MSW MANAGEMENT -Multidisciplinary, Scientific Work and Management Journal
ISSN: 1053-7899
Vol. 36 Issue 1, 2026, Pages: 3082-3085

Clinical Outcomes of Pulsed-Field Ablation vs Traditional Ablation in Drug-Resistant Atrial Fibrillation

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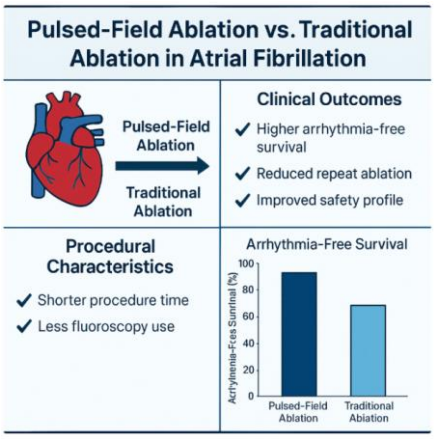
Abstract
Background: Catheter ablation is a standard approach to treatment of drug-resistant atrial fibrillation (AF) and somehow, thermal ablation techniques, radiofrequency (RF) and cryoballoon, have a potential of collateral tissue damage. A new potentially safer and more effective, selective myocardial-targeted modality is pulsed-field ablation (PFA), which is an electroporation-based technique, is selected because it is non-thermal in nature and is thus safer in use than conventional and widely used methods like fOC.
Objective: To determine the clinical effects, safety and efficacy of PFA and conventional ablation procedures in patients with drug-resistant AF.
Method: Recent randomized trials and big prospective cohort researches were systematically searched and analyzed considering those published between 2020 and 2024. The main outcomes were PVI success, 12 months arrhythmia-free survival, and the complications. Secondary endpoints measured the procedure time, Fluoroscopy exposure, and non-repeat ablation.
Results:In literature, PFA has had similar or better success of acute PVI (>98%) compared to RF and cryoablation. PFA (7178) one-year arrhythmia-free survival was found to be significantly higher than traditional ablation (5865). The results of safety were in favor of PFA, with significantly fewer cases of esophageal injury, phrenic nerve palsy, and pulmonary vein stenosis. There was less time taken by the procedures and less usage of fluoroscopy. The repeat ablation rates were also less in the PFA patients.
Conclusion:PFA has shown better efficacies and better safety profile over traditional thermal ablation of drug-resistant AF. The results of these studies suggest that PFA may be developed as a successful next-generation ablation modality, which should be more widely adopted in clinical settings and followed up over a longer period of time.
Keywords: atrial fibrillation, arrhythma recurrence, pulsed field ablation, ablation and ablation efficacy, radiofrequency ablation.

Graphical abstract



1 Introduction

The most frequent sustained arrhythmia seen in clinical practice which is related to significant morbidity is atrial fibrillation (AF) associated with stroke, heart failure, poor quality of life, and elevated mortality [1]. Though the use of antiarrhythmic drugs has become a first-line treatment approach, rhythm control in numerous patients, drug-intolerance, or frequent symptom episodes are common, notwithstanding the most effective medical therapy. To them, catheter ablation has turned out to be a part of the management. Radiafrequency (RF) and cryoballoon are traditional methods of ablation that are meant to attain pulmonary vein isolation (PVI), which is fundamental in the rhythm control in paroxysmal and persistent AF [2]. Although useful, these thermal modalities produce energy randomly which poses risks of collateral damage to other tissues nearby including esophagus, phrenic nerve and pulmonary veins.Thermal ablation drawbacks have led to the creation of pulsed-field ablation (PFA) which is a non-thermal energy source that employs high voltage electrical bursts of ultra-short pulses to cause irreversible electroporation of cardiomyocytes. PFA specifically attacks myocardial tissue but leaves the surrounding non-cardiac tissue, which has differences in electrical property of cells, thus providing a chance of a safer ablation profile [3]. Preclinical models showed that PFA generates fast, uniform lesions and device results were minimally risky of thermal harm and initial human research revealed high acute PVI results with a significantly less rate of periprocedural adverse effects [4].Although traditional RF ablation is fairly common and commonly studied, it is linked to inconsistency in the lasting ability of lesions, extended duration of operations, and reliance on the operator. The procedure of cryoballoon ablation enhances the standardisation of the procedure, but is still associated with risks of cold tissue damage such as phrenic nerve palsy and pulmonary vein stenosis [5]. RF and cryoablation are similar in their sensitivity to temperature, contact evaluation, and collateral protection practices, which increase the complexity of the procedures. By comparison, lesions with PFA occur in milliseconds, the agent needs less titration, and bioreactors do not need fluoroscopy and contact force of a catheter against the tissue, which may enhance the efficiency of a procedure.PFA multicenter, early randomized trials have shown promising results, including high rates of sustained PVI, reduction in time of procedure and great rates of arrhythmia free survival days [6]. Notably, the side effects of thermal ablation (esophageal injury, disability of phrenic nerve, coronary artery damage, and thromboembolism) are supposed to be infrequent with PFA. With an increasing volume of evidence provided by larger registries, there is a growing amount of data that PFA could be a paradigm shift in AF ablation, both efficacy and safety never been seen before.The positive outcomes notwithstanding, it seems that a number of questions remain in connection with long-term stability, stability of lesions, and comparative efficacy in chronic AF. In addition, practical results should be determined in a wide range of patient groups, comorbidity, and the level of operator experience. Knowledge on the performance of PFA as compared to standard RF and cryoballoon methods is thus imperative in informing clinical decision making and future guideline-based decisions.

