INPLASY PROTOCOL

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Corresponding author:
Feng Li

lifeng212910@njmu.edu.cn

Author Affiliation:
Department of Cardiology, Wuxi People's Hospital Affiliated to Nanjing Medical University.

Support: **None.**

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None declared.

Ablation strategy and vein of Marshall ethanol infusion group sample size may increase the long-term outcomes in patients received combined ablation with vein of Marshall ethanol infusion for atrial fibrillation: a meta-analysis

Li, F[1]; Sun, JY[2]; Ma, JY[3]; Wang, R[4].

Review question / Objective: **This meta-analysis investigated whether ablation with vein of Marshall ethanol infusion (VOM-ABL) showed better long-term benefits compared with ablation alone in atrial fibrillation (AF). P: Atrial fibrillation patients; I: Ablation with vein of Marshall ethanol infusion (VOM-ABL); C: Ablation alone; O: The long-term (one-year or longer) efficacy and safety between VOM-ABL and ablation alone; S: Randomized controlled trials and cohort and observational studies.**
Condition being studied: **Radiofrequency ablation (RF) has been proven as an effective strategy for rhythm control in symptomatic and drug-refractory atrial fibrillation (AF) patients. Whereas, challenges still remain on AF ablation, including unsatisfied long-term successful rates, high risk of atrial tachycardia (AT) after AF ablation, and deficiency of atrial function. Preliminary study revealed that compared to ablation alone, ablation with VOM ethanol infusion (VOM-ABL) increased the likelihood of freedom from AF/AT for persistent AF. However, the long-term outcomes of VOM-ABL compared with ablation alone in AF patients remains elusive.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 24 September 2021 and was last updated on 24 September 2021 (registration number INPLASY202190088).

INTRODUCTION

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METHODS

Participant or population: Atrial fibrillation patients

Intervention: Ablation with vein of Marshall ethanol infusion (VOM-ABL).

Comparator: Ablation alone.

Study designs to be included: Randomized controlled trials and cohort and observational studies.

Eligibility criteria: (1) randomized controlled trials and cohort and observational studies; (3) studies with a follow-up of one-year or longer; (3) studies comparing the outcomes of VOM-ABL and ablation alone for AF patients, including long-term freedom from AF/AT, long-term successful MI block, pericardial effusion, stroke/transient ischemic attack (TIA), and all-cause death. (4) studies with full-text availability published in English in peer-reviewed journals. (5) for multiple publications of the same trial or cohort, only the study containing the most data was included.

Information sources: A comprehensive literature search was conducted in four online search engines, including PubMed, Cochrane Library, Web of Science, and Embase by two independent reviewers.

Main outcome(s): Studies comparing the outcomes of VOM-ABL and ablation alone for AF patients, including long-term freedom from AF/AT, long-term successful MI block, pericardial effusion, stroke/transient ischemic attack (TIA), and all-cause death.

Quality assessment / Risk of bias analysis: Given the heterogeneity of the eligible studies, the quality of each study was assessed using two different critical appraisal tools by two independent researchers (J.-Y. Sun and L.-D. Wu). For randomized clinical trial included in our review, the Cochrane risk of bias assessment tool was used, which provides a grade of risk of bias for the eligible study in five aspects of the study design (selection bias, performance bias, detection bias, attrition bias, and reporting bias). The Newcastle-Ottawa Quality Assessment Scale (NOS) was used to assess observational studies. In this scale, three domains with a total of nine points were involved, and the quality of studies was graded as moderate-to-high quality (score ≥ 6) and low quality (score < 6). Any potential disagreements were discussed and resolved by consulting a third researcher (R.-X. Wang).

Strategy of data synthesis: Categorical variables were presented as frequencies or percentages, and continuous variables were presented as means ± standard deviations, or median with interquartile range, as appropriate. Relative risk (RR) and corresponding 95% confidence interval (CI) were calculated for each outcome in our study, respectively. The Stata version 12.0 (College Station, Texas 77845 USA, StataCorp LP) was used for all statistical analyses, and $P < 0.05$ was considered statistically significant.

Subgroup analysis: We performed subgroup analyses to explore the sources of heterogeneity and identify potential determinants for the long-term outcomes with VOM-ABL procedure. Based on the

characteristics of eligible studies, previously reported factors and some potential factors, the subgroup factors contained a total of nine points, including study design, VOM-ABL group sample size, history of PeAF/AT, history of AF/AT ablation, procedure strategy, ablation strategy, ablation energy sources, repeat ablation procedure during follow-up, and statistical analysis style.

Sensitivity analysis: When significant heterogeneity was presented, we performed a sensitivity analysis to exam the effect of a single study on the overall risk estimate by sequentially omitting one study at a time. We also assessed the potential publication using Egger's and Begg'stest.

Country(ies) involved: China.

Keywords: Vein of Marshall; Ethanol effusion; Ablation; Atrial fibrillation; Meta-analysis.

Contributions of each author:

Author 1 - Feng Li.
Email: lifeng212910@njmu.edu.cn
Author 2 - Jin-yu Sun.
Email: sunjinyu@njmu.edu.cn
Author 3 - Jun-yang Ma.
Email: irvingma1999@163.com
Author 4 - Ruxing Wang.
Email: ruxingw@aliyun.com