograms or telemetry strips through emergency department visits, outpatient cardiology follow-up visits, or hospital admissions. Heart rhythm monitoring was also performed on a limited number of subjects by a combination of temporary monitoring device (e.g., Holter monitor), implantable loop recording device, or permanent existing monitoring device. Heart rhythm data were collected immediately following the procedure as well as following a 90-day post-procedural blanking period. Any episode of AF lasting more than 30 seconds after the initial 90-day blanking period was considered a recurrence. Post-procedural outcomes and major complications were collected starting immediately following the procedure.

Statistical analysis

Data were retrospectively collected and entered into an electronic database. Statistical analysis was performed with assistance of a statistician. Descriptive and frequency statistics were used to answer the research questions. Baseline and follow-up values are reported as

Table 1 Study patient demographics

Patient characteristic	No. of patients	% of patients
Sex		
Male	26	72.2%
Female	10	27.8%
Race		
Caucasian	35	97.2%
African American	1	2.8%
Hypertension	29	80.6%
Hyperlipidemia	20	55.6%
Coronary artery disease	3	8.3%
Left ventricular hypertrophy	11	30.6%
Obstructive sleep apnea	16	44.4%
Diabetes mellitus	13	36.1%
Left ventricular ejection fraction		
LVEF 50% or greater	26	72.2%
LVEF 31–49%	6	16.7%
LVEF 30% or less	4	11.1%
NYHA Class Symptoms		
NYHA Class I	29	80.6%
NYHA Class II	5	13.9%
NYHA Class III	2	5.6%
NYHA Class IV	0	0.0%
Left atrial size		
Normal (< 4.0 cm)	15	41.7%
Abnormal (> 4.0 cm)	21	58.3%
Thyroid disorder	4	11.1%
Prior stroke	18	50.0%
Pulmonary hypertension	20	55.6%
COPD	2	5.6%
Tobacco use	4	11.1%
Alcohol use	4	11.1%
Mitral valve disease		
Mitral regurgitation (mild)	25	69.4%
Mitral regurgitation (moderate)	3	8.3%
Mitral stenosis (mild)	1	2.8%
Aortic valve disease		
Aortic regurgitation (mild)	6	16.7%
Aortic stenosis (mild)	1	2.8%
History of atrial flutter	8	22.2%
Prior atrial flutter ablation	7	19.4%
Prior atrial fibrillation ablation	6	16.7%
Failed electrical cardioversion	29	80.6%
Failed anti-arrhythmic drugs (AAD)	36	100.0%
Failed 2 AAD	10	27.8%
Failed 3 AAD	1	2.8%
CHADS ₂ Vasc Score		
Score of 2 or less	16	44.4%
Score of 3 or more	19	52.8%

AAD: anti-arrhythmic drugs; COPD: chronic obstructive pulmonary disease;
LVEF: left ventricular ejection fraction; NYHA: New York Heart Association

mean \pm SD for numeric measures and counts and percentages for categorical measures. Means and standard deviations are reported for continuous variables. Frequency and percentage statistics are presented for categorical

variables. Freedom from recurrence analysis was performed for the total patient population. Analyses were conducted using SPSS Version 25 (IBM Corp., Armonk, NY, USA).

