

ADVANTAGE AF US IDE

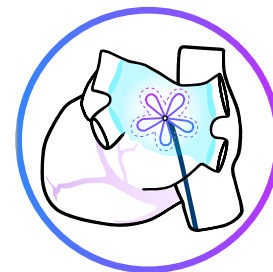
Clinical Trial Results (Phase I)

Reddy, V et. al., 2025

A Prospective Single Arm Open Label Study of the FARAPULSE Pulsed Field Ablation System in the subjects with Persistent Atrial Fibrillation (ADVANTAGE AF) NCT05443594

▶ OBJECTIVE

Establish the safety and effectiveness of the FARAPULSE™ Pulsed Field Ablation System for treatment of drug refractory, symptomatic persistent atrial fibrillation (PersAF). This is Boston Scientific's first clinical trial to include ablation treatment with FARAWAVE™ Pulsed Field Ablation Catheter in both pulmonary vein isolation (PVI) and posterior wall ablation (PWA) for PersAF patients.



▶ ADVANTAGE US IDE CLINICAL TRIAL DESIGN

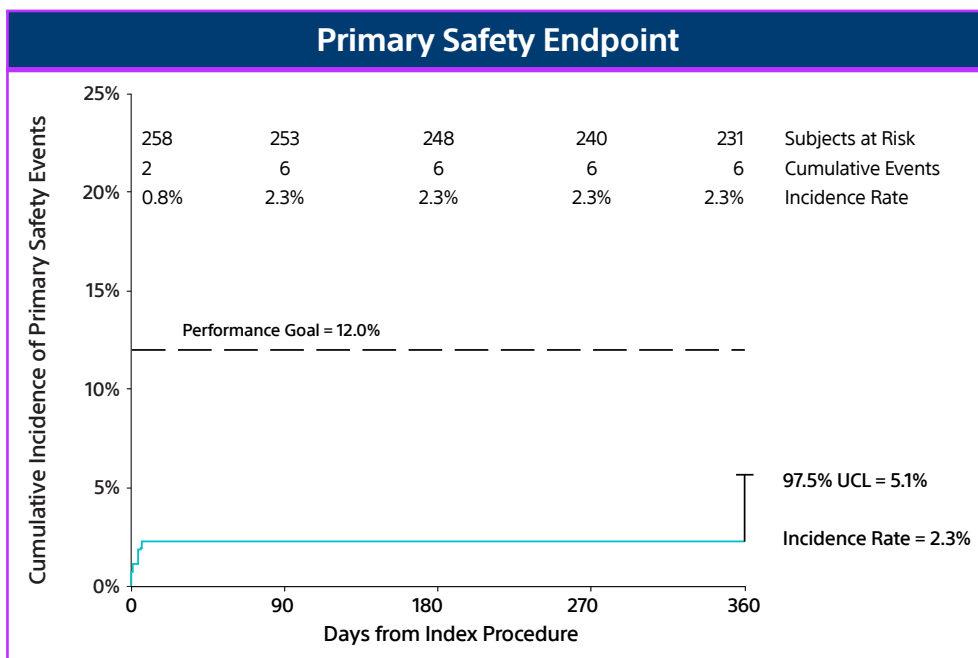
- ▶ ADVANTAGE AF included 43 US/OUS sites, 87 investigators (67% of the investigators had no prior FARAWAVE experience).
- ▶ 260 PersAF patients underwent PVI and PWA with post-blanking period monitoring of 2x monthly TTM and symptomatic and 24-hour Holter monitoring at 6 and 12 months and 12-lead ECGs at 3 and 12 months.

▶ SAFETY

Primary Safety Endpoint

A composite endpoint defined as serious adverse events related to either the use of an ablation catheter or the ablation procedure with onset within 7 days of the primary procedure and pulmonary vein stenosis or atrio-esophageal fistula out to 12 months.

