P2846

Focal impulse and rotor modulation ablation versus pulmonary vein isolation for the treatment of paroxysmal atrial fibrillation (FIRMAP AF study)

R. Tilz[1], C.L. Lenz[2], P.S. Sommer[3], N. Sawan[1], R. Meyer-Saraei[1], S. Shpun[4], A. Sarver[4], C. Heeger[1], G. Hindricks[3], J. Vogler[1], C. Eitel[1]

[1]University Heart Center, Luebeck, Germany; [2]UKB Berlin, Cardiology, Berlin, Germany; [3]Heart Center of Leipzig, Electrophysiology, Leipzig, Germany; [4]Abbot, Plymouth, United States of America

Funding Acknowledgement: Abbot

Background: Based on the assumption of trigger elimination, pulmonary vein isolation (PVI) currently presents the gold standard of atrial fibrillation (AF) ablation. Recently, rapidly spinning rotors or focal impulse formation has been raised as a crucial sustaining mechanism of AF. Ablation of these rotors may potentially obviate the need for trigger elimination with PVI.

Purpose: This study sought to compare the safety and effectiveness of Focal Impulse and Rotor Modulation (FIRM) guided catheter ablation only with the gold standard of pulmonary vein isolation (PVI) in patients with paroxysmal AF.

Methods: This was a post-market, prospective, single-blinded, randomized, multi-center trial. Patients were enrolled at three centers and equally (1:1) randomized between those undergoing conventional RF ablation with PVI (PVI group) vs. those treated with FIRM-guided RF ablation without PVI (FIRM group). Data was collected at enrollment, procedure, and at 7-day, 3-month, 6-month, and 12-month follow-up visits. The study was closed early by the sponsor. At the time of study closure, any pending follow-up visits were waived.

Results: From February 2016 until February 2018, a total of 51 (out of a planned 170) patients (mean age 63±10.6 years, 57% male) were enrolled and randomized. Four patients withdrew from the study prior to treatment, resulting in 23 patients allocated to the FIRM group and 24 in the PVI group. Only 13 patients in the FIRM group and 11 patients in the PVI group completed the 12-month follow-up. Statistical analysis was not completed given the small number of patients.

Single-procedure effectiveness (freedom from AF/atrial tachycardia recurrence after blanking period) was 52.9% (9/17) in the FIRM group and 85.7% (12/14) in the PVI group at 6 months; and 31.3% (5/16) in the FIRM group and 80% (8/10) in the PVI group at 12 months. Repeat procedures were performed in 45.8% (11/24) patients in the FIRM group and 7.4% (2/27) in the PVI group.

The acute safety endpoint [freedom from procedure-related serious adverse events (SAE)] was achieved in 87% (20/23) of FIRM group patients and 100% (24/24) of PVI group patients. Procedure related SAEs occurred in three patients in the FIRM group: 1 femoral artery aneurysm and 2 injection site hematomas. No additional procedure-related SAEs were reported $>$7 days post-procedure.

Conclusions: These partial study effectiveness results reinforce the importance of PVI in paroxysmal atrial fibrillation patients and suggest that FIRM-guided ablation alone (without PVI) is not an effective strategy for treatment of paroxysmal AF in most patients. Further study is needed to understand the effectiveness of adding FIRM-guided ablation as an adjunct to PVI in this patient group.