**AFS2022-01**

**Abstract Title:** Clinical Outcomes of Lattice-Tip Focal Ablation for Atrial Fibrillation: Toggling Between Pulsed Field and Radiofrequency Energy

**Author(s):** Vivek Reddy, MD

**Co-Author(s):**
petr Peichl, MD PhD
Elad Anter, MD
Gediminas Rackauskas, MD PhD
Jan Petru, MD PhD
Moritoshi Funasako, MD
Kentaro Minami, MD
Jacob Koruth, MD
Andrea Natale, MD
Hiroshi Nakagawa, MD
Pierre Jais, MD
Germanas Marinskis, MD PhD
Audrius Aidietis, MD PhD
Josef Kautzner, MD PhD
Petr Neuzil, MD PhD

MOUNT SINAI MEDICAL CENTER

vivek reddy one gustave levy place, box 1030 mount sinai hospital

**Introduction | Objectives:**

In first-in-human trials (NCT04141007, NCT04194307), a lattice-tip catheter using focal RF or PF (pulsed field) energy proved able to treat PAF or PerAF with a PVI strategy of either RFA anteriorly / PFA posteriorly (RF/PF), or PFA throughout (PF/PF) with good lesion durability. Herein, we assessed the long-term clinical outcomes of safety and efficacy.

**Methods:**

The 8Fr lattice catheter has a compressible 9 mm nitinol tip, and is used with a custom mapping system and RF & PF generators (Affera Inc, MA). Toggling between RF & PF, point-by-point PVI was performed using biphasic PFA (2-5 sec; 1.3-2.0 kV [±]) posteriorly, and either temp-controlled irrigated RFA ($T_{max}$ 73°C; 5 sec) or PFA anteriorly. Linear lesions were placed with PFA and/or RFA. Protocol-driven remapping was at ~3 mo post-index ablation. Based on remap data, the PF waveform/delivery evolved: PULSE1 (2-5s, 76 pts), PULSE2 (4s, 47 pts) and the final optimized PULSE3 (4s, 55 pts).

**Results:**

A total of 178 pts (3 centers-14 operators, age 59.7±9.4 yrs; M / F = 128 / 50; PAF / PerAF = 70 / 108) underwent PVI with RF/PF (79 pts) or PF/PF (99 pts). The PVI duration time (transpired from 1$^{st}$ to last lesion) was 21.3±5.8 min. Linear lesions included 78 mitral, 121 CTI and 130 LA roof lines (including 38 box lesions), with transpired ablation times of 3.9±2.2, 2.0±1.4 and 1.9±1.7 min/pt, respectively. All lesion sets (100%) were acutely successful. Fluoroscopy time was 4.3±3.1 min. At

96±43 days, remapping was performed on 122 pts (69%). Per-PV / per-patient durability rates were 51% / 32%, 87% / 64% and 97% / 90% for PULSE1, PULSE2 and PULSE3, respectively. After 325±67 days follow-up, the 1-yr KM estimates for freedom from AT/AF/AFL for the full cohort were 78.3±5.0% and 76.8±4.4% for PAF and PerAF, respectively; for PULSE3 cohort alone, the outcome for PerAF was 84.5±5.1% at 308 days. There was 1 primary adverse event – inflammatory pericardial effusion not requiring intervention. There was no esophageal fistula, stroke/TIA, phrenic injury, PV stenosis, or other late safety events.

**Conclusions:**

AF ablation using the lattice-tip RF/PF catheter reveals excellent clinical outcomes, providing strong rationale for the recently commenced FDA randomized trial.

