INPLASY

A meta-analysis comparing the efficacy differences between cryoballoon ablation and laser balloon ablation in the treatment of AF

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ADMINISTRATIVE INFORMATION

Support - No.

Review Stage at time of this submission - Preliminary searches.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 14 August 2024 and was last updated on 14 August 2024.

INTRODUCTION

Review question / Objective To collect existing data and compare the efficacy differences between cryoballoon ablation and laser balloon ablation techniques in the treatment of AF through a meta-analysis.

Condition being studied Atrial fibrillation (AF) is a common arrhythmia characterized by the loss of regular and organized electrical activity in the atria, replaced by rapid and chaotic fibrillation waves. It typically presents as an accelerated and irregular heart rate. AF can also lead to several serious complications such as thromboembolism, heart failure, and stroke. In the field of AF treatment, balloon ablation has gradually emerged due to its ease of operation, high safety, and low complication rates. In recent years, cryoballoon and laser balloon ablation have received significant attention in clinical practice, demonstrating great potential; however, the specific advantages and disadvantages of the two techniques have yet to be definitively established. This study aims to compare and analyze the efficacy differences between these two balloon ablation techniques in the treatment of atrial fibrillation, providing richer decision support for clinical practice.

METHODS

Participant or population The study population consists of patients diagnosed with paroxysmal atrial fibrillation or persistent atrial fibrillation.

Intervention The interventions include cryoballoon ablation and laser balloon ablation.

Comparator Patients with atrial fibrillation who choose different balloon ablation methods for treatment are used as the control group.

Study designs to be included Restricted to randomized controlled trials (RCTs).

Eligibility criteria Literature screening and data extraction were completed by two researchers.

Information sources We searched four major databases: PubMed, Cochrane Library, Web of Science, and Embase, collecting various literature from 2008 to 2023. The search terms included: Atrial Fibrillations, Fibrillation, Atrial, Fibrillations, Atrial, Auricular Fibrillations, cryoablation, cryoballoon, cryoballoon, Laser balloon ablation, and Laserballoon, etc.

Main outcome(s) Procedural time, phrenic nerve paralysis, complete pulmonary veins isolation, stroke, hematoma, cardiac tamponade, recurrence rate of atrial fibrillation in 12 months.

Quality assessment / Risk of bias analysis As the study type is limited to RCT, the risk of bias assessment was conducted by two personnel using the Cochrane ROB tool. The assessment process mainly considered the following seven aspects: random sequence generation, allocation concealment, blinding of participants and trial personnel, blinding of outcome assessors, incomplete outcome data, selective reporting, and other biases. The assessment of risk levels in a particular area will affect the overall risk of bias. At the same time, this study also conducted a Grade evidence grading of each outcome indicator from five aspects: bias risk, imprecision, inconsistency, indirectness, and publication bias, ultimately making an overall quality rating of theevidence.

Strategy of data synthesis Based on traditional meta-analysis methods, using Stata 18.0 software to draw forest plots, Egger's test plots, and funnel plots. For binary variables, the odds ratio (OR) is used as the effect analysis statistic, providing a 95% confidence interval (CI). Continuous variables are represented by the standardized mean difference (SMD) as the effect indicator. In this study, most outcome indicators showed no significant heterogeneity, and a fixed-effect model was mostly used. The heterogeneity analysis of the included studies mainly combines i^2 to quantitatively assess the degree of heterogeneity, and the differences between the two intervention methods are judged by the combined OR value. Publication bias is qualitatively analyzed using a funnel plot and quantitatively analyzed using the Egger test.

Subgroup analysis Dividing the subgroups according to the generations of the two types of balloons, providing clues for further research as an exploratory analysis.

Sensitivity analysis The stability of the conclusions was examined using the method of sequential exclusion and changing the combined model.

Country(ies) involved China - The First Clinical Medical College of Lanzhou University.

Keywords Atrial fibrillation, cryoballoon ablation, laser balloon ablation, meta-analysis.

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