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Pulmonary vein isolation using multi-electrode radiofrequency vs conventional point-by-point radiofrequency ablation: A meta-analysis of randomized and non-randomized studies

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ABSTRACT

Aims: Pulmonary vein isolation is effective in reducing atrial fibrillation (AF) episodes. Previous studies suggest single-shot techniques are effective and safe for this purpose. Procedural and clinical outcomes were compared between multi-electrode and point-by-point radiofrequency ablations by performing a meta-analysis of all randomized and non-randomized studies.

Methods and results: Systematic reviews of MEDLINE and Cochrane Library databases were performed. Studies comparing procedural (procedure and fluoroscopy times) and clinical (AF recurrence) outcomes were included in the meta-analysis. A total of 13 clinical studies (5 randomized and 8 non-randomized) including 2152 patients met the inclusion criteria. In patients underwent multi-electrode ablation, there were significant reductions in both total procedure and fluoroscopy times, compared with point-by-point ablation (mean difference = −34.3 min [95% CI (−50.1 to −18.5)], $p < 0.001$ and mean difference = −7.1 min [95% CI (−12.0 to −2.2)], $p < 0.01$, respectively). These significances also continued in patients with paroxysmal AF. No such difference was observed in regard to AF recurrence between the 2 ablation strategies (RR = 0.90 [95% CI (0.80−1.01)], $p = 0.066$). This insignificance was also observed in patients with paroxysmal AF.

Conclusions: In a heterogeneous AF population, multi-electrode ablation is as effective as point-by-point ablation, with better procedural and fluoroscopy durations.

1. Introduction

Pulmonary vein isolation (PVI) is the cornerstone of atrial fibrillation (AF) management, especially in patients with paroxysmal AF. Various energy sources and specially designed catheters have been introduced for catheter ablation of AF [1]. Conventional point-by-point radiofrequency ablation using thermocouple catheters whether irrigated tip or not have been widely used for circumferential isolation of pulmonary veins [2,3]. However, this technique requires a long-lasting learning-curve and needs substantial time to achieve complete isolation of all pulmonary veins. To overcome these disadvantages single-shot catheters using multiple energy sources such as radiofrequency, cryo-energy, laser, and ultrasound have been developed [4–9]. Performing PVI using multi-electrode radiofrequency ablation is one of the above-mentioned single-shot techniques. Specially designed circumferential multi-electrode catheters giving radiofrequency energy (PVAC®, Medtronic, Minneapolis, MN, USA) (nMARQ®, Biosense Webster, Irwindale, CA, USA) have been proposed to fast circumferential ablation of pulmonary veins over the past few years [4,5,7,10,11]. The effect of this novel treatment modality on procedural and clinical outcomes in patients with AF has not been systematically examined across the studies, either randomized or non-randomized. Therefore, our aim was to evaluate the effect of multi-electrode radiofrequency ablation, in comparison with conventional point-by-point radiofrequency ablation on procedural and clinical outcomes using data from randomized and non-randomized studies.

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2. Methods

2.1. Literature search

A systematic search of MEDLINE and Cochrane Library Databases from inception to August 2016 was performed to determine all published randomized and non-randomized trials of multi-electrode radiofrequency vs. conventional point-by-point radiofrequency ablation that reported procedural characteristics (including procedure and fluoroscopy times) and clinical outcomes (including AF recurrences and adverse events). Database search terms of duty-cycled radiofrequency ablation, phased radiofrequency ablation, Pulmonary Vein Ablation Catheter (PVAC®), multi-electrode ablation, nMARQ®, and atrial fibrillation returned 129 published articles. Additional search of the ClinicalTrials.gov website returned 3 trials of PVAC® vs. conventional radiofrequency ablation; one study is currently recruiting participants, the second study has been terminated and the third one is ongoing, but not recruiting participants. An additional trial comparing nMARQ® and conventional ablation is also ongoing, but not recruiting participants. None of the trials has posted the study results. The complete results of the literature search were shown in Fig. 1.

2.2. Study selection

Trials which reported procedural outcomes (i.e. procedure and fluoroscopy times) and clinical outcomes (i.e. AF recurrences and procedure-related adverse events) of groups or subgroups with either radiofrequency ablation method were included in the meta-analysis. All of the 129 articles identified from the literature search were reviewed for such information. Trials were excluded from the analysis if they did not have a comparative control group with conventional radiofrequency ablation, had a control group with other ablation energy sources such as cryo-ablation, did not report procedural and clinical outcomes of interest, or reported outcomes <6 months.