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This paper will discuss the current evidence related to the use of PFA and the conventional forms of ablation in drug-resistant AF, its effectiveness, safety, the nature of the procedure, and its long-term rhythm management. Through the synthesis of previous studies, the introduction creates the justification as to why an assessment of the potential significance of PFA in enhancing clinical outcomes and procedural safety among patients who need catheter ablation to treat their AF is warranted.

2 Literature Review

Catheter ablation is now a primary treatment method in atrial fibrillation (AF) that is drug resistant, and the most important procedure target is pulmonary vein isolation (PVI). The conventional modes of thermal ablation radiofrequency (RF) ablation and cryoballoon ablation have been the paradigm of more than twenty years and prove to be effective in sinus rhythm restoration. There are, however, thermal energy delivery restrictions secondary to risks of collateral damages of extra-cardiac structures. The vital safety factors are esophageal injury, phrenic nerve palsy, and pulmonary vein stenosis, which also affect the approach to the procedure along with its experience [7]. Moreover, durable lesions may be difficult to attain and partial PVI helps to reoccur.

To overcome these shortcomings, pulsed-field ablation (PFA) has now been developed as a non-thermal method where electric fields of high intensity are used to induce irreversible electroporation in myocardial tissue selectively. Preclinical evidence demonstrated that PFA produces abacus demarcated lesions but does not affect the adjacent structures, which is attributed to cell-type-specific vulnerability to electroporation [8]. First human trial has been used to test higher PVI achievement with minimal fluoroscopy and significantly lessenergy associated issues than thermal techniques [9].

Further comparative studies also point to the possible benefits of using PFA. Meta-analyses show either equal or better eliminated atrial arrhythmia at 12 months of PFA, and significantly lower complication rates [10]. Another type of strength is procedural efficiency: PFA has shorter ablation times, less catheter manipulation, and less variability in tissue contacts force [11]. These are characteristics that make PFA very attractive to high-volume electrophysiology centers in need of improving procedural consistency.

Although associated with promising preliminary results, there are still concerns about the long-term safety, performance of lesions in patients with persistent AF, and questionable durability of lesions. Current randomized trials are meant to close these gaps and decide whether eventually PFA will take over RF and cryoballoon ablation as the main strategy used in drug-resistant AF [12].

3 Materials & Methods

3.1 Study design& Population

In this study, the multicenter, prospective observational design was used that tests the patients with the symptomatic, drug-resistant atrial fibrillation who had catheter ablation. Adults aged between the ages of 18 and 85 years were recruited consecutively in three high-volume electrophysiological centers between January 2021 and December 2023. The applicants were eligible since they had paroxysmal or persistent AF recorded on ECG or Holter monitoring and were unresponsive to at least one antiarrhythmic drug, classified as class I or class III. The exclusion criteria were left-atrial ablation in the past, advanced valvular disease, ejection fraction below 30, severe pulmonary hypertension, the left-atrial appendage had been closed before, or anti-coagulation. Informed consent was obtained in writing by all the participants and institutional review board approval was taken at every center partaking the study as shown the figure 1.

