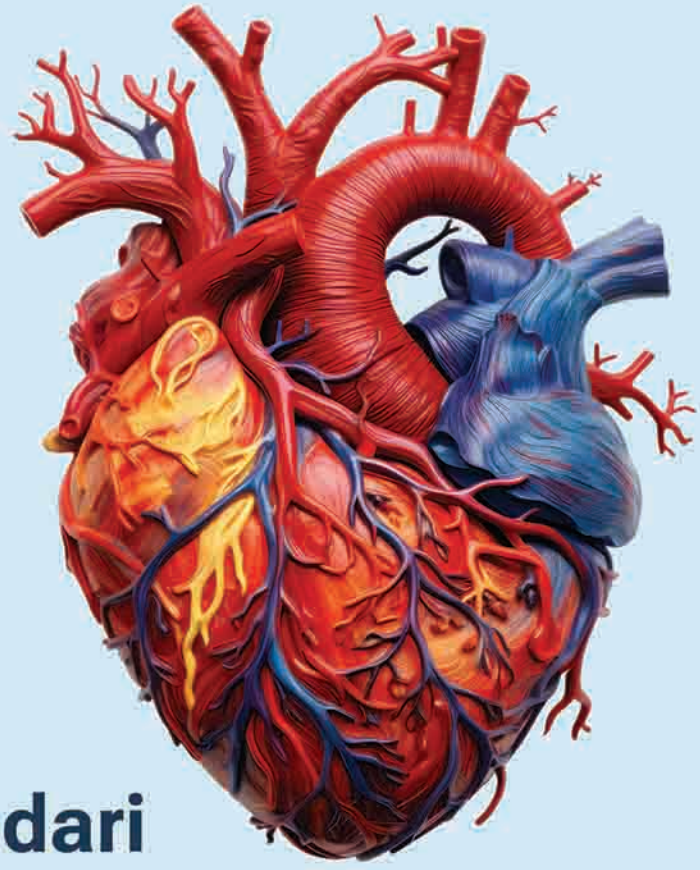
PROGRESS IN CARDIOLOGY



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Forewords
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Contents

CHAPTER 13

Advances in Atrial Fibrillation Ablation: Technology and Technique

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INTRODUCTION

The prevalence of atrial fibrillation (AF) is steadily increasing, driven largely by the aging of the global population.[1] A growing body of evidence indicates that utilization of an early, aggressive rhythm control strategy for AF is associated with improved patient outcomes.[2] Although clinicians can use either antiarrhythmic drug therapy or catheter ablation as part of a rhythm control strategy for managing AF, catheter ablation has consistently demonstrated superiority over medical therapy across a variety of patient populations.[3-5]

The combination of rising AF prevalence and the expanded indications for ablation therapy has led to a marked increase in the number of AF ablation procedures performed worldwide. In many regions, electrophysiology (EP) laboratories have needed to adjust procedural workflow to meet the growing demand for ablation procedures. Recent advances in ablation technology, most notably the development of pulsed field ablation (PFA), have improved both the safety profile and efficiency of the procedure. These innovations have allowed EP laboratories to perform more ablation procedures without compromising procedural safety or effectiveness.

EXPANDING INDICATIONS FOR RHYTHM CONTROL MANAGEMENT OF ATRIAL FIBRILLATION

The *EAST-AFNET 4* trial[2] established that an early, aggressive rhythm control strategy improves outcomes in patients with AF. In this study, patients were randomized to receive an early aggressive rhythm control strategy or a rate control strategy. The 2,789 patients treated according to a rhythm control strategy in this study (antiarrhythmic drugs and catheter ablation) within 1 year of the initial diagnosis of AF exhibited a lower likelihood of meeting the composite study endpoint of cardiovascular death, stroke, or hospitalization for acute decompensated heart failure or acute coronary syndrome.

