Ablation as First-Line Treatment for Atrial Fibrillation: 5 Things to Know

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Atrial fibrillation (AF), the most common cardiac arrhythmia, affects approximately 3-6 million people in the United States — a figure expected to increase to around 6-16 million by 2050. Globally, the prevalence of AF is estimated to be around 37,574 million, a number expected to increase. A known risk factor for stroke, cardiovascular events, and death, AF poses a significant public health threat.

Although early diagnosis and treatment of AF are important to reduce the risk for stroke, there has been continued debate regarding the best first-line treatment option for AF. Major guidelines, including those of the American College of Cardiology/American Heart Association/Heart Rhythm Society, European Society of Cardiology/European Association for Cardio-Thoracic Surgery, and Canadian Cardiovascular Society/Canadian Heart Rhythm Society recommend systemic anticoagulation for those with increased risk for stroke and anti-arrhythmic drugs (AADs) as the initial treatment for AF before considering ablation. Some clinicians consider AADs for initial treatment, whereas others follow a more invasive approach, such as cryoballoon ablation (also referred to as cryoablation) or radiofrequency ablation shortly after the initial diagnosis.

Here are five things to know about cryoablation as a first-line therapy for AF.

1. Two recent studies find that early intervention with cryoablation may be more effective than are medications in preventing AF recurrence for patients with paroxysmal AF.

Results from the randomized trials EARLY-AF and STOP AF showed that cryoablation was a promising first-line treatment for paroxysmal AF. Both studies compared the effectiveness of traditional AADs vs cryoablation in treating and preventing AF recurrence.

In EARLY-AF, 303 symptomatic treatment-naive participants who had at least one episode of AF within the last 24 months or paroxysmal AF were randomly assigned to receive either an AAD or undergo cryoablation. Patients in both groups were monitored with an implantable cardiac monitoring device for 1 year posttreatment. Results at 1 year showed a significantly lower recurrence of AF in the ablation group compared with the AAD group: 42.9% vs 67.8%, respectively.

Similarly, in STOP AF, 203 treatment-naive participants with HF were randomly assigned to receive an AAD or undergo cryoablation. Unlike EARLY-AF, STOP AF used intermittent cardiac monitoring (electrocardiography and telephone monitoring) instead of continuous monitoring through an implantable device. Results from STOP AF also showed a lower recurrence rate in the cryoablation groups vs the AAD group: 74.6% and 45.0%, respectively.

2. Though research on ablation as a first-line treatment for AF is promising, study limitations exist.

Although the EARLY-AF and STOP AF trials demonstrate the potential use of cryoablation as a first-line treatment for AF, these studies were limited by their small sample size and had other significant potential limitations.

A limitation of both studies relates to the reporting of adverse events associated with each of the interventions. For example, though EARLY-AF reported serious adverse events in 3.2% of patients in the cryoablation group and 4% in the AAD group, adverse events in the cryoablation group included phrenic-nerve palsy compared with wide-complex tachycardia, syncope, and heart failure (HF) exacerbation in the AAD group. The severity of the adverse events for both groups is significant, but the nerve palsy experienced by the ablation group could be considered a more severe event.

Other EARLY-AF and STOP AF trial limitations include potential sponsor/support and endpoint biases. Each trial received support from Medtronic, whose cryoablation device was used in both studies. Medtronic's implantable cardiac monitor was also used in the EARLY-AF trial. In a commentary, electrophysiologist John Mandrola, MD, stated that though the potential for bias should be considered when interpreting findings from EARLY-AF and STOP AF, it does not necessarily "nullify the results." Another electrophysiologist, Dhiraj Gupta, MD, noted the potential for bias against the AAD arm in the STOP AF trial since more than 15% of participants in that group crossed over to the ablation group and crossover was included in the treatment success endpoint.

3. Ablation is a mainstay of AF treatment, but disagreement persists regarding its use as a first-line option.

Electrophysiologists agree that ablation for AF is beneficial in some cases but disagree about when this invasive procedure should be performed in the trajectory of the patient's condition.

Conservative clinicians may recommend less invasive treatment options or, in some cases, no treatment, instead adopting a wait-and-see approach. The RACE 7 ACWAS trial studied 427 patients who presented to the emergency department with new-onset AF. Half of the participants were treated with immediate cardioversion, but the other half were treated with a wait-and-see approach and delayed intervention. Results of RACE 7 ACWAS found a significant number of participants in the delayed intervention group spontaneously converted back to normal sinus rhythm without intervention.

Though findings from RACE 7 ACWAS support a wait-and-see approach in some patients with recent-onset AF, it is important to note that patients in this study were hemodynamically stable and did not require immediate intervention. Therefore, additional studies are needed to determine the appropriate timing and type of initial treatment on the basis of the patient's risk profile.

4. Early catheter ablation may benefit patients with HF, regardless of whether it is systolic or diastolic dysfunction.

Though electrophysiologists debate catheter ablation as a first-line treatment for AF in the general population, studies have shown significant benefits in patients with HF. The CASTLE-AF trial studied 363 patients with HF and coexisting AF who did not respond to AADs, were unwilling to take them, or had "unacceptable side effects." Participants were randomly assigned to undergo catheter ablation or rate- or rhythm-control therapy (in addition to guideline-recommended HF therapies). Patients in the ablation group had a significantly lower hospitalization and mortality rate compared with the medical therapy group.

Results of another study, the CABANA trial, were similar to CASTLE-AF. In this trial, 778 of the 2204 patients enrolled in the trial had New York Heart Association class II or III HF with AF (32% with paroxysmal AF and 55% with persistent AF) and were assigned to undergo catheter ablation or receive rate or rhythm control medications. There was a significant improvement in recurrence rate of AF, quality of life, and overall survival in the catheter ablation group vs the medication group.

Though CASTLE-AF and CABANA demonstrate significant benefits of catheter ablation in patients with coexisting HF and AF, future research is warranted to explore the value of catheter ablation as a first-line treatment for this specific patient population.

5. Findings on pulsed-field ablation in AF may influence the decision to implement ablation as a first-line treatment option.

Recently, there has been much research on the use of pulsed field ablation (PFA) to treat AF. More traditional catheter ablation techniques target only pulmonary vein isolation, whereas PFA targets a wider cardiac tissue area, which could benefit patients with more severe cases of AF. In addition, PFA uses nonthermal electrical waveforms, which results in less damage to surrounding tissues.

PFA may offer a shorter procedure time and higher efficiency in correcting atrial dysrhythmias than does traditional catheter ablation. In a recent study, PULSED-AF, patients with paroxysmal or persistent symptomatic AF were treated with PFA and monitored weekly for 1 year. At the end of the study period, PFA was effective in 66.2% of patients with paroxysmal AF and 55.1% with persistent AF. Adverse events associated with PFA were 0.7%, further supporting its potential as a first-line treatment for AF in the future.

However, it is important to note that this trial was a nonrandomized, single-arm study with a relatively small number (n = 300) of enrolled participants. These factors reflect the need for larger, more robust studies to be conducted regarding the use of PFA for the treatment of AF.

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