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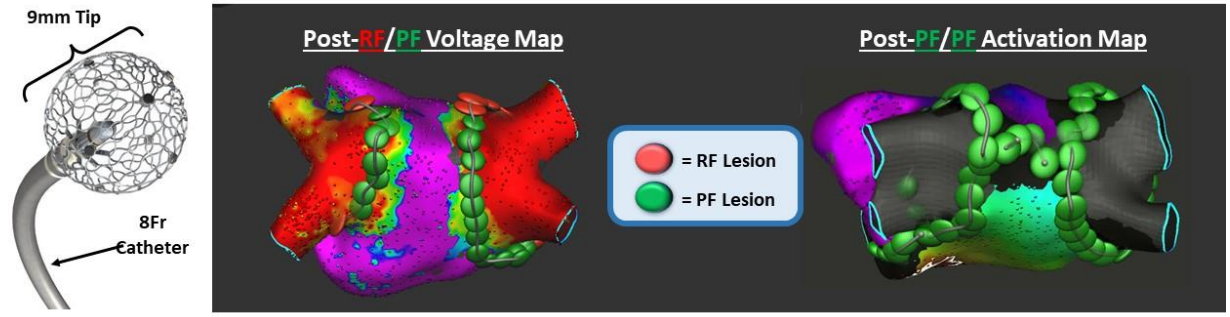
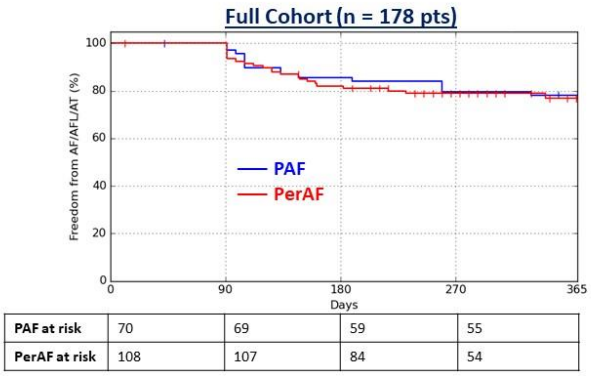
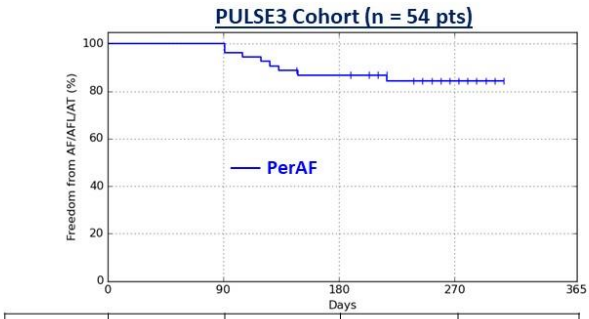
**Lattice-Tip RF/PF Ablation Catheter: 1-Year Clinical Effectiveness**




| | | | | |
|---|---|---|---|---|
| PAF at risk | 70 | 69 | 59 | 55 |
| PerAF at risk | 108 | 107 | 84 | 54 |




| | | | | |
|---|---|---|---|---|
| PerAF at risk | 54 | 54 | 43 | 15 |

**AFS2022-02**

**Abstract Title:** 12M Safety/Effectiveness Of Very High Power Short Duration Pulmonary Vein Isolation With A Contact Force-Sensing, Temperature-Controlled Radiofrequency Catheter: The Prospective, Nonrandomized, Multicenter Q-FFICIENCY Trial

**Author(s):** Jose Osorio, MD

**Co-Author(s):**
Ayman Hussein, MD - Cleveland Clinic Foundation
M. Craig Delaughter, MD - Texas Health Heart & Vascular
George Monir, MD - AdvantHealth Orlando
Andrea Natale, MD - Texas Cardiac Arrhythmia Institute
Srinivas Dukkipati, MD - Mount Sinai School of Medicine
Saumil Oza, MD - St Vincent's Medical Center
Emile Daoud, MD - Ohio State University Medical Center
Luigi Di Biase, MD - Montefiore Medical Center at Albert Einstein College of Medicine
Moussa Mansour, MD - Massachusetts General
Robert Fishel, MD - JFK Medical Center
Miguel Valderrabano, MD - Houston Methodist Research Institute
Kenneth Ellenbogen, MD - Virginia Commonwealth University

Grandview Medical Center Alabama Cardiovascular Group

3686 Grandview Pkwy #720 Birmingham, AL 35243

**Introduction | Objectives:**
A novel contact force (CF) sensing catheter was optimized for temperature-controlled radiofrequency (RF) ablation. It has 3 microelectrodes and 6 thermocouples allowing power modulation to maintain a target temperature and the delivery of very high-power, short-duration (vHPSD; 90 W, 4 s) RF. We evaluated the 12-month (M) safety and effectiveness of the catheter for paroxysmal atrial fibrillation (PAF) ablation, primarily with vHPSD mode in combination with conventional power (CP; 25–50 W) mode, as needed.

