Low Rate of Atrial Fibrillation Recurrence Verified by Implantable Loop Recorder Monitoring Following a Convergent Epicardial and Endocardial Ablation of Atrial Fibrillation

Gersak, B., et al. (2012)

Since the initial diagnosis of AF is long-standing persistent (LSP) AF for 50% of patients, clinicians need more comprehensive approaches for this patient population. Endocardial ablation to achieve PVI does not treat reentrant circuits common in persistent and LSP patients, who often have developed structural heart disease and atrial enlargement.

The Convergent procedure (CP) targets persistent and LSP patients—who are at increased risk of heart failure, stroke, and mortality—by combining endoscopic creation of epicardial linear lesions followed by endocardial mapping and ablation. EP testing is performed to assure lesion transmurality, pattern completeness, and PV isolation. This article reports the results of a study in which a total of 50 patients were enrolled, with 94% having persistent AF or LSPAF; 78% of the patients had structural heart disease.

Investigators evaluated long-term outcomes in consecutive patients undergoing the CP. Mean duration of AF was 5.0 ± 4.7 years. The results revealed:

Follow-Up Timeframe	Patients in Sinus Rhythm	Median AF Burden	< 3% AF Burden on Continuous Monitoring
Irrespective of AADs			
6 months	95%	0.0%	81%
12 months	88%	0.1%	81%
24 months	87%	0.1%	87%
Off AADs			
6 months	67%	Not reported	Not reported
12 months	75%	Not reported	Not reported
24 months	67%	Not reported	Not reported

Two patients receiving the CP were in continuous AF beyond the blanking period, and both had LSPAF pre-procedure, as well as hypertension and enlarged left atria ≥ 5.0 cm. There were 2 atrioesophageal fistulas reported. In one patient, the fistula resulted in death at 33 days post procedure; in the second, the fistula was surgically repaired but the patient died 8 months post procedure from a CVI. Consequently, investigators introduced added safety measures and temporarily staged the procedure—after which no other serious events were observed.

AF: atrial fibrillation; PV: pulmonary vein; CP: Convergent procedure; EP: electrophysiology; AADs: anti-arrhythmic drugs; CVI: cerebrovascular insult

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The investigators determined that, given the results of continuous loop recording, the CP was successful in treating persistent AF and LSPAF. Given that 87% of patients continued to have a cumulative AF burden less than 3% at 24 months post procedure, the dual epicardial/endocardial ablation was able to maintain outcomes throughout follow-up. The authors noted that the durability achieved—in maintaining sinus rhythm and eliminating redo procedures—compares favorably to catheter ablation study data.

Reference: *Gersak, B. et al. (2012). Low rate of atrial fibrillation recurrence verified by implantable loop recorder monitoring following a Convergent epicardial and endocardial ablation of atrial fibrillation. J Cardiovasc Electrophysiol, 23:1059-106.*

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.