FIRST REPORT OF LONG-TERM (3-YEAR) CLINICAL OUTCOMES IN PATIENTS TREATED WITH PULSED FIELD ABLATION FOR PAROXYSMAL ATRIAL FIBRILLATION
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Background: Pulsed field ablation (PFA) has gained prominence due to its enhanced safety profile, durable pulmonary vein isolation (PVI), and high 1-year rates of freedom from recurrent paroxysmal AF. However, the long-term (beyond 1 year) safety and efficacy outcomes of PFA in paroxysmal patients remains unknown.

Objective: To assess 3-year clinical safety and efficacy outcomes of PFA for paroxysmal AF.

Methods: In 3 multicenter trials (IMPULSE - NCT03714178, PEFCAT - NCT03714178, PEFCAT2 - NCT04170608), of similar design and utilizing a multielectrode penta-spline PFA catheter (Farawave, Farapulse Inc; Figure 1), paroxysmal AF patients underwent PVI. A protocol-driven remapping procedure at 2-3 months assessed PVI durability, and standardized rhythm monitoring to 1 year. Following study exit, patients returned to institutional standard-of-care monitoring. At a recent timepoint, 7-day Holter monitors and symptom and safety assessments were performed.

Results: The overall patient cohort included 121 patients enrolled at 3 centers. Long-term safety data is available for 112 of 121 patients, with follow-up of 1049 ± 205 days. Patients had no long-term ablation-related adverse events - including no deaths (1 patient had a brain tumor treated with radiation). Long-term efficacy data is available for 81 of 121 patients, with follow-up to 1116 ± 193 days. Repeat catheter ablation after the 1 year time point was performed on 10 of 78 (12.8%) patients. The mean time to re-ablation was 934 ± 269 days. Of these 10 patients, 3 patients had initially received the optimized PFA waveform at the index procedure - all PVs had remained isolated at both the protocol-mandated remapping procedure, as well as at the late re-ablation procedure. The remaining 7 patients had initially received the index PVI procedure with an early version of the PFA waveforms. Data at re-ablation was available for 6 of the 7 patients: 1 patient had 2 PVs reconnected, 3 patients had 1 PV reconnected, and 2 patients had durable PVI.

Conclusion: In this long-term (3 years) evaluation of PFA, there were no untoward late safety events, and efficacy appears to remain good. During redo procedures, patients initially receiving the optimized PFA waveform retained durable PVI, while the patients receiving the earlier waveforms had a higher rate of PV reconnections.

SIX-MONTH FOLLOW-UP OF FIRST REAL-WORLD EXPERIENCE WITH PULMONARY VEIN ISOLATION USING PULSED FIELD ABLATION FOR PAROXYSMAL ATRIAL FIBRILLATION
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Background: Catheter ablation for AF using thermal energy can cause collateral damage. Pulsed field ablation (PFA) is a novel nonthermal energy source. Only a few small clinical studies have been published.

Objective: We report on the first, real-world experience with 6-month follow-up with PVI with PFA for paroxysmal AF.

Methods: Pre and post ablation, phrenic nerve function was assessed. A high-density LA bipolar voltage map was created. All PVs were individually isolated using a steerable sheath and a pentaspline over-the-wire PFA catheter. After ablation, mapping was repeated to assess lesion formation. Patients had a scheduled follow-up visit at days 30, 90 and 180 after ablation.
Objective: Ganglionic plexi ablation. On the contrary, pulsed electric field (radiofrequency energy or cryoenergy) results in collateral ablation.

Background: Pulmonary vein isolation (PVI) by thermal energy has become a mainstay catheter ablation strategy for paroxysmal atrial fibrillation (AF). However, heart rhythm disorders (HRD) after PVI are observed commonly. The underlying mechanisms of HRD are not well understood.

Methods: A study enrolled 49 patients who underwent PVI in the AV node (AVN) when four different ablation strategies were used. Patients were in SR, 1 patient had a cardioversion because of symptomatic atrial tachycardia with 4:1 conduction. On day 90, 27 (90%) patients were in SR, 3 patients had AF/AT recurrence. During redo LA procedure, 2 patients with isolated PVs had inducible LA macro-reentrant tachycardia (1 roof and 1 mitral isthmus dependent) and 1 patient had LIPV reconduction. All 3 patients had uncomplicated RF ablation. On day 180, all 30 patients were off anti-arrhythmic drugs and in SR.

Conclusion: PVI using PFA for paroxysmal AF in a “real-world” setting is safe and feasible. Post-ablation clinical course and 6-month follow-up are favorable.

ABSTRACT CA-537:
A Critical Appraisal of Tools for Improving Success or Safety of Atrial Fibrillation Ablation

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ACUTE CHANGE OF CARDIAC AUTONOMIC REGULATIONS AFTER THERMAL AND NON-THERMAL PULMONARY VEIN ABATION

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Background: Pulmonary vein isolation (PVI) by thermal energy (radiofrequency energy or cryoenergy) results in collateral ganglionic plexi ablation. On the contrary, pulsed electric field (PEF) energy presumably spares neural tissue.

Objective: We investigated and compared the effect of PVI on parasympathetic input into the sinus node (SAN) and AV node (AVN) when four different ablation strategies were used.

Methods: A study enrolled 49 patients who underwent PVI in general anesthesia (age: 57 ± 13 years, 71% males). In 17 patients, point-by-point radiofrequency energy delivery by the irrigated-tip catheter was used for ablation while 7 patients were ablated using a second-generation cryoballoon catheter. In 7 patients, PEF energy was delivered using a single-shot Farawaii catheter (Boston Scientific) while 18 patients were ablated using Sphere9 lattice-tip catheter (Affera, Inc.); both subgroups with manufacturer-specific PEF settings. Before and after PVI, the responsiveness of the SAN and AVN was assessed by extracardiac vagal nerve stimulation (ECVS) via a diagnostic catheter in the right internal jugular vein. Five-second stimulation trains were delivered with a frequency of 50 Hz, pulse width of 0.05 ms, and output of 1 V/kg (<70V) both in sinus rhythm and during atrial pacing. Substantial reduction of response to ECVS was arbitrarily defined as a maximum induced pause of <1.5 seconds.

Results: At baseline, physiological response to ECVS (long sinus arrest and/or AV block) was demonstrated. After PVI, a substantial reduction of SAN response was observed in 21/24 (88%) patients after thermal PVI and 7/25 (25%) patients after non-thermal PVI (P = 0.0001). Similarly, a substantial reduction of AVN response was observed in 21/24 (88%) patients after thermal PVI and 9/25 (36%) patients after non-thermal PVI (P = 0.0003). The Figure shows on the continuous scale the post-PVI pauses in sinus rhythm (maximum P-P interval) and atrial pacing (maximum R-R interval) induced by ECVS.

Conclusion: Vagal responses of SAN and AVN are preserved in most AF patients after non-thermal PVI. This contrasts with the much stronger effect of thermal PVI. Whether this may influence the clinical outcome of AF ablation procedures remains to be investigated in future studies.