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FARAPULSE™
Pulsed Field Ablation System

MANIFEST-17K
Multicentre Registry

OBJECTIVE

To assess if FARAPULSE™ Pulsed Field Ablation is:

- Tissue-selective and spares the esophagus, pulmonary veins and phrenic nerve
- Associated with any unusual adverse events that would only be apparent after thousands of ablation procedures

STUDY DESIGN

The data expands beyond the previously published MANIFEST-PF registry to include a total of 17,642 new patients treated over a 2-year window (3/2021-3/2023).

106
Centres

91.4%
of all commercial centres using FARAPULSE

413
Operators

17,642
Patients
(35% PersAF)

SAFETY

<1%
Major Adverse Event Rate*

The major adverse event rate was 0.98% with the most common complication being pericardial tamponade (0.36%).

0
Reports

There were no reports of oesophageal fistula or dysmotility, pulmonary vein stenosis or persistent phrenic nerve injury.

*Due to the retrospective nature of the registry, the adverse event rate was not reported at a pre-specified timepoint.

SAFETY

Low rates of PF energy specific AEs

3 adverse events classified as related to pulsed field energy delivery:

- Transient phrenic nerve paresis (0.06%)
- Coronary spasm (0.14%)
- Hemolysis/renal failure (0.03%)

The remaining events (mortality, stroke, pericardial tamponade, TIA, and vascular access complications) were classified as non-PF energy related.

Minor Adverse Event Rate

The minor adverse event rate was 3.21% with the most common complication being vascular access site complication (2.2%).

SAFETY

Pericardial tamponade	Pericardial tamponade **significantly improved** in MANIFEST-17K (0.36%) vs MANIFEST-PF[1] (0.97%) (p<0.05)
Stroke	The stroke rate **improved** from 0.39% in MANIFEST-PF[1] to 0.12% in MANIFEST-17K
Coronary Spasm	The rate of coronary spasm was low (0.14%) with a majority (88%) being proximity related occurring with off-label use of the catheter during MI or CTI ablation There were 3 (0.02%) reports of generalised spasm which is **lower than the (RFA/CBA) rate** of 0.19%
Hemolysis	Hemolysis resulting in acute renal failure was rare (<1 in 1000) and likely manageable with hydration and being aware of number of lesions applied

LEARNING CURVE

	MANIFEST-PF[1] 24 Sites (n=1,758)	MANIFEST-17K 106 Sites (n=17,642)
Pericardial Tamponade*	0.97%	0.36%
Stroke	0.39%	0.12%
Transient Phrenic Nerve Paresis	0.46%	0.06%
Minor Vascular Complications*	3.28%	2.20%

*Significant difference (p<0.05)

Comparing the MANIFEST-PF[1] registry of the first 1,758 patients treated with FARAPULSE™ to the MANIFEST-17K registry, there was:

- A **significant improvement** in rates of pericardial tamponade and minor vascular complications
- **Improvements** in stroke and transient phrenic nerve paresis rates

Vascular Ultrasound **significantly reduced** the number of vascular complications requiring intervention (p=0.046).

CONCLUSION

- This data expands beyond the initial 24 centres involved in the MANIFEST registry, showing that the low rate of safety events continues as the technology is adopted by additional centres
- The **major adverse event rate was <1% in 17,642 patients** with no reports of oesophageal fistula or dysmotility, pulmonary vein stenosis or persistent phrenic nerve injury
- Evidence of learning curve at both the physician/site level was seen by:
  - The **significant decrease** in rates of pericardial tamponade and minor vascular complications
  - **Improvements** in stroke and transient phrenic nerve paresis rates from the initial MANIFEST-PF[2] registry to MANIFEST-17K
- The **FARAPULSE™ safety profile** demonstrated in this study should not be applied to other PFA systems

1. Ekanem, Emmanuel, *et al.* "Multi-national survey on the methods, efficacy, and safety on the post-approval clinical use of pulsed field ablation (MANIFEST-PF)." Europace 24.8 (2022): 1256-1266.

2. Reddy & Ekanem, *et al.* Multi-National Survey on the Safety of the Post-Approval Clinical Use of Pulsed Field Ablation in 17,000+ Patients (MANIFEST-17K). AHA 2023.

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