Catheter ablation has become the cornerstone of AF management as it has been shown to be more effective in reducing the burden of AF than antiarrhythmic drug therapy.[3-5] Contemporary guideline statements reflect expanded indications for the use of ablation therapy.[6] Multiple randomized controlled trials (RCTs) have demonstrated the superiority of catheter ablation over antiarrhythmic therapy, particularly with respect to freedom from AF recurrence and improvement in AF-related symptoms. The *STOP-AF*,[3] *EARLY-AF*,[4] and *THERMOCOOL*[5] trials reported significantly higher rates of freedom from AF compared with medical therapy. While most RCTs have enrolled patients with paroxysmal AF, the *SARA* trial demonstrated similar benefits in those with persistent AF.[7]

The *CABANA* trial,[8] the largest RCT comparing catheter ablation with medical therapy, did not meet its primary composite endpoint; however, ablation was associated with substantially lower rates of AF recurrence in the study population. Further evidence of the benefits of ablation therapy was provided by the *SHAM-PVI* trial,[9]

which confirmed a direct causal effect of ablation on symptom improvement, and demonstrated significant improvement in quality-of-life outcomes among patients randomized to ablation versus a sham procedure.

The impact of catheter ablation is particularly striking in patients with AF and concomitant heart failure. In the *CASTLE-AF* trial,[10] which enrolled patients with left ventricular ejection fraction <35% and NYHA class II–IV symptoms, ablation reduced both all-cause mortality [hazard ratio (HR) 0.53; 95% confidence interval (CI) 0.32–0.86; $p = 0.01$] and hospitalizations for worsening heart failure (HR 0.56; 95% CI 0.37–0.83; $p = 0.004$). These results support an especially central role for catheter ablation in this high-risk population.

Taken together, the findings from these RCTs support the hypothesis that catheter ablation is the most effective strategy for reducing AF burden. Updated versions of AF treatment guidelines now include ablation as part of the first line of treatment for AF. The resultant increases in demand for AF ablation procedures have tested the capacity limits of many EP laboratories.

NEW ABLATION THERAPIES AND TECHNIQUES

The three most widely used techniques for catheter-based AF ablation are PFA, radiofrequency ablation (RFA) ablation, and cryoablation (CA). The key characteristics of these techniques are summarized in **Table 1**. The ablation catheters available for use with PFA, RFA, and CA are described in **Table 2**. Open-chest ablation strategies are not included in this document.

RFA and CA are thermal modalities that achieve tissue necrosis and electrical inactivation through tissue heating (RFA) or freezing (CA). In contrast, PFA generates a strong electrical field that produces cellular death through electroporation, which is generally not associated with thermal injury.[11,12] PFA lesions tend to not affect tissues outside of the heart,[13] thereby reducing the risk of collateral injury to adjacent structures (e.g., esophagus and phrenic nerve) as compared with RFA and CA.

The first PFA catheter ablation system to treat cardiac arrhythmias was approved by the US Food and Drug Administration in 2023. This is much more recent than the approval of the cryoballoon (2010) and the open-irrigated RFA catheter (2008). Despite its recent arrival, PFA is already the most commonly utilized ablation system in many hospitals worldwide. The rapid adoption of PFA has been attributed to its favorable safety profile and reduction in ablation procedure time as compared with RFA and CA. Utilization of PFA technology has helped many EP laboratories keep up with the ever-increasing clinical demand for AF ablation.

RADIOFREQUENCY ABLATION

RFA is the most extensively studied technique for AF ablation, with well-established safety characteristics and postablation outcomes.[5,14] While effective, RFA carries notable limitations, including the risk of collateral injury to surrounding structures due to tissue heating. In addition, many available RFA ablation catheters deliver ablation lesions at single points of the tissue. Effective isolation of pulmonary veins (or other atrial structures) requires delivery of multiple adjacent point lesions, which is relatively time-consuming.[14] In addition, gaps between ablation lesions can lead to pulmonary vein reconnection and AF recurrence.

Recent innovations have shortened RFA procedure time. High-power, short-duration (HPSD) ablation delivers higher energy (up to 90 W) over shorter intervals (4–10 seconds), compared with conventional settings (20–35 W for 20–40 seconds). Shorter lesion delivery times translate to shorter procedure times. The HPSD

TABLE 1: Attributes of the most commonly utilized ablation techniques.