2.3. Data extraction

Information on the inclusion criteria, study intervention and control, type of AF, follow-up duration, definitions of procedural and clinical outcomes, drop-out and cross-over rates, and baseline patient characteristics were extracted from each trial independently by 2 of the investigators. Subsequently, data on the mean ± SD and event numbers or rates, whichever is available, for the study groups according to ablation method were extracted. Data of the last follow-up were extracted from the main text, tables or survival curves, whichever is available, if trials had follow-up duration >6 months.

2.4. Statistical analysis

Data was analyzed using Comprehensive Meta-Analysis software (Biostat Inc. Englewood, NJ). The differences in the meta-analytic mean value and risk ratio in AF patients according to radiofrequency ablation strategy were assessed with heterogeneity analysis. Statistical heterogeneity was tested by Cochran's Q statistic and reported as I^2. Random effects model was used when there was an evidence of heterogeneity ($I^2 > 40\%$) and *vice versa*. Sensitivity analyses were performed using the one-study out method to evaluate whether any single study was primarily responsible for the main findings. Additional sensitivity analyses were performed for trials reported patients with paroxysmal AF in both treatment arms. Funnel plot was created according to ablation strategy to assess the possibility of publication bias. The Egger's regression test was also used for this purpose. Separate groups of paroxysmal and persistent AF for total procedural and fluoroscopy times were used for analyses due to separate reported data in the study of Tivig [12]. In subgroup analyses of paroxysmal AF for arrhythmia recurrence, data extracted from studies by Choo, De Greef and Rosso were also used [13–15]. In addition, in subgroup analyses of paroxysmal AF for total procedural and fluoroscopy times, data extracted from the study by Rosso were used [15].

The authors of the current meta-analysis are solely responsible from the design, literature search and data collection, analyses, and editing of the paper.

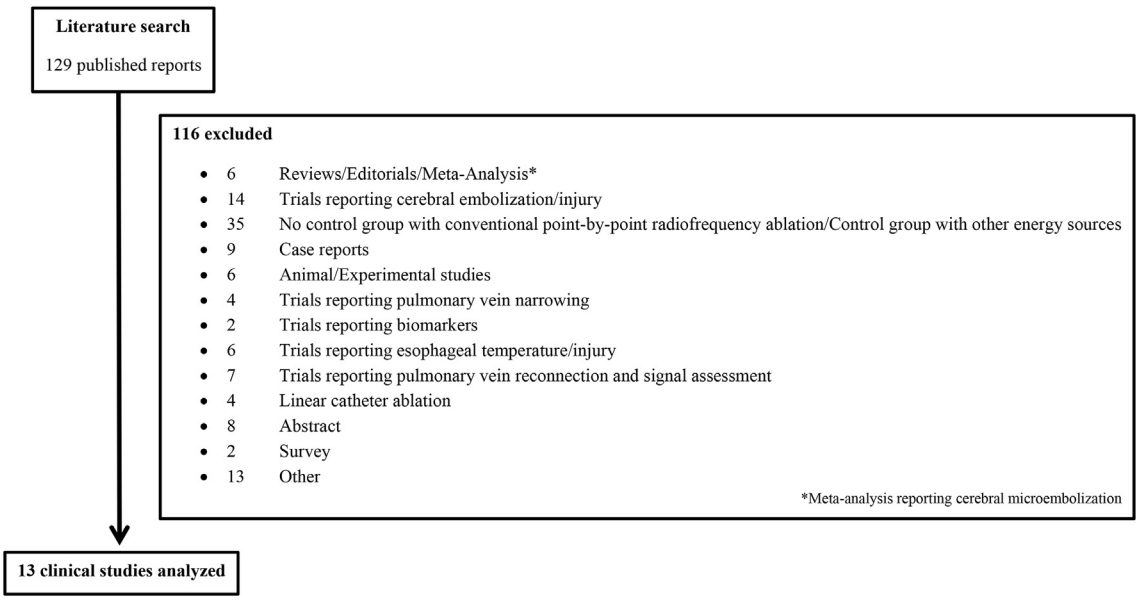

Fig. 1. Flowchart of multi-electrode radiofrequency ablation of AF studies.

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