

## **Radiofrequency Ablation for Atrial Fibrillation**

This guide summarizes the clinical evidence on the effectiveness and safety of catheter-based radiofrequency ablation (RFA) compared with anti-arrhythmic drugs (AADs) for the treatment of atrial fibrillation (AF). This guide does not address other aspects of AF treatment, including anticoagulation, rate control medications, or treatments other than RFA and AADs used to restore sinus rhythm.

## **Clinical Issue**

Atrial fibrillation (AF) is the most common sustained cardiac arrhythmia. AF can be paroxysmal, persistent (more than 7 days), or chronic (more than 1 year). AF often causes significant symptoms, such as palpitations, shortness of breath, and fatigue, and is associated with a fivefold increased risk of stroke and approximately a twofold increased risk of death. Many people with AF can be adequately treated with drugs that control heart *rate* without restoring normal heart *rhythm*. However, for some people, rate control alone does not relieve the symptoms. Those people may benefit from therapies to restore normal cardiac rhythm. Sometimes a normal rhythm can be

maintained with medications, but anti-arrhythmic drugs (AADs) can have serious side effects.

An alternative method for restoring normal cardiac rhythm is radiofrequency ablation (RFA). With RFA, a catheter is advanced into the heart and positioned in the area of an abnormal electrical circuit. On contact, the catheter tip heats the cardiac tissue using radiofrequency energy. The resulting tissue destruction prevents the abnormal electrical signals from being conducted. Several different ablation techniques are used for AF. With most techniques, the ablation targets are sites in the pulmonary veins and the left atrium.

## **Clinical Bottom Line**

Evidence is insufficient to determine the effectiveness of RFA as first-line therapy compared with AADs.

Among patients with AF who have failed at least one course of AADs, RFA is more effective than another trial of AADs for maintaining sinus rhythm at 1 year.

*Level of Confidence:*  $\bullet \bullet \circ$ 

Serious complications are uncommon after RFA, but stroke and cardiac tamponade each occur in about 1 percent of cases.

*Level of Confidence:*  $\bullet \circ \circ$ 

#### **Confidence Scale**

The confidence ratings in this guide are derived from a systematic review of the literature. The level of confidence is based on the overall quantity and quality of clinical evidence.

High ••• There are consistent results from good quality studies. Further research is very unlikely to change the conclusions.

Medium ••• Findings are supported, but further research could change the conclusions.

Low  $\bullet \bigcirc \bigcirc$  There are very few studies, or existing studies are flawed.





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## Effectiveness

#### **Comparative Effectiveness**

Table 1 summarizes the evidence on the comparative effectiveness of RFA and AADs for various outcomes. Most trials examined the effectiveness of RFA as second-line therapy; they compared RFA with AADs among patients who had failed at least one previous trial of AADs. Evidence is insufficient to determine the effectiveness of RFA as first-line therapy compared with AADs.

## Table 1. Comparative effectiveness of RFA andAADs as second-line therapy for atrial fibrillation

Outcome	RFA vs. AADs	Level of Confidence	
In sinus rhythm at 1 year	RFA better (74% vs. 20%)		
Off anticoagulants at 1 year	More often with RFA (60% vs. 34%)	• • •	
Improved quality of life <sup>1</sup>	RFA better		
Avoiding stroke within 1 year	No difference	• • •	
Improved heart function and size at 1 year	No difference		
Avoiding congestive heart failure	Unknown	INSF	
<sup>1</sup> General or physical functioning. RFA = radiofrequency ablation. AADs = anti-arrhythmic drugs. INSF = insufficient evidence.			

### **Technical Aspects**

Different techniques are used to perform RFA. With ostial pulmonary vein isolation (PVI), energy is applied at or near the junction of the pulmonary veins and the left atrium. For wide-area circumferential ablation (WACA), energy is applied in the left atrium, around the pulmonary veins. Ablation lines (energy applied in a linear pattern in the left or right atrium) may be used in conjunction with PVI or WACA.

Among patients with paroxysmal or persistent AF, WACA, when coupled with ablation of residual potentials, is superior to ostial PVI in preventing AF recurrence.

Level of confidence:  $\bullet \bullet \circ$ 

### **Factors Affecting Efficacy**

#### Patient characteristics

Studies have examined the efficacy of RFA in subgroups of patients with AF (see Table 2). These studies show that many patient characteristics do not affect the efficacy of RFA.

