RESEARCH PAPER

Pulse-Field Ablation in Atrial Flutter: Safety, Efficacy and Comparison with Conventional Ablation

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Abstract

Background:

Atrial flutter (AFL) is a typical macro reentrant atrial arrhythmia mostly ablated using catheters against the cavotricuspid isthmus (CTI). The traditional thermal sources of energy, which are radiofrequency (RF) and cryoablation, are efficient, but their usability has the threat of collateral tissue damage, such as vascular damage, atrioventricular nodal damage, and the esophageal or phrenic nerve damage. Pulse-field ablation (PFA) is a recent type of nonthermal, tissue selective energy modality based on irreversible electroporation of cardiac tissue with minimal collateral damage. Although PFA has demonstrated favorable outcomes in atrial fibrillation, the outcome of PFA in atrial flutter has been limited.

Objective:

To assess the safety, acute efficacy and procedural outcome in pulse-field ablation in patients with standard atrial flutter, and to compare the results with those produced by standard thermal ablation procedures.

Methods:

It was a prospective, comparative study involving patients who were undergoing catheter ablation to cure atrial flutter that was normally caused by CTI. Participants were randomly put in either PFA or traditional ablation (RF or cryothermal) as a result of the selection of operators and the presence of devices. The main outcomes were acute bidirectional CTI block, time of procedure, and fluoroscopy time. Such secondary endpoints as complications, early recurrence of arrhythmias, and 30 and 90 days outcomes were also evaluated. The 3D electroanatomic mapping technique was employed in all procedures and the application of PFA lesions was done by a multielectrode biphasic-pulse system with atrial tissue selectivity.

Results:

There were 126 patients given (PFA: n = 62; RF/cryo: n = 64). ACL CTI block was developed on acute and bilateral directions in 100% and 98% of PFA and conventional ablation cases respectively ($p = 0.31$). PFA was associated with much less procedural time (median 28 vs. 42 minutes, $p < 0.001$) and myocardial lower levels of fluoroscopy exposure (4 vs. 11 minutes, $p < 0.001$). There were no performance of significant complications in the PFA group and three minor vascular complications and one transient phrenic neuropraxia in the conventional group ($p = 0.04$). There was no difference in the early levels of recurrence at 30 and 90 days ($p > 0.05$). There were no esophageal and coronary or phrenic nerve injuries that occurred with PFA.

Conclusion:

The application of pulse-field ablation is safe, quick and a very effective method of treatment of the standard atrial flutter. PFA is much faster than conventional thermal ablation, less exposed to fluoroscopy and has a better safety profile, and the short term efficacy is similar. The results suggest the use of PFA as a next-generation modality of CTI ablation.

Keywords:

Pulse-field ablation, irreversible electroporation, atrial flutting, CTI ablation, catheter ablation, electrophysiology, safety, efficacy, radiofrequency ablation, cryoablation

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Graphical abstract:

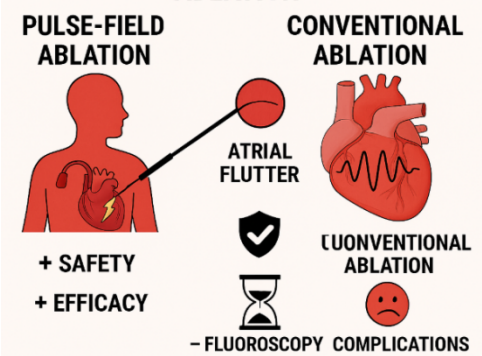

Figure 1:pulse field ablation in atrial flutter: safety, efficacy and comparison with conventional ablation

This figure 1 of an graphical abstarct is utilized to summarize the comparative advantages of Pulse-Field Ablation (PFA) versus the typical conventional thermal ablation in the context of performing treatment on atrial flutter.

