Reported Improved Left Ventricular Ejection Fraction After Hybrid Convergent Ablation in Patients with Atrial Fibrillation and Reduced Ejection Fraction

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Introduction

A hybrid convergent ablation approach has been demonstrated as an effective treatment strategy to reduce atrial fibrillation (AF) and restore sinus rhythm in patients with normal left ventricular ejection fraction (LVEF). However, data on the use of this technique in AF patients with heart failure (reduced LVEF) is limited.

Methods

A multicenter, retrospective analysis, led by Dr. Saumil R. Oza and colleagues (Ascension Medical Group St. Vincent, Jacksonville, FL), was conducted to determine if a hybrid approach combining epicardial and endocardial ablation improved LVEF.[1] A total of 158 consecutive patients (98% persistent AF, PersAF or long-standing persistent AF, LSPAF) were included in the study. At baseline, they had a mean pre-operative AF duration of 6.4±6.5 years, and approximately one-third (42/155, 27%) had a previous failed endocardial catheter ablation.

Surgical access for the hybrid epi-endo procedure was obtained via a subxiphoid or transdiaphragmatic incision. The epicardial ablation, which involves ablation of the left atrial posterior wall (LAPW), was conducted using the EPi-Sense device (AtriCure Inc, Mason, OH). Following epicardial ablation, endocardial mapping and ablation were conducted to address any gaps in the LAPW lesion set and complete isolation of the pulmonary veins.

At baseline and post-hybrid procedure, LVEF was measured using 2D echocardiography. For the outcomes analysis, patients were evaluated together and then stratified based on LVEF at baseline as normal (≥55%) or reduced (<55%), and then further parsed as severely to moderately reduced (<40%) or moderately to mildly reduced (≥40% and <55%). After the 3-month blanking period, AF recurrence was defined as having no AF with or without an implantable monitor or having AF < 5 minutes or <1% AF burden on an implantable device through LVEF assessment post-procedure.

Results

Patients with reduced LVEF (<55%, n=70) demonstrated a significant improvement in LVEF of +6.84%, p<0.0001 after a mean 7.75 months of follow-up after the hybrid convergent procedure. Those with more severely to moderately reduced LVEF (<40%; n=22) experienced the largest LVEF improvement after hybrid (+10.9%, p=0.0002) with a mean 9.31 months of follow-up, thus increasing their EF classification to moderate-to-mild. Those with moderately to mildly reduced baseline EF (≥40 to <55%; n=48) also saw a benefit of +5%, p=0.0005 after a mean 7.01 months of follow-up. No statistical change in LVEF was observed in patients with normal baseline EF who underwent hybrid (n=88, p=0.7762). See Table 1

Table 1. Change in Left Ventricular Ejection Fraction (LVEF)		
LVEF Group	**% LVEF Improvement (mean follow-up)**	**P-value**
LVEF <55% n=70	+6.84±10.25% (7.75±8.67 months)	0.0001
LVEF <40% n=22	+10.86±11.24 (9.31±10.91 months)	0.0002
LVEF ≥40 to <55% n=48	+5.0±9.31% (7.01±7.42 months)	0.0005
Normal LVEF ≥55% n=88	-0.22±7.33% (10.85±12.5 months)	0.7762
All Patients N=158	+2.9±9.4% (9.5±11.1 months)	0.0001

Of 115 patients with available rhythm data after a 3-month blanking period, 59% were free from AF (mean follow up of 14.26 ± 7.85 months). Freedom from AF was achieved in 66% of patients classified with moderately to mildly reduced baseline LVEF (mean follow-up 13.19 ± 6.48 months); in 57% (27/47) with reduced baseline EF (mean follow-up 15.18±8.90 months); and in 40% (6/15) with severe-to-moderate reduced baseline EF (mean follow-up 19.41 ± 11.78 months).

Mean LVEF improvement was 3.4 ± 9.9% in patients who did not experience a recurrence prior to their LVEF echo assessment whereas it was 0.3 ± 8.1% in patients who experienced a recurrence prior to echo. This was not statistically significant and could have been confounded by differences in follow up time to LVEF assessment. Since continuous rhythm monitoring was only available for a subset of the entire cohort, AF burden could not be definitively determined.

Limitations

- This was a non-randomized, retrospective, single arm study which included a small sample size and short follow-up period.
- Rhythm monitoring was only available on a subset of patients, thus evaluation of sinus rhythm maintenance during the course of follow up was limited.
- Changes in New York Heart Association Functional Class and quality of life, parameters typically employed to measure heart failure status, were not evaluated.

Conclusion

The hybrid convergent procedure improved LVEF in patients with persistent and LSPAF. This study adds to the limited published evidence in support of hybrid to treat patients with AF and depressed LVEF.

Reference:
1. Oza SR *et al.* JAFIB-EP 2024;17(1):1-5. DOI: 10.23096/JAFIBEP-20200741

EPi-Sense® Coagulation Device

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).*

EPi-Sense Coagulation System/EPi-Sense ST™

U.S. Indications: *The EPi-Sense Coagulation System/EPi-Sense ST™ Coagulation Device 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. 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/EPi-Sense ST device are well informed, the benefits, potential risks and procedural outcomes associated with the EPi-Sense/EPi-Sense ST 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/EPi-Sense ST 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.*

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