INTELLANAV STABLEPOINT™
Ablation Catheter

Boston Scientific
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NEwTON AF

Clinical Evaluation of the STABLEPOINT™ Catheter and Force Sensing System for Paroxysmal Atrial Fibrillation

NEwTON AF Study (NCT04580914) presented at AHA 2023

CAUTION: Investigational device. Limited by US law to investigational use only. Not available for sale.

Objective

The purpose of the NEwTON AF Clinical Study was to demonstrate that the INTELLANAV STABLEPOINT™ Catheter and Force Sensing System with DIRECTSENSE™ Technology is safe and effective for the treatment of drug refractory, recurrent symptomatic paroxysmal atrial fibrillation.

Methods

- Prospective, single-arm, multi-center, global study conducted at 46 sites: North America (27), Europe (12), Asia-Pacific (7).
- 299 atrial fibrillation (AF) patients were treated for de novo pulmonary vein isolation (PVI) with the investigational INTELLANAV STABLEPOINT™ catheter and guided by RHYTHMIA™ HDx.

Procedural characteristics and safety

- **Procedural Characteristics:**
  - Mean procedure time was 166 min, mean LA dwell time was 136 min, mean fluoroscopy team was 15 min, total radiofrequency (RF) duration was 11.5 ± 6 seconds, and mean contact force was 13.5 ± 7g.
  - High-power short-duration (45-50W) was used exclusively in 210 cases (148 min procedure time), and conventional (<45W) power was used in 82 cases (208 min procedure time).
- **Safety:** There were no steam pops or recorded cases of esophageal fistulas.

Results

- **Local Impedance (LI):**
  - Starting LI was 155.1 Ω with an absolute LI drop of 21.2 Ω and a 13.6% LI drop.
  - LI drops of ≥20 Ω trended toward better 6m outcomes (84.2% vs 73.3%, p=0.04).
  - At 12m, LI drop was predictive of freedom from recurrence (HR 0.6, p=0.003), CF alone was not.
- **Outcomes:**
  - Acute procedural success, defined as isolation of all PVs with STABLEPOINT, was achieved in 294 (98.3%) of patients.
  - The freedom from predefined adverse events was 96.0%; events included pericarditis (6), access complications (2), pulmonary edema (2), pulmonary embolism (1), cerebrovascular accident (1), tamponade (1).
  - At 12 months, freedom from documented recurrence of AF was 73.9%, while freedom from AFL and AT was 90.2% and 97.6%, respectively.

Results

83% First pass isolation rate

96% Freedom from adverse events

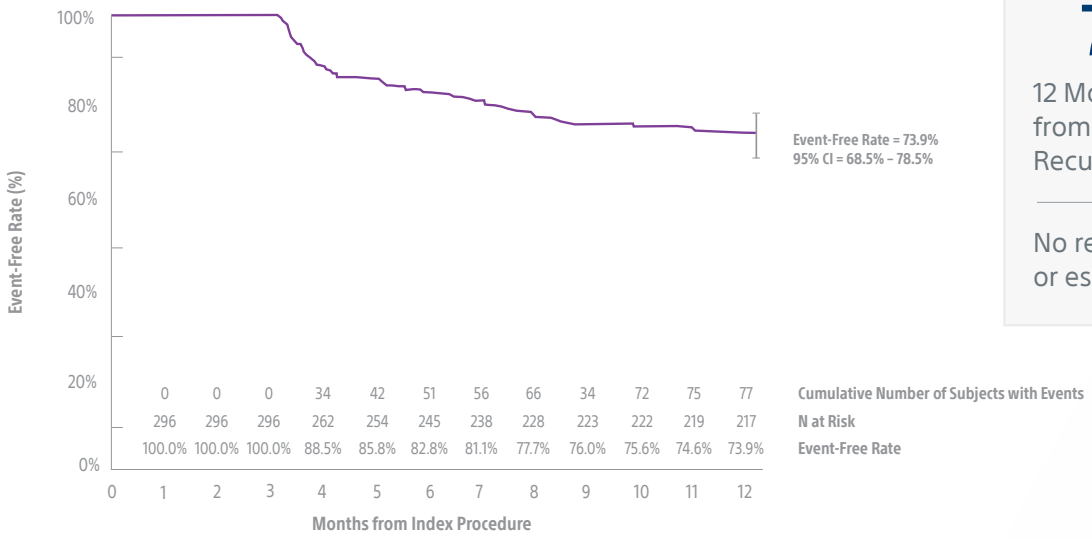
0 Steam pops or esophageal fistula

74% Freedom from documented recurrence of AF

72% Cases performed with HPSD

21Ω/14% Mean LI drop and %LI drop

AF Recurrence



74%

12 Month Freedom from Documented Recurrence of AF

No reported steam pops or esophageal fistulas

Conclusions

The NEwTON AF Study met all safety and effectiveness endpoints. The 30-day and 12-month primary safety as well as the acute, 6-month and 12-month primary effectiveness endpoints met the specified performance criteria for the use of the catheter in this patient population. This data will be used to support submissions for FDA approval of this STABLEPOINT Ablation Catheter.

For more information,
visit our Clinical evidence webpage and educare.bostonscientific.com

Scan for more information

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