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EDITORIAL

Catheter ablation using pulsed-field energy: Do we finally have the magic wand to defeat atrial fibrillation?

Ernesto Cristiano, Hussam Ali, Eduardo Celentano, Riccardo Cappato

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Abstract

Clinical outcomes of catheter ablation remain suboptimal in patients with atrial fibrillation (AF), particularly in those with persistent AF, despite decades of research, clinical trials, and technological advancements. Recently, pulsed-field ablation (PFA), a promising non-thermal technology, has been introduced to improve procedural outcomes. Its unique feature of myocardial selectivity offers safety advantages by avoiding potential harm to vulnerable adjacent structures during AF ablation. However, despite the global enthusiasm within the electrophysiology community, recent data indicate that PFA is still far from being a "magic wand" for addressing such a complex and challenging arrhythmia as AF. More progress is needed in mapping processes rather than in ablation technology. This editorial reviews relevant available data and explores future research directions for PFA.

Key Words: Atrial fibrillation; Pulsed field ablation; Radiofrequency ablation; Electroporation; Electroanatomic mapping; Catheter ablation; Interventional cardiology; Cardiac arrhythmias

Core Tip: Pulse-field ablation is an emerging technology in the field of arrhythmia ablation based on electroporation method, particularly adopted for atrial fibrillation. While there is growing interest in the safety and efficacy of catheter ablation using electroporation, several aspects of its long-term effectiveness and procedural limitations require further investigation before pulse-field ablation can be considered a definitive solution for atrial fibrillation.

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INTRODUCTION

Atrial fibrillation (AF) is the most common sustained arrhythmia, associated with increased mortality and morbidity, and has a substantial impact on the global health system. Catheter ablation (CA), primarily based on pulmonary vein isolation (PVI), represents a valid approach to managing this arrhythmia, particularly when symptomatic and drug-refractory. However, outcomes of CA remain suboptimal in AF patients, especially in those with persistent arrhythmia[1,2].

In recent years, pulsed-field ablation (PFA), a non-thermal energy source based on irreversible electroporation, has been introduced into clinical practice with the aim of improving CA outcomes in AF patients[3]. However, electroporation has a longstanding history as a therapeutic modality in various medical fields, such as oncology. In the 1980s, direct current shock was used for CA, but significant complications, including arcing and barotrauma, coupled with the success of the emerging request for comments technology, led to the discontinuation of PFA in clinical settings[4].

Over the past decade, preclinical studies have shown that modern PFA has the potential to create tissue-selective ablation lesions through short, high-energy electrical pulses that induce cell death while minimizing the side effects associated with thermal energy sources[5]. Initial human trials of PFA have demonstrated the safety and efficacy of AF ablation procedures, with high rates of immediate PVI and durable results confirmed through invasive remapping, along with relatively low rates of arrhythmia recurrence. Consequently, various catheter platforms utilizing electroporation have been developed and tested for the catheter-based ablation of cardiac arrhythmias, primarily AF.

This editorial examines the methodology of PFA, preclinical and clinical data, and explores future directions for its development. Although several studies have reported promising results with this new technology, limited data are available on long-term outcomes, healthcare utilization, and costs compared to standard radiofrequency CA. Due to its tissue selectivity and rapid induction of cell death, PFA could represent an efficient and potentially safer option compared to conventional ablation techniques[2,3], with potential applications in other ablation procedures beyond AF. In this editorial, current evidence on the use of PFA for the treatment of AF and its potential impact on healthcare utilization and costs will be discussed, drawing on relevant clinical studies published in the literature and offering insights for future research directions. Additionally, we will address the possible limitations and drawbacks of this technology.

CURRENT KNOWLEDGE

PFA mechanism of action

The exposure of cells to high-voltage electric pulses induces an increase in membrane permeability through electroporation[6]. This cellular membrane injury can be either reversible or irreversible. The former is typically used in gene transfer and enhanced drug delivery[7], while the latter leads to cell death in the targeted area. PFA can trigger various types of cell death, including apoptosis, necrosis, necroptosis, and pyroptosis[8]. The specific type of cell death induced by electroporation depends on pulse parameters, cell and tissue type, treatment conditions, and other factors[9,10]. This approach has been successfully employed as a novel non-thermal ablation method for soft tissues, such as tumors.

