



First in Human Clinical Use of a Novel Pulsed Field Ablation System with a Conformable Ablation Catheter for Ablation of Atrial Fibrillation: Nano-AF Clinical Registry

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Background

Pulsed-field ablation is a promising method of treating atrial fibrillation (AF) due to its improved safety compared with thermal ablation.^{1,2}

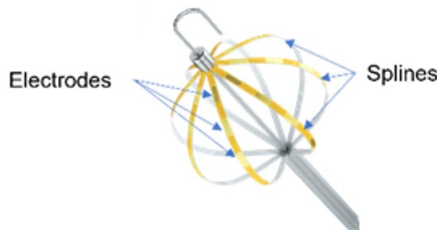
Objective(s)

To demonstrate the safety and efficacy of a novel conformable basket ablation catheter and PFA waveform (biphasic, bipolar, 750V) in a first-in-human feasibility trial (Nano-AF).

Method

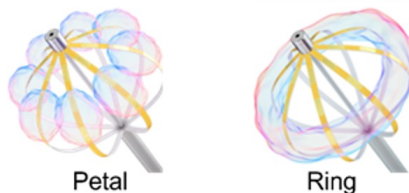
- Eleven patients with paroxysmal AF were enrolled from five hospitals. General anesthesia or conscious sedation was administered.
- The 12-Fr PFBasket Catheter (EnChannel Medical) was introduced and localized in LA. PFBasket has eight splines, each with three flat electrodes delivering unidirectional energy to the tissue.
- The catheter diameter can be adjustable up to 32 mm, accommodating pulmonary vein (PV) anatomies of varying sizes.
- PFA was delivered at PV ostia (Figure) between electrodes on the spline (petal) or across electrodes on the splines (ring).
- Pre- and post-ablation voltage maps were acquired to confirm PV isolation. Patients will be remapped at 3 months and followed up at 12 months.

Results



- Patients were comprised of 45% male, 63.0 ± 8.5 years, and the time since diagnosis ranges from 1-84 months.
- Acute PV isolation was confirmed in all patients (100%).
- The average duration of PFA applications was 4.6, 4.7, 5.1, and 5.9 sec for left superior PV, left Inferior PV, right superior PV, and right inferior PV, respectively.
- The total ablation time was 15.1 ± 4.4 min, and the total procedure time was 107.0 ± 17.0 min.
- No procedural-related adverse events were reported.

Energy delivery configurations



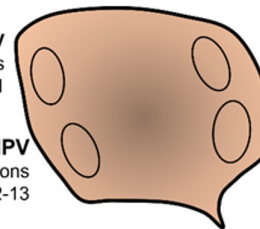
Average PFA applications in each vein

RSPV
Mean: 5.1 applications
Range: 2-11

RIPV
Mean: 5.9 applications
Range: 2-13

LSPV
Mean: 4.6 applications
Range: 2-11

LIPV
Mean: 4.7 applications
Range: 2-8



Conclusion

- The conformable PFBasket catheter with PFA waveform successfully and safely achieved acute PV isolation.
- Additional patient enrollments and long-term follow-up are required to fully test this PFA system's safety and effectiveness.

Disclosures/References

- Verma et al. Pulsed Field Ablation for the Treatment of Atrial Fibrillation: PULSED AF Pivotal Trial. Circulation 2023
- Reddy et al., Pulsed Field or Conventional Thermal Ablation for Paroxysmal Atrial Fibrillation, NEJM, 2023