**Methods:**
In this US multicenter (22 sites), nonrandomized investigational study, patients underwent pulmonary vein (PV) isolation with vHPSD as primary ablation mode; CP was used for PV touch-up or non-PV ablation. Primary safety endpoint was incidence of primary adverse events (PAE) ≤7 days postprocedure. Primary effectiveness was freedom from documented atrial tachyarrhythmia recurrence and additional predefined failure modes (acute failure, repeat ablation, new/higher dose AAD).

**Results:**
Of 191 participants (63.5±10.7 years, $CHADS_2$–VASc 2.4 ±1.5, 60.7% male), 166 were ablated with the investigational catheter. PVI with vHPSD-only was achieve in 89/164 participants with confirmed entrance block for all PVs. Median (Q1/Q3) procedure time (including 20-minute waiting time) and RF application time were 132 (108/171) and 9.8 (6.8/15.7) minutes, respectively. Mean number of RF applications was 121.2±43.7, most using vHPSD (median of 93.3%). Mean maximum temperature, impedance drop, and CF per RF application were similar between vHPSD and CP modes (45.1±5.3 vs 44.5±3.9 °C; 9.8±8.5 vs 9.1±3.7 Ω; 15.5±9.7 vs 15.2±8.9 g, respectively). PAE rate was 3.6%, with no reports of device- or procedure-related death, atrioesophageal fistula, stroke, transient ischemic attack, or severe PV stenosis. Kaplan-Meier estimated 12M primary effectiveness and freedom from repeat ablation during the evaluation period were 76.7% and 92.1%, respectively.

**Conclusions:**
Temperature-controlled PAF ablation with vHPSD, alone or in combination with CP, is effective and highly efficient without compromising safety.

**AFS2022-03**

**Abstract Title:** Impact Of High-frequency Low-tidal-volume Mechanical Ventilation On First-pass Pulmonary Vein Isolation And Procedural Times During Radiofrequency Ablation Of Atrial Fibrillation: A Multicenter Experience

**Author(s):** Jose Osorio, MD, FHRS

**Co-Author(s):**
Allyson Varley, PhD - Heart Rhythm Clinical and Research Solutions
Chris Thorne, PhD - Heart Rhythm Clinical and Research Solutions
Gustavo Morales, MD - Arrhythmia Institute at Grandview
Anil Rajendra, MD, FHRS - Arrhythmia Institute at Grandview
Gunther Schrappe, MBA - Heart Rhythm Clinical and Research Solutions
Joshua Silverstein, MD
Paul Zei, MD, PhD, FHRS
Jorge Romero, MD, FHRS

Arrhythmia Institute at Grandview

3686 Grandview Pkwy #720, Birmingham, AL 35243, United States

**Introduction | Objectives:**
Catheter stability is crucial for predictable energy delivery to the myocardium and the resultant creation of durable lesions during radiofrequency (RF) ablation of atrial fibrillation (AF). Brief periods of apnea and JET ventilation can improve catheter stability but have limitations and potential complications. High-frequency, low-tidal-volume (HFLTV) ventilation was shown in single center studies to be a simpler and safer alternative with similar benefits. We evaluated the impact of HFLTV during RF AF ablation on procedural short-term efficacy, efficiency, and safety in a large multicenter study.

**Methods:**
1,052 patients from 25 institutions were prospectively enrolled in a multicenter RF AF ablation registry (REAL-AF) from January 2018 to November 2021. Conventional ventilation only was used up until April 2020 [standard ventilation (SV) group] when HFLTV was implemented progressively at different centers (30 breaths/min and tidal volume 200ml). High-power, short-duration ablation with 40-50 watts was used in all cases, and other ablation parameters remained unchanged. Procedural characteristics and incidence of severe anesthesia and procedural relate adverse events (AE) were compared.

