CONTEMPORARY REVIEW

Efficacy and safety of atrial fibrillation ablation with phased radiofrequency energy and multielectrode catheters

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Introduction

Focal radiofrequency (RF) ablation guided by 3-dimesnional (3D) mapping systems has shown considerable success in treating paroxysmal and persistent atrial fibrillation (AF).[1] Unfortunately, the procedure remains complex, time-consuming, and highly dependent on operator competency. Multielectrode catheters were developed to address technical difficulties. The pulmonary vein (PV) ablation catheter (PVAC, Medtronic Ablation Frontiers, Carlsbad, CA) is a 9F deflectable circular multielectrode catheter that enables mapping and circumferential PV ablation. For persistent AF, 2 additional catheters, that is, the multiarray septal catheter (MASC) and the multiarray ablation catheter (MAAC), were developed to facilitate left atrial mapping and substrate modification. The accompanying GENius multichannel, duty-cycled RF generator (Medtronic Ablation Frontiers) enables the delivery of energy in a unipolar or bipolar configuration to all electrodes simultaneously or individually. During an RF application, energy delivery to individual electrodes is temperature controlled by a software algorithm that modulates power to reach the user-defined target temperature (maximum 8 W per electrode with the PVAC in a 4:1 power setting or 10 W in all other settings). Our objective was to systematically review the current knowledge with regard to the efficacy and safety of AF ablation with the PVAC ± MASC and MAAC.

KEYWORDS Atrial fibrillation; Catheter ablation; Multielectrode ablation; Duty-cycled bipolar; PVAC, Pulmonary vein ablation catheter

ABBREVIATIONS AADs = antiarrhythmic drugs; **AF** = atrial fibrillation; **CI** = confidence intervals; **CMC** = circular mapping catheters; **MAAC** = multiarray ablation catheter; **MASC** = multiarray septal catheter; **PAF** = paroxysmal AF; **PV** = pulmonary vein; **PVAC** = pulmonary vein ablation catheter; **PVI** = pulmonary vein isolation; **RF** = radiofrequency; **RSPV** = right superior PV; **3D** = three-dimensional; **TIA** = transient ischemic attack (Heart Rhythm 2012;9:289–296)

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Methods

This systematic review was performed by using a predetermined protocol and in accordance with the PRISMA statement.[2]

Search strategy

To identify and retrieve all potentially relevant literature describing the outcomes of PVAC ablation for AF, we conducted a literature search with assistance of reference librarians and investigators trained in systematic review procedures. Search terms included "atrial fibrillation" [MeSH and All Fields], "atrial fibr.tw," "PVAC.mp," "pulmonary vein ablation catheter.mp," "Multi-electrode ablat:.tw," "Multi-electrode ablation.tw," and "duty-cycled bipolar.tw." The search was performed in MEDLINE, EMBASE, and BIOSIS and limited to humans, adults (19+ years), and a publication date between January 2000 and May 2011. The language was not restricted to English. In addition, secondary source documents were identified by manual review of reference lists, review articles, editorials, and guidelines. A manual review of the Science Citation Index was undertaken for articles selected for inclusion.

Study selection

Identified abstracts were retained if they made specific reference to the use of the PVAC ± MASC and MAAC for AF ablation. Articles identified from abstract screening underwent full-text review to determine eligibility for data extraction based on the following criteria: (1) original human data reported; (2) study design consisting of a case series, case–control study, cohort study, or a controlled trial (case reports, letters, comments, reviews, and meta-analyses were excluded); (3) absolute numbers for study end points were reported or could be derived from available data. Given that multielectrode ablation is relatively novel, an attempt was made to be as inclusive as possible with study selection. While data from peer-reviewed publications meeting inclusion criteria were prioritized, data from symposia and meeting abstracts were included if they provided independent or

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supplemental information. Authors/working groups, recruitment periods, and catchment areas were evaluated to avoid potential double counting of patient data.

Data collection and analysis

The following information was obtained by using a standardized data extraction form: study population; number of patients; cohort demographics; echocardiographic parameters (left ventricular ejection fraction and left atrial dimension and/or volume); presence and composition of a comparator group (antiarrhythmic drug therapy only, RF ablation, and cryoablation); procedural data (duration, fluoroscopy time, number of applications per vein, ablation time, and need for RF "touch-up"); procedural and delayed complications (phrenic nerve injury, PV stenosis, esophageal complications, thromboembolic complications [stroke, transient ischemic attack (TIA), and myocardial infarction], pericardial effusion/tamponade, and groin complications); and outcome data (duration of follow-up, freedom from recurrent AF, and repeat ablation procedures).