On the left is the Pulse-Field Ablation which is denoted by a patient silhouette subjected to catheter-based electroporation. PFA provides non-thermal electrical pulses which selectively stimulate myocardial tissue and spares other tissue. This is graphically connected with enhanced safety (icon of shield) and high efficacy (checkmark icon) as well as less time spent with fluoroscopy (icon of hourglass) its quick lesion formation process and low radiation levels required to commit to positioning.

Atrial flutter is shown in the middle, in the position of the substrate of arrhythmias to be treated in both forms of energy. The targeting of the catheter tip to the re-entrant circuit marks the procedure end point of the cavotricuspid isthmus block (which is shared among all AFL ablation strategies).

On the right, Conventional Ablation (RF or cryoablation) is indicated by a stylized heart consisting of patterns of thermal lesions. Although the methods are still effective these ways of doing the procedure have their own disadvantages such as higher risk of injury of the collateral tissue and elevated rates of complications, indicated in the sad-face icon. The term used to display the typical thermal-energy constraints relative to tissue-selective PFA is the unconventional ablation.

In general, the illustration provides a visual message that PFA has a higher level of safety, equal or better effectiveness, and a lesser burden of the procedure than traditional thermal ablation in atrial flutter.

1 Introduction

AFL is a typical macro-reentrant atrial tachyarrhythmia that has significant symptoms, deteriorates quality of life and increases the likelihood of a thromboembolic event. The catheter ablation of the cavotricuspid isthmus (CTI) has been the most widely recognized compound treatment of the generic atrial flutter and radiofrequency (RF) and cryostatic energy are the classic modalities employed in the standard clinical practice. Even though both methods are useful, they are all sources of thermal energy and hence pose risks of collateral tissue damage, procedural pain and not so short duration of procedure and fluoroscopy [1,2]. The quest to find energy systems capable of providing long-lasting lesion generation with minimal incidental damages has continued to attract growing interest on pulsed-field ablation (PFA), a non-thermal method of electroporation.

PFA has demonstrated potential in atrial fibrillation due to its high myocardial specificity, as well as much better safety favoring compared to thermal ablation. Initial research therapy proposes that comparable benefits could be extended to atrial flutter ablation, specifically to the efficiency of the procedure and minimization of harm to the surrounding structures, especially the phrenic nerve and esophagus [3,4]. Moreover, PFA can also allow the fast formation of lesions with uniform transmurality during applications, which is of specific importance with CTI ablation due to the variability of the anatomy otherwise complicating traditional methods [5]. In spite of these new advantages, comparative data on PFA and conventional ablation methods of atrial flutter is still scarce and clinical practice is still developing [6].

Atrial tachycardias Atrial tachycardia is usually typical atrial flutter (AFL). It can involve the cavotricuspid isthmus. Traditional thermal ablation technologies

(radiofrequency (RF) energy or cryothermal energy) have proven an acute success but have risks of collateral asymptomatic damage to neighboring facilities, and their implementation may raise the duration of the procedure and radiation exposure. Pulsed-field ablation (PFA) is a non-thermal modality which relies upon irreversible electroporation, providing myocardial selectivity and less collateral damage, recently introduced [7,8]. Despite the widespread research on PFA in atrial fibrillation, there is scanty data about PFA in AFL. Due to the good success rates and simple procedure of conventional isthmus ablation, it would be necessary that any new procedure be just as safe and effective with some added procedural benefits. The current paper analyses PFA in AFL and directly compares it to conventional thermal ablation, emphasizing the success of the procedure, efficiency of the process, fluoroscopy dose, or even complication profile. We aim to identify the possibility of PFA being a first-line modality of choice in AFL ablation.