**Results:**
Patients in the HFLTV group (n=413) had significantly shorter procedure time when compared to SV group (n=639) (77.5±38.7 min vs 103.3±46.5 min, $p< 0.001$). Similarly, total and pulmonary vein RF times were shorter in the HFLTV group when compared to the SV group (16.44±8.3 min vs. 23.58±10.3 min, $p< 0.001$ and 12.42±5 min vs 18.2±6.9 min, $p< 0.001$, respectively). First-pass pulmonary vein (PV) isolation rates were higher in the HFLTV group [(84% vs. 80%, p=0.02) (left PVs: 90% vs. 84%, p=0.01 and right PVs: 78% vs. 75%, p=0.37)]. AEs at 30-day follow-up were similar.

**Conclusions:**
HFLTV mechanical ventilation during RF AF ablation was associated with a significantly higher first-pass PV isolation rate, and shorter total procedural and pulmonary vein RF times without an increase in complications. Further studies are indicated to better understand the impact of HFLTV on catheter stability and long-term outcomes in AF ablation.

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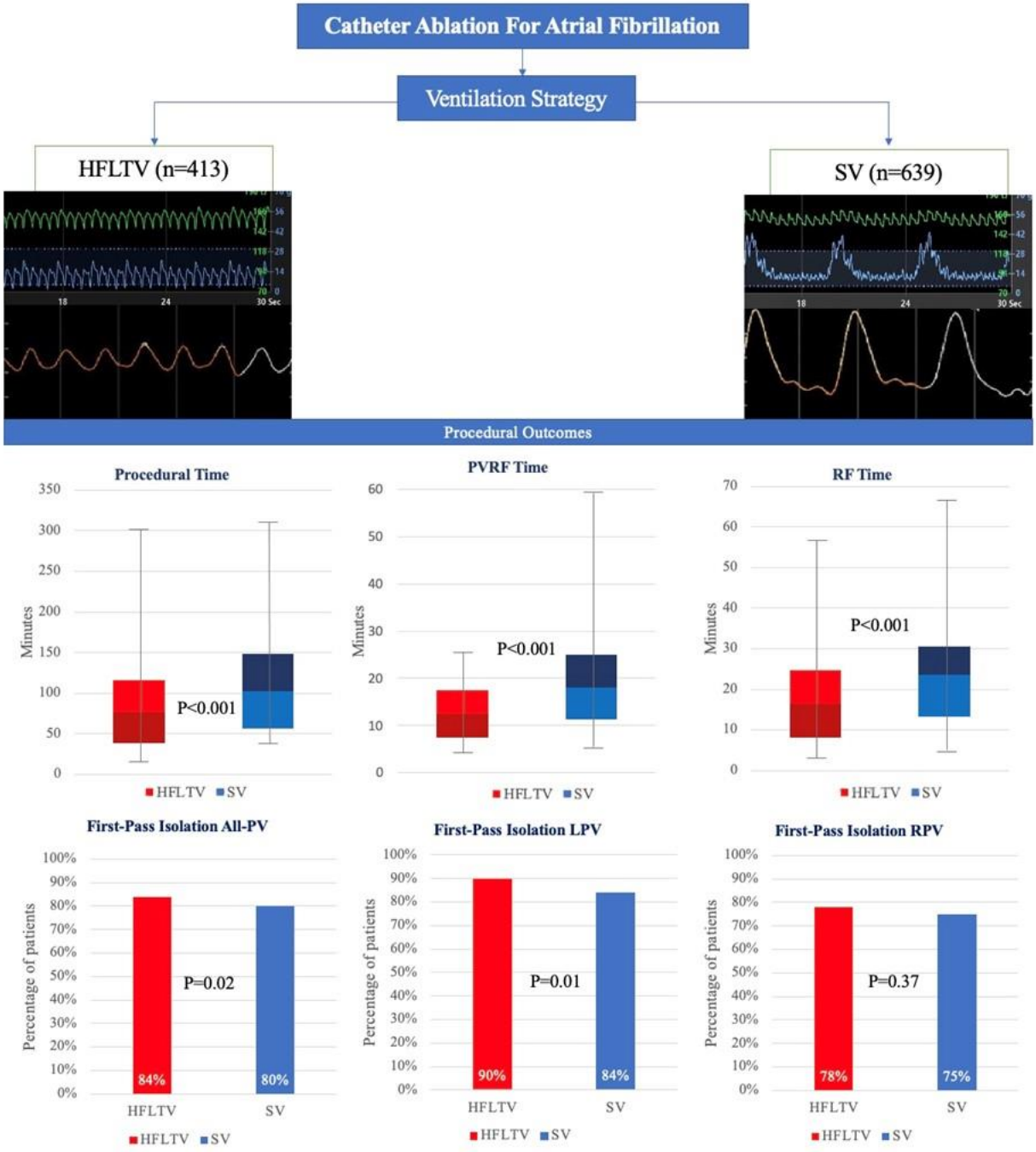
**High Frequency Low Tidal Volume Mechanical Ventilation During RF Atrial Fibrillation Ablation**



