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## Effect of Catheter Ablation vs Antiarrhythmic Drug Therapy on Mortality, Stroke, Bleeding, and Cardiac Arrest among Patients with Atrial Fibrillation: The CABANA Randomized Clinical Trial

### Original Investigation

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# Abstract

## Importance:

Catheter ablation is effective in restoring sinus rhythm in atrial fibrillation (AF), but its effects on long-term mortality and stroke risk are uncertain.

## Objective:

To determine whether catheter ablation is more effective than conventional medical therapy for improving outcomes in AF.

## Design, setting, and participants:

The Catheter Ablation vs Antiarrhythmic Drug Therapy for Atrial Fibrillation trial is an investigator-initiated, open-label, multicenter, randomized trial involving 126 centers in 10 countries. A total of 2204 symptomatic patients with AF aged 65 years and older or younger than 65 years with 1 or more risk factors for stroke were enrolled from November 2009 to April 2016, with follow-up through December 31, 2017.

## Interventions:

The catheter ablation group (n = 1108) underwent pulmonary vein isolation, with additional ablative procedures at the discretion of site investigators. The drug therapy group (n = 1096) received standard rhythm and/or rate control drugs guided by contemporaneous guidelines.

## Main outcomes and measures:

The primary end point was a composite of death, disabling stroke, serious bleeding, or cardiac arrest. Among 13 prespecified secondary end points, 3 are included in this report: all-cause mortality; total mortality or cardiovascular hospitalization; and AF recurrence.

## Results:

Of the 2204 patients randomized (median age, 68 years; 37.2% female; 42.9% had paroxysmal AF and 57.1% had persistent AF), 89.3% completed the trial. Of the patients assigned to catheter ablation, 1006 (90.8%) underwent the procedure. Of the patients assigned to drug therapy, 301 (27.5%) ultimately received catheter ablation. In the intention-to-treat analysis, over a median follow-up of 48.5 months, the primary end point occurred in 8.0% (n = 89) of patients in the ablation

group vs 9.2% (n = 101) of patients in the drug therapy group (hazard ratio [HR], 0.86 [95% CI, 0.65-1.15]; P = .30). Among the secondary end points, outcomes in the ablation group vs the drug therapy group, respectively, were 5.2% vs 6.1% for all-cause mortality (HR, 0.85 [95% CI, 0.60-1.21]; P = .38), 51.7% vs 58.1% for death or cardiovascular hospitalization (HR, 0.83 [95% CI, 0.74-0.93]; P = .001), and 49.9% vs 69.5% for AF recurrence (HR, 0.52 [95% CI, 0.45-0.60]; P < .001).

## Conclusions and relevance:

Among patients with AF, the strategy of catheter ablation, compared with medical therapy, did not significantly reduce the primary composite end point of death, disabling stroke, serious bleeding, or cardiac arrest. However, the estimated treatment effect of catheter ablation was affected by lower-than-expected event rates and treatment crossovers, which should be considered in interpreting the results of the trial.

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