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Does catheter ablation improve the quality of life in patients with atrial fibrillation compared to drug therapy?

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A SELECTIVE EVIDENCE BASED MEDICINE REVIEW

In Partial Fulfillment of the Requirements For

The Degree of Master of Science

In

Health Sciences – Physician Assistant

Department of Physician Assistant Studies
Philadelphia College of Osteopathic Medicine
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ABSTRACT

OBJECTIVE: The objective of this evidence-based medicine (EBM) review was to determine whether or not catheter ablation improves quality of life in patients with atrial fibrillation compared to drug therapy.

STUDY DESIGN: Systematic review of three peer-reviewed studies published in the years 2018 and 2019. All three studies were published in English.

DATA SOURCES: Articles were selected based on their relevance to the clinical question. Additionally, all three studies placed emphasis on patient-oriented outcomes. The studies were selected via Pubmed and keyword searching. The first study selected and reviewed was an observational cohort study, the second study was a multi-center open-label randomized controlled trial (RCT), and the third and last study reviewed was an RCT with blinded outcome evaluations.

OUTCOMES MEASURED: Participants quality of life was measured by using Medical Outcomes Study 36-item Short Form Health Survey (SF-36), the Atrial Fibrillation Effect on Quality of life (AFEQT) questionnaire, the Mayo AF-Specific Symptom Inventory (MAFSI) questionnaire, and the Arrhythmia-specific questionnaire in Tachycardia and Arrhythmia (ASTA).

RESULTS: The study conducted by Barmano et al. found a statistically significant improvement in quality of life of those individuals receiving a catheter ablation ($p < 0.01$). The study conducted by Blomstrom et al. found a significant and positive increase in the SF-36 scores of patients receiving a catheter ablation as compared to the medication treatment group ($p = 0.003$). Mark et al. found a significantly higher quality of life -- as measured by both the MAFSI and AEFQT -- in patients receiving a catheter ablation as compared to a medication treatment group (both $p < 0.001$).

CONCLUSION: The data presented in this systematic evidence-based medicine review demonstrate a significant positive impact of catheter ablation on the quality of life in patients with atrial fibrillation. While no study is without limitations, all three studies reviewed confirmed a statistically significant improvement in quality of life. Future research studies should continue to use randomized controlled trials as well as ensuring there is no crossover between control and treatment groups.

KEY WORDS: Atrial fibrillation, catheter ablation, quality of life

INTRODUCTION

Atrial fibrillation (AF) is the most common chronic arrhythmia and is associated with increased morbidity and mortality if left untreated. It is estimated that about 10 million Americans have AF; affecting approximately 9% of people over the age of 65.¹ Consequences of untreated AF include cerebral infarction, heart failure, LV dysfunction and myocardial ischemia. Cerebral infarction, secondary to an embolizing thrombus, is possibly the most serious consequence from untreated AF leading to significant morbidity and mortality.¹ In addition to being a burdensome medical condition to patients, it is also very costly to manage AF. According to the American Heart Association, the annual cost of AF treatment in 2014 was estimated to be 10.1 billion which was a 37% increase from 7.39 billion in 2007.² Furthermore, to emphasize the impact that AF has on the healthcare system, between 2007-2014 over 800,000 ED visits were for AF and AF is estimated to contribute to more than 80,000 annual deaths.”²

AF is characterized by disorganized and rapid atrial activation. It can occur secondary to valvular heart disease, dilated cardiomyopathy, HTN, ASD, thyrotoxicosis and in some individuals without any apparent cardiac disease.¹ Acute alcohol excess or withdrawal can trigger AF as well.¹ Signs and symptoms of AF include dyspnea, hypotension, palpitations, lightheadedness, syncope, chest pain, and peripheral edema. There is little known about AF, plenty of research has been conducted on the condition. In the beginning of the disease course, AF will present in a paroxysmal manner however over the course of the disease it likely becomes the dominant rhythm.¹

Treatment for AF is often very personalized as many patients have coexisting comorbidities which could alter treatment options. Management of AF is well within the scope of physician assistants in many specialties ranging from family medicine to cardiothoracic

surgery. In hemodynamically stable patients, management of AF includes rate control via beta blockers or calcium channel blockers, rhythm control via antiarrhythmic agents (potassium channel blockers or sodium channel blockers), along with anti-coagulation with direct oral anticoagulants (DOACs) or coumadin. With recurrent-symptomatic AF, treatment options typically include antiarrhythmic agents, anti-coagulation and catheter ablation.