**AFS2022-04**

**Abstract Title:** First in Human Experience and Acute Procedural Outcomes using a Novel Pulsed Field Ablation System: The PULSED AF Pilot Trial

**Author(s):** Atul Verma, MD

**Co-Author(s):**
Lucas Boersma, MD - St Antonius Hospital, Amsterdam, Netherlands
David Haines, MD - Beaumont Hospital, Royal Oak, USA
Andrea Natale, MD - St David's Hospital, Austin, USA
Francis Marchlinski, MD - Hospital of the University of Pennsylvania, Philadelphia, USA
Prashanthan Sanders, MBBS - Royal Adelaide Hospital, Adelaide, Australia
Hugh Calkins, MD - Johns Hopkins Hospital, Baltimore, USA
Douglas Packer, MD - Mayo Clinic, Rochester, USA
John Hummel, MD - OSU Wexner Medical Center, Columbus, USA
Birce Onal, PhD - Medtronic
Sofi Rosen, PhD - Medtronic
Karl-Heinz Kuck, MD - University Heart Center Lübeck, Lübeck, Germany
Gerhard Hindricks, MD - The Heart Center Leipzig, Leipzig, Germany
Bradley Wilsmore, MD - John Hunter Hospital, Newcastle, Australia

Southlake Regional Health Centre

596 Davis Dr, Newmarket, ON L3Y 2P9, Canada

**Introduction | Objectives:**
Pulsed field ablation (PFA) is a novel form of ablation using electrical fields to ablate cardiac tissue. There is limited data assessing the feasibility and safety of this type of ablation in humans. This is a first-in-human extended pilot phase study describing the usage of PFA for atrial fibrillation (AF) ablation.

**Methods:**
PULSED AF (NCT04198701) is a non-randomized, prospective, multi-center, global, pre-market clinical study. This first-in-human pilot phase evaluated the feasibility, acute safety and efficacy of pulmonary vein isolation (PVI) using a novel PFA system (PulseSelect™; Medtronic, Inc). The system delivers bipolar, biphasic electrical fields through a circular multi-electrode array catheter. Thirty-eight patients with paroxysmal or persistent, drug-refractory AF undergoing first-time ablation were treated in six centers in Australia, Canada, the United States, and the Netherlands. The primary outcomes were ability to achieve acute PVI intra-procedurally and safety at 30 days.

**Results:**
Of 38 patients, 35 (92%) had paroxysmal AF with a mean age of 62 ± 11 years and a left atrial (LA) diameter of 37 ± 6 mm. Acute electrical PVI (n = 152) was achieved in all 38 patients. Skin-to-skin procedure time was 160 ± 91 min, LA dwell time was 82 ± 35 min, including a required 20-minute waiting period after PVI. Fluoroscopy time was 28 ± 9 min. The maximum esophageal temperature recorded was 36.1 ± 0.3°C, with a mean change of 0.06°C from baseline (n=7). No serious adverse events related to the PFA system occurred in the 30-day follow-up including phrenic nerve injury, esophageal injury, stroke or death.

**Conclusions:**
In this first-in-human extended pilot study, 100% PVI was achieved using only PFA with no PFA system-related serious adverse events. Data will be published simultaneously to the AF Symposium and Circulation AE.

