



Long-Term Single-Procedure Clinical Results with an Endoscopic Balloon Ablation Catheter for Pulmonary Vein Isolation in Patients with Atrial Fibrillation

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ABSTRACT:

Background: During catheter ablation of AF, placing contiguous point ablation lesions to electrically-isolate the PVs can be technically challenging. A novel balloon catheter (Endoscopic Ablation System (EAS); CardioFocus, Inc.) which utilizes an endoscope for real-time visualization during ablation has been developed. This system employs arcs of light-energy that are adjustable (rotating, advancing, retracting) independent of the balloon to aim energy to the PV-LA ostial region. This report details long-term follow-up results from a prospective, multicenter study.

Methods: In this three-center study, 26 patients with a history of symptomatic drug-resistant paroxysmal AF were studied: Sex: M/F = 23(88.5%) / 3 (11.5%); Age 53 ±12 years (28-73); AF duration: 6.5±5.0 years (range 1.2-24.1); LA diameter: 4.2±0.5 cm (range 3.1-4.9); LVEF 66.4±8.4% (range 45-86). A single treatment consisting of isolation of the pulmonary vein ostia was delivered using the EAS. There were no exclusion criteria related to shape/number of PVs.

Results: Electrical PV isolation was achieved in 89% (83/93) of the targeted PVs. An average of 13 energy deliveries/PV were delivered (range 2-40). One patient experienced pericardial tamponade (not device-related); one patient experienced a prolonged reversible ischemic event, and one other patient experienced reversible phrenic nerve paralysis. Following a 60-day blanking period, 75% (15/20) of patients were free from symptomatic AF episodes >1 min at 6-month follow-up, and 80% (4/5) were free from symptomatic AF episodes lasting >1 minute through one-year follow-up. At the 6-month follow-up visit, 9/70 veins (12.9%) had mild stenosis present (20-50% narrowing) and none had moderate or worse stenosis (>50% narrowing). At the 12-month follow-up visit, 1/8 veins (12.5%) had mild stenosis present (20-50% narrowing) and none had moderate or worse stenosis (>50% narrowing).

Conclusions: A single treatment with EAS ablation of paroxysmal AF appears feasible, safe and efficacious.

INTRODUCTION:

- Pulmonary venous isolation is a standard part of the catheter ablation procedure in the treatment of paroxysmal atrial fibrillation.
- However, it is technically challenging to place electrically contiguous point-to-point ablation lesions to isolate these veins.
- To this end, this study evaluates the clinical experience from the use of a novel endoscopic balloon ablation catheter system for PV isolation to treat patients with paroxysmal AF.

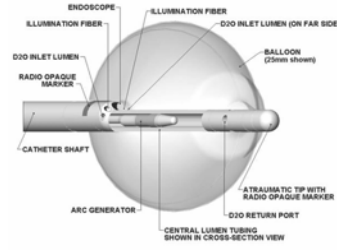
Endoscopic Ablation System

- Endoscopic Ablation System Catheter (20, 25 & 30 mm)
- Endoscope
- Light Energy (Laser) Console
- Deflectable Sheath
- Cooling Console



Endoscope with 110° Field of View

15F OD Deflectable Sheath capable of 180° Deflection

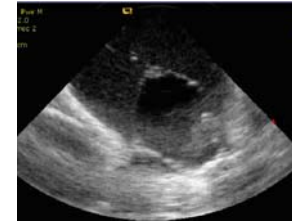


90° Arc is Rotatable & Axially Translatable

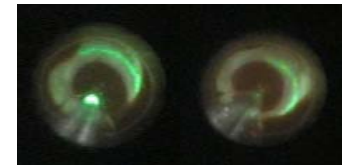
METHODS:

- Key Inclusion Criteria**
 - 18 – 75 years
 - Recurrent symptomatic paroxysmal AF
 - At least 2 AF episodes in the prior 2 months
 - Refractory to at least one antiarrhythmic drug
- Key Exclusion Criteria**
 - Previous AF ablation
 - Significant co-morbidities such as pulmonary disease, pulmonary hypertension, infection, bleeding diathesis, hypercoagulable state
 - Pulmonary veins > 24 mm in diameter
 - Left atrium diameter > 5.0 cm
- Ablation procedure**
 - Baseline CT or MRI to establish baseline PV size / morphology
 - Double transseptal puncture
 - Anticoagulation with heparin; target ACT > 300 sec
 - Pre-ablation images (ICE or angiography) to assess PV size
 - One ablation procedure (index procedure) per patient consisting of attempted isolation of all PVs
 - Pre- and post-ablation mapping (circular catheter)
 - Use of ICE or angiography to guide the EAS to the PV
- Post-ablation**
 - Telemetry or Holter monitoring for 24 hours
 - TTE or TEE the day after the procedure
 - Low molecular weight heparin
 - Resume previous antiarrhythmic drug for 30 days
- Follow up**
 - Event recorders: transmit weekly and with symptoms for 6 months
 - Office visits: 1, 3, 6 and 12 months
 - Cardiac CT scan or MRI to assess for PV stenosis at 3 and 6 months

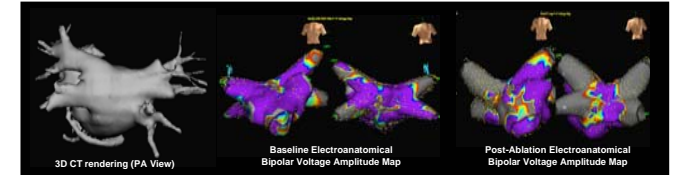
PRIMARY ENDPOINT: Freedom from symptomatic AF episodes lasting more than one minute (documented by event monitor or other ECG reporting) after the index procedure beyond the blanking period.



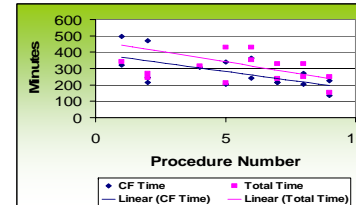
ICE imaging to visualize the location of the EAS at the Left Superior PV ostium.



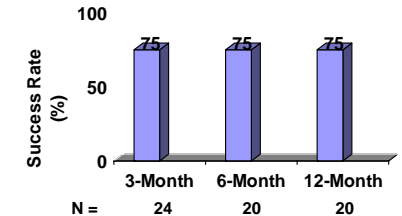
Internal views of the face of the balloon using the miniature endoscope. The white represents contact with tissue, the red is the blood, and the green arc is the aiming beam (from this same optical fiber, laser energy is transmitted).



RESULTS: 26 Patients were enrolled and treated at the three study sites. Follow-up was conducted as described in Methods. Using a 60-day blanking period, AF-free success rates after a single-procedure were 75% (15/20) at 6 months and 75% (15/20) after 12 months for the first 20 patients. Three & 2 patients were on AADs at 6 & 12 months respectively, none for AF.



Learning Curve: Case times were reduced within 10 cases



SAFETY:

- 3 Primary Adverse Events
 - Ischemic Event resolved within 48 hours
 - Asymptomatic, reversible phrenic nerve paralysis
 - Cardiac tamponade with pericardial effusion during procedure
- No significant (>50%) PV stenosis or Atrioesophageal fistula formation

CONCLUSIONS: The efficacy of the Endoscopic Ablation System to isolate PVs for the treatment of drug-refractory, paroxysmal AF has been demonstrated. The single-procedure, AF-free success rate of 75% at 12 months is comparable to reports of other approaches for the isolation of PVs after multiple treatments/procedures. The complications reported are similar to those for other AF ablation procedures. The absence of significant PV stenosis is encouraging.