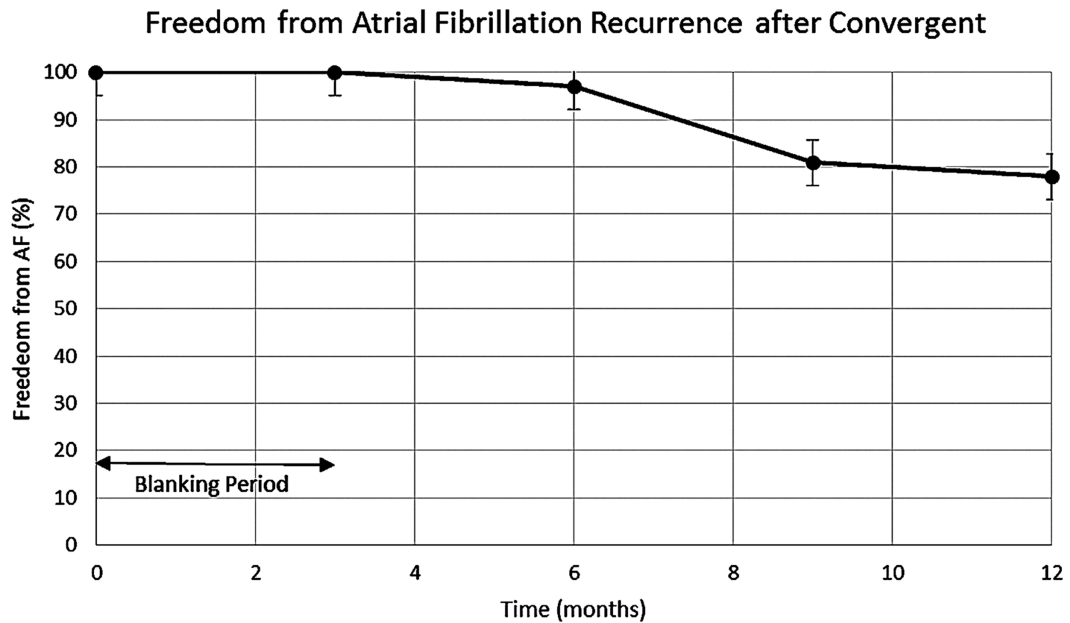


Fig. 2 Procedure success presented as freedom from AF recurrence after the Convergent procedure. The three-month blanking period follows current Heart Rhythm Society guidelines for rhythm assessment after ablation procedures. AF: atrial fibrillation

Results

Baseline patient demographics are listed in **Table 1**. There were a total of 36 patients included in the study. In all, 26 (72.2%) patients were men, 35 (97.2%) were Caucasian, and the mean age was 61 years. All patients had symptomatic AF, with 4 (11.1%) having paroxysmal AF and 32 (88.8%) having persistent or long-standing persistent AF. All patients had previously failed at least one antiarrhythmic medication, 11 (30.5%) had failed at least two antiarrhythmic medications, and 29 (80.6%) had failed prior electrical cardioversion. Six (16.7%) had failed at least one prior catheter ablation and had developed recurrent AF. The mean BMI was 35.2 kg/m².

All patients successfully underwent completion of both the surgical and catheter ablation portions. In total, 13 (36.1%) patients underwent concomitant LAA occlusion by epicardial clip placement. At the time of endocardial ablation, 18 (50%) patients underwent right atrial flutter line creation, 5 (14%) underwent left atrial flutter line creation, and 2 (5%) underwent both right and left atrial flutter line creation. All patients were in normal sinus rhythm at the time of discharge. Mean follow-up was 11.1 ± 4.5 months. The 12-month freedom from atrial arrhythmia recurrence was 78% (**Fig. 2**). Of the patients who had recurrent AF, 66% occurred in the first 10 patients to have the procedure performed, and none of the patients with AF recurrence had undergone LAA exclusion.

Arrhythmia recurrence

Eight patients (22%) had recurrent atrial tachyarrhythmia during the 12-month follow-up period, which included either recurrent AF, atrial flutter, paroxysmal atrial tachycardia, or sinus node dysfunction. Of these patients, one underwent repeat endocardial PVI and atrial flutter ablation, three underwent cardioversion for atrial flutter, two underwent repeat endocardial atrial flutter ablation, one underwent atrioventricular (AV) node ablation with permanent pacemaker implantation, and one underwent permanent pacemaker implantation. In the patients who underwent repeat endocardial voltage mapping and ablation, none showed a gap in the posterior left atrial wall epicardial ablation site.