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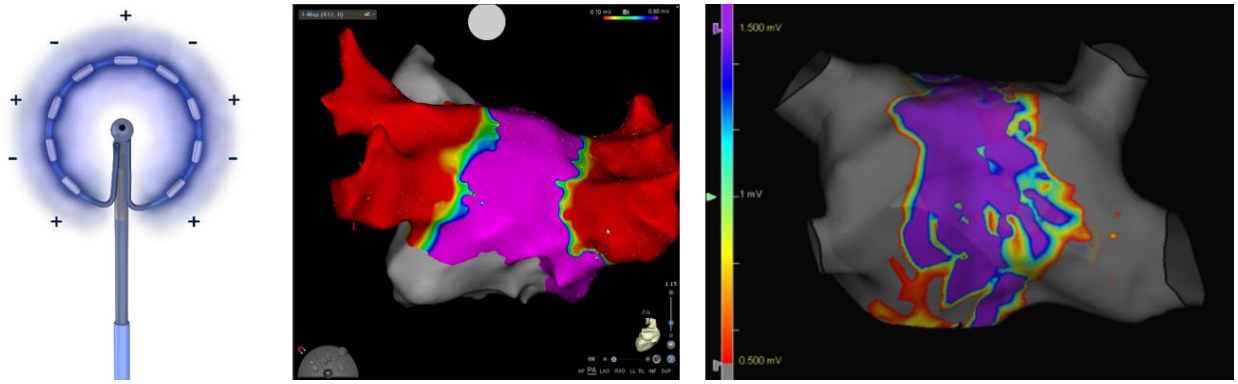
**Pulsed Field Ablation catheter (left) and two post-ablation voltage maps (middle, right).**



**AFS2022-05**

**Abstract Title:** Safety and Feasibility of Home-Care Neuromodulation and Monitoring Wearable Device for Treatment of Atrial Fibrillation

**Author(s):** Avi Sabag, MD

**Co-Author(s):**
Roy Beinart, MD
Eran Leshem, MD
Avi Epstein, MD
Amos Ziv, MSc
Tsahi Holland, MSc

Division of Cardiology, Davidai Arrhythmia Center, Sheba Medical Center

Sheba Medical Center Hospital- Tel Hashomer, Derch sheba 2, Ramta Gan, 52662, IL

**Introduction | Objectives:**
Autonomic modulation is an evolving field in arrhythmia management. tVNS Vagus nerve stimulation suppressed atrial fibrillation (AF) in humans. Median nerve neuromodulation was shown to reduce ventricular and atrial arrhythmias in pre-clinical models. We report the feasibility and safety of CardiaCare RR2, a wristband wearable device with neuromodulation and single lead ECG monitoring capabilities.

**Methods:**
Patients arriving to the emergency room (ER) with symptomatic AF were recruited, underwent pharmacological or electrical cardioversion, received standard of care medication, and received a 24-hour ECG Holter monitor. They returned the next day for a supervised in-hospital first neuromodulation session and received the device and phone app for 8 weeks of home use. Patients were asked to conduct two neuromodulation sessions a week and three 30 sec ECG monitoring sessions daily.

**Results:**
Eleven patients were recruited from the ER (age 66±12 yrs, 64% male). One dropped out prior to protocol initiation, ten completed the protocol. Usability rates were 94.7% for ECG monitoring (1675 recorded and analyzed) and 96.8% for neuromodulation (155 treatments, Avg 15.5 per patient). No Adverse Events were observed during the supervised in-hospital treatments or the follow up period. No unscheduled emergency department re-visits occurred. One patient reported minimal itching during use of the device, one patient reported feeling more tired, one patient had non-device related bradycardia and a patient with high AF burden received an ablation at week 6. A total of 289 ECG's were taken immediately before and immediately after neuromodulation. In 7 instances, multiple PACs (13.7±12.7 PACs/2 min) were observed. In all these cases we observed an acute reduction in the PAC burden following the neuromodulation (5.7±10/2 min, 58% reduction; p=0.0005). Two (20%) patients had AF recurrences during the 8-week follow-up period.

**Conclusions:**
The use of CardiaCare neuromodulation and monitoring system is safe. Home-use compliance and usability in a real-world AF population is high. Acute PAC reductions and low AF recurrence rates show compelling early indications of possible AF burden reduction with use of the device.

