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INPLASY

Pulsed-Field Ablation: Revolutionizing Atrial Fibrillation Treatment with Reduced Recurrence and Procedure Times

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ADMINISTRATIVE INFORMATION

Support - None.

Review Stage at time of this submission - Completed but not published.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202510083

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 20 January 2025 and was last updated on 20 January 2025.

INTRODUCTION

Review question / Objective Population (P):
Patients with paroxysmal or persistent atrial fibrillation undergoing catheter ablation.
Intervention (I):
Pulsed Field Ablation (PFA).
Comparator (C):
Radiofrequency Ablation (RFA), Cryoballoon Ablation (CBA), or combined Thermal Ablation techniques (TA).
Outcomes (O):
Primary outcome: Recurrence of atrial fibrillation during follow-up.
Secondary outcomes:
Procedural characteristics (e.g., procedure time, fluoroscopy time).
Safety (e.g., rates of complications, classified as major or minor).
Study Design (S):
Randomized controlled trials (RCTs), prospective studies, and retrospective cohort studies comparing PFA with RFA, CBA, or TA.

Review Question/Objective:
To evaluate the efficacy, safety, and procedural characteristics of Pulsed Field Ablation (PFA) compared to either Radiofrequency Ablation (RFA), Cryoballoon Ablation (CBA), or Thermal Ablation techniques (TA) for the treatment of atrial fibrillation (AF).

Rationale Atrial fibrillation (AF), the most common sustained arrhythmia, significantly impacts morbidity, mortality, and quality of life. While catheter ablation, particularly pulmonary vein isolation (PVI), is an effective treatment, traditional thermal techniques like radiofrequency (RFA) and cryoballoon ablation (CBA) are limited by risks such as collateral tissue damage and prolonged procedure times. Pulsed-field ablation (PFA), a novel non-thermal modality, selectively ablates myocardial tissue while sparing surrounding structures, showing promise in early studies for improved safety and efficacy. However, comprehensive evidence comparing PFA to RFA and CBA remains limited. This study addresses

this gap by performing a systematic review and meta-analysis of their efficacy, safety, and procedural characteristics to inform clinical decision-making and advance AF ablation strategies. Atrial fibrillation (AF) is the most common sustained cardiac arrhythmia worldwide and is associated with significant morbidity and mortality, including an increased risk of stroke, heart failure, and reduced quality of life. Catheter ablation, particularly pulmonary vein isolation (PVI), has emerged as an effective treatment option for symptomatic AF. Despite advancements in ablation techniques, traditional thermal methods such as radiofrequency ablation (RFA) and cryoballoon ablation (CBA) have notable limitations, including risks of esophageal injury, phrenic nerve damage, and collateral tissue injury.

Pulsed-field ablation (PFA) is a novel, non-thermal ablation technique utilizing irreversible electroporation. It selectively targets myocardial tissue while sparing surrounding structures, thus potentially mitigating complications associated with thermal methods. However, despite promising initial results, data comparing PFA to RFA and CBA on key outcomes such as recurrence rates, complications, and procedural characteristics remain limited and inconsistent.

This study aims to address these knowledge gaps by conducting a systematic review and meta-analysis to compare the efficacy and safety of PFA against traditional thermal ablation techniques in the treatment of AF. The study evaluates critical endpoints, including recurrence rates, procedure times, fluoroscopy times, and complications. By synthesizing evidence from a large pool of studies, the findings can provide a comprehensive understanding of the comparative performance of PFA, its potential advantages, and its role in optimizing clinical outcomes for AF patients.

Condition being studied Atrial Fibrillation.

METHODS

Search strategy We conducted a literature search on MEDLINE/PubMed, Embase, Scopus, and Cochrane Central Register of Controlled Trials up to September 2024. The search included the following terms: (pulsed field ablation OR Electroporation) AND (pulmonary vein isolation OR atrial fibrillation ablation OR Atrial Fibrillation OR Catheter Ablation). In addition, a manual search of the reference lists of the included articles was performed. Potentially eligible studies were fully reviewed, and the final selection was made by consensus.

Participant or population Patients with atrial fibrillation undergoing ablation procedures.

Intervention Pulsed Field Ablation (PFA).

Comparator Radiofrequency Ablation (RFA), Cryoablation (CBA), and Thermal Ablation (TA) (combined group of RFA and CBA).

Study designs to be included Randomized controlled trials (RCTs), prospective, and retrospective studies comparing PFA with RFA, CBA, or TA.

Eligibility criteria Inclusion: Studies comparing PFA with RFA or CBA or TA in AF patients, reporting outcomes such as recurrence, complications, procedure time, and fluoroscopy time.

Information sources MEDLINE/PubMed, Embase, Scopus, and Cochrane Central Register of Controlled Trials.

Main outcome(s) Recurrence Rates.

Additional outcome(s) Complications, Procedure Time and Fluoroscopy Time.

Data management Data will be extracted and collected in an Excel spreadsheet.

Quality assessment / Risk of bias analysis Newcastle-Ottawa Scale for cohort studies.

Strategy of data synthesis Depending on heterogeneity, common or random-effects models will be applied for analysis. Heterogeneity among studies will be assessed using the I^2 test, with >50% indicating significant heterogeneity. If I^2 is >50%, a random-effects model will be used. Recurrence rates during follow-up, complications, procedure time, and fluoroscopy time will be summarized as pooled estimates with 95% confidence intervals (CIs). Odds ratios (ORs) and mean differences (MDs) with 95% CIs will be presented as effect measures for categorical and continuous variables, respectively. For data reported as medians and interquartile ranges, mean and standard deviation (SD) will be estimated. Significance in the statistical analysis will be set at $P < 0.05$.

Subgroup analysis No subgroup analysis will be performed.

Sensitivity analysis A sensitivity analysis will be conducted to assess the influence of individual studies on overall effect size and heterogeneity.

Language restriction None.

Country(ies) involved India, U.S.A.

Keywords Catheter Ablation; Atrial Fibrillation; Pulsed Field Ablation; Thermal Ablation; Radiofrequency Ablation; Cryoballoon Ablation.

Contributions of each author

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