When examining the six patients who had previously undergone catheter ablation, two had undergone that ablation at our institution, and four had undergone ablation at an outside facility. We did not have access to the outside procedure records, but the records of the two patients from our institution did not indicate any untoward or particularly abnormal findings that would increase the risk of recurrent AF. The EP study at the time of the endocardial portion of the Convergent procedure revealed that four of the six patients had electrical activity in at least one pulmonary vein. The other two patients had electrical vein isolation of all four pulmonary veins but had discernible voltage signals in areas of the posterior wall and LAA. At 12-month

Table 2 Adverse events following convergent procedure

Adverse Events	No. of patients	% of patients
Phrenic nerve palsy	1	2.8
Atrio-esophageal fistula	0	0.0
Cardiac tamponade	1	2.8
Stroke	0	0.0
Death	0	0.0
Pericardial effusion	2	5.6
Pericarditis (severe)	2	5.6

follow-up, three of these six patients remained free from arrhythmia recurrence while three had undergone repeat EP study and focal catheter ablation for recurrent atrial tachyarrhythmia.

Adverse events

Table 2 shows the adverse events and complications following the Convergent procedure. There were no peri-procedural deaths, need for re-operation, stroke, or major complications. No patients required conversion to sternotomy or thoracotomy or need for cardiopulmonary bypass support. Post-procedure adverse events included phrenic nerve palsy (n = 1), severe pericarditis (n = 2) requiring extended hospital stay, and significant pericardial effusion requiring pericardiocentesis (n = 3).

Anti-arrhythmic and anticoagulant use

The rates of anti-arrhythmic drug and anticoagulant use were decreased following the Convergent procedure (**Fig. 3**). At 12 months after the procedure, there was an absolute reduction of 69.4% in patients being treated with antiarrhythmic medications and an absolute reduction of 25% in anticoagulant use.

Discussion

Our initial experience with the Convergent procedure demonstrates that this is a safe procedure with good short- and intermediate-term outcomes. Our results show a 78% freedom from symptomatic AF at one-year follow-up, which is similar to Convergent procedure success rates reported by others.^{14–17} Because this patient population experiences significant distress and limitations due to AF symptoms, we have focused on clinical symptom improvement, rather than purely electrocardiographic rhythm recordings, as the primary indicator of procedural success. Our findings show that the Convergent procedure represents a reasonable therapeutic option to maximize

likelihood of AF control and symptom relief in the difficult-to-treat persistent/long-standing persistent and refractory AF patient population.

The major strategic advantage of Convergent over catheter ablation alone is the ability to attain broad area ablation of the entire posterior left atrial wall. PVI alone is often insufficient in persistent and long-standing persistent AF patients because the arrhythmia triggers and waveforms are more likely to be located in non-pulmonary vein regions and there may also be associated atrial substrate remodeling. Thus, it becomes important to ensure ablation of non-pulmonary vein sites such as the posterior left atrial wall. Catheter ablation of the posterior wall is limited in its ability to effect wide area coverage and carries the risk of esophageal injury during ablation, which may help explain why success rates of catheter ablation for these patients are relatively low. One of the most devastating complications of catheter ablation is atrio-esophageal fistula, which can occur since the ablation energy is directed from the endocardium outwards away from the heart and toward the esophagus. In contrast, with the epicardial ablation during the Convergent procedure the posterior wall ablation is performed under direct pericardioscopic vision with the energy source directed from the epicardium inwards toward the heart and away from the esophagus, thus reducing the risk of esophageal thermal injury. Furthermore, with the epicardial ablation catheter, there is no return electrode necessary (there is only a grounding pad positioned on the lower back) to potentially serve as an inadvertent pathway through the esophagus. The risks of esophageal injury with the surgical part of the Convergent procedure stem from collateral damage due to elevated tissue temperature adjacent to the catheter during ablation line creation. We did not identify any esophageal injuries in our series and found excellent transmural posterior wall ablation on voltage mapping.

