The Effect of Left Atrial Appendage Closure on Patients Undergoing Hybrid Convergent AF Ablation

A recently published single-site, retrospective analysis conducted by N. Gegechkori and colleagues (Maimonides Medical Center, Brooklyn, NY) aimed to determine if hybrid convergent ablation with left atrial appendage exclusion (LAAE) using the AtriClip® LAAE System offers additional benefit in reducing atrial arrhythmia (AA) recurrence and longer-term stroke risk.[1]

A total of 139 consecutive patients from the TRAC AF Registry (sponsored by AtriCure Inc, ClinicalTrials.gov identifier: NCT05111015), who presented with persistent atrial fibrillation (AF) and without prior ablation, underwent hybrid convergent ablation alone (HA, n=59, 48%) or HA with LAAE using AtriClip (n=64, 52%). Outcomes including freedom from AF and any AA on or off antiarrhythmic drugs (AADs) outside of the 90-day blanking period were assessed. Patients completed a minimum of 3 months of follow-up and outcomes were evaluated at one year.

Results demonstrated freedom from any AA off AAD was significantly improved in the HA+AtriClip group compared to HA alone (77% vs 58%; p=0.04), and a trend to improved freedom from any AA on or off AADs in the HA+AtriClip group (88% vs 76%; p=0.15) was also observed. In addition, fewer repeat catheter ablations were required at one year for the HA+AtriClip group (p<0.05). Furthermore, discontinuation of oral anticoagulation therapy occurred in 25% and 7% of patients treated with HA+AtriClip and HA alone, respectively, at 12 months. Of patients who underwent HA+AtriClip, 98% had complete closure of their LAA with residual stumps measuring < 1 cm. No strokes, trans-ischemic attacks, myocardial infarctions, phrenic nerve injuries, atrioesophageal fistulas or deaths occurred in either group.

Outcomes at one-year post-procedure			
	HA + AtriClip	HA Alone	P-Value
Freedom from any AA off AAD	77%	58%	P=0.04
Patients requiring repeat ablations at 1 year	0%	10%	P<0.05
Freedom from any AA on or off AADs	88%	76%	P=0.15
Freedom from oral anticoagulation	25%	7%	NS

AA = atrial arrhythmias; AADs= antiarrhythmic drugs; HA = hybrid convergent ablation; NS = non-significant

Key Takeaways

- In this study, patients with persistent AF who underwent HA+AtriClip demonstrated improved freedom from AA recurrence over HA alone without any increased risk of stroke at one year.
- Fewer patients treated with HA+AtriClip were using AADs and required fewer repeat ablations at one year.
- These results are in line with those of the CONVERGE Trial which demonstrated a significant improvement in freedom from atrial arrhythmias (AA, absent change in antiarrhythmic drugs, AAD) with hybrid convergent ablation as compared to endocardial catheter ablation alone (67.7% vs 50.0%, p=0.036) in patients with persistent and long-standing persistent AF.[2]

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Hybrid Convergent: Effects of Left Atrial Appendage Closure

References:
1. *Gegechkori, N. et al. (2022). J Afib-EP, 15(3), in press.*
2. *Delurgio, D. et al. (2020). Circ Arrhythm Electrophysiol, 13: e009288.*

AtriClip LAA Exclusion System
Argentina, Belarus, Brazil, Chile, Colombia, EU Region, Hong Kong, Korea, New Zealand, Serbia, South Africa, UAE and UK Indications: *AtriClip LAA Exclusion System is indicated for open occlusion of the heart's left atrial appendage.*

Canada Indications: *The AtriClip LAA Exclusion System is indicated for the occlusion of the left atrial appendage, under direct visualization, in conjunction with other open cardiac surgical procedures.*

Japan Indications: *This device is intended for the occlusion of a left arterial appendage on cardiovascular surgeries in thoracotomy or thoracoscopic for patients with a risk of thrombosis embolism related to atrial fibrillation and so on.*

U.S. Indications: *The AtriClip LAA Exclusion System is indicated for the exclusion of the heart's left atrial appendage, performed under direct visualization and in conjunction with other cardiac surgical procedures.*

Direct visualization, in this context, requires that the surgeon is able to see the heart directly, with or without assistance from a camera, endoscope, etc., or other appropriate viewing technologies.

EPi-Sense® Guided Coagulation System
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).*

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 postprocedure 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.*