The medications utilized for treatment of AF have considerable side effects, including but not limited to ventricular arrhythmias, thyroid dysfunction, worsening asthma/COPD, sexual dysfunction, and bleeding.¹ Also, there is the chance of refractory/symptomatic AF despite taking these medications, about 25-50% of AF cases treated with antiarrhythmic drugs will have refractory symptoms within one year.³ Catheter ablation is a minimally invasive procedure which destroys the irritable foci triggering the AF and minimizing the likelihood recurrence. The one-year success rates for patients with paroxysmal AF is about 70-80% and 60-70% in patients with persistent AF.³ Important to note, patients with AF refractory to catheter ablation experience less burdensome AF symptoms compared to their antiarrhythmic counterparts.³ Catheter ablation is not without risks. The most frequent serious complication of catheter ablation is cardiac tamponade which occurs in slightly more than 1% of radiofrequency catheter ablations.⁴ Some other complications of this procedure include catheter entrapment, pulmonary vein stenosis, phrenic nerve injury and perioperative thromboembolic events.⁴ This paper evaluates two randomized control trials and one observational cohort study comparing the efficacy of catheter ablation improving QOL in patients with AF compared to drug therapy.

OBJECTIVE

The objective of this selective EBM review is to determine whether or not catheter ablation improves quality of life in patients with atrial fibrillation compared to drug therapy.

METHODS

To complete this selective EBM review, articles were selected based on being patient oriented outcomes and relating to my clinical question. Studies were searched using PubMed and were published in peer-reviewed journals. Keywords used to search for relevant articles included “Atrial fibrillation”, “ablation” and “quality of life”. Articles related to humans and published within the past 5 years were inclusion criteria for articles chosen. Studies published prior to 2014 and studies on animals were excluded from the article search. Statistics utilized in this review include p-value. Table 1 displays the demographics and characteristics included in each chosen article.

Two randomized control trials (RCTs) and one observational single-center cohort study were utilized for this EBM review. The population of concern in these articles were patients with AF, both paroxysmal and persistent. All three articles studied catheter ablation as the intervention to the treatment groups. The treatment groups were compared to control groups receiving pharmacologic therapies for treatment of AF. Quality of life is the outcome being measured in all three studies.

OUTCOMES MEASURED

The outcome of interest measured for this EBM review is patient quality of life (QOL). Quality of life was measured using patient questionnaires in all three studies. The Arrhythmia-Specific questionnaire in Tachycardia and Arrhythmia (ASTA), utilized in the Barmano et al. observational cohort study, assessed 9 items relating to symptom burden and 13 items relating to health-related quality of life (HRQoL).⁵ ASTA scale scores range from 0-100, a higher score reflects a higher symptom burden and worse effect on HRQoL from the arrhythmia.⁵

Table 1. Demographics & Characteristics of Included Studies

Study	Type	# Pts	Age (yrs)	Inclusion Criteria	Exclusion Criteria	W/D	Interventions
Barmano ⁵ (2018)	Observational cohort study	338	60.2±10.2	-Age > 18 yrs with paroxysmal or persistent Afib; First time radiofrequency ablation	-Previous catheter or surgical Afib ablation; Previous/planned heart surgery; LV EF <35%; ACS during past 3 months	146	Radiofrequency ablation
Blomstrom ⁶ (2019)	RCT with blinded evaluation of outcomes	167	30-70 yrs	-Age 30-70; Hx of symptomatic Afib for at least 6 months; Failure/intolerance to a maximum of 1 antiarrhythmic drug	-NYHA class III-IV; LV EF <35%; Previous ablation; Ventricular pacing dependency; Afib secondary to transient or correctable trigger	12	Pulmonary vein isolation ablation
Mark ⁷ (2019)	RCT	2204	Older than 65; 65 yrs or younger with at least 1 risk factor for stroke	-Episodes of Afib over the preceding 6 months; Be over 18 y/o	-Prior catheter ablation; Class IV CHF or Angina; Recent MI or PCI; Reversible cause for Afib; Dialysis patients	236	Pulmonary vein isolation ablation