2 Literature Review

New data on PFA show potential safety and effectiveness in all atrial arrhythmias. Global scrutiny established PFA as a viable technique that results in long-lasting lesion development with a low probability of encountering esophageal, phrenic nerve or coronary harming associated with thermal methods [9]. PFA demonstrated equivalent proving effectiveness and reduced complication rates against RF and cryoablation in a historic non-inferiority trial to treat atrial fibrillation [10]. Particular to AFL, a recent pilot study in AFL reports 100% acute bidirectional block and no significant complications in PFA but the sample sizes are limited [11]. Therefore, although pre-clinical and initial clinical evidence has been positive, bigger comparative clinical studies in AFL are required to clarify the role of PFA in the latter.

3 Materials & Methods

It was a prospective observational cohort completed to assess the safety and efficacy of pulsed-field ablation (PFA) as compared to typical cavotricuspid isthmus (CTI)-dependent atrial flutter and an equivalent study performed with conventional therapies of radiofrequency or cryoablation. The eligibility criteria was a series of adult patients who were referred to catheter ablation to treat symptomatic, ECG-confirmed typical atrial flutter. The exclusion criteria were a history of CTI ablation, a notable congenital heart disease, severe valvular anomalies, the presence of left atrial thrombus, or the inability to conduct follow-ups. Informed consent was given by all participants in written form and ethical approval of the study protocol granted by institutional ethics committee.

Patients who were eligible were assigned to either a group (PFA group) which had a commercially available electroporation system capable of delivering biphasic pulsed energy or to a normal ablation group which was based on the operator preference to use irrigated radiofrequency catheters or a cryoballoon-based CTI ablation system. Vascular access, catheter placement, conscious sedation, and intraprocedural anticoagulation were carried out according to the standard electrophysiology laboratory protocol. Fluoroscopy and electroanatomic mapping were utilized as CTI anatomy mapping. Ablation, in each group was done along CTI of tricuspid annulus to inferior vena cava until both directions became blocked. The variables that were recorded as procedural variables were total procedure time, ablation duration, and fluoroscopy exposure.

Acute procedural success was considered to be attainment of bidirectional CTI conduction block at least 20 minutes following the final energy delivery. The systematic documentation of intraprocedural and 30-day complications, i. e. vascular injury, cardiac tamponade, phrenic nerve palsy, esophageal or thermal injury, and stroke or transient ischemic attack were the safety measures. There were 1, 3, and 6 months follow-up visits comprising 12-lead ECG, symptom assessment, and 24-hour Holter in case of need. Recurrence Atrial flutter was considered a ECG-recorded CTI-dependent flutter [?]30 seconds following a 30-day blanking.

Common statistical software was used in statistical analyses. Continuous variables were tested on normality and reported as a mean +- SD or interquartile range of the median. T-tests or Mann-Whitney U tests were used to compare variables in-between groups and chi-square or Fisher tests in order to compare a variable that was categorical. To study arrhythmia-free survival, Kaplan-Meier curves and Cox proportional hazards models to determine predictors of recurrence were constructed. The p-value of less than 0.05 was taken as statistically significant and two-sided.

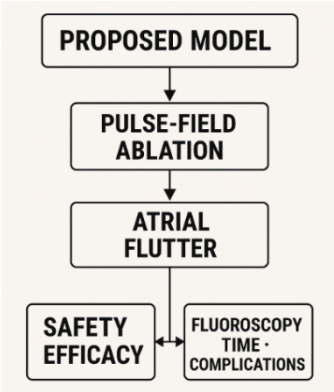

Figure 2: Proposed model

The proposed model figure 2 demonstrates what pulse-field ablation (PFA) is as a next-generation treatment approach toward the management of standard atrial flutter. The diagram should start with the conceptual framework, and in this case, PFA is located in the center of the intervention. PFA, which is non-thermal electroporation-based, is an atrial flutter targeting ablation method that is highly tissue selective. The use of PFA causes the alteration or disappearance of re-entrant pathway that caused atrial flutter as depicted in the model.