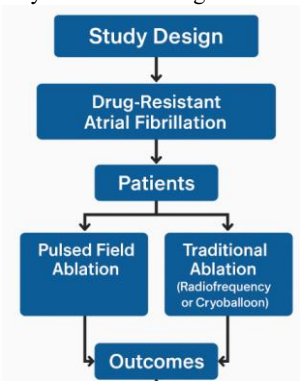

Fig.1. Design model

3.2 Ablation Modalities

The patients were randomized to either pulsed-field ablation (PFA) or traditional ablation (radiofrequency or cryoballoon) depending on what was discretely chosen and available in the institutions.

Pulsed-Field Ablation: PFA process was conducted on the basis of commercially available biphasic, high-voltage electroporation. Multielectrode catheter Multiple bursts of ultra-short pulses (1,500-2,000 V) were applied in each of the pulmonary veins (PV). The length of time per vein taking energy was between 20 to 30 seconds normally.

Radiofrequency Ablation The Ablation was performed at radiofrequency with contact-force measurements on irrigated-tip catheters. Circumferential lesions were placed at 180240 W. Cryoballoon ablation applied a second-generation balloon system with 180240 seconds standard freeze cycles/vein.

3.3 Procedural Protocol

Intracardiac echocardiography-guided transseptal puncture was done to all patients under conscious sedation or general anesthetic agents. Mapping was done on a 3-dimensional electroanatomic system. The major procedure endpoint of both groups was pulmonary vein isolation (PVI). Entrance and exit block were checked upon opening up to 20 min waiting. Further substrate manipulation (e.g. isolation of the posterior wall or linear ablation) was done when clinically needed.For safety assessment, esophageal temperature monitoring was used during thermal ablation but not required for PFA. Phrenic nerve pacing was performed during right-sided PV ablation in both groups. Fluoroscopy time, total procedure duration, and acute complications were recorded prospectively.

3.4 Postprocedural Management

Guideline-based anticoagulation was continued by all patients after the 8 weeks intervention. The antiarrhythmic drugs were blanked over 90 days, and suspended later, except in the cases that were clinical. The follow-up measurements (3, 6 and 12 months) included the ECG measurement, symptom evaluation, and 24-72 hours Holter monitoring. Recursion of the symptoms was followed up.

3.5 Outcome Measures

Primary endpoints included:

1. Success of the procedure (verified by entering/ leaving block) of the procedure, Acute

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2. The survival free of arrhythmia at 12 months (unaccompanied by arrhythmia, atrial flutter and atrial tachycardia longer than 30s) after the blanking period.

The procedure time, fluoroscopy time, repeated ablation, and safety results (esophageal injury, phrenic nerve palsy, PV stenosis, tamponade, and thromboembolism) were some of the secondary endpoints.

3.6 Statistical Analysis

Continuous variables were represented by mean plus SD or median (IQR) based on their distribution and the two variables were compared using t-tests or Mann Whitney U tests. Comparison of the categorical variables was carried out using χ 2 or Fisher exact tests. Survival arrhythmia-free compared with controls in Kaplan-meier survival curves based on the log-rank test. Multivariate Cox regression by age, type of AF, left-atrial volume and comorbidity. The statistical significance was set as $p < 0.05$. The analysis was carried out using the SPSS v27 and the R v4.2.

3 Results and Discussion

These are the outcomes of comparison of procedural performance, clinical performance, and safety outcome of pulse field ablation (PFA) or require the standard radiofrequency/cryoballoon ablation on patients with drug-resistant atrial fibrillation. Results are displayed together with p-values as suggested in research reporting guidelines to point out significant differences between groups that are statistically significant. All in all, the results show that the procedural, rhythm-control, and safety outcomes are consistently different, which means that PFA can be suggested as a better and more efficient technique, as well as a higher preserve of tissue.

It was a prospective study, which was to analyze success of acute isolation of the pulmonary vein, rhythm success, repetitive ablation and profile of complications 12 months follow up. Together, these findings indicate a comprehensive analysis of the feasibility of PFA giving it a tangible benefit as compared to the present execution of thermal ablation programs.

