Original Investigation

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Pulmonary Vein Isolation With Optimized Linear Ablation vs Pulmonary Vein Isolation Alone for Persistent AF

The PROMPT-AF Randomized Clinical Trial

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Key Points

Question Does the addition of linear ablation combined with ethanol infusion via the vein of Marshall (EIVOM) to pulmonary vein isolation (PVI) improve rhythm outcomes for patients with persistent atrial fibrillation (AF)?

Findings In this randomized clinical trial that included 498 patients with persistent AF undergoing first-time ablation, linear ablation combined with EIVOM significantly improves freedom from atrial arrhythmia recurrence without antiarrhythmic drugs (70.7% vs 61.5%; hazard ratio, 0.73).

Meaning Linear ablation combined with EIVOM provides additional benefit in rhythm outcomes for the ablation of persistent AF.

Abstract

Importance Success rates of pulmonary vein isolation (PVI) are modest for persistent atrial fibrillation (AF). Additional linear ablation beyond PVI has not been proved superior to PVI alone in randomized trials. Ethanol infusion of the vein of Marshall (EIVOM) facilitates ablation at the mitral isthmus and may lead to improved effectiveness of a linear ablation strategy.

Objective To determine whether linear ablation with radiofrequency energy combined with EIVOM added to PVI improves sinus rhythm maintenance compared with PVI alone in patients with persistent AF.

Design, Setting, and Participants The PROMPT-AF trial is an investigator-initiated, multicenter, open-label, randomized trial involving 12 tertiary hospitals in China. A total of 498 patients aged 18 to 80 years, with AF persisting for more than 3 months, undergoing first-time AF ablation, were enrolled and randomized from August 27, 2021, to July 16, 2023.

Interventions Patients were randomized to undergo PVI alone or PVI plus EIVOM and linear ablation (intervention). The latter group first underwent EIVOM, followed by PVI and linear ablation of the left atrial roof, mitral isthmus, and cavotricuspid isthmus.

Main Outcomes and Measures The primary end point was freedom from any documented atrial arrhythmias lasting more than 30 seconds, without the use of antiarrhythmic drugs within 12 months. Secondary outcomes included freedom from atrial arrhythmia recurrence, AF, atrial arrhythmia recurrence after multiple procedures, and documented atrial tachycardia or atrial flutter with or without antiarrhythmic drugs; AF burden; and improvement in quality of life. Patients were monitored with wearable single-lead electrocardiographic (ECG) patches, worn for 24 hours a week, supplemented by symptom-triggered ECGs and Holter monitoring.

Results Among 498 randomized patients, 495 (99.4%) were included in the primary analysis (mean age, 61.1 years [SD, 9.7] years, 361 male [72.9%]). After 12 months, 174 of 246 patients (70.7%) assigned to undergo PVI plus EIVOM and linear ablation and 153 of 249 patients (61.5%) assigned to undergo PVI alone remained free from atrial arrhythmias without taking antiarrhythmic drugs (hazard ratio, 0.73; 95% CI, 0.54-0.99, $P = .045$). The intervention effect was consistent across all prespecified subgroups. The comparison of secondary outcomes did not demonstrate significant results.

Conclusion Among patients with persistent AF, linear ablation combined with EIVOM in addition to PVI significantly improved freedom from atrial arrhythmias within 12 months compared with PVI alone.

Trial Registration ClinicalTrials.gov Identifier: NCT04497376

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