Selection of Patients for Hybrid Ablation Procedure

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Introduction

Cardiac ablation can be conducted using catheter, surgical and more recently, hybrid epicardial-endocardial approaches to treat atrial fibrillation (AF). Assessing which patients may be more aptly suited for an ablation strategy depends on patient characteristics, comorbidities, and type of AF diagnosis (paroxysmal, persistent or long-standing persistent AF, LSPAF). In addition, a multi-disciplinary team approach can help facilitate the most beneficial treatment option.[1]

It is well known that patients with paroxysmal AF who undergo standalone endocardial catheter ablation experience greater freedom from atrial arrhythmias (92%) and fewer instances for repeat ablation compared to those with persistent and LSPAF.[2] Those with more advanced forms of AF tend to be more difficult to treat and have a lower success rate with endocardial ablation alone. In fact, endocardial ablation among persistent AF patients yielded effectiveness rates of 54.8% to 61.7% at 12 and 15 months, respectively, after a single ablation procedure.[3,4] Furthermore, Tsai and colleagues demonstrated a one-year AF recurrence rate of 61.9% among 100 patients with non-paroxysmal AF and only 16% of patients remained AF free at 10 years after the index procedure.[5]

The premise of this invited review article by David B Delurgio (Emory University, St. Joseph's Hospital, Dunwoody, Georgia) focuses on a minimally invasive hybrid convergent (HC) ablation approach to treat patients with non-paroxysmal AF.

Hybrid Convergent Ablation Approach

A hybrid approach involves a cardiothoracic surgeon who first performs an epicardial ablation to create consistent, parallel lesions along the left atrial posterior wall. This is followed by an endocardial ablation performed by an electrophysiologist (EP) where ablation lines are created on left and right pulmonary veins. Intracardiac mapping allows the EP to identify and touch up any gaps in the lesion set.[1] Both ablations target the left atrium to ensure durable, transmural lesions. Thoracoscopic or endoscopic access to the posterior left atrium is attained via a subxiphoid incision. The endoscopic approach is utilized in the HC procedure.

Tested in the multicenter, randomized, controlled CONVERGE trial, a minimally invasive HC approach demonstrated superior effectiveness over endocardial ablation alone [67.7% (67/99) with HC vs 50.0% (25/50) with catheter ablation, on/off previously failed antiarrhythmic drugs, p=0.36] to treat patients with persistent and LSPAF.[6] Most studies which report on HC utilized commercially available radiofrequency endocardial catheters.

Single versus Staged Approach

Since the HC procedure requires a multidisciplinary team, the two ablation approaches can be conducted in a single setting in a hybrid operating room (OR), separately in an OR and EP lab or in a staged setting with the two procedures occurring at least 30 days apart.

Regardless of the surgical setting, the epicardial procedure occurs first. Hospital site logistics, patient preference and scheduling will determine feasibility of each option.

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Other Patient Selection Considerations
Patients with advanced forms of AF (persistent and LSPAF) may benefit from a HC approach over endocardial ablation alone absent an indication for concomitant surgical ablation or contraindication. In addition, consideration for left atrial appendage (LAA) and Ligament of Marshall management, both deemed responsible for the occurrence of non-pulmonary vein triggers in patients may be warranted particularly in patients with advanced AF disease. In addition, patients who previously failed endocardial catheter ablation, those who pose an atrioesophageal fistula (AEF) risk or have structural heart issues may also be candidates for HC ablation. As demonstrated in the CONVERGE trial, there were no AEFs that occurred among patients who underwent HC.[6] Other characteristics including an enlarged left atrium (>4 cm, shown to correlate with increased risk of recurring AF[7] and repeat ablations[1]), comorbid conditions like heart failure (left ventricular ejection fraction < 55%) and higher body mass index may also warrant consideration for HC.

Hybrid Convergent and Left Atrial Appendage Management
A recent non-randomized study with 139 persistent AF patients who underwent de novo ablation with HC with or without LAA exclusion with AtriClip® (AtriCure Inc, Mason, OH) demonstrated greater freedom from AF in patients who underwent HC+LAA vs HC alone (77% vs 58%; p=0.04).[8]

Contraindications for a Hybrid Procedure
Gastroesophageal reflux, chronic kidney disease, an inability to tolerate anesthesia, those with prior pericardiotomy and scar formed around the heart and surrounding tissue, including the lungs may preclude some candidates from HC.[1] Also, patients with pre-procedure, image-detected left atrial thrombus which can increase the risk of stroke and thromboembolism during catheter ablation may disqualify some candidates from receiving HC. However, treatment with oral anticoagulation and subsequent repeat imaging revealing no detectable thrombus may restore a patient's eligibility for HC.

Key Takeaways
- A working partnership between the cardiothoracic surgeon and electrophysiologist is critical when considering a patient for a hybrid procedure. In addition, appropriate training on the HC approach is needed to ensure an optimal patient outcome.
- Pre-surgical planning, determining logistics for a single vs staged approach, ensuring lesions are fully transmural and identifying and resolving gaps in the lesion set are important aspects when conducting a HC procedure.
- Treating other structures including the LAA and Ligament of Marshall, known for eliciting non-pulmonary vein triggers, should be considered in patients undergoing HC.
- Patients with advanced AF who underwent an unsuccessful endocardial catheter ablation, those at risk for an AEF, heart failure, higher body mass index, and/or enlarged left atrium should be prioritized for HC.

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EPi-Sense International Indications

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).*

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.*

EPi-Sense/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 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.*

AtriClip Indications

Not all lengths and models are available in all countries. Please discuss with your investigator for region specific information.

Argentina, Australia, Belarus, Brazil, Chile, Colombia, EU Region, Hong Kong, Israel, Korea, Kuwait, New Zealand, Panama, Saudi Arabia, Serbia, Singapore, South Africa, Taiwan, UAE, 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.*

US Indications: *The AtriClip LAA Exclusion System is indicated for the exclusion of the heart's left atrial appendage, performed under direct visualization1 and in conjunction with other cardiac surgical procedures.*

[1]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.

Rx Only

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