

# Atrial Fibrillation Symptom Reduction and Improved Quality of Life Following the Hybrid Convergent Procedure: A CONVERGE Trial Sub-Analysis

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## Introduction

The Hybrid Convergent procedure combines epicardial ablation performed by a cardiothoracic surgeon and endocardial catheter ablation (CA) performed by an electrophysiologist to achieve pulmonary vein (PV) and left atrial posterior wall isolation. Previous investigation showed that of the evaluable patients who received Hybrid Convergent, 67.7% (n=67/99) achieved freedom from atrial fibrillation (AF)/atrial flutter (AFL)/atrial tachycardia (AT) through 12 months compared with 50.0% (n=25/50) of evaluable patients who received CA off new anti-arrhythmic drugs (AADs) or increased dose of previously failed/intolerant antiarrhythmic drugs (AADs).<sup>1</sup> With this level of evidence for safety and effectiveness, Dr Jaswinder Gill (Guy's and St Thomas' Foundation Trust, London, UK) and colleagues describe the impact of Hybrid Convergent ablation on AF symptoms, patient quality of life (QOL), and AAD utilization from the CONVERGE trial.<sup>2</sup>

## Methods

AF-related symptoms and QOL were assessed at baseline and 12 months following treatment using the 19-item self-administered Atrial Fibrillation Severity Scale (AFSS) and the 36-Item Short Form Health Survey (SF-36), respectively. The AFSS is scored from 3 to 30 and higher values represent greater burden. The SF-36 is a general tool not specific to AF that generates the Physical Component Score (PCS) and Mental Component Score (MCS). SF-36 values range from 0 to 100 and higher values represent better QOL. A 5-point change in score is considered "clinically and socially" relevant. Class I/III AAD use was assessed at baseline and through 12- and 18-months following treatment and a 3-month blanking period.

## Results

AFSS Composite Symptoms Scores (Table) significantly improved at 12 months versus baseline for the Hybrid Convergent arm and the subgroup of Hybrid Convergent patients with long-standing persistent AF (LSPAF, -11.7,  $P<0.001$  and -13.0,  $P<0.001$ , respectively). Mean changes in AFSS Overall Symptom Scores for Hybrid Convergent were -10.1 and -9.9 from baseline to 12 months for the overall population and the LSPAF subgroup, respectively ( $P<0.001$  for both). Changes in AFSS Overall Symptom Scores were also significantly greater after Hybrid Convergent than after CA.

From baseline, reductions in the individual AF symptoms of palpitations, shortness of breath at rest, shortness of breath during physical activity, exercise intolerance, fatigue at rest, lightheadedness/ dizziness, and chest pain or pressure were observed at 12 months follow-up for both the Hybrid Convergent arm and its LSPAF subgroup.

The mean change in SF-36 MCS from baseline to 12 months was significantly improved in the Hybrid Convergent arm and its LSPAF subgroup (+5.6 for both,  $P<0.001$  and  $P=0.01$ , respectively). The mean change in SF-36 PCS from baseline to 12 months was +7.3 ( $P<0.0001$ ) in the Hybrid Convergent arm and +7.9 ( $P<0.001$ ) in the Hybrid Convergent LSPAF subgroup. Improvement in PCS from baseline to 12 months was comparable after Hybrid Convergent for the overall population compared with the overall CA population; however, for the LSPAF subgroups, improvement in PCS was significantly greater after Hybrid Convergent than after CA.

The proportion of patients in the Hybrid Convergent arm who used Class I /III AADs post-blanking period was significantly lower through 12-months (33.3%) and 18-months (37.3%) than baseline (84.3%;  $P<0.001$ ). For LSPAF patients who received Hybrid Convergent procedures, the proportions of AAD use were also significantly lower through 12- and 18-months (both 28.95%) than at baseline (71.1%;  $P<0.001$ ).

## Surgical Ablation of Atrial Fibrillation

### Key Takeaways

- AFSS and SF-36 Mental and Physical Component scores were significantly improved at 12-months versus baseline with Hybrid Convergent overall and for the subset of LSPAF patients treated with either Hybrid Convergent or CA.
- The proportion of Hybrid Convergent patients who used Class I /III AADs through 12- and 18-months was 33.3% and 36.3%, respectively, versus 84.3% at baseline (P<0.001).
- In LSPAF patients who underwent Hybrid Convergent, AADs use was 28.95% through 18-months follow up versus 71.1% at baseline (P<0.001).
- Hybrid Convergent reduced AF symptoms, significantly improved QOL, and reduced AAD use in patients with PersAF and LSPAF.

**Table.** AFSS scores, quality of life, and Class I/III AAD use in Hybrid Convergent versus catheter ablation procedures in the CONVERGE trial.

	Hybrid Convergent Overall	Hybrid Convergent LSPAF	Catheter Ablation Overall	Catheter Ablation LSPAF
AFSS* Composite Symptoms Score, change from baseline				
12 months	-11.7	-13.3	-10.2	-9.8
AFSS* Overall Symptoms Score, change from baseline				
12 months	-10.1	-9.9	-9.2	-8.0
SF-36** MCS, change from baseline				
12 months	+5.6	+5.6	+7.7	+6.5
SF-36** PCS, change from baseline				
12 months	+7.3	+7.9	+5.7	+3.0
Class I/III AADs use post-blanking period				
Baseline	84.3%	71.1%	80.4%	66.7%
12 months	33.3%	29.0%	56.9%	63.0%
18 months	37.3%	29.0%	56.9%	63.0%

AAD=anti-arrhythmic drugs; AF=atrial fibrillation; AFSS=Atrial Fibrillation Severity Scale; LSPAF=longstanding persistent atrial fibrillation; MCS=Mental Component Score; PCS=Physical Component Score.

\*The AFSS is scored from 3 to 30 and higher values represent greater burden.

\*\*SF-36 values range from 0 to 100 and higher values represent better QOL. A 5-point change in score is considered “clinically and socially” relevant.

# Surgical Ablation of Atrial Fibrillation

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**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.**

**Australia, Chile, EU Region, Hong Kong, Israel, Kuwait, New Zealand, UK Indications:** The EPI-Sense® Guided Coagulation System with VisiTrax® is intended for the coagulation of cardiac tissue using radiofrequency (RF) energy during cardiac surgery for the treatment of arrhythmias including Atrial Fibrillation (AFIB) or Atrial Flutter (AFL).

## **References:**

1. De Lurgio D, et al. Circ Arrhythm Electrophysiol 2020.
2. Gill J et al. Ann Cardiothorac Surg 2023. doi: 10.21037/acs-2023-afm-15. doi10.21037/acs-2023-afm-15.

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