

Revisiting pulmonary vein isolation alone for persistent atrial fibrillation: A systematic review and meta-analysis



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BACKGROUND Early studies demonstrated relatively low success rates for pulmonary vein isolation (PVI) alone in patients with persistent atrial fibrillation (PeAF). However, the advent of new technologies and the observation that additional substrate ablation does not improve outcomes have created a new focus on PVI alone for treatment of PeAF.

OBJECTIVE The purpose of this study was to systematically review the recent medical literature to determine current medium-term outcomes when a PVI-only approach is used for PeAF.

METHODS An electronic database search (MEDLINE, Embase, Web of Science, PubMed, Cochrane) was performed in August 2016. Only studies of PeAF patients undergoing a "PVI only" ablation strategy using contemporary radiofrequency (RF) technology or second-generation cryoballoon (CB2) were included. A random-effects model was used to assess the primary outcome of pooled single-procedure 12-month arrhythmia-free survival. Predictors of recurrence were also examined and a meta-analysis performed if ≥ 4 studies examined the parameter.

RESULTS Fourteen studies of 956 patients, of whom 45.2% underwent PVI only with RF and 54.8% with CB2, were included. Pooled single-procedure 12-month arrhythmia-free survival was 66.7% (95% confidence interval [CI] 60.8%–72.2%), with the majority of patients (80.5%) off antiarrhythmic drugs. Complication rates were very low, with cardiac tamponade occurring in 5 patients (0.6%) and persistent phrenic nerve palsy in 5 CB2 patients (0.9% of CB2). Blanking period recurrence (hazard ratio 4.68, 95% CI 1.70–12.9) was the only significant predictor of recurrence.

CONCLUSION A PVI-only strategy in PeAF patients with a low prevalence of structural heart disease using contemporary technology yields excellent outcomes comparable to those for paroxysmal AF ablation.

KEYWORDS Atrial fibrillation; Arrhythmia; Ablation; Pulmonary vein isolation; Cryoballoon

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Introduction

Although pulmonary vein isolation (PVI) is a well-established treatment of paroxysmal atrial fibrillation (AF), early studies of PVI only in patients with persistent AF (PeAF) reported suboptimal success rates. This led to the development of novel strategies to target atrial substrate, including linear lesion creation, ablation of complex fractionated atrial electrograms (CFAEs) and non-PV triggers, and more

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recently rotor ablation. However, data from STAR AF II indicated that addition of linear lesions or CFAE ablation did not improve outcomes over PVI alone.¹ Similarly, evidence for rotor ablation efficacy is observational and has not been widely reproduced. In this context, and with the advent of more advanced technologies (including contact force-sensing catheters and the second-generation cryoballoon [CB2]), a number of recent studies have revisited the approach of PVI only for management of PeAF. The focus of this systematic review was to examine these recently reported success rates for “PVI only” in PeAF using the latest technology iterations and to identify predictors of success.

Methods

Search strategy and data extraction

We performed a comprehensive literature search of MEDLINE, Embase, Web of Science, PubMed, and the Cochrane-controlled Trials Register in August 2016. The search was restricted to studies involving humans that were published in English. In addition, the reference lists of all relevant trials and reviews were hand searched. Key search terms were “persistent atrial fibrillation,” “catheter ablation,” “pulmonary vein isolation,” and “second generation cryoballoon.” With respect to trials involving the same group of patients, only the most recently published trial was used. Study selection, validity assessment, and data extraction were performed by 3 independent reviewers (A.V., N.H., J.M.) in an unblinded standardized manner. Another investigator (J.K.) was consulted whenever a disagreement arose about the eligibility of a trial. The study was performed in accordance with the MOOSE Guidelines for Meta-Analyses and Systematic Reviews of Observational Studies. The MOOSE checklist is included in [Online Appendix A](#).

