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SINGLE SHOT CHAMPION

CLINICAL DATA SUMMARY

FARAPULSE™
Pulsed Field Ablation System

SINGLE SHOT CHAMPION Clinical Trial Results

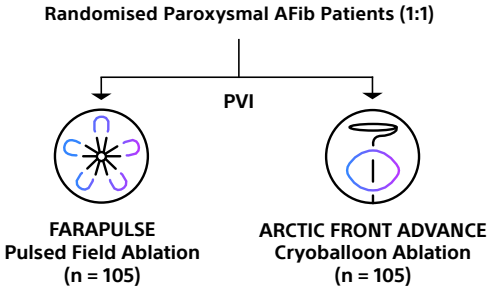
Reichlin, T *et al.*, 2025
Single Shot Pulmonary Vein Isolation: Comparison of Cryoballoon vs. Pulsed Field Ablation in Patients with Symptomatic Paroxysmal Atrial Fibrillation – A Multi-Centre Non-Inferiority Design Clinical Trial (The SINGLE SHOT CHAMPION Trial)
NCT05534581

OBJECTIVE

The Single Shot Champion trial was a randomised clinical trial that directly compared the safety and effectiveness of the FARAPULSE™ Pulsed Field Ablation System (PFA) versus Medtronic Arctic Front Advance™ Cryoballoon (CBA) to treat symptomatic, drug refractory paroxysmal atrial fibrillation (PAF) with continuous rhythm monitoring.

SINGLE SHOT CHAMPION TRIAL DESIGN

- Investigator-initiated, multi-centre, patient-blinded non-inferiority trial with blinded endpoint adjudication.
- 210 patients with symptomatic, drug refractory PAF were randomised 1:1 and underwent PVI with either PFA or CBA. Non-inferiority was assessed using a margin of 20% for the difference in cumulative incidence.
- Ablation effectiveness was assessed with continuous rhythm monitoring (Medtronic Reveal LINQ™).
- No repeat ablations were allowed during the 3-month blanking period and AADs were discontinued after the blanking period.



SAFETY

The primary safety endpoint was a composite of cardiac tamponade requiring pericardiocentesis, persistent phrenic nerve palsy lasting > 24 hours, serious vascular complications requiring intervention, stroke/transient ischemic attack, atria-esophageal fistula, or death within 30 days after ablation.

- The primary safety endpoint occurred in 1 (1.0%) FARAPULSE patient (ischemic stroke/TIA) and in 2 (1.9%) Arctic Front patients (cardiac tamponade requiring drainage).

THE OVERALL MAJOR ADVERSE EVENT RATES WERE **LOW**

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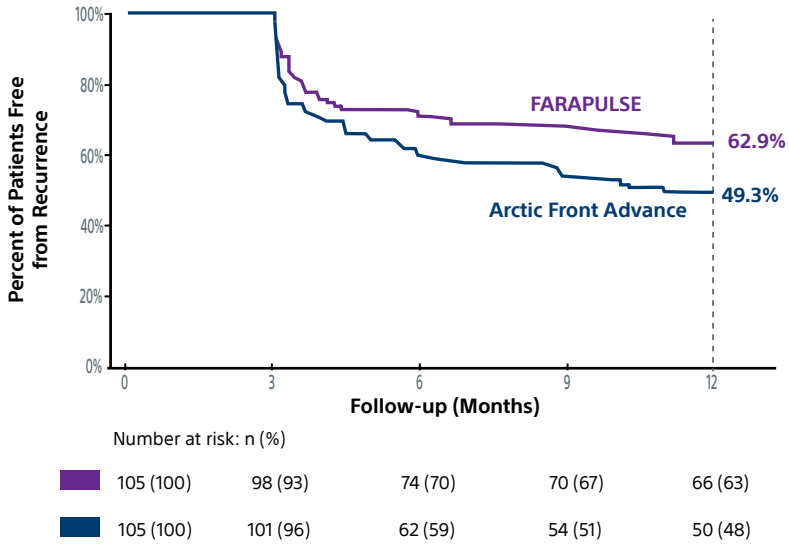
EFFICACY

Primary Efficacy Endpoint

The primary endpoint was the first recurrence of atrial tachyarrhythmia (AF/AFL/AT), (AA recurrence) after the blanking period (days 91-365) lasting > 30 seconds. Non-inferiority was assessed using a margin of 20% for the difference in cumulative incidence.

- At 12 months, FARAPULSE™ demonstrated superiority in freedom from AA recurrence (62.9%) compared to Arctic Front Advance™ (49.4%), ($p < 0.001$ for non-inferiority, $p = 0.046$ for superiority).