The main stages of electro-permeabilization are: (1) Initiation of membrane electrical conductivity and permeability [the transmembrane voltage (TMV), must exceed a "critical" potential value]; (2) Expansion and intensification of conductivity and permeability; (3) Partial recovery of membrane conductivity and permeability, while still allowing transmembrane diffusion of ions and molecules once the TMV drops below the "critical" value; and (4) Resealing of the membrane, with gradual restoration of its physiological impermeability. In the end, cells retain a memory of the alterations in physiological processes and reactions to stressors for several hours[6].

Main characteristics

This new form of ablative energy has several important characteristics that have quickly gained acceptance within the electrophysiology community. PFA has a tissue-specific effect, meaning that myocardial cells are damaged at specific energy frequencies and durations, while sparing fibroblasts, vascular tissue, and gastrointestinal structures[9]. Consequently, in theory, PFA delivery should not harm surrounding vessels, the esophagus, or nervous structures, including the phrenic nerve. This could eliminate the risk of esophageal damage, thereby preventing ulcers and atrio-

esophageal fistula. Additionally, PFA is not associated with permanent phrenic nerve injury[11]. Moreover, because connective tissue is unaffected by this energy form, the risk of pulmonary vein stenosis is minimized[12]. Current clinical studies appear to support these hypotheses.

Clinical data

Preliminary data suggest that PFA may result in shorter ablation times compared to PVI. The ADVENT trial demonstrated that, among patients with paroxysmal AF receiving catheter-based therapy, PFA was non-inferior to conventional thermal ablation after a 3-month blanking period, in terms of antiarrhythmic drug use, cardioversion, repeat ablation, as well as efficacy and serious adverse events at 1 year[13]. Aldaas *et al*[14], in their meta-analysis, confirmed these results, showing a significantly shorter procedural time compared to thermal ablation.

Safety data

In the ADVENT and MANIFEST-PF trials, the new procedure was confirmed to be safe in terms of pulmonary vein stenosis, esophageal injury, and phrenic nerve damage[13,15]. A recent meta-analysis[14] reported no significant differences in overall procedural complications between conventional ablation and PFA strategies. However, it is worth noting that one death in the ADVENT trial was due to peri-procedural cerebral hypoxia in the PFA arm. More recently, as experience with this technology has expanded, cases of acute renal failure secondary to PFA-induced hemolysis have been reported[16,17].

Overall, other data suggest that PFA is associated with longer fluoroscopy times compared to thermal ablation energy sources (greater than 20 minutes in the PFA group *vs* over 10 minutes in the thermal ablation group, according to Aldaas *et al*[14] analysis).

FUTURE APPLICATIONS

An increasing number of studies are focusing on the ablation of persistent AF, showing promising preliminary results, as demonstrated in the PULSE-AF trial, which recruited both paroxysmal and persistent AF patients[18], as well as in the single-arm study by Reddy *et al*[19].

Although still in its early stages, the application of this energy form in the ventricles for the ablation of ventricular tachycardias seems promising. PFA has shown potential in creating more effective lesions within scarred myocardial tissue, and its inherent repetition dependency could improve therapeutic outcomes[20].

Moreover, the use of PFA for epicardial ablation and mobile myocardial structures, such as papillary muscles and moderator bands, or for bipolar applications targeting mid-myocardial structures like the interventricular septum or the left ventricular free wall, could represent new frontiers in PFA application. However, the high rate of coronary spasm may limit this use, although no conclusive evidence has yet been presented in the literature[21,22].

Recently, Nies *et al*[21] reported initial experiences confirming that these targets can be successfully ablated with PFA *in vivo*, creating deep epicardial and transmural left ventricular lesions. However, much research is still needed to determine the long-term safety and efficacy of these applications.

Furthermore, hybrid approaches to AF ablation using PFA have not yet been evaluated. However, thermal radiofrequency approaches, including both convergent and robotic methods, have shown varying degrees of success, particularly for persistent and long-standing AF, as reflected in recent AF ablation consensus statements[23-25], potentially paving the way for future PFA research.

Given PFA's promising properties, it will be interesting to see whether using this energy form with a different ablation device could overcome the current technical limitations.