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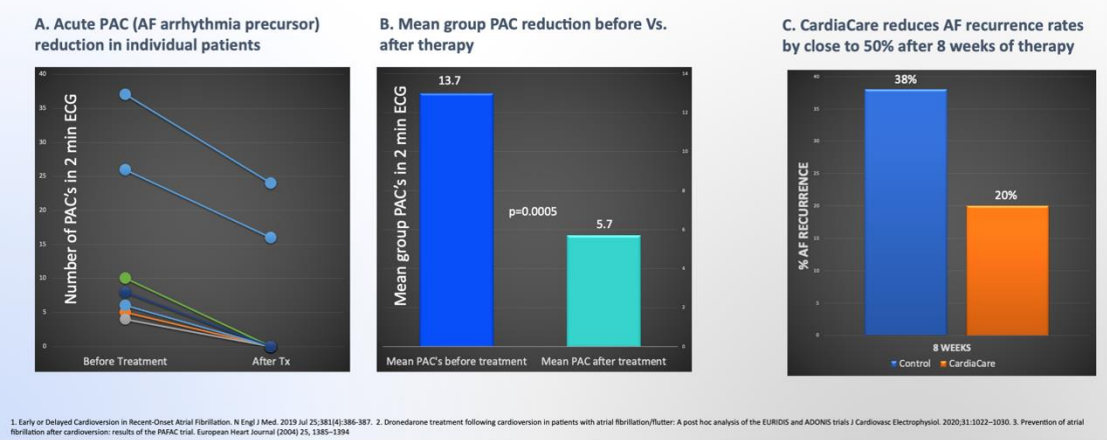
## Acute PAC reduction and 8 weeks AF reccurence



**AFS2022-06**

**Abstract Title:** First-in-Human Clinical Experience of a "Single-Shot" Map-and-Ablate Multielectrode Spherical Array Pulsed Field Ablation Catheter to Isolate Pulmonary Veins

**Author(s):** Vivek Reddy, MD

**Co-Author(s):**
Jacob Koruth, MD
Jan Petru, MD PhD
Moritoshi Funasako, MD
Pavel Hala, MD
Jan Skoda, MD
Milan Chovanec, MD
Lucie Sediva, md
Petr Neuzil, MD PhD

MOUNT SINAI MEDICAL CENTER

vivek reddy one gustave levy place, box 1030 mount sinai hospital

**Introduction | Objectives:**

Most "single-shot" pulsed field ablation (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. In a first-in-human clinical trial, we assessed the acute safety and efficacy of PV isolation (PVI) using this spherical array PFA catheter.

**Methods:**

In a single center 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:**

A total 11 PAF pts (age 62.8 ± 13.0 yrs; M / F = 5 / 6; LVEF 55 ± 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 1$^{st}$ to last lesion) was 30.6±6.3 min (range 22.6– 42.5). The total LA (PFA) catheter dwell time 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.

**Conclusions:**

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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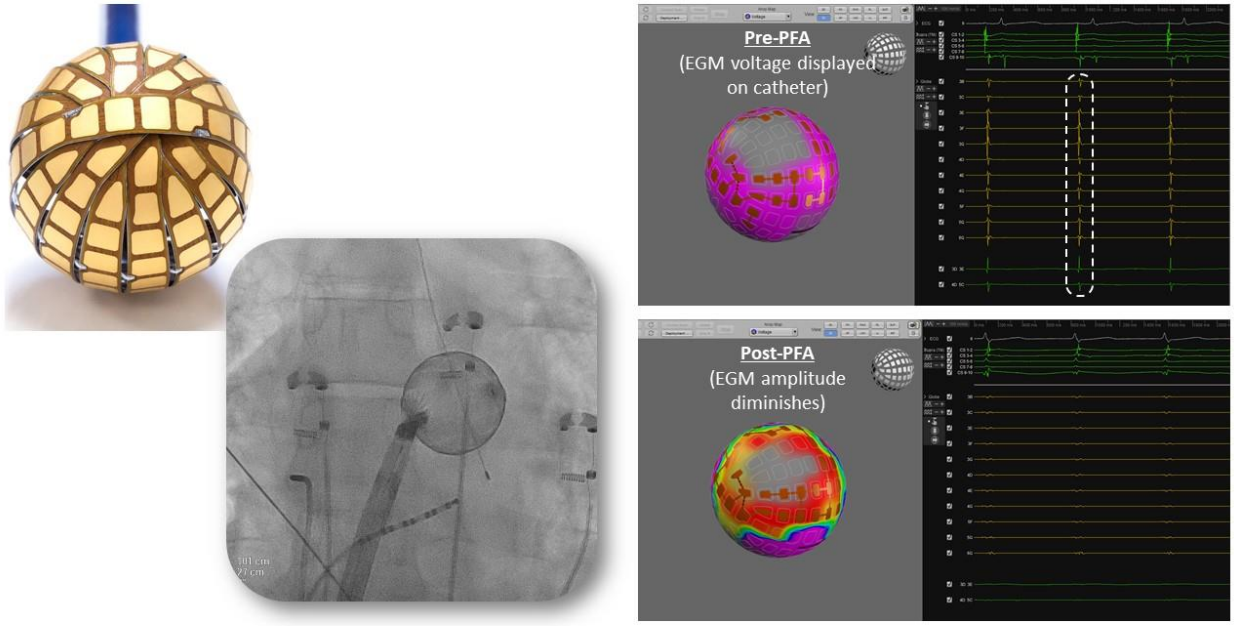
**Multielectrode Spherical Array PFA Catheter positioned at the LSPV ostium (fluoro), and the pre-PFA (top) and post-PFA (bottom) electrogram and voltage amplitude maps.**



