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The long-term efficacy of cryoballoon vs irrigated radiofrequency ablation for the treatment of atrial fibrillation: A meta-analysis

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ABSTRACT

Objectives: The main purpose of this meta-analysis was to compare the long-term efficacy of cryoballoon ablation (CBA) with irrigated radiofrequency catheter ablation (RFCA) for the treatment of atrial fibrillation (AF).
Methods: The Medline, Cochrane Library and Embase Database were searched for clinical studies published up to October 2014. Studies that fulfilled our predefined inclusion criteria were included. The primary clinical outcome was the proportion of patients free from AF (follow-up ≥ 3 months), and the secondary clinical outcomes included acute pulmonary vein (PV) isolated rate, fluoroscopy time, procedure time and complications.
Results: After a literature search in the major databases, three randomized controlled trials (RCTs) and eight retrospective trials with a total of 1216 patients were identified. Pool-analysis demonstrated that, as compared RFCA, CBA was associated with a similar proportion of patients free from AF at a mean 16.5 months follow-up (66.9% vs 65.1%; relative risk [RR]: 1.01; 95% CI: 0.94 to 1.07, P = 0.87). Acute PV isolation rate (RR: 0.92; 95% CI: 0.82 to 1.03) and fluoroscopy time (weighted mean difference WMD: −8.60; 95% CI: −18.29 to 3.69) were not statistically significant difference. The procedure time was shorter in CBA group ([WMD]: −31.94; 95% CI: −60.43 to −3.45). Transient phrenic nerve palsy was uniquely observed in the CBA group (5.4%, P < 0.00001) and resolved in all during the follow-up period, total complication was similar in both groups (RR: 1.30; 95% CI: 0.91 to 1.85).
Conclusions: CBA was as effective as RFCA for the treatment of atrial fibrillation during long-term follow-up with comparable procedural features.

1. Introduction

Atrial fibrillation (AF) is one of the most frequent cardiac arrhythmias and is a major cause of stroke, adversely affecting quality of life and is associated with increased mortality [1,2]. Pulmonary vein (PV) isolation is nowadays the cornerstone of percutaneous transcatheter ablation for drug-resistant AF [3–6].

Recent clinical trials have demonstrated that the success rate of radiofrequency catheter ablation (RFCA) is generally in the 58% to 80% range at 1 year follow-up [7–10]. Nevertheless, despite continuous improvements in catheter technology, standard point-to-point PV isolation is a relatively difficult, lengthy, operator-dependent, and expensive procedure. A simplified procedure for AF ablation is thus needed. In the last years, the use of novel alternative technologies such as cryoballoon ablation (CBA) is growing rapidly. CBA technology might offer more reproducible and standardizable procedures by significantly simplifying the ablation itself. A large number of clinical studies also demonstrated CBA with high success rate and low complications in the treatment of paroxysmal or persistent AF [11–14]. However, it is less clear whether the long-term success rate of CBA is superior to RFCA.

Therefore, we performed a systematical review and meta-analysis to evaluate the efficacy and safety of CBA compared with RFCA for the treatment of AF.

2. Methods

2.1. Search strategies

We performed an online search for published literature using the database of Medline, Cochrane and Embase database (to October 2014) to identify all the clinical trials that described CBA for the treatment of AF. The search strategy employed relevant keywords and medical subject heading terms including the following: atrial fibrillation, AF, cryoballoon, cryoablation, radiofrequency and pulmonary vein isolation. The reference lists of the accessed full-text articles were further researched for sources of potential information relevant to this meta analysis. The search was limited to English-language publications.

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2.2. Inclusion and exclusion criteria

The primary clinical outcome was the proportion of patients free from AF. Freedom from AF was defined as no symptoms of AF and no atrial arrhythmias lasting >30 s on electrocardiogram or Holter monitoring after a single procedure, without antiarrhythmic drugs, and after a 3-month blanking period. The secondary clinical outcomes were acute PV isolation rate, procedure time, fluoroscopy time and complications. Inclusion criteria are as follows: (1) to avoid 3-month blanking period, the duration of follow-up after ablation need to more than 3 months; (2) sample size ≥20; and (3) additionally, to be included, studies need to provide reliable information on the assessment of patients free from AF in both groups. To ensure that trials met the pre-specified inclusion criteria, search results were reviewed by two investigators (C.X. and H.Q.) who needed to be in agreement for the study selection.

2.3. Data extraction and quality assessment

Data were independently extracted by two authors (C.X. and H.Q.). Any discrepancies were resolved by the consensus of the authors. Data extraction and presentation for the preparation of this manuscript followed the recommendations of the PRISMA group [15]. The methodological quality of the included studies was assessed by two independent investigators using the Jadad score [16] for RCT and the Newcastle–Ottawa Quality Assessment Scale (NOS) [17] for observational trials, respectively. The Jadad score is a validated five-point scale that examines the methods of randomization, double-blinding, and the reporting of dropouts. The NOS consists of 8 questions with 9 possible points. A star system was used to judge the data according to the selected populations, the comparability of the groups and exposure/outcome of interest. The RCTs and observational studies with NOS ≥ 7 were rated as being of good quality.

