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Initial Clinical Experience with a Balloon Laser Ablation Catheter for Pulmonary Vein Isolation in Patients with Atrial Fibrillation

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Background: During catheter ablation of AF, placing contiguous point ablation lesions to electrically-isolate the PVs can be technically challenging. A novel Light Ring Balloon Catheter (LRBC; Cardiofocus, Inc) which ablates tissue by projecting forward a beam of laser energy (980nm) has been developed. Since the angulation/placement of the LRBC in relation to the PV axis is unknown using fluoroscopy alone, this system employs 1) a micro-endoscope to visualize the area of balloon-tissue contact, and 2) a 150° circular lasing arc that can be adjusted (rotating, advancing, retracting) to aim the energy to this region. This report details preliminary results from the initial clinical experience using the LRBC in a prospective, multicenter trial.
Methods: In this 2-center study, 9 patients with a history of symptomatic drug-resistant paroxysmal AF were studied: sex 9M/0F; age 57±15 years (33-73); AF duration 3.9±1.6 years (2.1-6.1); failed 2.2±1.1 AADs (1-4); LA 40±7 mm (31-48); LVEF 64±9% (45-74). After dual transseptal puncture, the LRBC (balloon diameters 20, 25 and 30mm) and a circumferential mapping catheter were placed at the PV ostia using a 12-Fr deflectable or 8-Fr standard sheath, respectively. Intracardiac ultrasound (ICE, Acuson, Inc.) aided positioning at the PV ostia. Laser ablation was performed using multiple connecting arcs of energy (5.5-6.0 W/cm, 60 secs) to isolate the PVs. Venous size was assessed pre- and post- ablation by ICE. CT was performed at baseline and 3-months.
Results: Electrical PV isolation was achieved using the LRBC in 26/35 targeted PVs (74% of attempted). An average of 2.1 energy delivery attempts/mappings (range 1-4) was applied per PV. One patient experienced pericardial tamponade (not device-related); no other complications (including atrial-esophageal fistula formation, phrenic nerve damage, and thromboembolism) were observed. Following a 60-day blanking period, 78% (7/9) of patients were free from symptomatic AF episodes > 1 min through 15 weeks follow-up. The 3-mo CT revealed a mean change in PV diameter of -1±14% (range -28% to +36%); there was no symptomatic PV stenosis.
Conclusions: LRBC ablation of AF appears feasible, and these preliminary efficacy and safety data are encouraging. Further study is warranted.

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