	Pulsed field	*Radiofrequency*	*Cryoablation*	*References*
Mechanism	Irreversible electroporation	*Thermal injury:* Heating	*Thermal injury:* Freezing	12,24
Myocardial tissue selectivity	High	Low with higher risk of damage to adjacent structures	Low with higher risk of damage to adjacent structures	13
Procedure time	Fastest	Slowest	Intermediate	25,26
Acute procedural success	98–99.9%	95–99%	98–99%	25,27
Major complication rate	~1%	~1%	~1%	11,14
Risk of esophageal fistula	Not reported	Possible, <0.1%	Possible, <0.1%	11,28,29
Risk of phrenic nerve injury	Low, reported cases have been transient	Possible, <0.5%	Possible, 1–2%	11,14,30
Risk of pulmonary vein stenosis	Not reported	<1%	<1%	31,32
Risk of coronary artery spasm	High if ablation is performed adjacent to coronary artery	Not reported	Not reported	21,33
Ablation of extra-pulmonary vein lesions	Concern for limited durability	Possible	Limited	23
Ablation catheter types available	Both multipoint and single-point catheters available (multipoint most common)	Both multipoint and single-point catheters available (single-point most common)	Both multipoint and single-point catheters available (balloon catheter more common for AF)	
Cost	Highest	Intermediate	Lowest	25

RFA approach also produces more superficial lesions, thus reducing the risk of collateral damage to adjoining structures. Trials such as *POWER-AF*[15] and *FAST AND FURIOUS*[16] have demonstrated the efficiency benefits of the HPSD RFA strategy.

Additional advances involve integration of RFA with artificial intelligence (AI)–guided mapping. For example, the Volta Medical system analyzes spatiotemporal electrogram dispersion to identify ablation targets. In the *TAILORED-AF* trial,[17] pulmonary vein isolation (PVI) plus AI-guided ablation was compared with PVI alone. The AI-guided strategy was associated with significantly lower AF recurrence at 1 year; however, no difference was observed in freedom from any atrial arrhythmias.

Multi-electrode RFA catheters that can ablate multiple points in space simultaneously have been described **(Table 2)**. Utilization of such catheters can increase the speed of RFA procedures by increasing the amount of tissue that is ablated per unit of time. These multi-electrodes are not as commonly used as single-point RFA catheters.

During RFA lesion delivery, sudden increase in tissue temperature are possible. These temperature spikes can produce "steam pops" which are a major safety concern as they can cause considerable damage to cardiac tissue as well as cardiac tamponade. Steam pops are not observed for CA or PFA.

TABLE 2: Description of novel ablation catheters that can be utilized with each type of ablation technique.

