Safety and Effectiveness of Pulmonary Vein Isolation for Paroxysmal Atrial Fibrillation With a Multi-Electrode Radiofrequency Balloon Catheter: Results From the Multicenter SHINE Study

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Introduction: The first-in-human RADIANCE study demonstrated feasibility of a novel multielectrode RF balloon catheter (RFB) with 10 irrigated, flexible gold surface electrodes to directionally-tailor energy delivery for PVI. The aim of the multicenter single-arm SHINE study was to evaluate safety and clinical efficacy of the RFB when used in conjunction with a circular mapping catheter.

Methods: 95 patients (age 60.3±9.8 yrs, 64.2% male) underwent PVI at 6 centres using the RFB, in conjunction with the 10-pole 3Fr circular catheter to provide real-time PV electrograms (Figure). Eight subjects were enrolled as part of the roll-in phase. Main population consisted of 87 subjects of whom two were considered ineligible, resulting in an evaluable cohort of 85 subjects. The primary safety endpoint was the occurrence of primary AEs within 7 days of the procedure. Acute success, the primary effectiveness endpoint, was defined as sustained PV entrance block upon Adenosine/Isoproterenol challenge. Single-shot success (SSS) was defined as PVI before adenosine challenge with one valid 60 sec ablation, or with up to 2 additional invalid ablation shots (less than 30 sec RF delivery or less than 5 active electrodes) to reach PV isolation. Time to isolation was the observed RF ablation time to reach a pure SSS; a pure SSS was achieved by one initial ablation shot, regardless of RF duration or number of activated electrodes. Recurrence of symptomatic AF/AT/AFL was documented with weekly transtelephonic monitoring from 3-6 months, and Holter monitoring at 6 months.

Result: Ablation procedures were performed under general anesthesia in 47/85 (55.3%) subjects, and under conscious sedation in 40/85 (47.1%) subjects. One primary AE (retroperitoneal bleed) occurred in 1/85 (1.2%) patient. Acute success was achieved in all 82 evaluable pts (100%) undergoing Aden/Iso challenge; 3 pts did not receive Aden/Iso challenge and were excluded from this analysis. Single-shot successes were 74.7%, 57.9%, 72.3%, and 68.7% for the LIPV, LSPV, RIPV, and RSPV. Time to isolation (for pure SSS) per vein was 8.2±4.9, 10.6±7.7, 8.7±4.7, and 8.8±6.4 sec for the LIPV, LSPV, RIPV, and RSPV, respectively. Touch-up with focal catheter was required in 1/85 (1.2%) pt. Ablations were performed with procedure time 87.6±22.2 min, RF time 6.1±2.37 min, with 7.5±3.25 RF applications, RFB LA dwell time 40.3±16.69 min, and fluoroscopy time 10.9±9.12 min. After the first roll-in cases, the total procedure and fluoroscopy times decreased to 76.0 min and 10.5 min. The Kaplan-Meier estimate of freedom from documented symptomatic AF/AT/AFL recurrence at 6 months...
was 80.9% (standard error [SE], 4.3%; Figure).

**Conclusion**: This study demonstrated acute safety and short term effectiveness of the new RFB with high procedural efficiencies and a short learning curve.