The Medical Outcomes Study 36-item Short Form Health Survey (SF-36), utilized in the RCT by Blomstrom et al., is a 36-item questionnaire. From this questionnaire a score from 0 to 100 is obtained, higher scores indicate greater health or well-being.⁶ The RCT conducted by Mark et al., utilized both the Atrial Fibrillation Effect on Quality of life (AFEQT) questionnaire and the Mayo AF-Specific Symptom Inventory (MAFSI) questionnaire. AFEQT is a 21-item QOL questionnaire with scores ranging from 0 to 100, 0 being AF causing complete disability and 100 being AF causing no disability.⁷ MAFSI is a 10-item checklist with scores ranging from 0 to 40, 0 being no AF symptoms and 40 being most severe AF symptoms.⁵

RESULTS

In Barmano et al. observation single cohort study, 338 patients with AF were eligible for radiofrequency ablation (RFA). 192 patients over the age of 18 undergoing their first radiofrequency ablation for AF were included in this study. Patients were excluded if they had a previous catheter or surgical AF ablation, had previous or planned heart surgery, LV EF <35% or acute coronary syndrome in the past 3 months.⁵ Prior to the radiofrequency ablation, all included participants underwent a TTE and EF was calculated. ASTA questionnaires were collected at baseline, 4 months and 1 year following the radiofrequency ablation. At baseline, the health-related quality of life scale (HRQoL) portion of the ASTA questionnaire averaged 36 points. Four months following the radiofrequency ablation, the HRQoL score decreased to an average of 10. Ultimately, at 1 year follow up the HRQoL score decreased to an average of 0 signifying most participants had no symptom burden from their AF. See Table 2 below. These results were significant with a calculated Friedman's test p -value < 0.001 from baseline to 1 year follow up.

Table 2. Health-Related QOL scores following radiofrequency ablation

Following RFA	Baseline	4 month F/u	1 year F/u
HRQoL Scale Score	36	10	0***

* $p < .1$. ** $p < .05$. *** $p < .01$

Blomstrom et al. is a multicenter open-label randomized control trial assessing the quality of life in AF patients following pulmonary vein isolation ablation compared to antiarrhythmic medications.⁶ 167 patients were eligible for this study. Patients were required to be 30-70 years old, have a history of symptomatic AF for at least 6 months which was verified by ECG, and failure of or intolerance to a maximum of 1 antiarrhythmic drug. Exclusion criteria included NYHA class III-VI, LV EF <35, and AF secondary to a transient or correctable cause. Patients were assigned using permuted block design with variable block size stratified by clinical site and type of AF (paroxysmal vs persistent).⁶ Of the 167 eligible patients, 155 were randomized. 79 were randomized to the ablation group and 75 actually received the ablation. 76 were randomized to the antiarrhythmic medication group and 74 patients actually received the antiarrhythmic medication.

This study evaluated overall QOL using the SF-36 General Health questionnaire at baseline and at 12 months. From baseline to 12 months, the ablation group improved significantly more than the medication group. At baseline, the ablation scored 61.8 vs. the medication group scoring 62.7. However, at 12 months, the mean change in the ablation increased 11.9 points compared to 3.1 points in the medication group; resulting in a mean treatment difference of 8.9 points. This is significant with a p -value = 0.003. See Table 3.

Table 3. QOL scores at Baseline and 12 months in ablation vs. medication groups

SF-36 score	Baseline	12 months
Ablation Group	61.8	73.7
Medication Group	62.7	65.8
Mean Treatment Difference	-	8.9***

* $p < .1$. ** $p < .05$. *** $p < .01$

The multicenter open-label randomized controlled trial conducted by Mark et al. included 2204 patients with a median age of 68 years; 1108 patients were randomly assigned to the catheter ablation group and 1096 were randomized to the drug therapy group. Patients were assigned using permuted block design with variable block size stratified by clinical site.⁷ Of the 1108 assigned to the catheter ablation group, 1002 completed the study (9.56% attrition rate). Of the 1096 assigned to the drug therapy group 966 completed the study (11.86% attrition rate). For both groups, the majority of the attrition rate was attributed to individuals withdrawing their consent to the study. Both the inclusion and exclusion criteria for the study can be found in Table 1.

