

Radiofrequency Ablation vs Antiarrhythmic Drugs as First-Line Treatment of Paroxysmal Atrial Fibrillation (RAAFT-2) A Randomized Trial

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IMPORTANCE Atrial fibrillation (AF) is the most common rhythm disorder seen in clinical practice. Antiarrhythmic drugs are effective for reduction of recurrence in patients with symptomatic paroxysmal AF. Radiofrequency ablation is an accepted therapy in patients for whom antiarrhythmic drugs have failed; however, its role as a first-line therapy needs further investigation.

OBJECTIVE To compare radiofrequency ablation with antiarrhythmic drugs (standard therapy) in treating patients with paroxysmal AF as a first-line therapy.

DESIGN, SETTING, AND PATIENTS A randomized clinical trial involving 127 treatment-naive patients with paroxysmal AF were randomized at 16 centers in Europe and North America to receive either antiarrhythmic therapy or ablation. The first patient was enrolled July 27, 2006; the last patient, January 29, 2010. The last follow-up was February 16, 2012.

INTERVENTIONS Sixty-one patients in the antiarrhythmic drug group and 66 in the radiofrequency ablation group were followed up for 24 months.

MAIN OUTCOMES AND MEASURES The time to the first documented atrial tachyarrhythmia of more than 30 seconds (symptomatic or asymptomatic AF, atrial flutter, or atrial tachycardia), detected by either scheduled or unscheduled electrocardiogram, Holter, transtelephonic monitor, or rhythm strip, was the primary outcome. Secondary outcomes included symptomatic recurrences of atrial tachyarrhythmias and quality of life measures assessed by the EQ-5D tool.

RESULTS Forty-four patients (72.1%) in the antiarrhythmic group and in 36 patients (54.5%) in the ablation group experienced the primary efficacy outcome (hazard ratio [HR], 0.56 [95% CI, 0.35-0.90]; $P = .02$). For the secondary outcomes, 59% in the drug group and 47% in the ablation group experienced the first recurrence of symptomatic AF, atrial flutter, atrial tachycardia (HR, 0.56 [95% CI, 0.33-0.95]; $P = .03$). No deaths or strokes were reported in either group; 4 cases of cardiac tamponade were reported in the ablation group. In the standard treatment group, 26 patients (43%) underwent ablation after 1-year. Quality of life was moderately impaired at baseline in both groups and improved at the 1 year follow-up. However, improvement was not significantly different among groups.

CONCLUSIONS AND RELEVANCE Among patients with paroxysmal AF without previous antiarrhythmic drug treatment, radiofrequency ablation compared with antiarrhythmic drugs resulted in a lower rate of recurrent atrial tachyarrhythmias at 2 years. However, recurrence was frequent in both groups.

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