**AFS2022-07**

**Abstract Title:** First Clinical Experience with Epicardial Pulsed Field Ablation of Ganglionated Plexi During Cardiac Surgery

**Author(s):** Vivek Reddy, MD

**Co-Author(s):**
Ivo Skalsky, MD PhD
Tamaz Shaburishvilli, MD
Martin van Zyl, MD
Barry O'Brien, PhD
Ken Coffey, BE
John Reilly, BE
Petr Neuzil, MD PhD
Joris de Groot, MD PhD

MOUNT SINAI MEDICAL CENTER

vivek reddy one gustave levy place, box 1030 mount sinai hospital

**Introduction | Objectives:**

The role of the autonomic nervous system in cardiac arrhythmias is increasingly being appreciated. However, studies of autonomic interventions have given mixed outcomes, particularly in the context of ganglionated plexi (GP) ablation for the treatment of atrial fibrillation. Selective GP ablation offers the potential for clearly elucidating the role of the GPs, by achieving GP neuronal cell destruction with minimal myocardial damage. This selective destruction of neuronal cells can be achieved through use of pulsed field ablation (PFA), with the energy applied directly to the epicardial fat pads in which the GPs are embedded. Herein, we present preliminary data from an ongoing first-in-human study (NCT 04775264) to evaluate the safety and feasibility of epicardial PFA to assess how atrial tissue refractoriness is influenced by this GP ablation.

**Methods:**

Atrial GPs were ablated in nineteen patients undergoing elective open-chest CABG surgery, using a monopolar, monophasic PFA system (AtriAN Medical). The Oblique Sinus GP, Right Superior GP, Transverse Sinus GP, Left Superior GP and Ligament of Marshall GP were each ablated with up to 60 ECG-gated PEF pulses of 1000 V amplitude and 100 μs pulse width. Atrial Effective Refractory Period (AERP) was measured epicardially at the left atrial appendage (LAA) and right atrial (RA) locations, before and after all ablations were completed. T-testing was used to compare pairs of pre- and post-PFA AERPs.

**Results:**

Successful GP ablations were completed in nineteen patients (mean age 61 years, 63% male) undergoing open-chest elective CABG surgery. An average AERP extension of 21% was obtained from thirteen valid pre- and post-ablation datasets (changed from 233 ± 51 ms to 260 ± 55 ms; $p < 0.01$). Patients progressed immediately to their planned elective surgery and were discharged on schedule. Three patients experienced post-operative AF.

**Conclusions:**

Selective pulsed field ablation of GPs in an open-chest setting has been demonstrated to be feasible and safe. An acute extension of atrial refractoriness is promising in terms of the potential to reduce AF recurrence. Further studies are required in symptomatic AF patients, using percutaneous epicardial access, to demonstrate long-term benefits.

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**GP Sites Targeted for PFA During Cardiac Surgery**