

## First-in-Human Experience and Acute Procedural Outcomes Using a Novel Conformable Pulsed Field Ablation Balloon Catheter for Pulmonary Vein Isolation in Atrial Fibrillation

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#### Background

- Thermal balloon catheters have improved the efficiency of pulmonary vein isolation (PVI) in atrial fibrillation (AF).
- Reports assessing additional safety and effectiveness of pulsed field ablation (PFA) balloon catheters for PVI are limited.

#### Objective(s)

Assess the 7-day safety and effectiveness of a conformable PFA balloon catheter for PVI in patients with AF.



- This single-center, single-arm, first-in-human trial used the PFBalloon catheter (28mm, 24 electrodes, EnChannel Medical) with a novel waveform (Biphasic, Bipolar, 750 V) to treat paroxysmal or persistent AF patients under general anesthesia.
- The balloon was inflated with 10:1 saline/contrast mix. Deployment-volume was adjusted to achieve a ball-shape, for performing wide antral catheter ablation (WACA), and a pear-shape, for ablating PV antra, ensuring optimal tissue contact (Panels A, B).
- PFA was delivered as a global electric field around the distal tropical-zone of the balloon (Panels A, C). Acute success was defined as absence of PV potentials and entrance/exit conduction block of all PVs upon completion of ablation.





Each application = 4 biphasic, bipolar, 0.4ms, 750V pulses. Catheter rotated to 4 positions at each pulmonary vein to complete circumferential isolation, with 8 applications/vein.

#### Results

Acute electrical isolation was achieved in 100% of pulmonary veins (n=155) in 39 patients (34 paroxysmal and 5 persistent AF) with a mean of  $33.9 \pm 8.7$  applications/patient.

Skin-to-skin procedure time was 161.5  $\pm$  57.4 minutes, left atrial dwell-time was 66.6  $\pm$  33.8 minutes, and fluoroscopy-time was 18.3  $\pm$  2.8 minutes.

No device-related serious complications occurred, such as cardiac tamponade, stroke, phrenic nerve injury, esophageal injury, hemolysis induced acute kidney injury, or death.

Characteristics	Results
Paroxysmal AF, n	34
Persistent AF, n	5
Acute PVI success, n(%)	155 (100%)
Applications per patient, n	33.9 ± 8.7
Skin-to-skin procedure time (minutes)	161.5 ± 57.4
Left atrial dwell time (minutes)	66.6 ± 33.8
Fluoroscopy time (minutes)	18.3 ± 2.8

#### Conclusion

This first-in-human clinical study demonstrates that the novel, conformable PFBalloon catheter and waveform safely and effectively achieved 100% acute PVI in patients with AF, with no serious adverse events.

### **Disclosures / Acknowledgments**

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