INPLASY

Safety and efficacy of the Pulsed field ablation for atrial fibrillation: a systematic review and updated meta-analysis

INPLASY202560081

doi: 10.37766/inplasy2025.6.0081

Received: 19 June 2025

Published: 19 June 2025

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ADMINISTRATIVE INFORMATION

Support - It is paid by the authors, with no funding support.

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

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202560081

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 19 June 2025 and was last updated on 19 June 2025.

INTRODUCTION

Review question / Objective Pulsed field ablation (PFA) has emerged as an innovative non-thermal approach with significant promise for treating atrial fibrillation (AF). However, comparative data between PFA and traditional ablation (TA, including cryoballoon ablation [CBA] and radiofrequency ablation [RFA]) remain limited.

Rationale We searched the PubMed, Embase, Cochrane Library databases and Medline to identify studies comparing PFA with TA.

Condition being studied We believe that at least 3 aspects of this manuscript will make it interesting to you.
(1) Pulsed field ablation (PFA) is an effective treatment for atrial fibrillation (AF) without an increased risk of complications.
(2) Compared with conventional traditional ablation (TA, radiofrequency ablation or cryoballoon ablation), PFA significantly reduces procedure time, making AF ablation more convenient and faster.
(3) Even with limited experience, operators can achieve good results with PFA in treating AF, with success rates even better than with TA. Therefore, PFA is expected to become a standard procedure for treating atrial fibrillation.

METHODS

Search strategy A comprehensive literature search was performed across PubMed, Embase, Medline, the Cochrane Library, and Elsevier's ScienceDirect databases. Non-English language publications were excluded from the analysis. The search strategy incorporated relevant keywords and medical subject headings (MeSH) terms, including: ((atrial fibrillation) OR (AF)) AND ((Pulsed field ablation) OR (PFA)) AND ((radiofrequency ablation) OR (RFA) OR (cryoballoon ablation) OR (CBA) OR (traditional)). The literature search was last updated in April 2025.

Participant or population Patient with atrial fibrillation.

Intervention Patient with atrial fibrillation receive pulsed field ablation.

Comparator Patient with atrial fibrillation receive traditional ablation (TA, including cryoballoon ablation [CBA] and radiofrequency ablation [RFA]).

Study designs to be included Randomized controlled trial ;ProspectiveNon-randomized; Retrospective.

Eligibility criteria The inclusion criteria were as follows: (a) patients diagnosed with drug-refractory symptomatic AF who underwent ablation; (b) Patients undergoing their first catheter ablation procedure; (c) Comparative studies between PFA and either RFA or CBA; (d) Studies with a sample size of at least 20 participants; (e) Studies that provided comprehensive and reliable data on procedural outcomes, complications, and follow-up for both intervention groups.

Information sources PubMed, Embase, Cochrane Library databases and Medline.

Main outcome(s) Procedure time: Defined as the duration from the administration of local anesthesia to the removal of all catheters. Fluoroscopy time: Refers to the total duration of fluoroscopy from the procedure initiation to its completion. Left atrial dwell time: Denotes the period during which the catheter remains within the left atrium. Complications: Included all-cause mortality, pericardial tamponade, persisting PNI, stroke/transient ischemic attack (TIA), esophageal lesions, and systemic thromboembolism. Atrial Arrhythmias Recurrence: Defined as the any symptomatic or asymptomatic atrial arrhythmia lasting >30 seconds after the post-catheter ablation blanking period.

Data management For dichotomous outcomes, risk ratios (RR) with 95% confidence intervals (CIs) were calculated, while continuous variables were analyzed using standard mean differences (SMD). Statistical analyses employed fixed and random-effects models, with weighting based on inverse variance methods following DerSimonian and Laird's approach. Between-study heterogeneity was evaluated using the I^2 statistic, where an I^2 >50% indicated substantial heterogeneity. A P value <0.05 was considered statistically significant for all tests. We performed a leave-one-out sensitivity analysis to address heterogeneity by sequentially excluding each study from the pooled analysis, and If significant heterogeneity persisted, the random-effects model was applied. Statistical analyses were performed using Review Manager version 5.4 (The Nordic Cochrane Center, The Cochrane Collaboration, 2014, Copenhagen, Denmark).

Quality assessment / Risk of bias analysis Two investigators (L-H and G-AW) independently used the Cochrane RoB 2 tool13 and Cochrane ROBINS-I tool14 for quality assessment of randomized controlled trials (RCTs) and nonrandomized studies, respectively. RoB 2 tool was used to assess the risk of bias in RCTs by judging five domains: randomization process, deviation from intended intervention, missing outcome data, how the outcomes were measured, and selection of the reported results, while ROBINS-1 tool was used to assess the risk of bias in nonrandomized studies by judging seven domains: confounding bias, bias arising from selection of the participants, bias in classification of the interventions, bias due to deviation from intended interventions, bias due to missing outcomes, bias in measurement of the outcomes, and bias in selection of the reported results. The reviewers resolved any conflicts by consensusFor bias risk assessment, the Robins-I tool was applied to non-randomized studies, with bias risk plots generated using the robvis software. Two reviewers extracted data collaboratively, resolving discrepancies through discussion to ensure consistency.

Strategy of data synthesis Two investigators assessed the study quality using the Delphi consensus criteria for randomized controlled trials (RCTs) and the Newcastle-Ottawa Quality Assessment Scale (NOS) for observational research. The NOS comprises eight items , with a maximum score of nine points, utilizing a star system to evaluate study populations, group comparability, and the exposure/outcome of interest. Studies scoring ≥7 on the NOS were considered high quality. This systematic review adhered to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines and Cochrane Collaboration's recommendations.

Subgroup analysis 1.compare PFA and cryoballoon ablation [CBA]; 2.compare PFA and radiofrequency ablation [RFA]).

Sensitivity analysis We performed leave-one-out sensitivity analyses for arrhythmia-free survival, procedure time, fluoroscopy time, fluoroscopy dose, redo procedures, complications overall,

cardiac tamponade and stroke or TIA with the aim of exploring heterogeneity and showing the independence of the results on one study alone. We performed a subgroup analysis of arrhythmia-free survival considering follow-up time. Additionally, we performed a metaregression analysis for arrhythmia-free survival to evaluate the relationship between the effect measure and age, paroxysmal and persistent AF, and follow-up.

Language restriction English languages.

Country(ies) involved China - Nantong rici Hospital, Yangzhou University.

Keywords Pulsed field ablation, Traditional ablation, Safety and efficacy, Meta-analysis, Atrial fibrillation.

Contributions of each author

Author 1 - Hui Li - contributed to design of this work, statistical analysis, wrote the article, reviewed the literature, performed the selection of the studies and helped gather references for the article.
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