EU-PORIA multicenter registry
Schmidt B, Bordignon S, Neven K, et al.
Europace. 2023;25:euad185. https://doi.org/10.1093/europace/euad185

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EUropean real-world outcomes with Pulsed field ablatiOn in patients with symptomatic atRIAl fibrillation: lessons from the multi-center EU-PORIA registry

Objective

- To describe real-world adoption, workflow, acute and long-term outcomes after pulsed field ablation (PFA) in an all-comer atrial fibrillation (AF) patient population in high-volume European centers, inclusive of learning curve

EU-PORIA registry design

- 7 high-volume EU centers (400-1400 AF ablations/year/center)
- 42 operators characterized by 1) number of years of AF ablation experience and 2) previous primary ablation modality
- All **FARAPULSE™ PFA** cases performed (inclusive of learning curve) between 3/25/21 and 5/31/22. Procedures and patient follow-up were based on each center's standard of care
- Endpoints were:
  - Procedural safety
  - One-year freedom from atrial arrhythmias
  - Learning curve

Baseline and procedural characteristics

- 1233 consecutive AF patients treated with the **FARAPULSE™ PFA System** were included
- 39% female, 60% paroxysmal AF, and 55% did not fail Class I / III anti-arrhythmic drugs prior to ablation
- 96% de novo ablations, 80% done under deep sedation, the 31 mm device was used in 77% of the procedures, 33% were 3D mapped, with 14% having ablation beyond the PVs (off-label)
- The median and [interquartile range] skin-to-skin procedure time was 58 [40-87] minutes

Safety

- The major complication rate was 1.7% (1.1% pericardial tamponade, 0.41% stroke, and 0.16% TIA)
- The minor complication rate was 1.9% with the most common complication being vascular access site complication (0.97%)
- There was one fatal stroke and one patient who suffered from phrenic nerve dysfunction who did not recover by the end of follow-up

Efficacy

- The Kaplan-Meier estimate of AF/AT-free survival at a median follow-up of 365 [323-386] days can be found in **Table 1**
- Outcomes based on operator experience showed significantly longer fluoroscopy time for the three operators with <2 years' experience, but there was no significant difference in procedure times or complication rates
- The previous primary ablation modality analysis showed that RF users had longer procedure times than CB or both modality users, but there was no significant difference in overall complication rate

Table 1: Freedom from AF/AT* and Vein Reconnection rate

One-Year Freedom from AF/AT	74% [95% CI, 71%-76%], full cohort 80% [95% CI, 77%-83%], paroxysmal AF 66% [95% CI, 61%-71%], persistent AF 67% [95% CI, 48%-82%], LS persistent AF
One-Year Freedom from AF/AT by Operator AF Ablation Experience	65% [95% CI, 31%-88%], <2 years of experience 72% [95% CI, 66%-77%], 2-5 years 76% [95% CI, 73%-79%], >5 years
Freedom from AF/AT Recurrence by Previous Primary Ablation Modality	75% [95% CI, 70%-80%], Radiofrequency (RF) 72% [95% CI, 65%-78%], Cryoablation (cryo) 75% [95% CI, 72%-79%], Both RF and cryo
Vein Reconnection Rate during Repeat Ablation	149/1233 repeat ablations at 226 [157-290] days Of the 584 veins that were remapped, 72% (418/584) were durably isolated

Table 1. *Kaplan-Meier estimate with a median follow-up of 365 [323-386] days

Conclusions

- This registry demonstrated consistent, short procedure times with a median of 58 minutes despite a large number of operators with varied experience and workflow
- There was a low rate of safety events (3.6%) and promising one-year efficacy rate (74%) in a large spectrum of AF patients
- Operator experience and previous primary ablation modality did not have an effect on the one-year AF/AT recurrence rates showing a rapid adoption of the technology by new operators and prior RF and cryo users
- A small subset of 149 patients (12%) returned for repeat ablation during follow-up. In these patients, EAM revealed a high rate of PVI with 72% of pulmonary veins being durably isolated

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