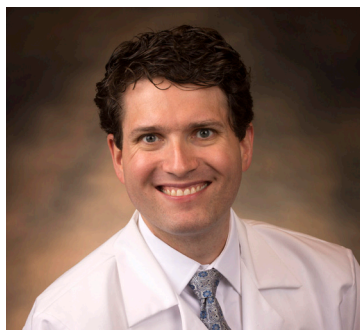


Case Study: Staged Hybrid AF Convergent Ablation for Highly Symptomatic Persistent Atrial Fibrillation After Multiple Failed Ablations and Medications



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Patient: 73-year-old male with long-standing persistent atrial fibrillation

Patient History

The patient was first diagnosed with atrial fibrillation in 2002 with symptoms of palpitations, fatigue, dyspnea, and weight gain. Management consisted of cardioversions and multiple anti-arrhythmic medications, culminating in the use of amiodarone, but without success. Due to the severity of symptoms, he underwent a pulmonary vein isolation (PVI) at a different facility in 2013, which provided some symptom relief. However he required a redo PVI in 2015 and a third ablation in 2019. At that time he had reconstructions of both inferior veins as well as multiple unstable atrial tachycardias, so he underwent a roof line and traditional mitral isthmus line ablation between the left inferior pulmonary vein and the mitral annulus. Unfortunately, AF recurred within 2 months. Again due to debilitating symptoms, he subsequently went through three more cardioversions—which were unsuccessful, even with the re-addition of amiodarone. He initiated lifestyle modifications, including substantial weight loss and discontinuation of caffeine, but he nonetheless reverted to atrial fibrillation. This left him with severe fatigue and a constant feeling of having a flu-like illness.

With his quality of life so diminished, he sought a second opinion. Echocardiogram revealed preserved left ventricular ejection fraction of 60% with moderate left atrial dilation and normal size right atrium. Given his symptoms, prior unsuccessful procedures, and echocardiographic findings, a Hybrid AF Convergent ablation was planned.

Treatment

In August of 2019, he underwent minimally invasive Hybrid AF Convergent epicardial ablation involving subxiphoid access with posterior wall silencing, utilizing 32 total ablations. After completion of the epicardial ablation, a pericardial drain was placed and a left-sided video-assisted thoracoscopic surgery was performed for left atrial appendage ligation using a #35 AtriClip PRO2 device, which required two 12-mm ports and a single 8-mm port. Total LAA closure was confirmed via intraoperative transesophageal echocardiogram, and a left pleural drain was placed. Drains were removed on post-operative day #2 and he was discharged home with planned endocardial ablation to follow in a month, as is our standard protocol.

He returned in September for the endocardial ablation. A voltage map of the left atrium demonstrated posterior wall silencing and intact isolation of all four pulmonary veins (Map #1). However, he presented in atrial fibrillation at the outset. In addition to these regions, multiple areas in the left atrium also demonstrated continuous fractionated electrograms and low voltage scar, mainly in Waterston's groove, bilateral pulmonary vein carinas, left perimitral region, and the anterior wall of the left atrium (Maps #2, #3). Box isolation of

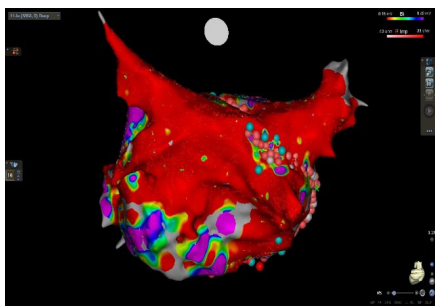
Staged Hybrid AF Convergent Ablation for Highly Symptomatic Persistent Atrial Fibrillation After Multiple Failed Ablations and Medications (continued)

these fractionated areas (BIFA) was performed, which converted the rhythm into an organized atrial flutter. Entrainment and activation mapping were consistent with right atrial, not left atrial, flutter. Activation and voltage mapping of the right atrium confirmed that the entire cycle length was confined to the right atrium. Cavotricuspid isthmus ablation was performed with evidence of block, but not termination of the flutter, so further ablation was performed in an area of low voltage scar near the inferior crista terminalis. This resulted in arrhythmia termination (Map #4). He was discharged home the same day, on oral anticoagulation and amiodarone.

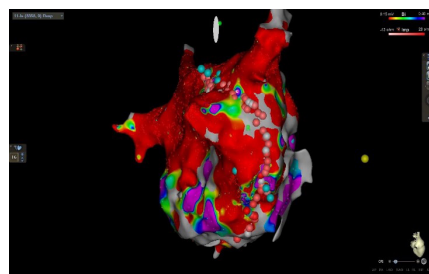
Outcome

The patient reported a markedly improved quality of life with maintenance of sinus rhythm following the two-stage Hybrid AF Convergent procedure. Amiodarone was discontinued two months later. He did have one clinical recurrence that required brief re-administration of flecainide in April of 2020 (a medication which had previously been unsuccessful), which led to spontaneous conversion.

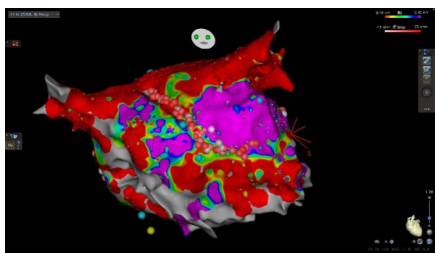
Map 1.



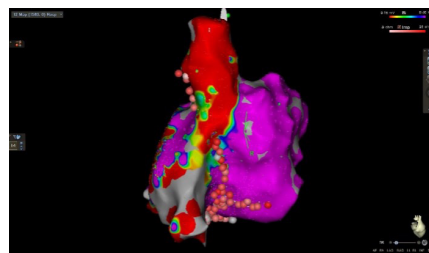
Map 2.



Map 3.



Map 4.



Note: Clinical results from case studies are not predictive of results in other cases. Results in other cases may vary.

EPI-Sense® Coagulation System/EPI-Sense ST™ Coagulation Device

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. 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-xiphoid 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.