Combined Minimally Invasive Surgical and Percutaneous Catheter Ablation of Atrial Fibrillation

Bisleri et al. JACC. 2023;81(6):606-619.

Introduction

Hybrid ablation combines minimally invasive surgical and percutaneous catheter-based techniques in the management of patients with atrial fibrillation (AF). Hybrid ablation is offered typically to patients with persistent or longstanding persistent AF (LSPAF) in a same-day or staged procedure that requires both epicardial surgical and endocardial catheter ablation (CA). Bisleri and colleagues[1] present a review of the clinical evidence for hybrid ablation is mainly based on observational studies, including one randomized trial (CONVERGE). CONVERGE demonstrated that hybrid ablation was more effective than CA, but with higher complication rates.[2]

Methods

Bisleri and colleagues reviewed the hybrid ablation procedure, its target AF populations, and summarized the effectiveness of the procedure in a pooled analysis of data from selected publications.

Results

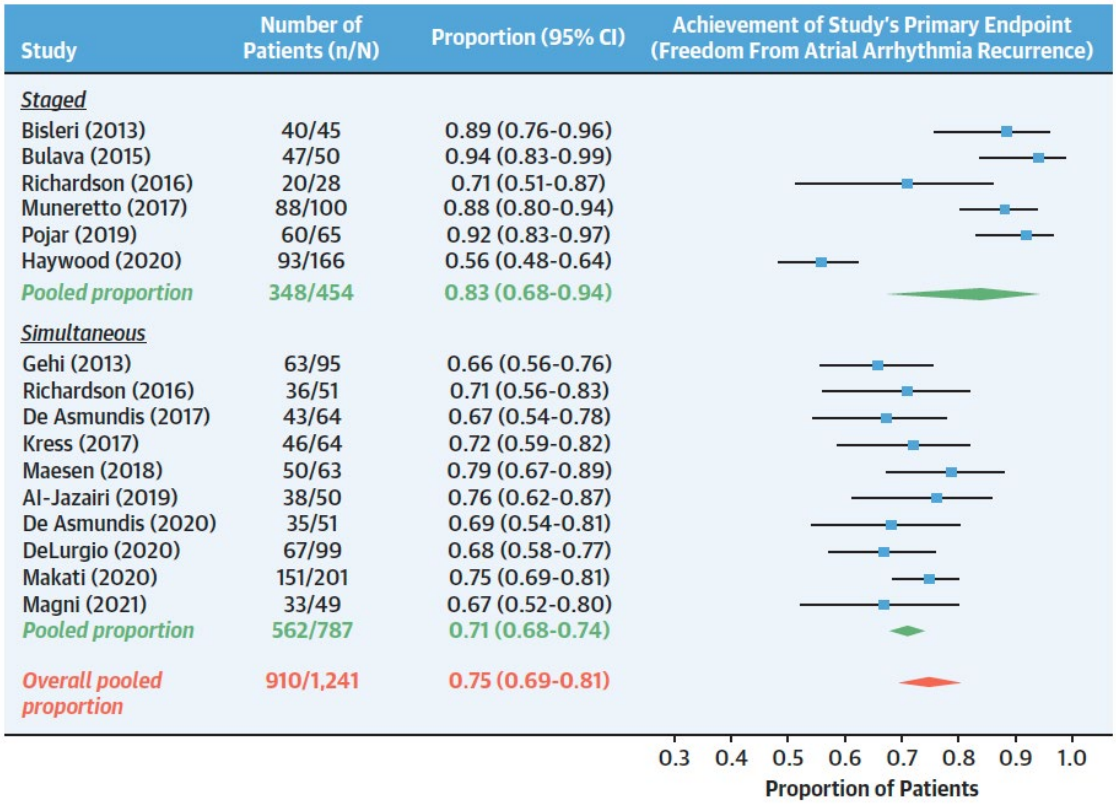
Bisleri and colleagues pooled the long-term success rates from 16 published reports since 2013 and found that freedom from arrhythmia was approximately 75% (Figure). Freedom from arrhythmia was 71% for the pooled patients from 6 studies of same-day hybrid ablation and 83% for the pooled patients from 10 studies of staged hybrid ablation. The authors summarized that the complication risk of hybrid ablation was 2.0-fold to 3.6-fold higher than catheter ablation (CA); however, the incidence of the most serious complications has decreased in contemporary studies. The authors suggest that hybrid ablation should be performed by experienced centers on selected patients with persistent or LSPAF. Additional randomized trials, they concluded, are needed to define the risks, benefits, and cost effectiveness of hybrid ablation to identify its most appropriate application in clinical practice. Several trials are being completed or are underway (i.e., HARTCAP-AF [Hybrid Versus Catheter Ablation in Persistent AF] NCT02441738; CEASE-AF [Combined Endoscopic Epicardial and Percutaneous Endocardial Ablation Versus Repeated Catheter Ablation in Persistent and Longstanding Persistent Atrial Fibrillation] NCT02695277; and HALT-AF [Hybrid AbLaTion of Atrial FibrillaTion] NCT05411614).

Key Takeaways

- Data from pooled studies showed that freedom from arrhythmia following hybrid ablation was approximately 75%.
- The risk of complications from hybrid ablation was 2.0-fold to 3.6-fold higher than catheter ablation but have decreased in contemporary studies of hybrid ablation.
- The authors concluded that additional randomized trials are needed to define the risks, benefits, and cost effectiveness of hybrid ablation to identify its most appropriate application in clinical practice.
- Future studies on hybrid ablation should be designed to address outcomes such as stroke, heart failure, and mortality.

Reference:
1. Bisleri, et al. JACC. 2023;81(6):606-619.
2. DeLurgio, et al. CircAE. 2020;13:e009288.

Figure. *Efficacy Outcomes of Hybrid Ablation Studies*



Among selected studies on hybrid ablation, the pooled proportion of patients (weighted random-effects) who met the studies' primary endpoint of freedom from recurrent atrial arrhythmia was 0.75 (95% CI: 0.69-0.81; $I^2 = 82\%$). The pooled proportions were 0.83 (95% CI: 0.68-0.94; $I^2 = 93\%$) and 0.71 (95% CI: 0.68-0.74; $I^2 = 0\%$) for staged and simultaneous hybrid ablation, respectively. Studies were selected on the basis of their cohort size, length and completeness of follow-up, and preferential inclusion of patients with persistent or longstanding persistent AF.

EPi-Sense® Guided Coagulation System

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[1]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 post-procedure to monitor for signs of delayed onset pericarditis or pericardial effusion. Rx Only.*

Indications for Chile, EU, Israel, New Zealand, UK, Kuwait, and Hong Kong: *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)*

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