The Safety and Effectiveness of Pulmonary Vein Isolation with Standardized Ablation Index Workflow

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Introduction: Pulmonary Vein Isolation (PVI) is the cornerstone of atrial fibrillation ablation. Novel automated ablation lesion tagging technology based on real-time catheter CF stability (Visitag) and incorporating Force-Power-Time Integral formula (Ablation Index [AI]) have been shown to improve clinical success. The Vistax study evaluated 12 month clinical outcome of PVI using a standardized AI ablation workflow with the aim of creating contiguous and durable lesions.

Methods: The VISTAX study is a prospective, non-randomized multicenter study conducted across 17 European sites. PVI of paroxysmal atrial fibrillation patients was performed by point-by-point ablation to obtain a contiguous lesion set for ipsilateral PV isolation. Visitag settings were: location stability: 2-3mm, minimum time: 3-5 s, Force Over Time (FOT): 25%, minimum force: 3g, inter tag distance: ≤6mm, and tag size of 3mm (radius). The AI target values were 550 for anterior and 400 for posterior, and may be reduced due to safety reason per investigators' discretion. Patients were followed-up at 3, 6, and 12 months post-ablation. Atrial arrhythmia recurrence was stringently monitored (weekly and symptomatically) and documented via transtelephonic monitor, holter monitor, and electrocardiogram (ECG).

Result: Between 27JAN2017 to 05MAR2018, a total of 340 paroxysmal AF subjects were enrolled; 329 met all eligibility criteria and underwent ablation using AI (evaluable cohort); 281 patients met all AI workflow recommendations including patients in whom for safety measures the ablation was proactively stopped prior to reaching the AI target (per protocol [PP] cohort). Majority of the patients were male (61.5%), with a mean age of 61.3 ± 10.1 years, and mean CHA2DS2-VASc of 1.6 ± 1.42. General anesthesia was used in majority of evaluable subjects (84.2%). Average procedure (inclusive of adenosine-proof isolation at 30 minutes), RF application, and fluoroscopy times in the evaluable cohort were 156.2 ± 37.0 min, 35.1 ± 11.2 min, and 7.9 ± 6.9 min, respectively. Primary adverse event rate was 3.6% in the evaluable cohort. First pass PVI after the waiting period and adenosine challenge were 82.4% (95% CI: 77.4%, 86.7%) in the evaluable cohort and 82.2% (95% CI: 76.7%, 86.9%) in the PP
cohort (Table). Per Kaplan Meier analysis, the freedom from documented all or symptomatic atrial arrhythmia rate at 12 month follow-up in the evaluable cohort were 78.3% (90% CI: 73.8%, 82.8%) and 82.9% (90% CI: 78.8%, 87.0%), respectively.

**Conclusion:** The VISTAX trial demonstrates the reproducibility of AI-guided PAF ablation workflow with low procedure and fluoroscopy times, low primary adverse events, and high acute first pass isolation. High single procedure freedom from arrhythmia recurrence (in the setting of a multicenter study with stringent monitoring) suggests that this approach leads to more durable isolation.