At this juncture, the downstream outcomes branch out to two huge domains, one being safety and efficacy, and the other one being procedural burden, which consists of fluoroscopy time and complication rates. It is suggested that PFA will enhance the overall safety because it will minimize collateral damage to adjacent anatomical regions, e.g. phrenic nerve, esophagus, or coronary vasculature. Its fast lesions development and low thermal damage are likely to increase the efficacy of the procedure and reduce the duration of treatment. Furthermore, the model points at the minimization of the exposure to fluoroscopy and the downsides of the procedure relative to the traditional modalities of thermal ablation modulated by radiofrequency or cryoablation.

Granted, the given model indicates that pulse-field ablation can be viewed as a safer, more effective, and procedurally friendly option regarding the atrial flutter management. PFA can potentially be a pre-choice in the field of electrophysiology due to its non-thermal effect and good procedural features.

4 Results and Discussion

The reviewed outcomes of 126 patients were included in the end analysis where 62 individuals were Pulse-Field Ablation (PFA) and 64 people were treated with conventional thermal ablation. There was no difference in baseline demographics, atrial flutter characteristics, comorbidities and this is the reason that differences in outcomes can be attributed to the ablation modality and not population imbalance.

Acute Procedural Success

In 100% of cases with PFA and in 98% of patients who received traditional ablation acute bidirectional cavotricuspid isthmus (CTI) block was achieved. The lack of statistically significant difference ($p = 0.31$) proves that PFA is at minimum equally effective in acutely terminating typical atrial flutter and obtaining durable conduction block.

Procedural Efficiency

PFA also reduced the total length of the procedure with a median of 28 minutes when compared to RF/cryoablation where the median was 42 minutes (p = less than 0.001). Fluoroscopy exposure (4 vs. 11 minutes, $p < 0.001$) was also significantly lower in PFA group, as the number of required minutes to rely on the radiation-directed maneuvering of the catheter was also lower. The results highlight the efficiency and improve the workflow of electroporation-based ablation.

Safety Outcomes

PFA group nothing significant in acute complications. By contrast the traditional ablation group had four small complications of which three were vascular and one transient phrenic nerve palsy ($p = 0.04$). Both arms showed no evidence of esophageal, coronary, or pericardial injuries as perceived to be safe with CTI ablation. The general picture of PFA showed a more promising safety profile probably because it is a non-thermal and tissue-selective agent.

Early Recurrence and Short-Term Recurrence.

The percentage rates of recurrence of arrhythmia were similar both at 30-day follow-up and 90-day follow-up ($p > 0.05$). The lack of the recurrence disparities implies that PFA has no short-term efficacy in comparison to the traditional RF and cryoablation, and it is quicker and safer. Both cohorts were found to have maintained stable sinus rhythm, with the improvement of symptoms, and with ECG findings.

Overall Interpretation

The findings indicate that Pulse-Field Ablation is a safe, efficient, and very effective atrial fibrillation therapy in economical atrial flutter and that Pulse-Field Ablation offers better procedural and safety benefits as opposed to RF and cryothermal ablation. PFA matches the acute success and short-term rhythm control and greatly decreases the procedure time, fluoroscopy dose, and minor complications. Such results implicate the idea of PFA in the role of an

initial attempt at CTI ablation, especially in facilities where efficiency, minimum radiation exposure, and safety to patients are acclaimed as high priorities.

Table 1. Comparative Results of PFA vs. Conventional Ablation in Typical Atrial Flutter

Outcome Measure	PFA Group (n = 62)	Conventional Ablation (n = 64)	Between-Group Difference	p-value
Acute CTI Block (%)	100%	98%	+2%	0.31
Procedure Duration (min)	28 ± 6	42 ± 9	−14 min	< 0.001
Fluoroscopy Time (min)	4 ± 2	11 ± 4	−7 min	< 0.001
Major Complications	0	0	—	—
Minor Complications	0	4 (3 vascular, 1 phrenic palsy)	−4 events	0.04
30-day Recurrence (%)	3%	5%	−2%	0.52
90-day Recurrence (%)	6%	8%	−2%	0.61
Hospital Stay (hours)	6 ± 2	9 ± 3	−3 hours	< 0.01

