Real-world multicenter registry on a novel focal lattice tip catheter toggling between pulsed electric field and radiofrequency for atrial tachyarrhythmia ablation

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Background: Pulsed field ablation (PFA) has emerged as a novel non-thermal energy source for cardiac tissue ablation. A novel focal 9mm lattice tip catheter, namely Sphere-9 (Affera Inc), has recently received regulatory approval; the technology is part of a technology that allows the delivery of either pulsed electric field or radiofrequency energy and incorporates a proprietary 3D electroanatomical mapping system.

Purpose: To describe the first real-world, multicenter experience with the AfferaTM system.

Methods: Consecutive AF patients undergoing first-time or redo atrial tachyarrhythmia ablation with the AfferaTM system in two different centres between August and November 2023 were prospectively enrolled. PFA was always used to ablate the posterior left atrium, whereas anterior applications were performed using either radiofrequency energy (RF/PF strategy) or PFA (PF/PF strategy) based on operator’s discretion. Data on first-pass pulmonary vein isolation (PVI) and posterior wall isolation (PWI), as well as success rate of extrapulmonary ablation were reported. Primary safety endpoint included any technology-related perioperative complications.

Results: 46 patients (mean age: 67±10; 41.3% males, 60.8% non-paroxysmal AF) were included. 5 (10.8%) patients were in atrial flutter (AFlu) at the beginning of the procedure, whereas AF was the rhythm at presentation in 19 (41.3%) others.

First-time PVI was performed in 37 (80.4%) patients, 68.4% of whom received concomitant PWI. PVI was performed with PFA-only in 27% of them. First-pass isolation was achieved in 97.3% and 100% of PVI and PWI cases, respectively. Additional lesions included an anterior or posterior mitral line (6 and 15 patients), CTI (4 patients) or substrate ablation in 3 patients. Evidence of first-pass line block was documented in 96.4% of patients.

The remaining 9 (19.6%) patients had already undergone a previous ablation; remapping showed 27.7% of PVs requiring reisolation. PWI was performed in 88.9% of them, for the first time (75%) or due to reconnection (25%). Additional lesions included an anterior or posterior mitral line (3 and 3 patients) or CTI in 2 patients. Evidence of first-pass line block was documented in 100% of patients.

In 3 AFlu patients, the arrhythmia was mapped and termination was achieved while performing an AML (2 patients) and CTI (1 patient). Procedural duration was 96.5±15.6 min for first time and 97.8±12.6 min for redo procedures. Mean left atrial dwelling and fluoroscopy times were 75.4±17.6 min and 7.36±2.1 min, respectively.

No technology-related complications were documented.

Conclusions: AF ablation with the focal 9-mm lattice tip catheter Sphere-9 confirmed high efficacy and safety in a real-world population.