

Long-Term Follow-up of Patients with Drug-Refractory Atrial Fibrillation Treated with a Percutaneous Endoscopic Laser Balloon Ablation System

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Background: This report details the long-term follow-up results from the initial 20-patient clinical experience using a novel endoscopic laser balloon ablation system (EAS; CardioFocus, Inc) for drug refractory atrial fibrillation (AF).

Methods: Twenty patients with a history of symptomatic antiarrhythmic drug-refractory paroxysmal AF were studied: sex 18M/2F; mean age 54 years (29-73); mean AF duration 6 years (1.5-24); mean LA diameter 42 mm (31-49); mean LVEF 65% (45%-86%). After double transseptal puncture, the EAS and a circumferential mapping catheter were placed at the pulmonary vein (PV) ostia using a 12-Fr deflectable or 8-Fr standard sheath, respectively. Intracardiac echocardiography (ICE) (Siemens AcuNav, Inc.) or angiography was used to guide the positioning of the EAS at the PV ostia. Light energy ablation was performed using multiple connecting arcs of energy to isolate the PVs. PV electrical isolation (entrance block) was verified by circular mapping. PV size was assessed pre- and post- ablation by ICE or fluoroscopy. Patients were followed clinically for recurrence of AF with arrhythmia transmitter and ambulatory Holter monitoring. Clinical recurrence of AF was defined as AF episodes > 1 minute duration. Cardiac CT was performed at baseline, 3 and 6-months.

Results: Electrical PV isolation was achieved using the EAS in 66/77 (86%) targeted PVs. A mean of 11.7 (range 2-29) energy deliveries were applied per PV. Three patients experienced complication: one pericardial tamponade (not device-related); one reversible ischemic neurological deficit that resolved without treatment and one asymptomatic phrenic nerve paralysis that subsequently resolved. Following a 60-day blanking period, 75% (15/20) of patients were free from symptomatic AF after 3-6 months of follow-up. The 3 and 6-month cardiac CT revealed no PV stenosis > 50%. Only one PV in each of 3 patients had a mild narrowing (20%-50% reduction).

Conclusions: In a subset of patients with paroxysmal AF, endoscopic guided light-energy ablation of the PVs appears to provide long-lasting cure of AF in 75% of patients.