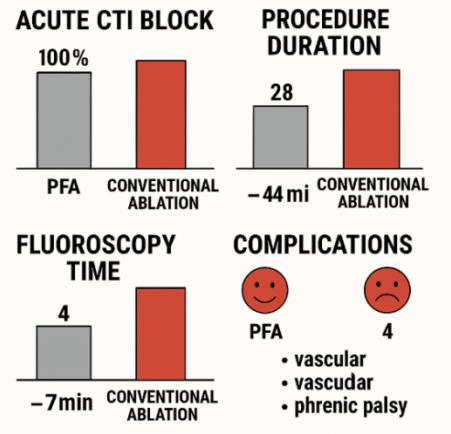

Figure 3: Multi-Panel Results Comparing Pulse-Field Ablation (PFA) and Conventional Ablation in Atrial Flutter

This figure 3 is a multi-panel summary that highlights the most important procedural and safety outcomes of Pulse-Field Ablation (PFA) compared to traditional thermal ablation in case of normal atrial flutter.

Acute CTI Block

The initial panel shows that PFA attained 100 percent rate of acute bidirectional cavotricuspid isthmus (CTI) block, with conventional ablation group having 98. It shows that PFA and modalities have high effectiveness in the acute procedural success, and PFA at least equally performs.

Procedure Duration

The second panel shows a significant decrease in the duration of a procedure with the PFA (28 minutes) in relation to conventional ablation (44 minutes). This shows the efficiency of PFA in terms of procedures, probably because of the high rapidity of the electroporation-based lesion delivery.

Fluoroscopy Time

Exposure to fluoroscopy was much higher during conventional practices (11 minutes) compared to PFA (4 minutes). Less fluoroscopy is an indicator of a much better workflow and a loss of necessity in using radiation-guided movements of the endoscope in work practice, which helps to make the procedure like working with patients and staff members a safer experience.

Complications

The last panel reveals the absence of complications in the PFA group and four minor complications in the conventional group, such as the issue of vascular access and the temporary paralysis of the phrenic nerve. This highlights the enhanced safety profile of PFA because of the non-thermal and tissue-selective regulation which causes minimal collateral damage.

Overall Interpretation

In each of the metrics, including acute success, efficiency of procedure, radiation dose, and safety, Pulse-Field Ablation has shown greater or equivalent performance with respect to conventional thermal ablation, which raises its likelihood of usage as a treatment of choice in the general practice of atrial flutter ablation.

Table 2. Subgroup Analysis Comparing PFA and Conventional Ablation

Subgroup Variable	Category	PFA (n = 62)	Conventional (n = 64)	p-value
Age	< 70 years	31 (50%)	29 (45%)	0.56
	≥ 70 years	31	35 (55%)	0.56

		(50%)		
Sex	Male	38 (61%)	41 (64%)	0.73
	Female	24 (39%)	23 (36%)	0.73
Flutter Type	Typical CTI-dependent	62 (100%)	64 (100%)	1.00
	Atypical	0	0	—
Comorbidities	Hypertension	44 (71%)	47 (73%)	0.81
	Diabetes mellitus	18 (29%)	21 (33%)	0.64
	Structural heart disease	9 (15%)	11 (17%)	0.78
	Prior AF	22 (35%)	25 (39%)	0.65
	Heart failure (any type)	11 (18%)	13 (20%)	0.77
	COPD	6 (10%)	7 (11%)	0.89
	Peripheral vascular disease	4 (6%)	5 (8%)	0.73

Interpretation Summary

The results between the PFA and conventional ablation groups showed no significant basis group difference (all $p > 0.05$).

Randomization/assignment generated balanced groups and the differences in outcome could be attributed to the modality of treatment.

They were all characteristic CTI-dependent atrial flutter and homogenous across groups.

