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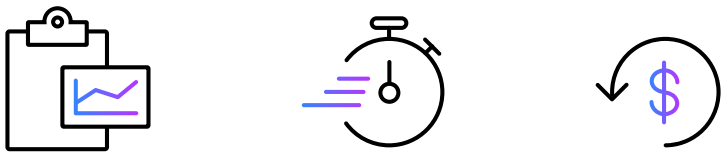
Pulsed Electric Field versus Cryoballoon to Treat Paroxysmal Atrial Fibrillation (PERFECT-PAF) Randomised Trial: A Periprocedural Clinical and Cost Analysis

Chierchia, et al. ESC Sept 2, 2024

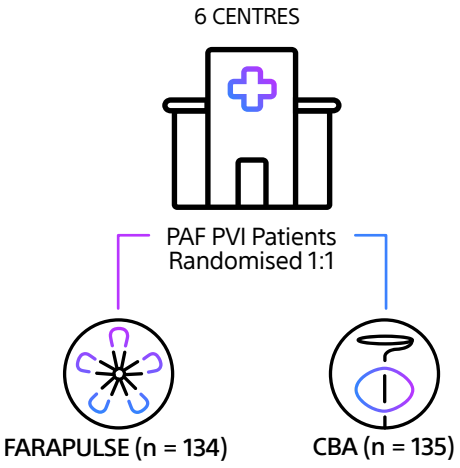
OBJECTIVE

- The PERFECT-PAF trial was designed to compare the safety, efficacy and procedural costs of FARAPULSE™ Pulsed Field Ablation versus cryoballoon ablation (CBA) for pulmonary vein isolation in paroxysmal atrial fibrillation (PAF) patients.



METHODS

- The clinical safety and economic value of FARAPULSE versus CBA was assessed in a multicentre, randomised, controlled, non-inferiority trial.
- Data was collected across 6 European centres between October 2023 and May 2024.
- The primary safety endpoint included procedure and device related adverse events (AEs) within 7 days post-ablation.
- Procedural parameters [procedure times, anesthesia, complications] were collected on FARAPULSE (n = 134) and CBA (n = 135) patients in addition to clinical management and heath care utilisation data ≤30 post procedure [length of stay, ICU admission, emergency (ED) and outpatient visits, and rehospitalisations].
- Total costs were calculated based on the cost of the procedure, anaesthesia, re-hospitalisation, ICU, ED and outpatient visit costs.



RESULTS

SAFETY

- The incidence of adverse events both during the procedure and within a 7-day period was significantly reduced with FARAPULSE, at 0.7%, compared to CBA's 8.1% (p = 0.0053), and 0.7% against 5.9% (p = 0.036) respectively.

7-day Adverse Event Rate

0.7%* vs. **5.9%**

FARAPULSE
*significantly lower p = 0.036

CBA

	PFA (n = 134)	CRYO (n = 135)	p-value
Overall periprocedural adverse events, n (%)	1 (0.7%)	11 (8.1%)	0.0053
Major adverse events, n (%)	1 (0.7%)	4 (3.0%)	0.3703
Femoral artery pseudoaneurysm*	1 (0.7%)	1 (0.7%)	1.000
Tamponade requiring drainage	0 (0.0%)	1 (0.7%)	1.000
Persistent phrenic nerve injury	0 (0.0%)	2 (1.5%)	0.4981
7-day adverse event rate, n (%)	1 (0.7%)	8 (5.9%)	0.0360

*requiring surgery

PROCEDURAL CHARACTERISTICS

- FARAPULSE had significantly lower ($p < 0.001$) room time, procedure time, LA dwell time and fluoroscopy times.

EFFICIENCY

	PFA	CBA	Time Savings
Room Time	77 ± 14	97 ± 20	20 min
Procedure Time	53 ± 12	69 ± 18	17 min
LA Dwell Time	28 ± 8	48 ± 15	20 min
Fluoroscopy	12 ± 5	15 ± 6	3 min

Mean ± SD

More predictable** procedures with **FARAPULSE**

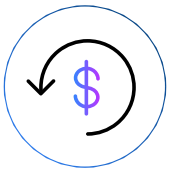
**Lower standard deviations – F-statistic analysis

COST PER PATIENT

- The total costs per patient* within 30-days were 13.7% lower with FARAPULSE.

  *Product material is not included in the cost

- The driver of the cost savings with FARAPULSE was the significantly shorter procedure times ($p < 0.001$). Length of hospital stay, ICU, ED usage, outpatient visits, and re-hospitalisations within 30-days of the intervention did not differ between FARAPULSE and CBA.



COST

13.7% lower with **FARAPULSE** due to lab efficiency

CONCLUSIONS

- FARAPULSE had fewer overall peri-procedural and 7-day adverse event rates compared to CBA in PAF patients.
- FARAPULSE procedure times were shorter and more predictable resulting in an overall lower cost per patient at 30-days due to lab efficiency.
- Long-term follow-up data will be analysed to further investigate the potential clinical and economic impact of FARAPULSE vs. CBA.

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