The importance of addressing the LAA in AF patients has traditionally revolved around mitigating the risk of thromboembolic events originating from within this structure. More recent studies have implicated the LAA as a focus of AF triggers and consequently as a potential interventional target for rhythm management. Our analysis seems to support this view and suggests a likely benefit of LAA exclusion in arrhythmia control. We found no AF recurrence after the 90-day blanking period in patients who had undergone concomitant LAA exclusion. Our study was not powered to detect a significant difference between patients who did and did not undergo LAA exclusion, but our data trend seems to support the theory that

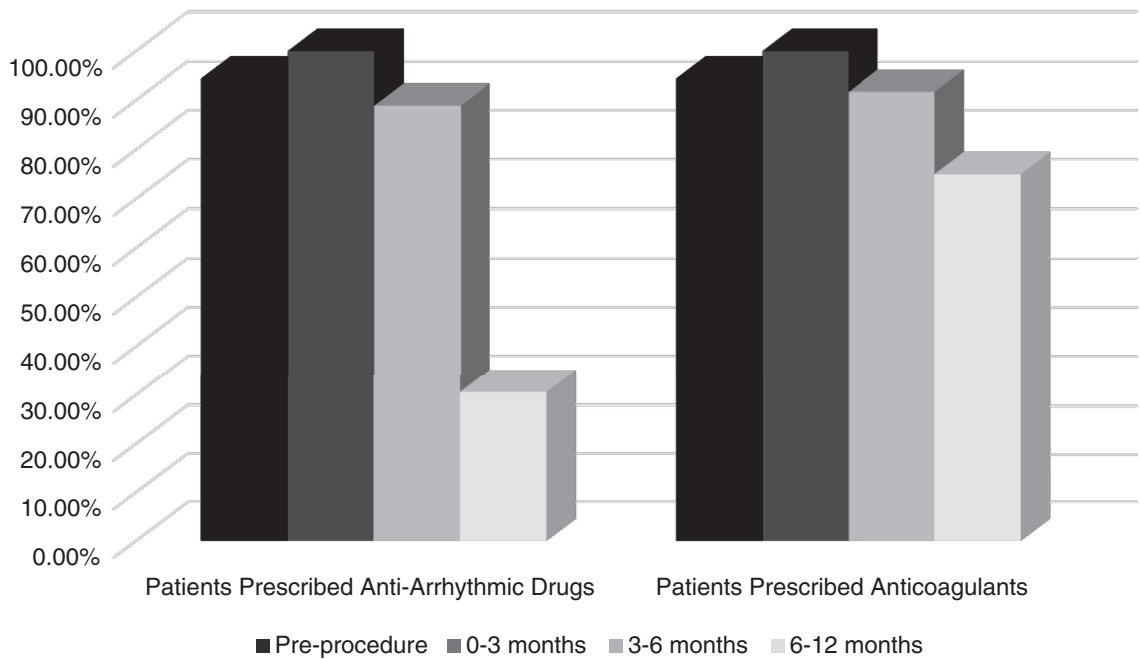


Fig. 3 Patient prescriptions pre- and post-procedure. Patients were prescribed fewer anti-arrhythmic medications (left) and anti-coagulants (right) in the months following the Convergent procedure.

excluding the LAA augments the success rates of ablation alone. The ability to effect electrical silence, and thus arrhythmia suppression, is perhaps the key underappreciated benefit of an epicardial LAA clip over percutaneous endocardial occlusion devices.¹⁸⁾ The molecular or electrophysiologic mechanism by which LAA exclusion might contribute to arrhythmia control is unknown. We suspect that the LAA is a site of dominant AF triggers in a small subset of patients, and that electrical isolation of the LAA by epicardial closure may serve as a type of “ablation” of these triggers. Comparison between percutaneous endocardial occlusion devices and epicardial exclusion by clip placement or complete excision would help better elucidate the role of the LAA in AF. LAA exclusion was performed in a minority of our patients, but this was due primarily to the fact that our group wished to attain familiarity with the new Convergent procedure before including the separate LAA exclusion portion. Once we started to perform the LAA exclusion, this was completed in all patients who could tolerate the single lung ventilation necessary for the thoracoscopic approach.

