Simultaneous Catheter and Epicardial Ablations Enable a Comprehensive Atrial Fibrillation Procedure

Kiser, A. C., et al. (2011)

A simultaneous endocardial and epicardial ablation procedure, the Convergent procedure, precludes the treatment limitations related to epicardial AF procedures alone. The procedure achieves a comprehensive and bilateral ablation.

The epicardial portion is performed via a 2-cm subxiphoid incision vs a chest incision. To assess the potential advantages of adding endocardial ablation, investigators compared two types of epicardial procedures to the Convergent procedure. Patients undergoing (1) the open-chest concomitant Ex-Maze procedure and (2) the thoracoscopic/pericardioscopic Ex-Maze procedure did not receive endocardial ablation therapy.

Most of the patients evaluated in all three groups had persistent or long-standing persistent (LSP) AF:

- 89% among open-chest concomitant Ex-Maze patients
- 100% among pericardioscopic /thoracoscopic Ex-Maze patients
- 92% among Convergent procedure patients

Results related to restoration of SR are as follows.

Comparative 12-Month Outcomes of the Convergent Procedure

	Open Chest Concomitant Ex-Maze (n = 117)		Pericardioscopic / Thoracoscopic Ex-Maze (n = 61)		Convergent Procedure (n = 65, 42 with 12-month data)	
Evaluation Method	**Holter or ECG**	**Holter**	**Holter or ECG**	**Holter**	**Holter or ECG**	**Holter**
Patients in SR	80% (53/66)	77% (37/48)	57% (30/53)	47% (22/47)	88%* (37/42)	82%* (32/39)
Patients in SR and Off AADs	71% (47/66)	67% (32/48)	55% (29/53)	47% (22/47)	83%* (35/42)	77%* (30/39)

**Reveal = 19 (sinus rhythm >97%)*

The authors concluded these results indicate that, compared with surgical ablation procedures alone, collaboration with electrophysiologists improves outcomes.

Safety data revealed that, of the patients undergoing the Convergent procedure, 2 patients developed a pericardial effusion 2 weeks post procedure requiring percutaneous drainage; both patients fully recovered and continued to be in sinus rhythm at 12 months. (After investigators added a pericardial drainage tube for 48 hours post procedure, the Convergent patients experienced no pericardial effusions.) One patient who was discharged on Dofetilide experienced SCD 7 days post procedure, presumably related to torsades de pointes since no other cause of death was discovered. Two patients developed atrial-esophageal fistulas which resulted in death.

AF: atrial fibrillation; SR: sinus rhythm;
AADs: anti-arrhythmic drugs; SCD: sudden cardiac death

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The authors stated that by providing endocardial ablation and verifying lesion transmurality during the Convergent procedure, the authors felt confident that all had been done to fully address any potential arrhythmias.

The authors concluded that use of both epicardial and endocardial ablation improves outcomes for patients with persistent or longstanding persistent atrial fibrillation. The authors furthermore stated that the outcomes observed with this collaboration—cardiac surgeons and electrophysiologists both delivering ablation therapy—reveals that this is an important treatment option for patients with atrial enlargement and chronic atrial fibrillation

Reference: *Kiser, A. C. et al. (2011). Simultaneous catheter and epicardial ablations enable a comprehensive atrial fibrillation procedure. Innovations, 6:243-7.*

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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