Currently, the inspIRE study has evaluated the safety and efficacy of a fully integrated biphasic PFA system with a variable-loop circular catheter for treating drug-refractory paroxysmal AF, confirming the novel system's safety and effectiveness[26]. Additionally, the SmartfIRE system recently tested a dual-energy focal catheter designed to deliver both radiofrequency and unipolar/biphasic PFA, integrated with a three-dimensional mapping system, and demonstrated acute success with an acceptable safety profile in the treatment of paroxysmal AF, confirming PVI durability at 3-month remapping[27].

The development of more flexible devices that better adapt to anatomy and are less cumbersome, such as point-by-point ablation catheters, could represent an upgrade to current PFA technology, making it suitable for more challenging ventricular or even epicardial ablations. However, the effectiveness and potential advantages of this method in these regions remain to be demonstrated. Notably, while the atrium is a thin structure, the ventricle has considerable thickness, and given that the electric field strength diminishes inversely with the square of the distance, even a few extra millimeters could render PFA ineffective in thicker myocardial tissue.

The other side of the coin

All that glitters is not gold. Currently, the only commercially available system for PFA is FARAPULSE (Boston Scientific). This system was designed specifically for AF ablation, leading to some limitations, primarily its poor maneuverability, as reported by Zhang *et al*[20]. In fact, the device is not well-suited for more complex structures such as valve apparatuses or recesses, making energy application challenging, particularly in cases of complex or anomalous anatomies. This limitation could at least partially be addressed by routinely using computed tomography imaging to select appropriate cases for this type of device. Additionally, the potential risk of entrapment should not be overlooked, due to the complex flower-shaped structure of the catheter and the possible excessive manipulations required in some challenging anatomies[20,28].

Secondly, there is currently no electroanatomical mapping system available. This limitation results in increased fluoroscopy times and challenges in approaching unusual anatomies. However, this issue is expected to be resolved soon, as the NAVIGATE-PF study of the FARAVIEW software module is ongoing, which will allow for the integration of FARAPULSE with the RHYTMIA HDx mapping system.

Contact has always been an important parameter for ablative success in the main thermal technologies, already implemented in ablation indices (conventional radiofrequency and very-high short-duration techniques)[29-31]. The absence of a catheter-tissue contact parameter may present a limitation in current PFA technology. Moreover, the flower structure of the catheter does favor uniform contact, which may lead to non-uniform, incomplete, or reversible lesions.

Beyond technical challenges, there are also electrophysiological issues that need to be addressed. The AF ablation procedure with FARAPULSE seems designed to make it as accessible as possible to the "new generation" of electrophysiologists, reducing the complexity of the procedure and increasing the learning curve[32]. While this is beneficial, it may trivialize the electrophysiological approach underlying the evaluation of the substrate. Currently, the evaluation of electrical insulation of the pulmonary veins appears to be rudimentary. No solid studies have yet confirmed the long-term efficacy of PVI or its correlation with the maintenance of sinus rhythm.

Two significant complications arise with PFA that do not have direct counterparts in radiofrequency ablation. The first is coronary spasm; there is evidence that energy application, particularly in the mitral isthmus region, can potentially lead to arrhythmias or intraprocedural ST-elevation myocardial infarction in up to 40% of patients undergoing mitral isthmus ablation[33,34]. The second complication is acute kidney injury related to hemolysis; specifically, the number of applications correlates with an increased risk of acute kidney injury, as shown in two independent studies[16,17].

Furthermore, the long-term results of this method regarding AF are not yet known. The randomized ADVENT study itself was published only in 2023, with a follow-up period of just one year.

CONCLUSION

PFA represents a viable alternative to traditional thermal ablation, which has been extensively studied. However, due to this novelty, there is currently insufficient evidence regarding its long-term efficacy in treating AF, particularly in cases of persistent and long-standing persistent AF. In these instances, randomized trials comparing PFA to conventional and hybrid/convergent ablation techniques, as well as to antiarrhythmic drug therapy, will be crucial for future research. Despite the technological advancements and the innovative potential introduced by PFA in the management of AF, considerable challenges remain. It is akin to having discovered a new "magic formula" that is yet to be fully understood. Nevertheless, there is certainly ample opportunity for improvement in this "magic wand".

FOOTNOTES

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