Our results also demonstrate that the Convergent procedure can be implemented with good outcomes and an excellent safety profile starting with the very first cases in an institution. An interesting secondary finding from our analysis is that the AF and atrial tachyarrhythmia recurrence rate was higher among the earlier patients in the

series. Our overall atrial tachyarrhythmia recurrence rate was approximately 22%, with the majority of these recurrences being atrial flutter and occurring in the first 10 patients of our series. This may suggest that there might be a learning curve associated with the procedure, particularly as it relates to the surgical portion. We suspect this learning curve regards the extent of epicardial ablation necessary; the extent of ablation should not proceed caudad (or inferior) to the inferior pulmonary veins, since ablation of this region (the isthmus) between the inferior veins and coronary sinus can increase the risk of perimitral/atypical atrial flutter. An inexperienced surgeon could easily inadvertently ablate onto the isthmus due to either confusion about anatomic location or lack of understanding of the role the isthmus plays in tachyarrhythmias. There are some factors which may confound our conclusion, however. The early patients in our study did not have LAA exclusion performed, which, as mentioned above, could play a role in AF control. Our study is not able to distinguish whether it was operator experience or LAA exclusion which led to the different recurrence rates in the early versus later patients.

Invasive treatment options such as the Convergent procedure are just one component of a multi-faceted approach to AF treatment. At our institution, preoperatively, we discuss with patients the variables that may contribute to ongoing AF including obesity and obstructive sleep

apnea. All patients are evaluated for these comorbidities and referred to appropriate specialists for treatment as part of their comprehensive AF treatment paradigm. Our current practice is to recommend the Convergent Procedure rather than catheter ablation alone for patients with symptomatic persistent or long-standing persistent AF who have been deemed candidates to pursue ablation therapy (i.e., failed medical therapy or cardioversion, patient preference for rhythm control, previous catheter ablation). We perform concomitant LAA exclusion in these patients as long as there are no contraindications (i.e., moderate to severe chronic obstructive pulmonary disease (COPD), prior left thoracic surgical operations, inability to tolerate single lung ventilation).

One challenge in our experience was related to postoperative rhythm monitoring. We had considerable difficulty in obtaining insurance approval for implantable rhythm monitoring devices post-procedure. This limited our ability to evaluate long periods of rhythm data. A major component of our follow-up was patient reporting of symptom improvement, since this was the primary concern for all of our patients. The majority of patients reported significant improvement in quality of life due to reduced AF episode symptoms. While we considered AF episodes lasting longer than 30 seconds to be a recurrence (and procedural failure) for the purposes of this study, we found that patients considered their procedure to be a success if the frequency and severity of AF episodes were reduced after the Convergent procedure. This clinical definition may be ultimately one of the key benefits of offering a hybrid option such as the Convergent procedure since these patients have few other successful treatment options. Further studies will help to elucidate numerous unanswered questions regarding the Convergent procedure including long-term outcomes, optimal patient selection, results relative to aggressive and newer techniques of catheter ablation, and the role of LAA exclusion as part of the overall procedure.

Conclusions

The Convergent procedure is a safe and effective treatment option that leverages the strengths of minimally invasive surgery and percutaneous endocardial catheter approaches to confer significant symptomatic relief from persistent and long-standing persistent AF. Such a multidisciplinary, hybrid approach may be the key to optimizing outcomes for this difficult patient population and should be considered as part of the armamentarium in a comprehensive AF treatment program.

Disclosure Statement

Lawrence S. Lee serves as a consultant to AtriCure, Inc. The remaining authors have no conflict of interest to report.

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