

Convergent Ablation for Persistent Atrial Fibrillation: Single Center Experience

This retrospective study examined 31 symptomatic patients—with persistent AF (n =16) or long-standing persistent (LSP, n = 15) AF—who were treated with the Convergent procedure. All patients underwent surgical epicardial ablation via subxiphoid approach, followed by radiofrequency endocardial ablations on the same day. Median LA size was 4.3 cm. All but 4 patients, who were lost to follow-up, completed 2-year follow-up.

Arrhythmia Recurrence with or without AADs		
Type of Arrhythmia	At 1 Year	At 2 Years
AF only	13%	29%
AF/AFL	29%	48%

Freedom from Arrhythmias	
Type of Arrhythmia	At 2 Years
AF only	71%
Atrial Tachyarrhythmias	52%

Interestingly, there was no statistical significance in AF/AFL recurrence in patients with or without AADs. Perioperatively, there was a 12.9% (4/31 patients) complication rate, but “some of these complications occurred early in our experience and steps were taken to avoid” these complications in the future. Of the 3 mortalities, 2 were from noncardiac causes within 18 months, and one was from cardiac arrest due to unknown causes at 4 months post intervention.

It is important to point out that 16.1% of this patient cohort had hypertrophic cardiomyopathy, and these patients are known to have much higher AF recurrence rates.

The Convergent procedure emphasizes the importance of silencing the posterior LA, which is an important area of arrhythmogenicity. This study demonstrates that the Convergent approach can be a reasonable alternative for treating patients with advanced stages of AF and severely dilated LA.

The authors concluded the hybrid procedure is a relatively safe and effective option for patients with PAF. Further studies are needed to better determine its long-term outcomes.

Convergent Ablation for Persistent Atrial Fibrillation

Reference: Gulkarov, I. et al. (2019). Convergent ablation for persistent atrial fibrillation: single center experience. *Journal of Cardiac Surgery*, 34(10):1037-43.

Epi-Sense® Guided Coagulation System

U.S. Indications: The Epi-Sense Guided Coagulation System is intended for the treatment of symptomatic long-standing persistent atrial fibrillation (continuous atrial fibrillation greater than 12 months duration) when augmented in a hybrid procedure with an endocardial catheter listed in the instructions for use, in patients (1) who are refractory or intolerant to at least one Class I and/or III antiarrhythmic drug (AAD); and (2) in whom the expected benefit from rhythm control outweighs the potential known risks associated with a hybrid procedure such as delayed post-procedure inflammatory pericardial effusions. **Contraindications** include patients with Barrett's Esophagitis, left atrial thrombus, a systemic infection, active endocarditis, or a localized infection at the surgical site at the time of surgery. **Adverse Events:** Reported adverse events associated with epicardial ablation procedure may include, but are not limited to, the following: pericardial effusion/cardiac tamponade, pericarditis, excessive bleeding, phrenic nerve injury, stroke/TIA/neurologic complication. Please review the Instructions for Use for a complete listing of contraindications, warnings, precautions and potential adverse events located at the following AtriCure web address: <https://www.AtriCure.com/Epi-Sense-Coagulation-Device>. **Warnings:** Physicians should consider post-operative anti-inflammatory medication to decrease the potential for post-operative pericarditis, and/or delayed post-procedure inflammatory pericardial effusions. Physicians should consider post-procedural imaging (i.e. 1-3 weeks post-procedure) for detection of post-procedure inflammatory pericardial effusions. **Precautions:** Precautionary measures should be taken prior to considering treatment of patients: (1) Deemed to be high risk and who may not tolerate a potential delayed post-procedure inflammatory pericardial effusion. (2) Who may not be compliant with needed follow-ups to identify potential safety risks. To ensure patients undergoing treatment with the Epi-Sense device are well informed, the benefits, potential risks and procedural outcomes associated with the Epi-Sense Hybrid Convergent procedure should be discussed with the patient. Physicians should document accordingly in the medical record. Qualified operators are physicians authorized by their institution to perform surgical sub-xiphoid pericardial access. The coagulation devices should be used by physicians trained in the techniques of minimally invasive endoscopic surgical procedures and in the specific approach to be used. Operators should undergo training on the use of Epi-Sense device before performing the procedure. Safety and effectiveness of concomitant left atrial appendage closure was not evaluated in the CONVERGE study. Follow-up should be conducted at approximately 30 days post-procedure to monitor for signs of delayed onset pericarditis or pericardial effusion. **Rx Only.**

This material is intended to provide objective information about the use of AtriCure's Technology, including where and how the device can be used within the continuum of care. The enclosed publication includes information regarding patients with persistent or long-standing persistent atrial fibrillation treated with the Epi-sense technology in a hybrid procedure. This material is being provided to demonstrate use of the Epi-Sense system in the treatment of long-standing atrial fibrillation and its clinical outcomes. This publication was chosen for this purpose because the study summarized herein utilized a trial design similar to that used in the CONVERGE IDE study which supported FDA approval of the Epi-Sense System for the indication stated above.