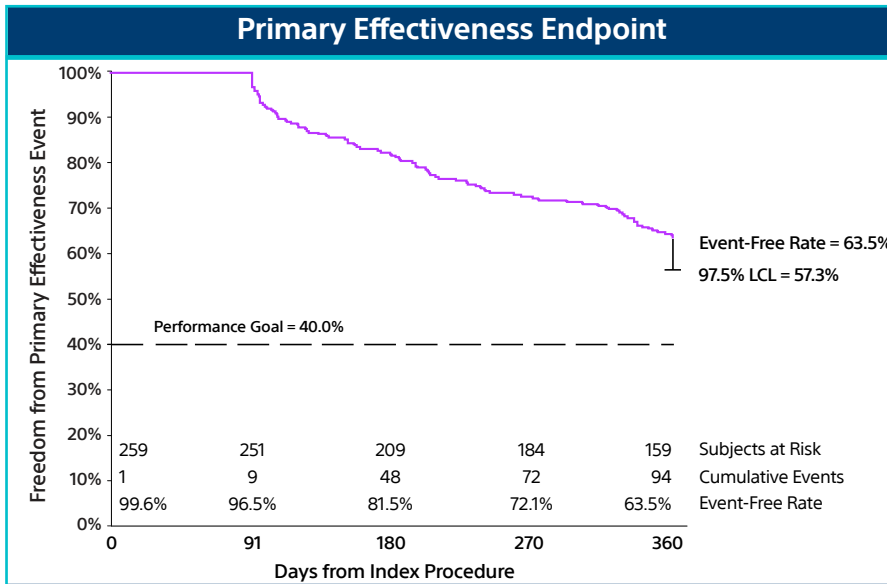
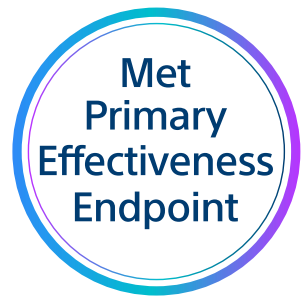
- ▶ At 12 months, the primary safety event rate was 2.3% [5.1% UCL] which met the 12.0% performance goal.
 - ▶ Events included pulmonary edema (n=4), coronary spasm (n=1), and pericarditis (n=1)
- ▶ There were no reports of stroke, PV stenosis, esophageal fistula, pericardial tamponade or major vascular access complications.
- ▶ Other safety events included transient phrenic paresis which resolved prior to discharge (n=1) and laboratory confirmed hemolysis (n=2).



EFFICACY

Primary Effectiveness Endpoint

A composite endpoint defined as acute and chronic ablation success through 12 months. After the 90-day blanking period, chronic success was defined as freedom from AF, AFL or AT, re-ablation, cardioversion and use of a new or escalated dose of Class I/III AADs or Amiodarone.

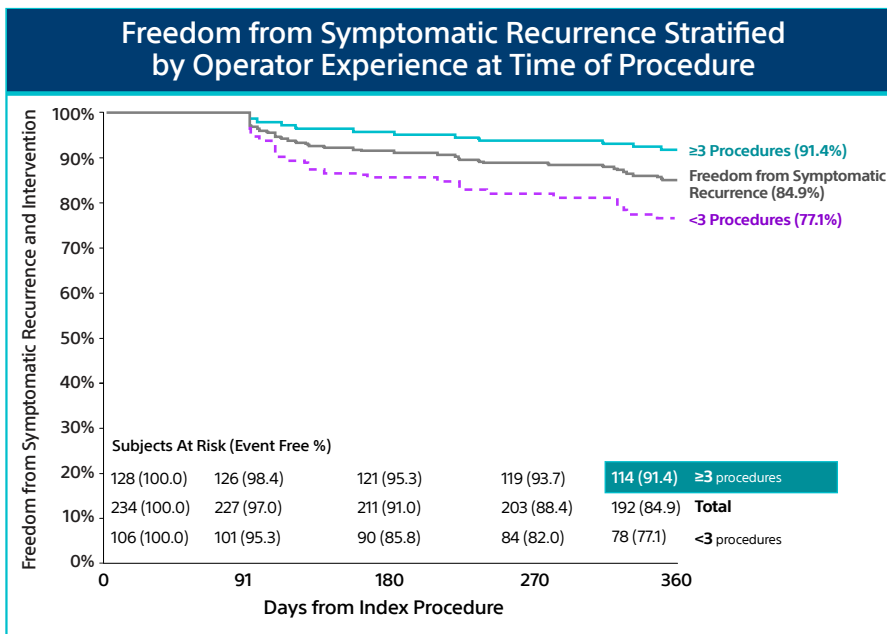


- At 12 months, the primary effectiveness rate was 63.5% [57.3% LCL] which met the acceptance criteria of 40.0%. The primary reason for treatment failure was atrial arrhythmia (AF/AFL/AT) recurrence (defined as ≥ 30 seconds detected on TTM or Holter or ≥ 10 seconds on 12-lead ECG) with the majority being AF (28.8%) followed by AFL (10.1%) and AT (6.3%).
- Repeat LA ablations were performed in 4.6% (12/260) patients. The PVI durability in re-ablated patients as determined by gap assessment was 84.4% of veins (68.8% of patients). The posterior wall durability was 68.8%.