Number at risk: n (%)

FARAPULSE	105 (100)	98 (93)	74 (70)	70 (67)	66 (63)
Arctic Front Advance	105 (100)	101 (96)	62 (59)	54 (51)	50 (48)

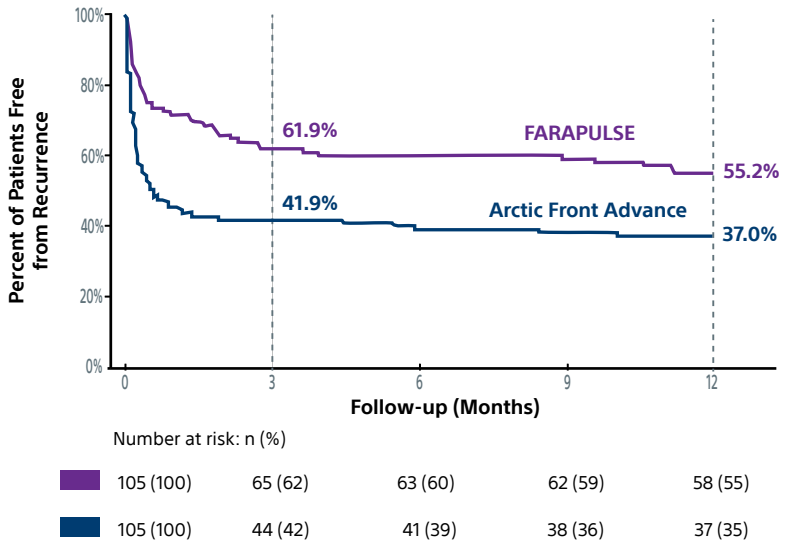
FARAPULSE
SIGNIFICANTLY REDUCED AA RECURRENCE

FARAPULSE treatment resulted in a 13.6% reduction in AA recurrence ($p = 0.046$) at 12 months vs. Arctic Front Advance

Secondary Efficacy Endpoints

Additional secondary endpoints included the first recurrence of atrial tachyarrhythmia (AF/AFL/AT) during days 1-90 and days 1-365; atrial arrhythmia burden (% time in atrial arrhythmia) during days 1-90 and days 91-365.

- There was a 20% reduction in atrial arrhythmia recurrence during the 3-month blanking period (days 1-90). The recurrence-free rate for FARAPULSE was 61.9% and 41.9% for Arctic Front Advance (95% CI, -33.2 to -6.8%).
- At 12 months, inclusive of the blanking period (days 1-365), there was an 18.2% reduction in atrial arrhythmia recurrence. The recurrence-free rate for FARAPULSE was 55.2% and 37.0% for Arctic Front Advance (95% CI< -31.5% to -4.9%).



Number at risk: n (%)

FARAPULSE	105 (100)	65 (62)	63 (60)	62 (59)	58 (55)
Arctic Front Advance	105 (100)	44 (42)	41 (39)	38 (36)	37 (35)

FARAPULSE showed an
EVEN GREATER REDUCTION
in AA recurrence
vs. Arctic Front Advance
DURING THE BLANKING PERIOD

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ADDITIONAL ENDPOINTS

Clinical Interventions and Quality of Life (QoL)

- There were no significant differences in the number of hospitalisations or cardioversions for AA recurrence or repeat ablations between patients treated with PFA or CBA.
- There was no significant health-related QoL difference at 3 and 12 months between patients treated with FARAPULSE™ vs. Arctic Front Advance™.

PROCEDURAL CHARACTERISTICS

- The FARAPULSE ablation procedure time (54.8 ± 22.7 min) and catheter LA dwell time (36.1 ± 16.6 min) were 18 minutes and 15 minutes shorter than Arctic Front Advance (73.2 ± 26.7 min and 51.5 ± 20.0 min, respectively).
- Troponin levels were significantly higher in the FARAPULSE group signaling that FARAWAVE created larger, possibly more antral lesions vs. Arctic Front (1920 ± 954 vs. 1114 ± 419; difference 823; 95% CI 612-1034).

	FARAPULSE (n = 105)	Arctic Front Advance (n = 105)
Procedure time (min)	54.8 ± 22.7	73.2 ± 26.7
LA dwell time (min)	36.1 ± 16.6	51.5 ± 20.0
Fluoroscopy time (min)	14.6 ± 7.2	15.1 ± 7.9
Increase in hsTroponin on day 1 (ng/L)	1920 ± 954	1114 ± 419
Total # of applications	36 (32-40)	5 (5-7)
CTI ablation (%)	14 (13.3)	12 (11.4)