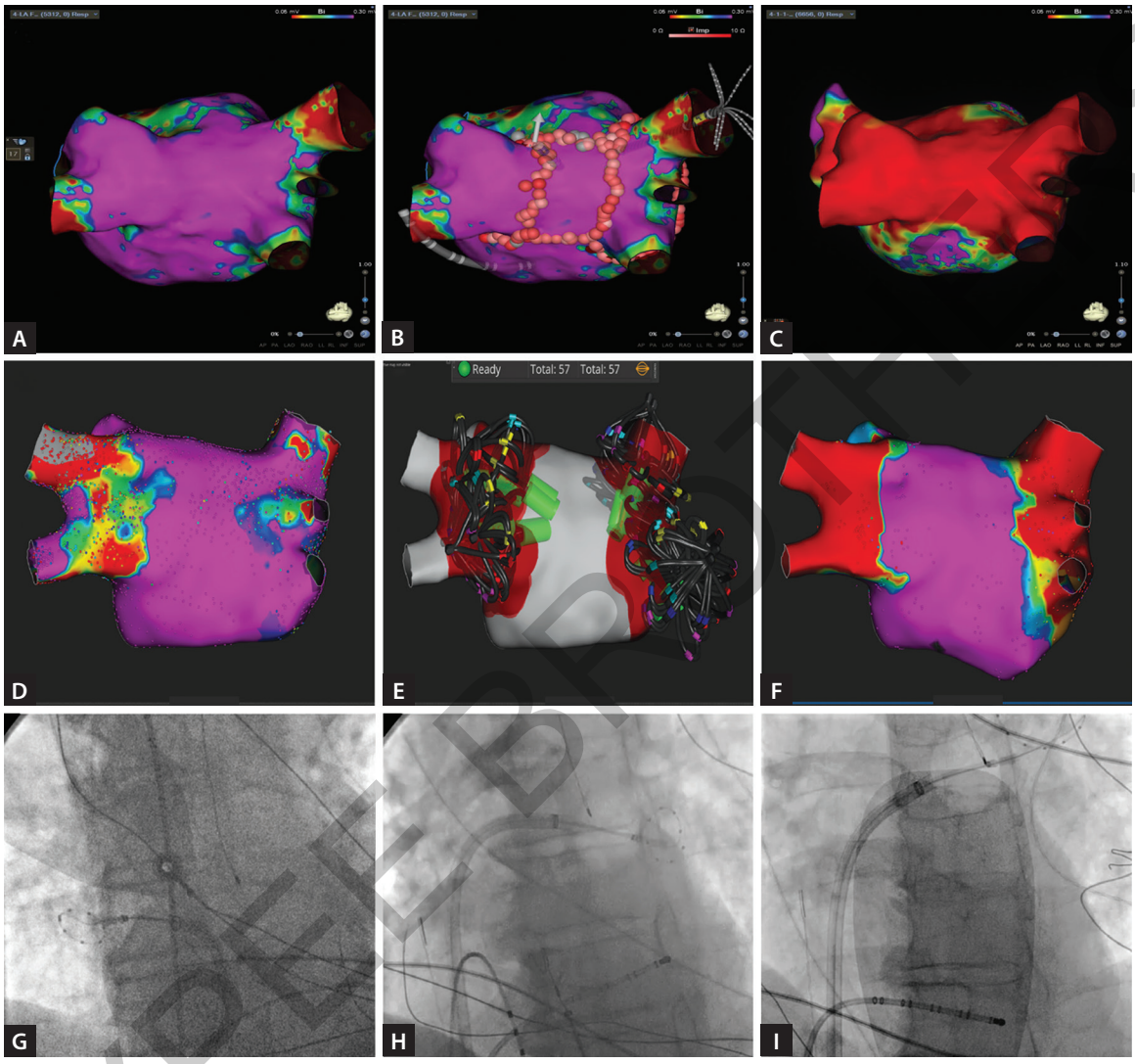
	Pulsed field	*Radiofrequency*	*Cryo*
Single point	Sphere-9 Catheter with Affera mapping system (Medtronic)[34]	• QDOT MICRO RF catheter (Johnson and Johnson)[16] • DiamondTemp RF catheter (Medtronic)[35] • TactiFlex catheter (Abbott)[36]	Not used for atrial fibrillation ablation
Multispline array	• Farawave catheter (Boston Scientific)[20] • Varipulse catheter (Johnson and Johnson)[37] • PulseSelect catheter (Medtronic)[38] • Volt system (Abbott)[39] • Omnypulse (Johnson and Johnson)[40] • Globe (Kardium)[41]	N/A	N/A
Balloon	N/A	• Luminize RF balloon catheter (Boston Scientific)[42] • Heliostar (Johnson and Johnson)[43]	• PolarX (Boston Scientific)[44] • Arctic Front (Medtronic)[45]

CRYOABLATION

Cryoablation of AF is typically performed using balloon-tipped catheters, which are positioned at the pulmonary vein ostia. Temperature of the balloon is decreased leading to freezing of all cardiac tissue in contact with the surface of the balloon. CA balloon catheters are intended to contact the tissue through the entirety of the circumference of a pulmonary vein ostium, thus facilitating "single-shot" pulmonary vein isolation. The randomized *FIRE AND ICE* trial[18] demonstrated noninferiority of CA compared with RFA for the composite endpoint of AF or atrial tachycardia (AT) recurrence during a mean follow-up period of 1.5 years. Safety outcomes were similar for RFA and CA, but procedure times were shorter for CA.

Recent advances in cryoballoon design have resulted in lower nadir temperatures and improvements in procedural efficacy, with acute pulmonary vein isolation success rates of approximately 99%.[19] Despite this improvement, cryoballoon ablation can lead to incomplete pulmonary vein isolation due to incomplete contact between spherical balloons and sometimes irregularly-shaped pulmonary vein ostia. Other drawbacks associated with cryoballoon use include the inability to address arrhythmia substrates outside of the pulmonary veins. Although single-point CA catheters are available, they are not frequently used for AF ablation because of the relatively long time required to deliver a CA lesion. Another key limitation of CA is the risk of phrenic nerve palsy, which is reported in up to 2.5% of patients in recent meta-analyses.[19]

CA is potentially better-suited for use in resource-constrained areas than RFA and PFA. CA does not require use of an electroanatomic mapping system and is potentially more straightforward to maintain. In addition, CA systems tend to be less expensive than RFA and PFA systems.