Documented Symptomatic Atrial Arrhythmia Recurrence

Analysis showed that 55 out of 94 patients with treatment failures were asymptomatic, with 22 of those 55 only having one documented recurrence.

- At 12 months, the documented symptomatic recurrence-free rate of 85.3% was calculated based on freedom from cardioversion, re-ablation, escalated or new Class I/III AADs or documented symptomatic arrhythmia.



Operator Experience with FARAWAVE™

- Univariate analysis showed that symptomatic recurrence outcomes varied based on:
 - Patient sex, patient age, prior cardioversion and operator experience with FARAWAVE.
- When symptomatic recurrence was further stratified by FARAWAVE operator experience at time of procedure, the recurrence free rate was:
 - 91.4% with operators with ≥ 3 procedures vs 77.1% with operators with < 3 procedures
- The average procedure time was reduced by more than 10 minutes from 103 min to 91.2 min with increased operator experience (≥ 3 procedures).

Atrial Arrhythmia Burden

- TTM and Holter data was used to calculate the AA burden. Total AA burden was estimated by the greater of 2 values:
 - 1) % AA over total duration of Holter data or
 - 2) % of weeks of TTM with AA over total # of weeks with TTMs recorded
- Patients with an estimated AA burden below 0.1% (64.5%) experienced significantly fewer hospitalizations, less cardioversions and re-ablations, and significantly greater improvements in quality of life than patients with high burden ($\geq 10.0\%$).

► PROCEDURAL DETAILS

- Mapping was utilized in 75% of the procedures, and 50 patients (19.2%) underwent CTI ablation using a radiofrequency catheter.
- The majority of procedures (90%) utilized the smaller 31 mm FARAWAVE catheter.
- PVI took an average of 27 minutes with 45 applications, while PWA averaged 18 minutes with 32 applications.

| Procedural Characteristics | |
|-------------------------------------|--------------|
| Procedure Time (min)* | 103.0 ± 34.8 |
| LA Dwell Time (min)* | 58.5 ± 19.9 |
| Fluoroscopy Time (min) | 19.5 ± 13.1 |
| Pulmonary Vein Isolation Time (min) | 26.8 ± 15.0 |
| Posterior Wall Ablation Time (min) | 18.4 ± 15.0 |

| PFA Applications | |
|--------------------------|-------------|
| Pulmonary Vein Isolation | 45.1 ± 9.3 |
| Posterior Wall Ablation | 32.0 ± 12.7 |

*Includes a mandatory 20-minute post-PVI waiting period

► CONCLUSIONS

- Phase I of the ADVANTAGE AF US IDE examined PVI and PWA using FARAWAVE with 260 persistent AF patients across 43 US/OUS sites and 87 investigators.
- At 12 months, the primary safety endpoint was met with a low incidence of major safety events (2.3%), [5.1% UCL] which met the 12.0% performance goal, with no reported stroke, PV stenosis, esophageal fistula or major access complications.
- At 12 months, the primary effectiveness endpoint was met with a freedom from primary effectiveness event rate of 63.5% [57.3% LCL] which met the acceptance criteria of 40.0%. Only 4.6% of patients required LA re-ablation.
- At 12 months, 85.3% of patients were free from documented symptomatic AA recurrence, improving to 91.4% with operator experience (≥3 procedures).
- The average LA catheter dwell time was under one-hour, with the pulmonary veins and posterior wall ablation times averaging 27 and 18 minutes, respectively.



FARAPULSE™ Pulsed Field Ablation

- Indications, Safety, and Warnings

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Medical Professionals:
1.800.CARDIAC (227.3422)
Customer Service:
1.888.272.1001

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