Hybrid Convergent Ablation for Atrial Fibrillation: A Systematic Review and Meta-Analysis

Shrestha, S. et al. (2022). Heart Rhythm O2. 2022 May 16. https://doi.org/10.1016/j.hroo.2022.05.006

This systematic review of two literature databases and meta-analysis, led by Dr. Felix Yang (Maimonides Medical Center, Brooklyn, NY), evaluated current published data on the safety and effectiveness of contemporary Hybrid Convergent procedures. Patient characteristics, procedural details, clinical outcomes at ≥1 year follow-up, and major adverse events (MAEs) were collected. Meta-analysis using a random-effects model was performed to aggregate data.

A total of 249 publications were identified and resulting in an analysis of 5 observational studies and the CONVERGE randomized controlled trial (Table). These studies included 551 patients. Seventy-three percent were male, mean ages ranged from 61–69 years, 96% had symptomatic persistent or longstanding persistent atrial fibrillation (AF), and where reported, most patients had failed at least 1 anti-arrhythmic drug (AAD). In 5 studies, Hybrid Convergent ablation was performed in a single setting, and in 1 study the procedures were staged by approximately 6 weeks. Authors noted a recent shift from transdiaphragmatic to subxiphoid pericardial access, the latter of which was used in 33% of cases. Endocardial ablation was performed with radiofrequency energy only (56%) or primarily cryoballoon (44%).

Meta-analysis of the 6 studies found freedom from atrial arrhythmias with or without AADs at 1-year or later was 69% (95% CI: 61–78%, n=523; Table). In 3 studies, freedom from arrhythmias off AADs was 50% (95% CI: 42–58%; n=343 patients; Table). AF burden after Hybrid Convergent ablation was qualitatively summarized with ≤5% AF burden in 88-95% of patients at ≥12-months follow-up in two studies, and ≥90% reduction in AF Burden in 74% and 80% of patients at 12- and 18-months follow-up in CONVERGE. Meta-analysis found the pooled 30-day AE rate was 6% (95% CI: 4¬–8%, n=551; Table). No atrioesophageal fistulas, tamponade from cardiac perforations, or periprocedural deaths were reported. The most frequent event was pericardial effusion. These are typically delayed, inflammatory effusions (1–3 weeks after the procedure), likely in response to pericardiotomy and ablation, not cardiac perforation. In the 6 studies, 80% of these events were treated with pericardiocentesis or managed medically, and 20% were treated with pericardial window. Risk mitigation strategies such as prophylactic anti-inflammatory drugs and post-procedure transthoracic and transesophageal echocardiograms were discussed. Two studies noted significantly decreased complication rates after transitioning to subxiphoid pericardial access.

The authors concluded that available published data support that hybrid convergent is an effective ablation strategy for treating patients with persistent or longstanding persistent AF.

Table

Endpoint	10 Years
Freedom from atrial arrhythmias at ≥1 year irrespective of anti-arrhythymic drugs (AADs)[1-6]	69% (95% CI: 61–78%, n=523 in 6 studies)
Freedom from atrial arrhythmias at ≥1 year off AADs[1-3]	50% (95% CI: 42–58%; n=343 patients in 3 studies)
30-day major adverse event rate[1-6]	6% (95% CI: 4-8%, n=551 in 6 studies)

[1]De Lurgio et al. Circ Arrhythm Electrophysiol 2020; [2]Makati et al. Circ Arrhythm Electrophysiol; [3]Maclean et al. Int J Cardiol 2020; [4]Gulkarov et al. J Cardiac Surg 2019; [5]Larson et al. J Cardiovasc Electrophysiol 2020; [6]Tonks et al. Ann Thorac Cardiovasc Surg 2020

AtriCure

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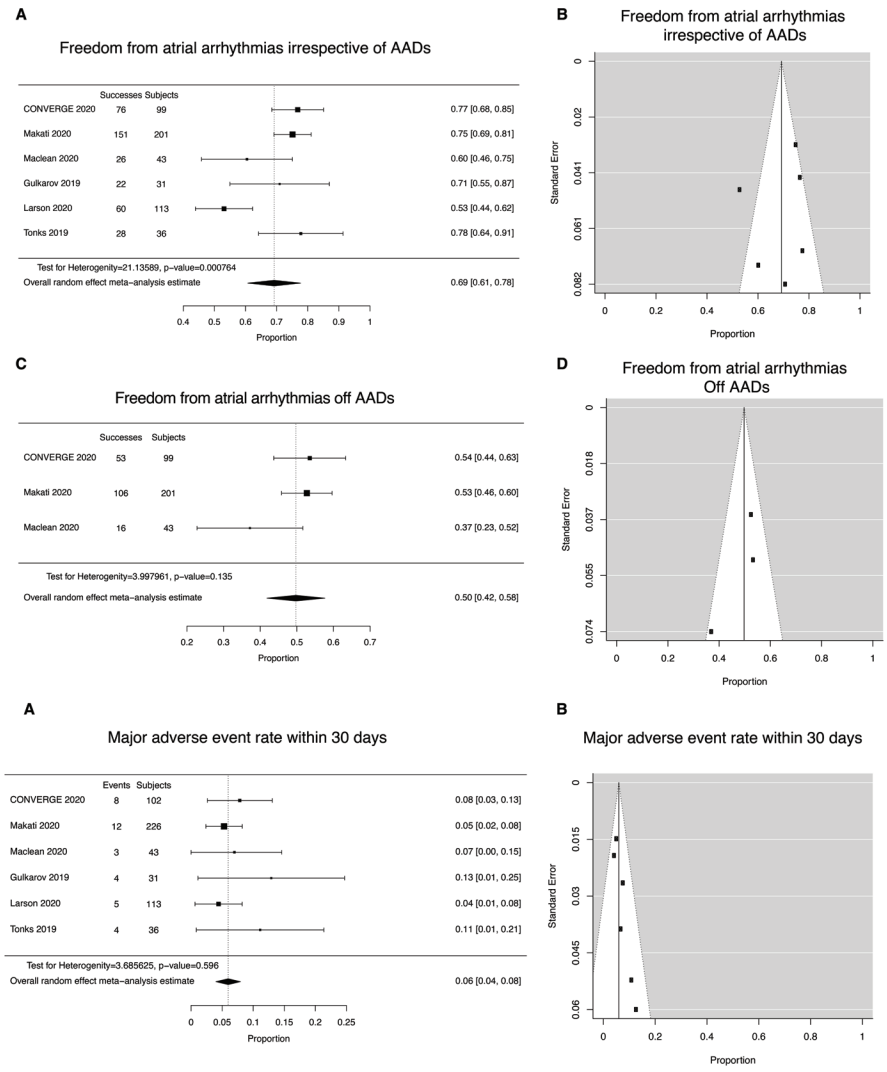

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EPi-Sense® Guided Coagulation System

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.**

Indications for Chile, EU, Israel, New Zealand, UK, Kuwait, and Hong Kong: *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).*

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