Table 2. Effect of patient characteristics           on RFA efficacy				
Characteristic	Effect on RFA Efficacy	Level of Confidence		
Gender	None	•••		
Age <sup>1</sup>	None	•••		
Structural heart disease	None	•••		
AF duration (time since diagnosis)	None	•••		
Paroxysmal vs. nonparoxysmal AF <sup>2</sup>	Better outcome with paroxysmal AF			
Reduced left ventricular function <sup>3</sup> Increased left atrial diameter <sup>4</sup>	Unknown Unknown	INSF		
INSFHypertension	Unknown	INSF		
<ul> <li><sup>1</sup>Most patients included in the studies were between 40 and 70 years of age.</li> <li><sup>2</sup>Few patients in the studies had nonparoxysmal AF.</li> <li><sup>3</sup>Few patients in the studies had ejection fractions below 40%.</li> <li><sup>4</sup>Few patients in the studies had left atrial diameters above 60 mm.</li> <li>RFA = radiofrequency ablation.</li> <li>AF = atrial fibrillation.</li> <li>INSF = insufficient evidence.</li> </ul>				

- To date, research on the benefits of left- or right-sided ablation lines in addition to standard RFA techniques is inconclusive.
- To date, research on different radiofrequency energy outputs is inconclusive.
- Research on the importance of RFA operator characteristics (e.g., clinical setting and level of experience) is limited.

## **Assessing Risk**

Serious complications are relatively uncommon after RFA (see Table 3). Adverse events were reported in 100 studies with over 22,000 patients. Sixteen studies, with more than 4,300 patients, reported mortality rates. Five deaths were reported within 30 days after RFA. Three deaths were caused by atrioesophageal fistula, one was caused by pulmonary infection, and one was due to anaphylaxis.

## **Treatment Selection**

# Which patients with AF should be referred for RFA?

RFA appears to be superior to AADs in restoring sinus rhythm for patients with AF.

- For patients with AF who are persistently tachycardic or symptomatic despite having tried rate-control medications, electrical cardioversion, and AADs, RFA is a reasonable option.
- There has been little research on the use of RFA as first-line therapy.

Thus far, no patient characteristics clearly predict which patients with AF will benefit from RFA and which will not.

## What should I tell patients about the risks of RFA?

- Common adverse events after RFA include bleeding or pain at the catheter insertion site.
- Pulmonary vein stenosis is not uncommon, but it is usually asymptomatic and does not require intervention.
- Cardiac tamponade occurs in about 1 percent of patients and may require pericardiocentesis or even surgery but is rarely fatal.
- Stroke occurs in about 1 percent of patients.

## **On the Horizon**

Results from the Ablation Versus Anti-Arrhythmic Drug Therapy for AF (CABANA) trial should be available in late 2015 or 2016. This long-term trial of first-line therapies compares catheter ablation with either rate-control or rhythm-control drugs for reducing total mortality in patients with untreated or incompletely treated AF. Cost effectiveness and quality of life will be evaluated.

#### Table 3. Rates of complications after RFA

Complication	Range(%)	Median(%)
Pulmonary vein stenosis <sup>1</sup>	0-19	0.3
Cardiac tamponade	0-5	1.0
Stroke	0-7	0.9
Atrioesophageal fistula	0-1	0

<sup>1</sup>The rate of symptomatic pulmonary vein stenosis that was severe enough to require treatment ranged from 0 to 0.9% (median 0%). RFA = radiofrequency ablation.

## **Resource for Patients**

*Radiofrequency Ablation for Atrial Fibrillation: A Guide for Adults* is a companion to this Clinician's Guide. It can help people talk with their health care professional about radiofrequency ablation. It provides information about:

- What atrial fibrillation is.
- Types of treatments for AF.
- Benefits and risks of rhythm-control treatments.
- Seeking advice from a health care professional about treatment options.

## **For More Information**

For electronic copies of the consumer's guide, this clinician's guide, and the full systematic review, visit this Web site: www.effectivehealthcare.ahrq.gov

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### Source

The source material for this guide is a systematic review of 120 research studies. The review, *Comparative Effectiveness of Radiofrequency Catheter Ablation for Atrial Fibrillation* (2009), was prepared by the Tufts Medical Center Evidence-based Practice Center. A summary of the report, including an additional analysis, was published in Ann Intern Med 2009;151:191-202. The Agency for Healthcare Research and Quality (AHRQ) funded the systematic review and this guide. The guide was developed using feedback from clinicians who reviewed preliminary drafts. The full systematic review is available at **www.effectivehealthcare.ahrq.gov**.

