Safety and Efficacy of Convergent Hybrid Procedure Using Cryo as Endocardial Energy Source for the Treatment of Atrial Fibrillation

This study showed that using endocardial cryothermy in Hybrid AF Convergent procedures achieved marked reductions in AF burden, even in long-standing persistent AF (LSPAF). Most Hybrid AF Convergent studies use radiofrequency as the endocardial and epicardial energy. This study reports the safety and efficacy of the Hybrid AF Convergent procedure using endocardial cryothermy.

Method: Retrospective analysis of 226 TRAC-AF Registry patients (2011-2018) who underwent epicardial RF ablation and endocardial cryothermy.

Parameter	All patients (mean 15.4 ± 6.5 months)	Persistent AF (mean 14.7 ± 6.1 months)	LSPAF (mean 16.8 ± 6.3 months)
Free of AF/AFL/AT: on or off previously failed AADs	75%	85%	70%
Free of AF/AFL/AT: off amiodarone	70%	84%	64%
Free of AF/AFL/AT: off AADs	53%		
AF Burden Reduction (3-12 months)	98.9%	99.3%	98.5%
AF Burden Reduction (12-24 months)	91.5%	89.3%	92.5%

AF: atrial fibrillation; AFL: atrial flutter; AT: atrial tachycardia; AADs: anti-arrhythmic drugs

Results indicate Hybrid AF Convergent using cryo energy provides a promising solution for treatment of persistent AF and LSPAF, evidenced by relatively low AF recurrence rates and marked AF burden reduction after treatment—even in LSPAF patients.

Reference: *Makati, K. J. et al. (2020). Safety and efficacy of Convergent Hybrid procedure using cryo as endocardial energy source for the treatment of atrial fibrillation. Circulation: Arrhythmia and Electrophysiology, 13:e008556.*

EPi-Sense® Guided Coagulation System
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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