Figs. 1A to I: Electroanatomic maps and fluoroscopy images of pulmonary vein isolation achieved with point-by-point RFA, "single-shot" PFA, and cryoballoon ablation. (A) The electroanatomic posterior-anterior voltage maps of the left atrium prior to ablation with radiofrequency (RF); (B) The point-by-point ablation lesions performed using an RF catheter; (C) The voltage map following ablation. Mapping was performed using the multi-spline catheter and electroanatomic mapping software. Purple areas indicate normal voltage, while red areas indicate low voltage; (D) The posterior-anterior voltage maps of the left atrium prior to ablation with pulsed-field ablation (PFA); (E) The sets of ablation lesions produced by a "single-shot" PFA catheter; (F) The voltage map following ablation; (G) The fluoroscopic images obtained during cryoablation of the right inferior; (H) Left inferior; (I) Left superior pulmonary veins.

PULSED FIELD ABLATION

The electroporation produced by PFA has been shown to be less likely to damage structures adjacent to the heart than RFA and CA.[12,13] The randomized *ADVENT* trial[20] compared PFA with RFA and CA in patients with drug-refractory, paroxysmal AF. In this study, PFA demonstrated noninferiority to RFA and CA with respect to procedural success and serious adverse events. Limitations of this study included relatively small sample size which could limit detection of rare complications such as phrenic nerve injury or atrial-esophageal fistula formation. The larger *MANIFEST 17k* registry[11] reported no esophageal complications, pulmonary vein stenosis, or persistent phrenic nerve palsy among >17,000 PFA procedures.

Several PFA systems are currently available. Some of the most widely used systems are listed in **Table 1**. Many PFA platforms employ catheters designed for simultaneous multipoint ablation **(Figs. 1A to I; Table 2)**. These "single-shot" catheters enable pulmonary vein isolation with fewer ablation applications. The lower number of ablation applications is associated with markedly reduced time required to achieve pulmonary vein isolation as compared with point-by-point RFA.

Despite its favorable safety profile, several PFA-specific complications have been described. These include coronary vasospasm when energy is delivered near coronary arteries. PFA-mediated coronary vasospasm can typically be mitigated with nitroglycerin but can prolong total procedure times.[21] PFA also produces intravascular hemolysis, which can lead to hemoglobinuria and acute kidney injury, especially when large numbers of PFA applications are delivered.[22] In addition, concerns also remain regarding PFA lesion durability in certain anatomical locations such as the coronary sinus and mitral isthmus.[23]

Perhaps the most significant limitation of PFA is cost. As PFA is the newest ablation modality, PFA-based ablation systems and their associated single-use components (notably ablation catheters) are significantly more expensive than RFA or CA platforms. Consequently, hospitals considering the adoption of PFA must weigh the high initial investment and per-procedure costs against the potential gains in procedural efficiency.

CONCLUSION

Catheter ablation is the most effective strategy for maintaining sinus rhythm in patients with AF. The number of ablation procedures continues to rise each year, driven by both the increasing prevalence of AF and the expanded indications for ablation in recently released treatment guidelines. The most commonly used catheter ablation techniques are RFA, CA, and PFA. Each of these techniques is associated with distinct advantages and limitations that may influence their suitability for different practice settings.

PFA is associated with shorter procedure times and lower complication rates than RFA and CA. However, the higher costs associated with PFA systems and their associated single-use catheters present a significant economic barrier to adoption. For many hospitals, the resources required to establish and maintain a PFA program may be prohibitive. Even hospitals that can afford the initial cost of establishing a PFA system may not have sufficient AF ablation volumes to make it feasible to maintain a PFA program long-term. These factors underscore the need to balance safety and efficiency gains against economic feasibility when considering use of PFA against lower-cost options such as RFA and CA.

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