Study eligibility and outcomes

Studies were eligible for inclusion if they included patients with PeAF (including long-standing PeAF [LsPeAF] > 12 months) undergoing “PVI only” using either radiofrequency energy (RF) with 3-dimensional mapping or the CB2. Contact force-sensing catheters were not mandated. Studies were excluded if isolation was not an endpoint of ablation, maximum follow-up was shorter than 12 months, outcome measures for paroxysmal AF and PeAF were not reported separately, and if studies had fewer than 20 patients or were only published as conference abstracts. Randomized controlled trials, prospective nonrandomized studies, and retrospective case-control studies were all included. Analyses of “PVI only” efficacy were limited to studies published after 2010. The primary outcome was arrhythmia-free survival at 12 months after the initial procedure. Arrhythmia events included a composite of AF, atrial flutter, or atrial tachycardia. The definitions of post-PVI blanking period and use of antiarrhythmic drugs were left to individual study design. If on-antiarrhythmic and off-antiarrhythmic success rates were reported, off-antiarrhythmic data were included. Predictors of recurrence were examined from studies using a

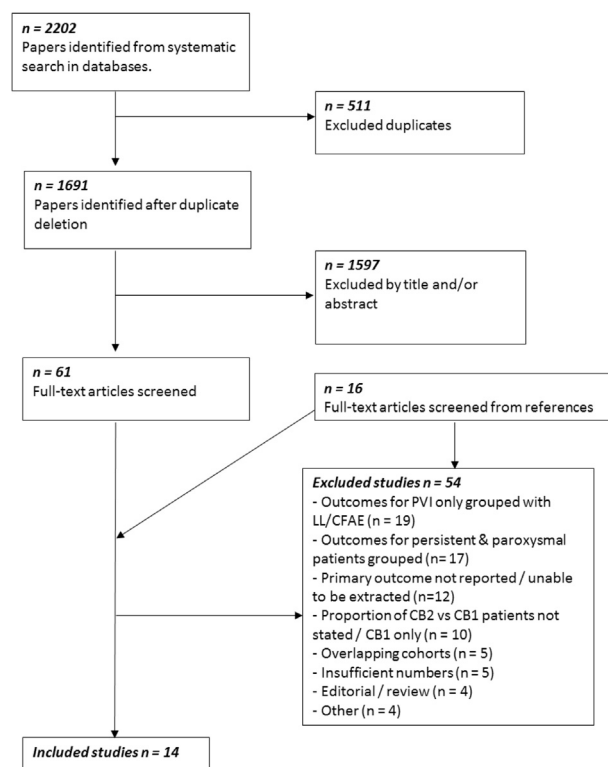


Figure 1 Flow diagram of included studies for primary outcome. CB = cryoballoon; CFAE = complex fractionated atrial electrogram; LL = linear lesion.

PVI-only approach, and a meta-analysis was performed if 4 or more studies examined the parameter. We also examined the incidence of complications.

Statistical analysis

Arrhythmia-free survival data presented as Kaplan–Meier analyses or actuarial recurrence rates were used, with a graphic digitization software (DigitizeIt, Share-it, Cologne, Germany) used for Kaplan–Meier data. Predictors of arrhythmia recurrence were examined using univariate hazard ratios. Study estimates and confidence intervals (CIs) were then pooled using the random-effects model based on logit transformed proportions. Statistical analysis was performed using Comprehensive Meta-Analysis software (version 3, Biostat, Englewood, NJ). Heterogeneity was assessed using the I^2 statistic, with $I^2 > 50\%$ defined as significant heterogeneity. Potential publication bias was assessed graphically using funnel plots. In all analyses, $P < .05$ was considered significant.

Results

From the 2218 citations first screened, 84 full-text articles were reviewed, and 14 met inclusion criteria for analysis of the primary outcome ([Figure 1](#)). Baseline patient characteristics and single-procedure 12-month arrhythmia-free survival rates of the included studies are given in [Tables 1](#) and [2](#), respectively. Of the 956 patients with PeAF undergoing PVI only included in the analysis, 419 (45.2%) underwent PVI

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