

Pulmonary Vein Stenosis and Atrial Fibrillation Recurrence: A Comparison of Clinical Outcomes of Radiofrequency Ablation versus Cryoablation

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ADMINISTRATIVE INFORMATION**Support** - None.**Review Stage at time of this submission** - Data extraction.**Conflicts of interest** - None declared.**INPLASY registration number:** INPLASY2026100035**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 8 October 2026 and was last updated on 8 October 2026.**INTRODUCTION**

Review question / Objective P:Patients with atrial fibrillation I:Radiofrequency Ablation C: CryoablationO:Pulmonary Vein Stenosis and Atrial Fibrillation Recurrence

Based on the data informs get from the results of clinical trial and randomized controlled trial, to explore the pathogenesis of pulmonary vein stenosis under different ablation strategies and whether it is associated with the long-term prognosis of atrial fibrillation ablation.

Rationale Catheter ablation is a cornerstone therapy for symptomatic atrial fibrillation (AF). Radiofrequency ablation (RFA) and cryoballoon ablation (CBA) are two mainstream thermal ablation modalities. Pulmonary vein stenosis (PVS) is a serious iatrogenic complication after AF ablation, while AF recurrence remains a major clinical challenge. To date, inconsistent results exist regarding the comparative risks of PVS and AF-free survival between RFA and CBA across published observational studies. Individual studies are often under-powered to detect differences in

rare adverse events such as PVS. This meta-analysis aims to synthesize available clinical evidence to compare the incidence of PVS and AF recurrence between RFA and cryoablation, providing evidence-based reference for clinical decision-making and operator training, especially for early-career electrophysiologists.

Condition being studied Atrial fibrillation (paroxysmal, persistent or long-standing persistent atrial fibrillation); procedure-related pulmonary vein stenosis after atrial fibrillation catheter ablation.

METHODS

Search strategy A systematic literature search will be performed in PubMed, Embase, Cochrane Library, Web of Science Core Collection. Search terms will combine MeSH / subject terms and free-text keywords related to “atrial fibrillation”, “radiofrequency ablation”, “cryoablation”, “cryoballoon”, “pulmonary vein stenosis”, “atrial fibrillation recurrence”. No language restriction will be applied; reference lists of included articles and relevant reviews will be manually screened for

additional eligible studies.(Definitions of pulmonary vein stenosis follow original study criteria.).

Participant or population Adult patients (≥18 years old) diagnosed with atrial fibrillation undergoing de-novo catheter ablation (radiofrequency ablation or cryoballoon ablation). Studies including redo ablation only will be excluded.

Intervention Radiofrequency catheter ablation for atrial fibrillation, mainly wide-antral circumferential ablation (WACA / pulmonary vein antrum isolation, PVAI).

Comparator Cryoballoon ablation (different sizes of cryoballoon) for atrial fibrillation.

Study designs to be included Cohort studies (prospective and retrospective), observational comparative studies. Randomized controlled trials (RCTs) will also be included if available.

Eligibility criteria Inclusion criteria:

1. Adult patients ≥18 years with atrial fibrillation undergoing first-time catheter ablation (RFA or cryoballoon ablation);
2. Comparative studies reporting at least one predefined primary outcome between RFA and cryoablation groups;
3. Original clinical studies with extractable event rate or survival data;
4. Full-text articles available.

Exclusion criteria:

1. Case reports, case series, reviews, editorials, animal experiments, simulation studies;
2. Studies only enrolling patients undergoing repeat ablation;
3. Unavailable or non-comparable outcome data;
4. Conference abstract without full-text published.

Information sources Electronic databases: PubMed, Embase, Cochrane Library, Web of Science Core Collection. Manual reference screening of included papers and relevant systematic reviews.

Main outcome(s) 1. Incidence of clinically relevant pulmonary vein stenosis (defined as ≥50% or ≥70% luminal narrowing assessed by CTA/MRA or invasive angiography);
2. Atrial fibrillation / atrial tachyarrhythmia recurrence after index ablation (beyond 3-month blanking period).
Secondary outcomes (optional for registry): incidence of phrenic nerve injury, major periprocedural complications.

Quality assessment / Risk of bias analysis For randomized controlled trials: Cochrane Risk-of-Bias tool 2.0 (RoB-2).

For non-randomized observational comparative studies: Risk Of Bias In Non-randomized Studies-of-Interventions (ROBINS-I). Two independent reviewers will perform quality assessment; discrepancies will be resolved by consensus or consultation with a third reviewer.

Strategy of data synthesis Pooled risk ratio (RR) with 95% confidence interval (CI) will be calculated for dichotomous outcomes. Heterogeneity will be assessed using I^2 statistic. If substantial heterogeneity ($I^2 > 50\%$) exists, random-effects model will be adopted; otherwise fixed-effects model will be used. All statistical analyses will be performed using R software or RevMan 5.4.

Subgroup analysis Planned subgroup analyses:

1. AF phenotype: paroxysmal AF versus non-paroxysmal (persistent / long-standing persistent) AF;
2. Cryoballoon size: 23 mm versus 28 mm cryoballoon (23mm or 28mm just indicate the different sizes of balloon);
3. Follow-up duration (<12 months vs ≥12 months).

Sensitivity analysis Sensitivity analyses will be performed by:

1. Excluding studies with high risk of bias;
2. Excluding abstract-only / small-sample studies;
3. Switching between fixed-effect and random-effect models to test robustness of pooled results. Publication bias will be assessed via funnel plot if ≥10 studies are included for one outcome.

Country(ies) involved China.

Keywords Atrial fibrillation; radiofrequency ablation; cryoballoon ablation; pulmonary vein stenosis; atrial fibrillation recurrence; catheter ablation; meta-analysis.

Contributions of each author

Author 1 - GuangWei Zhou - The first author drafted the manuscript.

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Author 2 - Jianqiang Zhang - The corresponding author conceived and supervised this meta-analysis, oversaw study design, resolved reviewer discrepancies, critically revised the manuscript, approved the final submitted version, and takes full accountability for the integrity of the whole work.

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