

Outcome of Remapping Three Months after Pulmonary Vein Isolation Using a Novel Conformable Pulsed Field Ablation Balloon Catheter in Patients with Paroxysmal Atrial Fibrillation

Hanxiong Liu , Shiqiang Xiong , Yan Luo , Guoshu Yang , Duan Luo , Zhen Zhang The Third People's Hospital of Chengdu, Affiliated Hospital of Southwest Jiaotong University, Chengdu Cardiovascular Disease Research Institute, China



Background

- Opportunity exists to improve pulsed-field ablation (PFA) workflow, safety, and effectiveness of pulmonary vein isolation (PVI).
- Data on safety and effectiveness of PFA balloon catheters for PVI in patients with paroxysmal atrial fibrillation (PAF) are limited.

Objective(s)

Assess 3-month safety and effectiveness of a conformable PFA balloon catheter for PVI in patients with PAF.



- Thirty-four (34) patients with PAF were treated under general anesthesia using the PFBalloon catheter (28 mm, EnChannel Medical).
- 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).
- Patients were monitored continuously with a wireless 12-lead ECG garment during the 3-month blanking period, and Class I/III antiarrhythmic drugs were permitted.
- · Remapping was performed at 3 months post-ablation.
- Primary endpoints were safety and PVI durability, while the secondary endpoint was freedom from atrial arrhythmias > 30 s during blanking.



| Characteristics | Results |
|---------------------------------------|---------------|
| Acute PVI success, n (%) | 135 (100%) |
| Applications per vein, n | 7.9 ± 1.7 |
| Skin-to-skin procedure time (minutes) | 141.3 ± 31.3 |
| Left atrial dwell time (minutes) | 53.1 ± 20.1 |
| PVI durability per vein, n (%) | 88/94 (93.6%) |
| PVI durability per patient, n (%) | 18/28 (78.3%) |
| Serious device-related complications | 0 |

Conclusion

The conformal PFBalloon catheter demonstrated safety, effectiveness, and efficiency in PVI for PAF patients, with durable lesions confirmed upon remapping.

Results

- Acute PVI was achieved in 100% of PVs with 7.9 ± 1.7 PFA applications/PV.
- Procedure times, including overall procedure and catheter dwell were 141.3 \pm 31.3 and 53.1 \pm 20.1 minutes, respectively.
- All patients maintained sinus rhythm and experienced no atrial arrhythmia > 30 s during the blanking period.
- Of the 28 patients who have been remapped, PVI durability was 78.3% (18/23) per patient and 93.6% (88/94) per vein.
- No serious device-related complications occurred, such as PV stenosis, tamponade, stroke, phrenic nerve or esophageal injury, hemolysis induced acute kidney injury, or death.

Disclosures / Acknowledgments

The authors thank the patients participated in this study and the team from EnChannel.





Ablation