The Convergent Procedure Versus Catheter Ablation Alone in Long-Standing Persistent Atrial Fibrillation: A Single Center, Propensity-Matched Cohort Study

In this challenging cohort of patients with refractory, long-standing persistent atrial fibrillation (LSPAF), the probability of long-term arrhythmia-free survival was significantly higher with Hybrid AF Convergent ablation (p=0.003).

The study by Maclean, et al., enrolled 43 consecutive patients with LSPAF, who were treated with the Hybrid AF Therapy. Outcomes were compared with a matched group of 43 patients who had catheter ablation alone. Both groups underwent multiple catheter ablations as needed.

Parameter	Hybrid AF Convergent Ablation Arm	Catheter Ablation Arm
AF-Free Survival with AADs at 12 months P = 0.002	60.5%	25.6%
AF-Free Survival with AADs at 30.5 months P = 0.016	58.1%	30.2%
AF-Free Survival without AADs at 30.5 months P = 0.036	32.5%	11.6%

AADs: *anti-arrhythmic drugs*

Although the survival data are lower than those reported in other studies, the authors suggest this may be due to electroanatomic heterogeneity of the study cohort, which included patients with:

- Severe left ventricular systolic dysfunction
- Cardiomyopathy
- Pacemakers
- Prior unsuccessful rhythm control in over one-third of cases

While the Hybrid AF Convergent group had an increased incidence of atrial tachycardia (AT, 32.6%) none of these arrhythmias originated from the posterior wall. Instead, the origin of the AT prompted the authors to suggest consideration of empirical cavotricuspid isthmus (CTI) lines.

This study reveals that in patients with LSPAF, the Hybrid AF Convergent procedure is associated with increased freedom from AF at one year—and improved arrhythmia-free survival long term—versus endocardial catheter ablation alone.

Reference: *Maclean, E. et al. (2020). The CONVERGENT procedure versus catheter ablation alone in long-standing persistent atrial fibrillation: a single center, propensity-matched cohort study. International Journal of Cardiology, 303:49-53.*

EPi-Sense® Guided Coagulation System
The EPi-Sense Coagulation System/EPi-Sense ST™ Coagulation Device 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. 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/EPi-Sense ST device are well informed, the benefits, potential risks and procedural outcomes associated with the EPi-Sense/EPi-Sense ST 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/EPi-Sense ST 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.

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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