



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

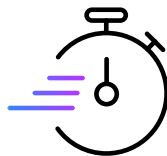
Chierchia, et al. ESC Sept 2, 2024

OBJECTIVE

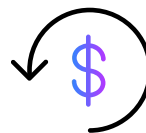
- The PERFECT-PAF trial was designed to compare the safety, efficacy and procedural costs of FARAPULSE™ Pulsed Field Ablation versus cryoballoon ablation (CBA) for pulmonary vein isolation in paroxysmal atrial fibrillation (PAF) patients.



SAFETY



EFFICIENCY

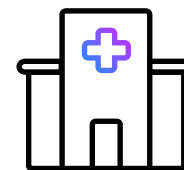


COST

METHODS

- The clinical safety and economic value of FARAPULSE versus CBA was assessed in a multicenter, randomized, controlled, non-inferiority trial.
- Data was collected across 6 European centers 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 health care utilization data ≤30 post procedure [length of stay, ICU admission, emergency (ED) and outpatient visits, and rehospitalizations].
- Total costs were calculated based on the cost of the procedure, anesthesia, re-hospitalization, ICU, ED and outpatient visit costs.

6 CENTERS



PAF PVI Patients
Randomized 1:1



FARAPULSE (n=134)



CBA (n=135)

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.



SAFETY

7-day Adverse
Event Rate

0.7%* vs 5.9%
FARAPULSE CBA
*significantly lower $p=0.036$

	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

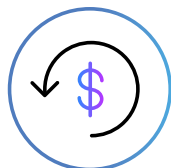
Mean ± SD

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:
 - ▶ FARAPULSE: 2,286€ (95% CI: 1,919.6€-2,076.1€)
 - ▶ CBA: 1,973€ (95% CI: 2,163.6€-2,418.6€)
- ▶ 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-hospitalizations 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 analyzed to further investigate the potential clinical and economic impact of FARAPULSE vs CBA.



[FARAPULSE™ Pulsed Field Ablation System
Indications, Safety, and Warnings](#)

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