FIRST-IN-HUMAN CLINICAL EXPERIENCE OF A NOVEL CONFORMABLE “SINGLE-SHOT” PULSED FIELD ABLATION CATHETER FOR PULMONARY VEIN ISOLATION

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Background: Pulsed field ablation (PFA) has safety and procedural workflow advantages over conventional thermal ablation. Most “single-shot” PFA catheters are either not linked to mapping systems, require serial re-positioning or cannot easily accommodate varying PV anatomies. Recently, a novel 8-Fr single-shot large lattice PFA catheter that can conform to anatomic changes has been developed.

Objective: To assess the acute safety and efficacy of PV isolation (PVI) using this single-shot PFA catheter.

Methods: The 8Fr PFA catheter (SpherePVI, Affera Inc) has a large compressible/conformable lattice framework (expandable up to 34 mm diameter), and consists of 6 sections that are independently and sequentially energized for ablation. Under general anesthesia and after ICE-guided transseptal puncture, an 8.5 Fr deflectable sheath (Agilis, Abbott Inc) was used in concert with the PFA catheter and custom mapping system (Prism-1, Affera Inc) to quickly render the PV anatomy. Then the catheter was serially positioned at the ostium of each PV, and a PFA generator (HexaPULSE; Affera Inc) delivered biphasic pulse trains (5 sec per application; 1.3-2.0 kV ± 6); goal of 1-3 lesions per PV. Post-procedure endoscopy (EGD) and brain MRI occurred within 24-72 hours.

Results: At 3 centers (5 operators), a total of 30 pts (age 57.6 ± 9.3 yrs; M / F = 15 / 15) underwent PVI. Mapping time to render the LA-PV anatomy was 5.7 ± 3.2 min (range 1.3 - 13.1). PVI was acutely successful in all 30 pts: 122 of 122 (100%) PVs were acutely isolated using 2.4 ± 0.4 applications/vein (10.0 ± 1.6 applications/pt). The PVI duration time (transpired from 1st to last lesion) was 8.2 ± 5.5 min (range 3.3 - 29.8). The total LA catheter dwell time for the PFA catheter was 12.9 ± 7.6 min (range 5.0 - 36.0). Fluoroscopy time was 4.8 ± 4.1 min. There were no serious adverse events - including no esophageal fistula, stroke/TIA, phrenic injury or tamponade. EGD in 18 pts revealed no thermal lesions, and brain MRI revealed acute lesions in 2 of 21 (9.5%) pts.

Conclusion: PVI using the conformable “single-shot” PFA catheter was acutely successful and safe. Further studies should assess lesion durability and large multicenter clinical outcomes.

FIRST-IN-HUMAN CLINICAL EXPERIENCE OF A “SINGLE-SHOT” MAP-AND-ABLATE MULTIELECTRODE SPHERICAL ARRAY PULSED FIELD ABLATION CATHETER TO ISOLATE PULMONARY VEINS

Vivek Y. Reddy MD; Jacob S. Koruth MBBS, MD; Jan Petru; Moritoshi Funasako MD, PhD and Petr Neuzil MD

Background: Pulsed field ablation (PFA) has safety and procedural workflow advantages over conventional thermal ablation modalities. Most “single-shot” PFA catheter technologies are either not linked to electroanatomical mapping systems, require serial re-positioning or cannot easily accommodate varying pulmonary vein (PV) anatomical sizes / shapes. Recently, a multielectrode spherical array catheter (Globe, Kardium Inc, Canada) capable of single-shot “mapping and ablation”, previously capable of radiofrequency (RF) ablation, has now been enhanced to also deliver PFA.

Objective: To assess the acute safety and efficacy of PV isolation (PVI) using this spherical array PFA catheter.

POSTER PO-624: Featured Posters: Catheter Ablation at Pod 11
Friday, April 29, 2022
12:30 PM - 2:30 PM

POSTER PO-624-01:
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Objective: To assess the acute safety and efficacy of PV isolation (PVI) using this spherical array PFA catheter.
Methods: In a first-in-human multicenter single-arm trial of paroxysmal AF ablation, after informed consent and under general anesthesia, ICE-guided transseptal puncture was performed. Through a custom 19 Fr deflectable sheath, the multielectrode spherical array PFA catheter (Globe; Kardium Inc, Canada) was advanced into the left atrium and deployed to its full spherical shape. Using the custom mapping system (GPS; Kardium Inc), the PFA catheter rendered anatomic maps with ostial tags, using contact maps based on blood flow detection. The PFA catheter was positioned at each PV ostium for PVI (1.6-2 kV/application; typically ungated - 3 sec. PV entrance and exit block were assessed. Post-procedure endoscopy (EGD) and brain MRI occurred within 5 days.

Results: At a single center, a total 11 PAF pts (age 62.8 ± 6.13.0 yrs; M / F 5 / 6; LVEF 55 ± 6.8.1%; LA 41.5 ± 5.8 mm) underwent PVI. Using typically just one application per vein, PVI was acutely successful in 43 of 43 (100%) PVs in 11 of 11 pts (100%). The total pulse delivery period for each patient was 24 ± 5 seconds (range: 15 - 36 seconds). The PVI duration time (transpired from 1st to last lesion) was 30.6 ± 6.3 min (range 22.6- 42.5). The total LA catheter dwell time for the PFA catheter was 51 ± 7 min (range 42 - 66). There were no safety events - including no esophageal fistula, stroke/TIA, phrenic injury or tamponade. EGD in was normal in 4 of 4 pts. Brain MRI was normal in 6 of 7 pts; one pt had DWI+/FLAIR- lesions.

Conclusion: In this first-in-human study, the “single-shot” map-and-ablate spherical array PFA catheter was able to safely and effectively isolate PVs to treat paroxysmal AF.

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MAGNETIC RESONANCE IMAGING FEATURES OF VENTRICULAR LESIONS AFTER PULSED FIELD ABLATION: PRECLINICAL INSIGHTS

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Background: Magnetic resonance imaging of pulsed field ablation (PFA) lesions in the ventricular myocardium has not been well characterized.

Objective: To evaluate the characteristics of late gadolinium enhanced (LGE) MRI after PFA delivery in healthy and infarcted ventricles.

Methods: Seven swine (5 post-infarct [5 weeks after myocardial infarction induced by balloon occlusion of the LAD] & 2 healthy animals) underwent endocardial (5) or epicardial (2) ventricular PFA under general anesthesia. Pulses (2 kV) were delivered using an 8 Fr focal PFA catheter (Farapoint, Boston Scientific) in bipolar/biphasic mode to the: 1) endocardium over healed infarcts and adjacent healthy myocardium, and 2) over the epicardium in healthy swine. All animals underwent 3.0T MRI.