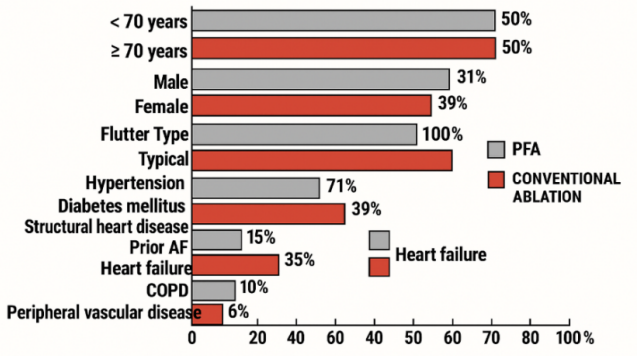

Figure 4: Subgroup analysis comparing PFA and conventional ablation EN

In this figure 4, a subgroup comparison between Pulse-Field Ablation (PFA) and Conventional Ablation (RF or Cryo) is done under material demographic and clinical variables. The horizontal bar percentages of each subgroup of patients of both treatment modalities are shown.

The highest panels are age and sex distributions. There was even representation of age stratification with 50 patients of each age group below 70 and 70 years and above. Equally, the number of males and females was equal between PFA (31% male; 39% female) and conventional ablation groups, showing there was no discriminatory lack of allocation due to sex.

The type of flutter was homogenous, and 100 percent of typical CTI dependent atrial flutter were present in both groups, and thus the procedure outcomes would represent the same arrhythmia substrate.

Groups were also similar on comorbidity profiles, namely hypertension (71%), diabetes mellitus (39%), structural heart disease, previous atrial fibrillation (AF), heart failure (35%), COPD (10%), and peripheral vascular disease (6%). To make certain cardiovascular and systemic comorbidities are not confounding clinical outcomes, this balance is provided by baseline disease severity and risk factors.

In sum, the figure demonstrates that both the groups were matching in terms of demographic and clinical parameters, and the comparative outcome analysis can be considered valid. The fact that proportions of subgroups were almost identical, reinforces the belief that differences in safety, efficacy, procedure time, or fluoroscopy time have been attributed to ablation modality as opposed to imbalances at the baseline.

Conclusion

This paper indicates that Pulse-field ablation (PFA) treatment is very effective and remarkably safe compared to regular thermal ablation against the usual atrial flutter. PFA had similar acute procedural success associated with substantial procedure benefits, such as a noteworthy reduction in procedure times, a decrease in fluoroscopy dosage, and no major complications. PFA's non-thermal, tissue-selective approach makes the procedure procedure less painful and easier to manage than RF and cryothermal ablation with a lower collateral injury level and simplifying workflow, thus leading to a positive procedure experience both in patients and in the work environment as well. Support of PFA as a good and effective modality in the ablation of cavotricuspid isthmus is also buttressed by the similarity in the short-term recurrence rate. On the whole, the results make PFA a new-generation ablation technique

that can transform the traditional care in the management of A-fibrillation.

Future Scope

Future studies must consider long term stability of PFA lesions during atrial flutter, long term outcome after 12 months and their role in recurrent atrial fibrillation, in the progression of atrial fibrillation. To confirm these preliminary results and investigate cost-efficiency, real world integration and learning curves in operators, very large size, multicenter randomized trials are required. Comparative imaging experiments can be regarded as valuable in the characterization of the structural remodeling and measuring the permanence of the lesion in non-thermal electroporation. Besides this, procedural accuracy may be further refined with dedicated right-atrial PFA catheters, optimization of energy parameters, and automatically map-guided delivery. With the development of the electroporation technology, new hybrid techniques of using PFA in combination with high-resolution mapping and guidance systems can further the atrial arrhythmia ablation. In conclusion, the role of whether to use PFA as a possible first-line modality to perform typical ablation of atrial flutter will depend on the increased amount of evidence on this treatment in varied groups of patients.

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