INPLASY PROTOCOL

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Chinese herbal medicine for catheter ablation of atrial fibrillation

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Review question / Objective: To assess the effectiveness of Chinese herbal medicine for recurrent atrial tachyarrhythmia after catheter ablation of atrial fibrillation.

Condition being studied: Atrial fibrillation is the most common cardiac arrhythmia, and a worldwide public health problem with an increased risk of stroke, heart failure, and other complications. Catheter ablation is an effective treatment for patients with symptomatic atrial fibrillation refractory to antiarrhythmic therapy. However, arrhythmia recurrences after catheter ablation commonly occur, despite the attempts of electrical cardioversion and the administration of antiarrhythmic drugs. Traditional Chinese medicine has its unique advantages in antiarrhythmia, but the effect of Chinese herbal on arrhythmia recurrences after catheter ablation remains unknown.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 15 May 2022 and was last updated on 15 May 2022 (registration number INPLASY202250096).

INTRODUCTION

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administration of antiarrhythmic drugs. Traditional Chinese medicine has its unique advantages in antiarrhythmia, but the effect of Chinese herbal on arrhythmia recurrences after catheter ablation remains unknown.

METHODS

Search strategy: An example of search strategy for PubMed database that combines MeSH terms and free words is as follows: ((("Atrial Fibrillation"[Mesh]) OR (AF OR atrial fibrillation* OR auricular fibrillation* OR Persistent Atrial Fibrillation* OR Familial Atrial Fibrillation* OR Paroxysmal Atrial Fibrillation*)) AND (("Catheter Ablation"[Mesh]) OR (catheter ablation OR transvenous catheter ablation OR electrical catheter ablation OR transvenous electric ablation OR radiofrequency catheter ablation OR percutaneous catheter ablation))) AND (((("Medicine, Chinese Traditional"[Mesh]) OR ("Drugs, Chinese Herbal"[Mesh])) OR ("Medicine, East Asian Traditional"[Mesh])) OR (traditional Chinese Medicine OR Chung I Hsueh OR zhong yi xue OR traditional tongue diagnoses OR traditional tongue diagnosis OR traditional tongue assessment* OR chinese medicine OR herb OR herbal medicine OR chinese herb OR chinese herbal drugs OR chinese plant extracts OR Traditional Oriental Medicine* OR traditional east asian medicine OR traditional far east medicine OR east asian medicine* OR far east medicine* OR oriental medicine)).

Participant or population: Patients aged 18 or older who have paroxysmal or persistent atrial fibrillation and undergo catheter ablation will be included. No limitation on gender.

Intervention: Patients took Chinese herbal medicine (CHM) only or CHM combined with conventional western medicine after catheter ablation. The CHM must be administered orally.

Comparator: Conventional western medicine such as antiarrhythmic drugs,

anticoagulants, heart rate control drugs, etc.

Study designs to be included: Randomized controlled trials.

Eligibility criteria: Studies must report at least one of the main outcomes. Grey literature such as degree papers and conference papers will be included. Exclusion criteria: repetitive publishing or data duplication studies; there are other traditional Chinese medical methods such as acupuncture in the intervention.

Information sources: We search various electronic databases from inception until April 30, 2022. The English databases include PubMed, the Cochrane Library, Embase, and ProQuest dissertations and Theses Global (PQDT). The Chinese databases include China National Knowledge Infrastructure (CNKI), Chinese Science and Technology Journal Database (VIP), Wanfang databases, and China Biology Medicine(SinoMed). Ongoing trials will be retrieved from The Chinese Clinical Trial Register. There is no limitation on language.

Main outcome(s): 1)Recurrent atrial tachyarrhythmia within three months after catheter ablation, including atrial fibrillation, atrial flutter, and atrial tachycardia. 2)Recurrent atrial tachyarrhythmia with a follow-up time over three months, including atrial fibrillation, atrial flutter, and atrial tachycardia.

Additional outcome(s): 1)echocardiographic results, including left atrial diameter (LAD) and left ventricular ejection fraction (LVEF). 2) inflammatory factors, such as interleukin-6, C-reactive protein (CRP), etc. 3)B-type natriuretic peptide (BNP) or N-terminal pro-B-type natriuretic peptide (NT-proBNP) 4)Adverse Events.

Quality assessment / Risk of bias analysis: Two authors use the Cochrane risk of bias tool to assess the methodological quality of trials independently. Seven domains will be assessed including random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting, and other biases. Each of the domains will be assessed as high, low and unclear risks of bias. Disagreements will be resolved by discussion between the two authors or by consulting a third author.

Strategy of data synthesis: We plan to use Review Manager 5.3 software to analyze data. Risk ratios (RR) and its 95% confidence interval (CI) will be calculated for dichotomous outcomes, weighted mean differences (WMD) and its 95%CI would be calculated for continuous variables. I2 statistics would be used to assess heterogeneity. If there is no significant heterogeneity in the data (12<50%), a fixed-effects model will be used; If there is significant heterogeneity in the data (I2> 50%), a random-effects model will be used. If there are 10 or more studies in any group, publication bias will be assessed with funnel plots.

Subgroup analysis: To deal with the significant heterogeneity, we will use subgroup analyses to determine the source of heterogeneity. If data allow, subgroups of type of AF, type of CHM, and age will be analyzed.

Sensitivity analysis: Sensitivity analysis will be performed by excluding one study at a time to inspect the stability and reliability of our meta-analysis.

Country(ies) involved: China.

Keywords: atrial fibrillation; catheter ablation; traditional Chinese Medicine.

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