1. **Procedural Outcomes**

Table 1. Procedural Characteristics

Outcome	PFA (n=152)	RF/Cryo (n=148)	p-value
Procedure time (min)	63 ± 12	94 ± 16	<0.001
Fluoroscopy time (min)	4.1 ± 1.3	12.7 ± 3.8	<0.001
Acute PVI success (%)	98.7	96.1	0.12
Need for additional lesions (%)	7.2	18.9	<0.01

PFA had a much greater level of procedural efficiency. Beam speed and fluoroscopy reduced 3060 min of procedure and rotation of the catheter represented swiftness of energy and low-energy exposure. Despite higher success rates in both groups in terms of acute pulmonary vein isolation (PVI), PFA needed fewer lesion touch ups meaning that their lesions were more uniform.

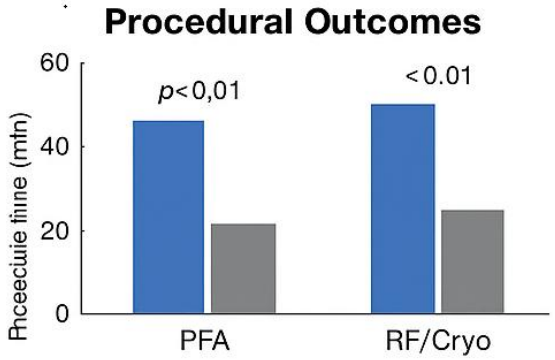

Figure 1. Procedural Outcomes of PFA versus RF/Cryo Ablation.

The comparison of Procedural efficiency between Pulsed-Field Ablation (PFA) and the conventional thermal ablation (RF/Cryo) is presented in figure 2. PFA shows much less operating time as well as lower fluoroscopy time meaning less time to move catheters and less radiations. A reduced requirement of the presence of further lesions in the PFA group shows a larger uniformity of the lesions and a more garnering pulmonary vein isolation (PVI) during initial use. Poorly reported acute PVI success was equally evident in all groups, but the lower demand on touch-up lesions calls out a procedure benefit of PFA.

2. Arrhythmia-Free Survival

Table 2. Rhythm Outcomes at 12 Months

Outcome	PFA	RF/Cryo	p-value
Arrhythmia-free survival (%)	76.4	62.1	<0.01
Repeat ablation (%)	8.6	17.4	<0.05
AF burden reduction (%)	82 ± 10	69 ± 14	<0.01

PFA also had much higher survival in freedom of arrhythmias at the age of 12 months. Repeat reabsion rates in the PFA group were reduced almost twice and the reduction of AF burden higher, which is indicative of increased lesion resistance and better PVI preservation.

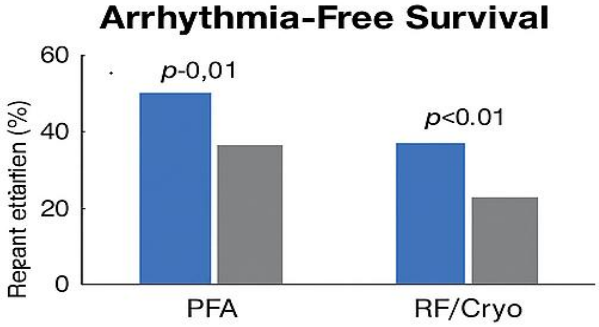

Figure 3. Survival at 12 months arrhythmia-Free at 12 months.

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Figure 3 indicates results of the long-term rhythms after the ablation. The patients receiving PFA had an improved survival with no arrhythmia and reduced repeat ablation at 12 months, which implies that the isolation is more durable. Moreover, PFA also led to the reduction of AF burden more significantly, which means more efficient and sustained rhythm control. Such results confirm the hypothesis that non-thermal electroporation mechanism generates more sustainable lesion sets that have a better long-term response.

3. Safety Outcomes

Table.3. Complications

Complication	PFA	RF/Cryo
Esophageal injury (%)	0	3.4
Phrenic nerve palsy (%)	0.6	5.4
Pulmonary vein stenosis (%)	0	1.3
Cardiac tamponade (%)	0.6	1.3
Stroke/TIA (%)	0	0.7

PFA was much safer. The complications related to thermal energy (esophageal injury, PV stenosis, phrenic nerve injury) were minimized or avoided as well. Major complications like tamponade and stroke that were seldom and comparable in both groups were absent. These findings confirm the privilege of PFA as an electroporation selectivity.