Efficacy outcomes were (1) acute procedural success (by patient and by vein) and (2) freedom from recurrent AF at 3, 6, and 12 months. Acute procedural success by patient was defined as complete isolation of all targeted PVs. Acute success by vein was defined as the successful electrical disconnection of a targeted PV in which PV potentials were previously demonstrated.

Data analysis

Outcomes of interest were extracted as proportions, and exact binomial confidence intervals (CIs) were calculated. For studies with sufficient methodological similarity, pooled estimates of recurrent AF and corresponding binomial CIs were calculated by using a fixed-effects model with weighting by sample size. To our knowledge, no random effects meta-analysis models have been developed for binary data and the assumption of effect size normality is clearly inappropriate for binary data. Heterogeneity was assessed for all analyses by using the Q statistic and quantified with the I^2 statistic. Where significant heterogeneity was found, additional stratified analyses were performed to explore potential causes. All statistical analyses were carried out by using STATA, version 10.1 (Stata-Corp, College Station, TX). The authors had full access to and take full responsibility for the integrity of the data. All authors gave their approval for submission of the final manuscript.

Results

Literature search and study characteristics

Figure 1 provides a flowchart of the systematic review. Of the 98 articles screened, 42 were retained for the final analysis. Study characteristics are listed in Online Data Supplement Table 1. Overall, 1162 patients had PVAC-based ablation for paroxysmal AF (PAF) and 347 for persistent AF. The average age was 58.5 ± 2.6 years, and 71.7% of patients were male. Average left ventricular ejection fraction was 60.5% ± 4.0%, and the left atrial dimension was 41.4 ± 1.9 mm. The predominant comorbidity was hypertension (41.0%).

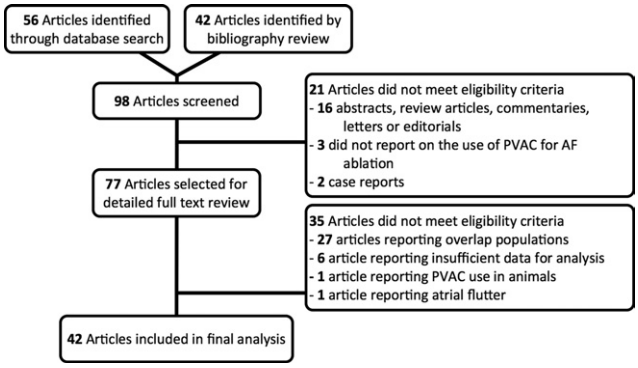

Figure 1 Flowchart showing the results of the search strategy and reasons for exclusion.

Acute procedural outcomes

For PAF, the average procedure time was 116.9 ± 33.4 minutes, fluoroscopy time was 26.5 ± 9.6 minutes, and the number of PVAC applications per patient was 25.1 ± 3.4. For persistent AF, the average procedure time was 137.1 ± 29.3 minutes with a fluoroscopy time of 31.6 ± 12.4 minutes. The average number of applications per patient was 26.9 ± 3.9 for PVAC, 7.4 ± 0.5 for MASC, and 10.4 ± 1.9 for MAAC. Significantly more PVAC applications were required to isolate common ostia when compared with individual PVs.[3–7] There was no statistically significant difference in the number of applications between right- and left-sided PVs (Online Data Supplement Table 2).[3–7]

Twenty-three studies reported the procedural success of PVAC-based ablation. Overall, 98.87% of patients had acutely successful complete PV isolation (PVI) (20 studies; N = 1147 patients; 95% CI = 98.07–99.40) and 99.50% of targeted veins were successfully isolated (14 studies; N = 3805 veins; 95% CI = 99.22–99.70) (Figure 2). Six studies reported the concomitant use of irrigated RF catheter ablation to complete PVI in a median of 5.7% of patients (4.9%–34.5%).[3,8–12] When the analysis was limited to studies employing a PVAC-exclusive strategy, complete PVI was achieved in 98.57% of patients (95% CI = 97.52–99.26) and 99.38% of targeted veins (95% CI = 99.04–99.63). There was no difference in acute procedural success between patients treated for paroxysmal vs persistent AF.

Predictors of failed acute PVI with PVAC included larger PV size (>25 mm) and increased left atrium size (>58 mm).[13] Compared to early procedures, centers with extensive experience reported a progressive decrease in procedural time (95 ± 26 vs 74 ± 21 minutes for PAF; 151 ± 50 vs 100 ± 17 minutes for persistent AF), fluoroscopy time (19 ± 9 vs 15 ± 7 minutes for PAF; 30 ± 15 vs 19 ± 6 minutes for persistent AF), and mean number of PVAC applications per patient (29 ± 7 vs 25 ± 7 applications for PAF; 29 ± 8 vs 23 ± 5 for persistent AF) (Online Data Supplement Table 3).[14–16] Acute success rates increased