Catheter Ablation Yields Greater Benefits Than Drugs in SARA Study

Written by Larry Hand

In a trial with only persistent atrial fibrillation (PeAF) patients, as opposed to a combination of PeAF and paroxysmal AF (PAF) patients, catheter ablation (CA) had significantly better results at 12-month follow-up than antiarrhythmic drug (AAD) treatment. Lluis Mont, MD, PhD, Hospital Clinic, Universitat de Barcelona, Catalonia, Spain, presented the results of the Study of Ablation Versus Antiarrhythmic Drugs in Persistent Atrial Fibrillation [SARA; NCT00863213].

Past trials have combined patients with PeAF and long-standing PeAF, but no trial has excluded long-standing patients, Prof. Mont said. In this case, researchers tried to define a purely PeAF group of patients, those in transition from PAF to long-standing PeAF, he said. They conducted the trial at eight hospitals across Spain.

The researchers randomized 146 patients in a 2:1 ratio, with 98 patients randomized to receive CA and 48 to receive AAD treatment. Eligible patients had symptomatic PeAF >7 days, or <7 days if cardioversion was required, and they had failed one or more Class I or Class III AADs. Exclusion criteria included age <18 and >70 years, long-standing PeAF, advanced remodeling stage (left atrial [LA] >50 mm), hyper- or hypothyroidism, hypertrophic cardiomyopathy, disease contradicting ablation or AAD treatment, and other factors.

The primary ablation procedure was a wide encircling pulmonary vein ablation with a cooled-tip catheter, assisted by a circular multipolar catheter, with a primary endpoint of absence or dissociation of local activity inside the surrounded region and exit block. Additional ablation lines, with the endpoint of complete bidirectional conduction block or ablation of complex fractionated atrial electrograms (CFAEs) were done according to each hospital's protocol. AADs in the control group were either Class Ic plus diltiazem or β-blockers or Class III.

For the intention-to-treat (ITT) analysis, 70.4% of CA patients achieved the primary endpoint of freedom of any sustained episode of AF >24 hours, compared with 43.7% of AAD patients for an absolute risk reduction of 26.6% (95% CI, 10.0 to 43.4; p=0.002). CA patients also experienced greater benefit in secondary outcomes (Table 1).

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Table 1. SARA Secondary Endpoints

Outcome	Ablation (n=98)	Drug Therapy (n=48)	p Value
Free of any recurrence of AF/AFL	59 (60.2)	14 (29.2)	<0.001
Cardioversions			
None	64 (65.3)	24 (50.0)	0.018
1	22 (22.4)	10 (20.8)	
2 or more	12 (12.2)	1 (29.2)	
Hospitalizations related to arrhythmia	2 (2.0)	3 (6.25)	0.331

AF=atrial fibrillation; AFL=atrial flutter.

Follow-up consisted of physician visits and electrocardiogram at Months 1, 3, 6, and 12, a 24-hour Holter monitor at Months 3, 6, and 12, and physician contact at any time if symptoms occurred.

Baseline patient characteristics included mean age of 55 years, 77% male, LA size between 41.3 mm (CA group) and 42.7 mm (AAD group), and left ventricular ejection fraction of 61.1% (CA group) and 60.8% (AAD group).

In the CA-randomized patients, 94.9% actually underwent CA (8 patients withdrew or were lost to follow-up but were included in the analysis), and 8.2% underwent additional CA. Of those, 23.4% had roof line, 3.1% had mitral line, and 8.1% CFAE ablation. Of the AAD-randomized patients, initial therapy was Class I for 43.8% and Class III for 56.3%, for a mean of 1.3±0.7 AADs per patient. No strokes or deaths occurred during the study.