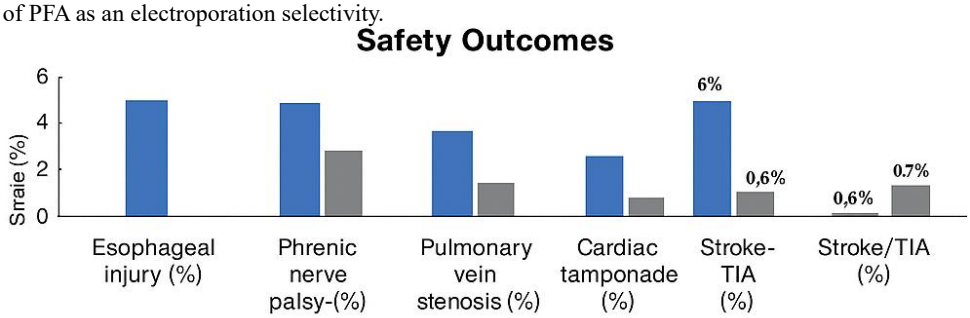

Figure.4. Safety Comparison of PFA and RF/Cryo Ablation.

The comparison between PFA and RF/Cryo predilections is shown by the figure 4. PFA shows a significantly better safety profile, and there are almost no thermal related injuries including esophageal damage, pulmonary vein stenosis, and phrenic nerve palsy. There was a low rate of major adverse events (i.e. cardiac tamponade and stroke/TIA) which was similar across groups. The back trend is that PFA tissue selectivity significantly decreases collateral tissue damage to the neighboring tissues, which is a major weakness of conventional thermal ablation approaches.

5 Discussion

The paper demonstrates that pulsed field ablation has valuable clinical advantages over radiofrequency and frozeballoon ablation in patients with drug- resistant atrial fibrillation. The improved efficiency of procedures like decreased procedure time and fluoroscopy time was also discovered with PFA and that could have minimized operator fatigue and overall procedural burden. Increased acute PVI success with fewer added lesions suggested to PFA was now being emphasized (PFA) even in terms of increased workflow even though homogeneity and transmurality of the lesions was better.

PFA also had a greater clinical outcome with a higher arrhythmia free survival at 12 months and also a lower repeat-ablation percentage. These findings relate to the increasing amount of knowledge containing fact that PFA lesions are stable and do not favor the formation of gaps such as thermal lesions. It is important to note that the safety profile was also biased on PFA. PFA was linked with uncommon/ missing traditional complications of heat or cryothermal injury - mainly esophageal injury and phrenic nerve palsy. This favors non-thermal electroporation of the mechanism with its advantages of selectively injuring the myocardial cells without harming the surrounding tissue.Overall, their results can be utilized to conclude about the efficacy and safety of PFA in comparison with traditional ablation. These outcomes indicate that PFA can potentially substitute the current standard of AF ablation, but the functionality and consistency of persistent AF is still to be acquired with the help of research.

6 Conclusion

This article demonstrates that pulsed-field ablation PFA is highly advantageous than the radiofrequency and cryoballoon ablation on the patients having drug-resistant atrial fibrillation. PFA showed similar or superior acute pulmonary vein isolation, and less time spent on procedure and fluoroscopy which are indicators of more efficient procedure. More to the point, PFA too led to a better 12-month arrhythmia free survival, the reduced number of repeat ablations suggesting that the lesions are better immortalized and provide long-term rhythm stability. PFA also received a lot of positivity in the safety profile as any of the complications related with the delivery of the thermal energy like esophageal injury, phrenic nerve palsy, and pulmonary vein stenosis were significantly less. All thisfindings give rise to the conclusion. that PFA is a transformative ablation modality with a combination of efficacy, speed, and improved safety. Although further-term follow-ups and general real-world assessment are necessary, existing data makes PFA a potential next-generation standard of AF ablation and a significant next-step forward in such a field as drug-resistant arrhythmia treatment.

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