CONCLUSIONS

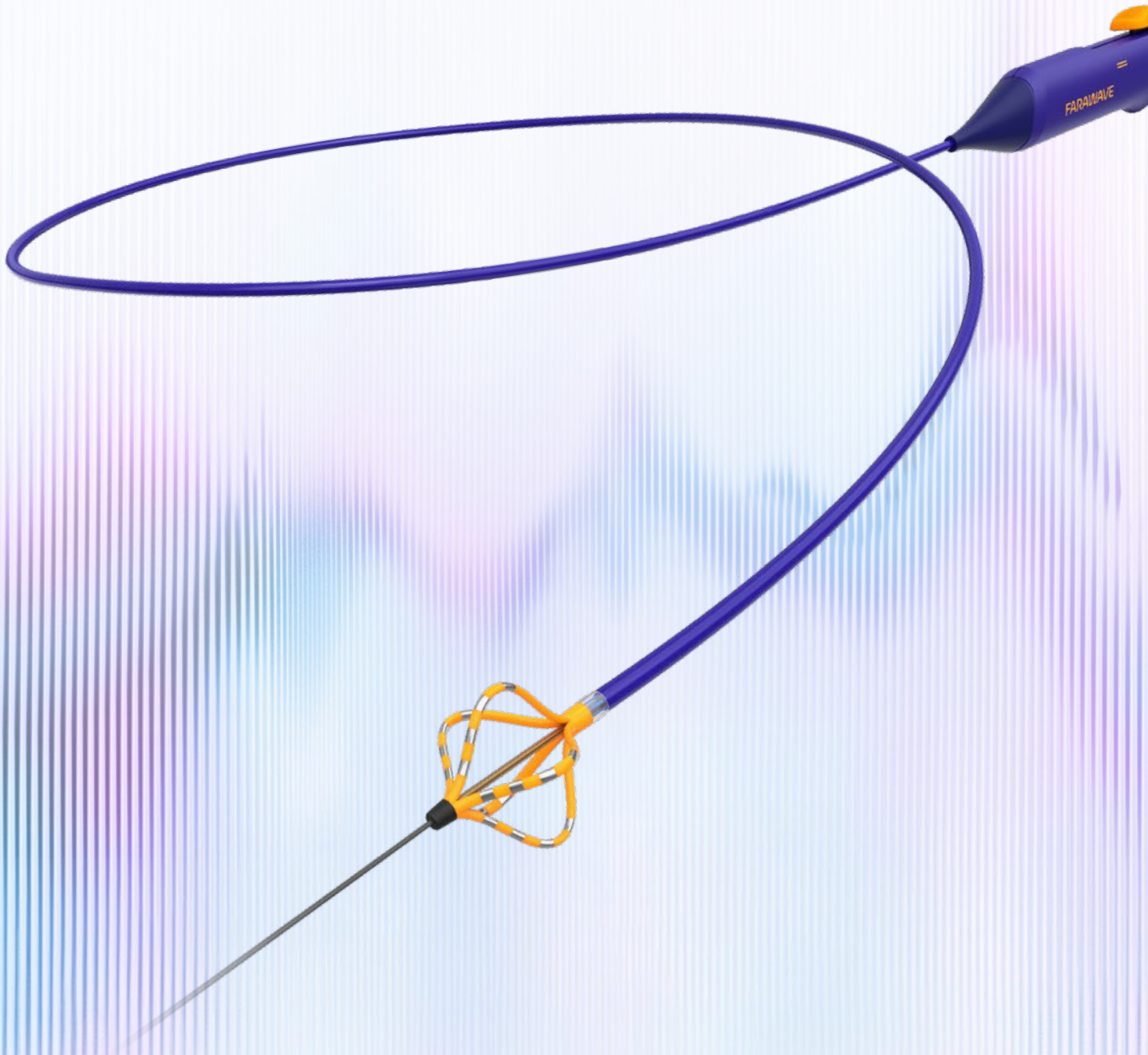
- Single Shot Champion was a randomised study where patients treated with FARAPULSE or Arctic Front Advance were monitored with a continuous monitoring device eliminating sampling error, giving a more comprehensive assessment of ablation efficacy.
- This study also had a stringent primary efficacy endpoint of first recurrence of atrial arrhythmia after the blanking period lasting > 30 seconds.
- The SINGLE SHOT CHAMPION trial, using a stringent monitoring strategy and endpoint definition, demonstrated that significantly more patients treated with FARAPULSE (62.9%) were recurrence-free, compared to those treated with Arctic Front Advance (49.3%), (p = 0.046), resulting in a 13.6% reduction in AA recurrence at 12 months.
- Additionally, there was a significant reduction in AA recurrence during the blanking period in patients treated with FARAPULSE (recurrence-free rate 61.9%) vs. Arctic Front Advance (recurrence-free rate 41.9%), (95% CI, -33.2 to -6.8%).
- When the blanking period was included, there was an 18.2% reduction in AA recurrence of FARAPULSE vs. Arctic Front Advance at 12 months (95% CI, -31.5% to -4.9%).
- There were no significant differences in the primary safety endpoint, clinical interventions or QoL between patients treated with FARAPULSE or Arctic Front Advance.
- FARAPULSE procedures were 18 minutes shorter on average than Arctic Front Advance and Troponin levels post-ablation were significantly higher.

FARAPULSE vs. ARCTIC FRONT ADVANCE

- **FARAPULSE SIGNIFICANTLY REDUCED AA RECURRENCE:**
  13.6% post-blanking (day 91-365)
  – 20% during the blanking period (day 1-90)
  – 18.2% throughout the full 12 months (day 1-365)
- There was **no significant difference** in major adverse event rates, clinical interventions or QoL.

SINGLE SHOT CHAMPION was supported by an unrestricted research grant from BSC.

Reference:
Reichlin, Tobias, *et al.* (in press). "Pulsed Field or Cryoballoon Ablation for Paroxysmal Atrial Fibrillation." *New England Journal of Medicine*.



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EP-2162603-AA

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