2.4. Statistical analysis

We analyzed outcomes by the intention-to-treat method. Dichotomous data were analyzed using relative risk (RR) with 95% confidence intervals (CI), whereas continuous variables were analyzed using weighted mean differences (WMD). Statistical heterogeneity was measured using the χ^2 test and was quantified using the I^2 statistic (ranging from 0% to 100%). Pooled analyses were calculated using random-effect models. To detect any publication bias, we visually examined funnel plots for the primary clinical outcome and further assessed asymmetry using the Begg adjusted rank correlation test and the Egger regression asymmetry test. All p values were 2-tailed, and the statistical significance was set at 0.05. Statistical analyses were performed using the Revman software package (Review Manager, Version 5.0, The Cochrane Collaboration, Oxford, UK) and STATA software 12.0 (StataCorp, College Station, Texas, USA).

3. Results

3.1. Eligible studies

As illustrated in the flow diagram (Fig. 1), our search strategy initially identified 758 potentially relevant studies, 671 of these were excluded based on review of the title and abstract. Of the remaining 87 studies, 76 studies were excluded after a detailed evaluation of the full-text due to the following: uncontrolled trials (n = 46), insufficient reporting of desired clinical endpoints (n = 15), studies followed up <3 months (n = 7), reviews (n = 3), studies that adopted multielectrode phased

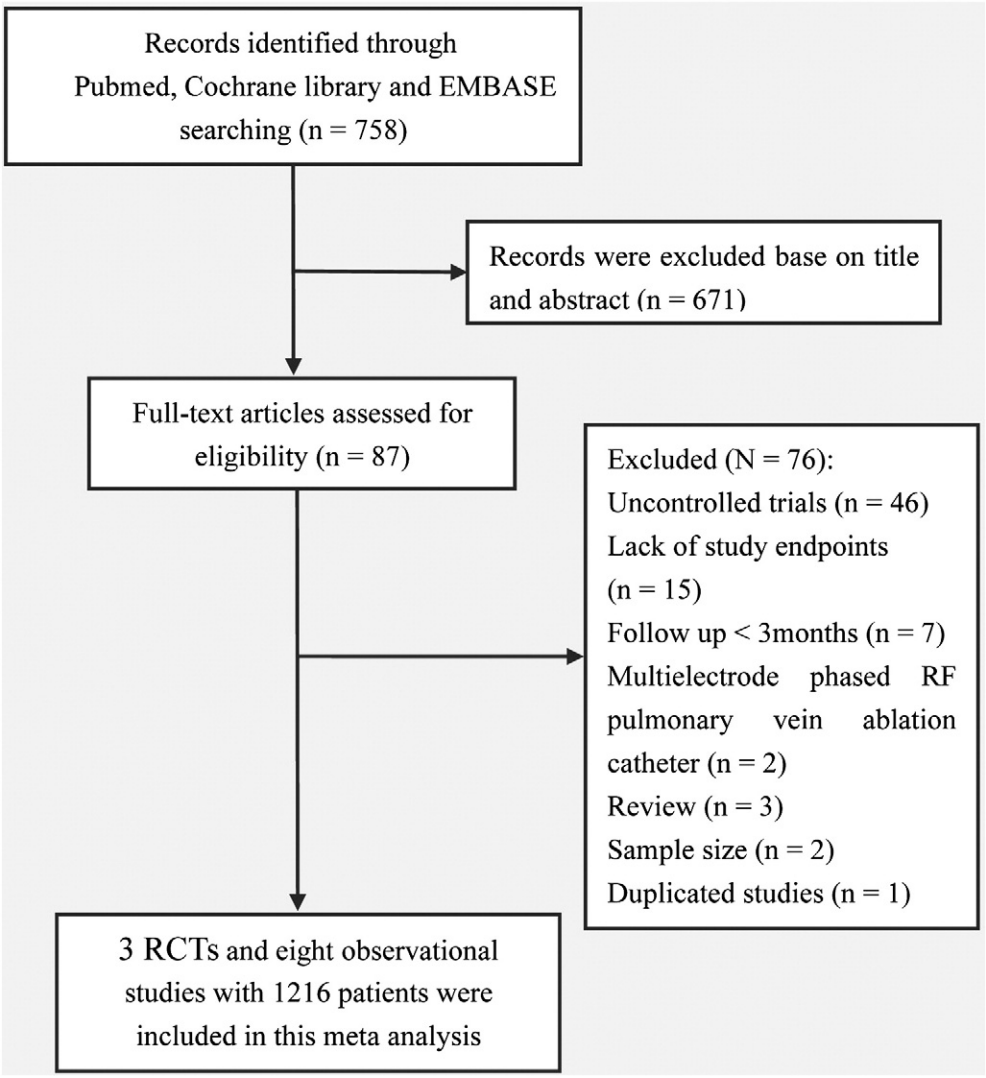

Fig. 1. Flow diagram of study selection process.