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Pulmonary Vein Isolation Using the Visually Guided Laser Balloon

A Prospective, Multicenter, and Randomized Comparison to Standard Radiofrequency Ablation

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ABSTRACT

BACKGROUND Balloon catheters have been designed to facilitate pulmonary vein (PV) isolation in patients with paroxysmal atrial fibrillation (AF). The visually guided laser balloon (VGLB) employs laser energy to ablate tissue under direct visual guidance.

OBJECTIVES This study compared the efficacy and safety of VGLB ablation with standard irrigated radiofrequency ablation (RFA) during catheter ablation of AF.

METHODS Patients with drug-refractory paroxysmal AF were enrolled in a multicenter, randomized controlled study of PV isolation using either the VGLB or RFA (control). The primary efficacy endpoint was freedom from protocol-defined treatment failure at 12 months, including symptomatic AF occurring after the 90-day blanking period. The primary efficacy and safety endpoints were powered for noninferiority.

RESULTS A total of 353 patients (178 VGLB, 175 control) were randomized at 19 clinical sites. The mean procedure, ablation, and fluoroscopy times were longer with VGLB compared with controls. The primary efficacy endpoint was met in 61.1% in the VGLB group versus 61.7% in controls (absolute difference −0.6%; lower limit of 95% confidence interval [CI]: −9.3%; $p = 0.003$ for noninferiority). The primary adverse event rate was 11.8% in the VGLB group versus 14.5% in controls (absolute difference −2.8%; upper limit of 95% CI: 3.5; $p = 0.002$ for noninferiority), and was mainly driven by cardioversions. Diaphragmatic paralysis was higher (3.5% vs. 0.6%; $p = 0.05$), but PV stenosis was lower (0.0% vs. 2.9%; $p = 0.03$) with VGLB.

CONCLUSIONS Despite minimal prior experience, the safety and efficacy of VGLB ablation proved noninferior to RFA for the treatment of paroxysmal AF. (Pivotal Clinical Study of the CardioFocus Endoscopic Ablation System-Adaptive Contact [EAS-AC] [HeartLight] in Patients With Paroxysmal Atrial Fibrillation [PAF] [HeartLight]; NCT01456000) (J Am Coll Cardiol 2015;66:1350-60) © 2015 by the American College of Cardiology Foundation.

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The mainstay of catheter-based therapy for patients with paroxysmal atrial fibrillation (AF) is pulmonary vein (PV) isolation (1). Despite high rates of acute electrical isolation, long-term efficacy is mainly limited by PV reconnections (2,3). This may be attributable to the technical difficulty in achieving a transmural and contiguous ring of necrosis around the PVs with point-by-point ablation. To facilitate this process, balloon catheters

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using a variety of energy sources, including radiofrequency, laser, and cryoenergy, have been introduced (4–6). Although many of these balloon catheters share similar features, the visually guided laser balloon (VGLB) is unique in that it uses: 1) a compliant, variable diameter balloon, thus allowing a single balloon catheter to accommodate multiple PV sizes/shapes; 2) a 2-F endoscope to provide real-time direct visualization of the target tissue; and 3) a maneuverable (~30°) aiming arc that allows the operator to easily target the location of the PV ostium/antrum and titrate the amount of laser energy delivered.

Clinical experience with the VGLB has been limited to several single and multicenter nonrandomized experiences that have demonstrated reasonable safety and efficacy (6–10). Although the VGLB is routinely used clinically in Europe, no multicenter, randomized studies have compared it with other technologies. Here, we report the first prospective, multicenter, randomized study comparing the safety and efficacy of the VGLB with standard irrigated radiofrequency ablation (RFA) in patients with paroxysmal AF.

METHODS

The study protocol was approved by the institutional review boards at each of the 21 sites in the United States. Of these sites, 19 entered the study's randomized phase (Online Appendix). Two sites enrolled subjects into the training phase of the study but did not randomize any patients. The study design stipulated that only randomized patients would be included in the primary analyses. All patients enrolled in the study provided written informed consent.

Patients with drug-refractory paroxysmal AF were enrolled in the study. Inclusion criteria included: ≥2 symptomatic AF episodes (≥1 min) within the previous 6 months; 1 documented AF episode within the previous 12 months; and refractory or intolerance to an antiarrhythmic drug (AAD) (class I, II, or III). The exclusion criteria included: PV size >35 mm; left atrial (LA) thrombus; LA diameter >50 mm; left ventricular ejection fraction <30%; previous LA ablation for AF or atrial flutter (AFL); New York Heart Association class III or IV symptoms; myocardial infarction within the previous 60 days; unstable angina; cardiac surgery within the previous 3 months; coronary artery bypass grafting within the previous 6 months; any history of cardiac valve surgery; a thromboembolic event within the previous 3 months; uncontrolled bleeding; active infection; atrial myxoma; severe pulmonary disease or gastrointestinal bleeding; a previous valvular cardiac surgical procedure; presence of an implantable cardioverter-defibrillator; women of childbearing potential who were pregnant, lactating, or not using adequate birth control; and inability to be removed from antiarrhythmic drug therapy.

STUDY PROTOCOL. Patients were randomized in a 1:1 manner to VGLB ablation or RFA (control). After randomization, patients underwent ablation according to their assignment. Following hospital discharge, telephone follow-up was performed at 1 week. Follow-up visits occurred at 1, 3, 6, and 12 months and included 12-lead electrocardiogram, physical examination, and assessment of adverse events. Continued use of oral anticoagulation therapy was recommended for 12 months. Use of any U.S. Food and Drug Administration-approved anticoagulation drug, including warfarin, dabigatran, or rivaroxaban, was permitted (apixaban and edoxaban were not approved as of this study's initiation). Patients were permitted to be discharged on the same AAD regimen for AF that was used pre-procedure until the end of the 90-day blanking period, at which time it was discontinued.

All patients were given transtelephonic monitors before the end of the blanking period, and monitoring was performed starting at 3 months and continuing through 12 months. Patients were required to transmit for all symptoms and also weekly irrespective of symptoms. Holter monitoring was performed at 6 and 12 months. Either a computed tomography (CT) scan or cardiac magnetic resonance imaging (CMR) was required within 6 months before enrollment and at 3 months after the procedure. Patients who had stenosis of 1 or more PVs (defined as >50% reduction in greatest diameter) were also required to have CT or CMR at 12 months. The National Institutes of Health Stroke Scale (NIHSS) was administered to participants before randomization, pre-discharge, and at the 12-month visit. A safety monitoring committee reviewed all serious adverse events throughout the conduct of the study.

ABBREVIATIONS AND ACRONYMS

AAD = antiarrhythmic drug
AF = atrial fibrillation
AFL = atrial flutter
AT = atrial tachycardia
CI = confidence interval
CMR = cardiac magnetic resonance imaging
CT = computed tomography
LA = left atrial
PAE = primary adverse event(s)
PV = pulmonary vein
RFA = radiofrequency ablation
VGLB = visually guided laser balloon