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

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

Background: Pulsed field ablation (PFA) has safety and procedural workflow advantages over conventional thermal ablation. Most “single-shot” PFA catheter technologies are either not linked to electroanatomical 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 PV anatomies has been developed.

Objective: To assess the acute safety and efficacy of PV isolation (PVI) using this spherical array 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 [±]); 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.

PO-623-08

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 the PV anatomy has been developed.

Objective: In a first-in-human single-arm trial (NCT05144503, NCT05115214) of PAF ablation, we assessed the acute safety and efficacy of 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 [±]); 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.

PO-624-01

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