Staged Hybrid Ablation for Persistent and Longstanding Persistent Atrial Fibrillation Effectively Restores Sinus Rhythm in Long-Term Observation

Zembala, M. et. al., 2017

While catheter ablation is effective in terminating paroxysmal AF, it lacks efficacy in patients with persistent AF and especially long-standing persistent (LSP) AF. Historically, surgical epicardial ablation was not commonly recommended for such patients.

This study enrolled 90 patients with persistent AF (n = 39, 43%) or LSPAF (n = 51, 57%) to undergo a Hybrid AF™ Convergent procedure. Of the 39 patients who had previously had a catheter ablation, 56.4% had two or more prior ablations. Outcomes are presented for the 70 consecutive patients who had completed the 12-month post-procedure follow-up (the remaining patients had shorter follow-up durations). The 1-year results revealed the following.

Freedom from Arrhythmias	
Parameter	**At 1 Month**
Patients in SR	84.1%
Patients in SR and Off Class I/III AADs	62.3%

Reverse Remodeling and Improved LV Function		
Parameter	**Improvement**	**From Baseline to 1 Year**
Mean LA Size	2.9-mm decrease	From 45.2 ± 5.9 mm to 42.3 ± 6.3 mm ($p < 0.01$)
LVEF	3.5% increase	From 48.6 ± 9.7% to 52.1 ± 7.5% ($p < 0.05$)

The fact that only 62.3% of patients were in SR and free of AADs reflects the authors' "philosophy of cautious AAD withdrawal," since in many LSPAF cases they prefer to perform AAD withdrawal over 18-24 months rather than 1 year.

During follow-up, only one patient required a repeat ablation for AFL. There were 4 serious adverse events over the study duration: death of unknown cause, bleeding requiring sternotomy, cardiac tamponade, and transient ischemic attack. Three minor, reversible complications occurred: transient ischemic attack, pericardial effusion, and temporary phrenic nerve palsy.

The authors concluded a combination of epicardial and endocardial RF ablation should be considered as a treatment option for patients with persistent and long-standing persistent atrial fibrillation as it is safe and effective in restoring sinus rhythm.

AF: atrial fibrillation; SR: sinus rhythm; AADs: anti-arrhythmic drugs; LA: left atrium LVEF: left ventricular ejection fraction; AFL: atrial flutter

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Reference: *Zembala, M. et al. (2017). Staged hybrid ablation for persistent and longstanding persistent atrial fibrillation effectively restores sinus rhythm in long-term observation. Archives of medical science: AMS, 13(1):109-17. https://doi.org/10.5114/aoms.2015.53960*

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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