Outcomes of Convergent Atrial Fibrillation Ablation with Continuous Rhythm Monitoring

The study involved 113 consecutive patients at one institution who underwent the Hybrid AF Convergent procedure. Among the patient characteristics: 88% had either persistent AF or long-standing persistent (LSP) AF; mean duration of AF before the procedure was 5.1 ± 4.6 years; 45% had undergone at least one prior catheter ablation; 31% had impaired LVEF; 62% had moderate or severe LA enlargement.

During follow-up, most patients (n = 92) had continuous rhythm monitoring. During the mean follow-up of 501 days, results were as follows.

Parameter	Finding	
AF/AT-Free Survival	53%	For any episode >30 sec at 12 months (after the 90-day blanking period) in all patients
AF/AT Mean Burden	<5%	Among patients (n=92) with continuous rhythm monitoring who had recurrences—with those very low rates remaining stable throughout follow-up
Off AADs	64%	At last follow-up

Procedural complications decreased significantly following the transition from transdiaphragmatic to subxiphoid surgical access: 23% vs 3.8% (p = 0.005). Other results included: 9% of patients had elective cardioversion outside the blanking period, and 9.7% of patients underwent repeat ablation at a mean of 229 ± 178 days post procedure.

As noted in the Discussion, the data "highlight the potential shortcomings of conventional definitions of AF ablation success which have utilized a definition of recurrence including any AF/AT episode lasting >30 seconds … [with most study results therefore showing] very modest success rates at approximately 50% to 60% at 1 year."

AF: atrial fibrillation; AT: atrial tachycardia; LVEF: left ventricular ejection fraction; LA: left atrial; AADs: anti-arrhythmic drugs

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Outcomes of Convergent Atrial Fibrillation Ablation

The authors noted that recent study results, such as those from CASTLE-AF, suggest AF burden may be more reflective of ablation efficacy than conventional freedom from recurrence. In the current study, the authors found nearly 95% of their continuously monitored patients with recurrences remained free from an arrhythmia burden >5%.

In summary, more than half of the patients were AF/AT-free, and among patients who did experience an AF recurrence, the Hybrid AF Convergent procedure was able to reduce AF burden to very low mean levels of <5%, a level which appeared consistent over time.

At time of study completion, it was noted that future trials will be necessary to best define which patients are most likely to benefit from the Convergent approach.

Reference: *Larson, J., et al. (2020). Outcomes of convergent atrial fibrillation ablation with continuous rhythm monitoring. Journal of Cardiovascular Electrophysiology, 31(6): 1270-6.*

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-xyphoid 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.

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