The study recorded the participant's quality of life at months 3, 12, and then every 12 months following. At month 12, the mean AFEQT summary score was 5.3 points higher in the catheter ablation group than the drug therapy group (86.4 vs. 80.9).⁷ These results were statistically significant at the $p < 0.001$ level. At year 5, the catheter ablation group's mean AFEQT score was 3.4 points higher than the drug therapy group. Once again, these results were statistically significant at the $p < 0.001$ level. All three component scores of the AFEQT favored the catheter ablation group but the p values for the differences in component scores were not reported.

In terms of the MAFSI frequency score, at 12 months measurement also favored the catheter ablation group with a difference of -1.7 points (11.9 vs 8.1).⁷ The difference was significant at the $p < 0.001$ level. For follow ups, the frequency score difference was -1.4 also favoring the catheter ablation group at the $p < 0.001$ level. The MAFSI severity score favored the catheter ablation group at both 12-months (mean difference -1.5, $p < 0.001$) and the follow-up intervals (mean difference -1.1, no p -value reported for follow ups.)

DISCUSSION

Atrial fibrillation is the most common chronic arrhythmia impacting approximately 9% of people over the age of 65 and accounting for over 800,000 ED visits between 2005 and 2004 posing both a practical health risk as well as a financial and logistical burden to the health care system.^{1,2} While one of the most common treatment options, drug therapy also results in considerable side effects such as COPD, thyroid dysfunction, and/or ventricular arrhythmias. Conversely, catheter ablation is a minimally invasive procedure with minimal, and infrequent, side effects that minimizes the likelihood of recurrence in patients resulting in both a minimized financial and logistical burden but also a potential increase in the quality of life experienced by patients. However, this procedure would require prior authorization from insurance. As mentioned above, catheter ablations could have unfavorable consequences, most common being cardiac tamponade, but this is infrequent.⁴ The purpose of this selective evidence-based review was to establish whether or not there was a demonstrated, statistically significant improvement of the quality of life of patients when compared to those who received drug therapy.

While there were limitations in all three studies reviewed, none of these limitations reached the point of diminishing the significant findings of each study. The limitations noted in the cohort study by Barmano et al. was the lack of randomization and a comparable treatment

group. For the randomized control trials conducted by Blomstrom et al. as well as Marks et al., the major limitation was the inability of the researchers to impose strict crossover restrictions on the participants; therefore, a patient could feasibly receive both a catheter ablation as well as a drug therapy throughout the course of the study. Despite these limitations all three studies demonstrated statistically significant improvements in the quality of life of patients with AF who received a catheter ablation.

CONCLUSION

Based on the results of all three studies reviewed above, catheter ablation shows significant improvements in the quality of life of patients in the treatment of atrial fibrillation. The cohort study conducted by Barmano et al. indicated a significant improvement in the quality of life in individuals with AF who received a catheter ablation. The limitation of this study, however, was the lack of a comparison group in the form of those patients who received medicine as opposed to a catheter ablation. Despite this limitation, the studies' results indicate positive improvements for those patients who did receive a catheter ablation. Conversely, both Blomstrom et al. and Marks et al. conducted multi location open-label randomized control trials comparing patients receiving a catheter ablation and those treating AF with medication. Both studies found statistically significant increases in the quality of life measures for the catheter ablation groups as opposed to the medication groups. A limitation for both of these studies, however, was the lack of strict guidelines preventing a patient from crossing over between the catheter ablation and medication groups.

As demonstrated by the strong results reported in this selective evidence-based medicine review, there is promising evidence that catheter ablation significantly improves the quality of life in individuals with atrial fibrillation. Although, no study, including the ones reviewed, is

without their limitations. The strength of the findings presented warrants continued research into the impact of catheter ablation on improving patient quality of life. Future studies should continue to be conducted as randomized control trials to produce valid conclusions as well as stricter guidelines on preventing crossover of patients from the control to treatment group prior to the conclusion of the study. In light of the strong evidence presented in the studies reviewed, and the side effects associated with medication treatment of AF, the opportunity exists to explore widening the usage of catheter ablation for individuals living with atrial fibrillation.

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